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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).

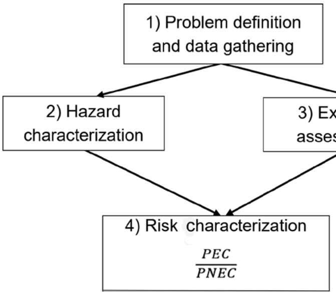
These materials opened potential doors to innovative products and benefits for our society; however, they also introduced some uncertain health and environmental risks due to their unknown releases and toxicity profiles throughout the life cycle of their corresponding applications. Consequently, the 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

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 values 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 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).

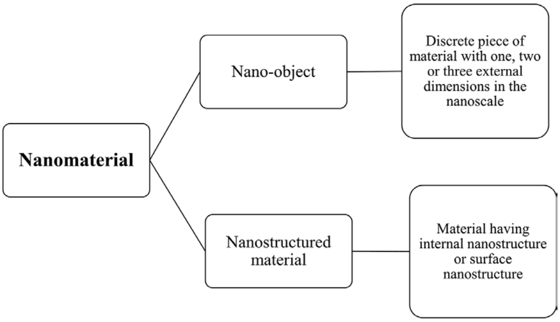
Governmental agencies in various countries have increasingly adopted a multi-tiered approach to nanomaterial regulation. Typically, going from low-tiered approaches with higher uncertainty to a higher-tiered approach with reduced uncertainty, using qualitative and quantitative approaches, respectively (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.

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).

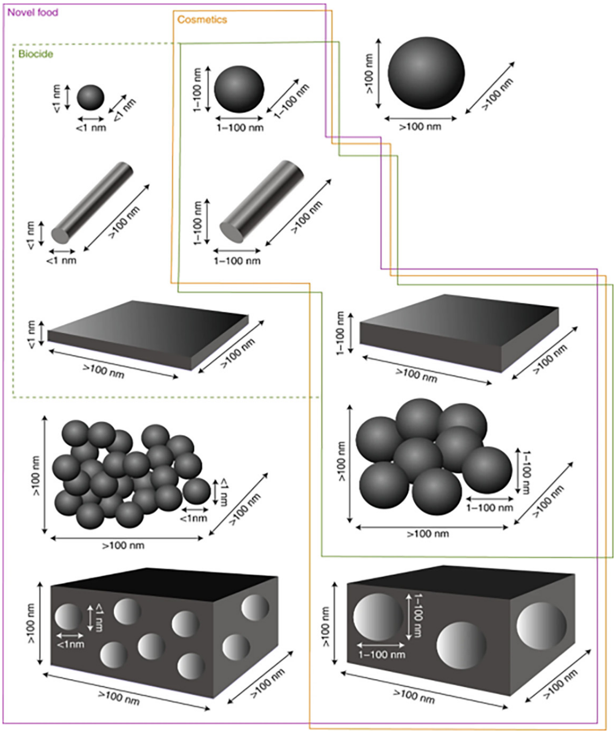
Another example comes from the European Commission (EC), which in 2022 updated the recommended definition, which focuses on solid particles (and aggregates) within at least 50% of the particle number-based size distribution below 100 nm in at least one (external) dimension, and the shape of the ENM (Rauscher *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.

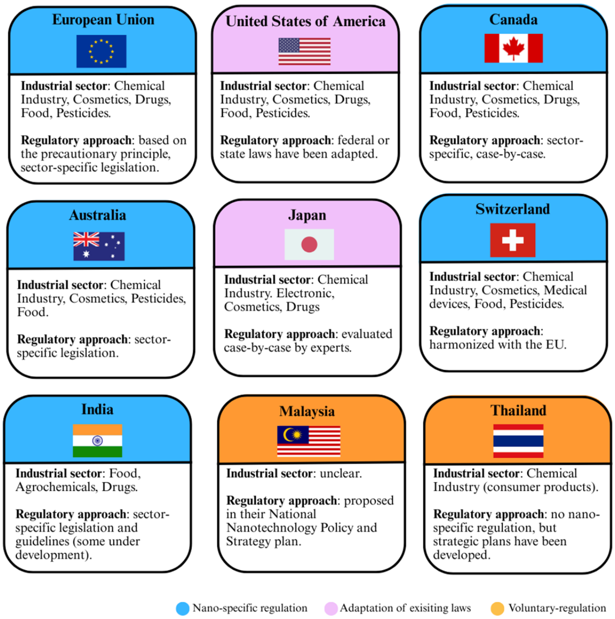


Source: Taken from Miernicki *et al*. (2019).

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.



European Union
Industrial sector: Chemical Industry, Cosmetics, Drugs, Food, Pesticides.
Regulatory approach: based on the precautionary principle, sector-specific legislation.

United States of America
Industrial sector: Chemical Industry, Cosmetics, Drugs, Food, Pesticides.
Regulatory approach: federal or state laws have been adapted.

Canada
Industrial sector: Chemical Industry, Cosmetics, Drugs, Food, Pesticides.
Regulatory approach: sector-specific, case-by-case.

Australia
Industrial sector: Chemical Industry, Cosmetics, Pesticides, Food.
Regulatory approach: sector-specific legislation.

Japan
Industrial sector: Chemical Industry. Electronic, Cosmetics, Drugs
Regulatory approach: evaluated case-by-case by experts.

Switzerland
Industrial sector: Chemical Industry, Cosmetics, Medical devices, Food, Pesticides.
Regulatory approach: harmonized with the EU.

India
Industrial sector: Food, Agrochemicals, Drugs.
Regulatory approach: sector-specific legislation and guidelines (some under development).

Malaysia
Industrial sector: unclear.
Regulatory approach: proposed in their National Nanotechnology Policy and Strategy plan.

Thailand
Industrial sector: Chemical Industry (consumer products).
Regulatory approach: no nano-specific regulation, but strategic plans have been developed.

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,

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[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-

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[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 Pharmaceutical 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-

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[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.

References

Abbasi, Ibtisam. (2025). *Global nanomaterial regulation: a country-by-country comparison*. https://www.azonano.com/article.aspx?ArticleID=6885.

Adam, Véronique, Alejandro Caballero-Guzman and Bernd Nowack. (2018). Considering the forms of released engineered nanomaterials in probabilistic material flow analysis. *Environmental pollution*, 243: 17-27. https://doi.org/10.1016/j.envpol.2018.07.108.

Aguilar-Aguilar, Angélica, Lorena Díaz de León-Martínez, Angélica Forgionny, Nancy Y. Acelas Soto, Sergio Rosales Mendoza and Ana I. Zarate-Guzman. (2023). A systematic review on the current situation of emerging pollutants in Mexico: a perspective on policies, regulation, detection, and elimination in water and wastewater. *Science of the Total Environment*, 905: 167426. https://doi.org/10.1016/j.scitotenv.2023.167426.

Ali, Faraat, Kumari Neha and Sana Parveen. (2023). Current regulatory landscape of nanomaterials and nanomedicines: a global perspective. *Journal of Drug Delivery Science and Technology*, 80: 104118. https://doi.org/10.1016/j.jddst.2022.104118.

Allan, Jacqueline, Susanne Belz, Arnd Hoeveler, Marta Hugas, Haruhiro Okuda, Anil Patri, Hubert Rauscher *et al*. (2021). Regulatory landscape of nanotechnology and nanoplastics from a global perspective. *Regulatory Toxicology and Pharmacology*, 122: 104885. https://doi.org/10.1016/j.yrtph.2021.104885.

Anzaldo Montoya, Mónica and Michelle Chauvet. (2016). Technical standards in nanotechnology as an instrument of subordinated governance: Mexico case study. *Journal of Responsible Innovation*, 3(2): 135-153. https://doi.org/10.108

0/23299460.2016.1196098.

Arteaga, Víctor Hugo. (2020). Nano Tutt, la empresa de nanotecnología que engaña a sus pacientes diabéticos y al gobierno mexicano. *El Financiero*. https://www.elfinanciero.com.mx/salud/nano-tutt-la-empresa-de-nanotecnologia-que-engana-a-sus-pacientes-diabeticos-y-al-gobierno-mexicano/.

Arvidsson, Rickard, Gregory Peters, Steffen Foss Hansen and Anders Baun. (2022). Prospective environmental risk screening of seven advanced materials based on production volumes and aquatic ecotoxicity. *NanoImpact*, 25: 100393. https://doi.org/10.1016/j.impact.2022.100393.

Arvidsson, Rickard, Sverker Molander and Björn A. Sandén. (2012). Particle flow analysis: exploring potential use phase emissions of titanium dioxide nanoparticles from sunscreen, paint, and cement. *Journal of Industrial Ecology*, 16(3): 343-351. https://doi.org/10.1111/j.1530-9290.2011.00429.x.

Auffan, Melanie, Marie Tella, Catherine Santaella, Lenka Brousset, Christine Paillès, Mohamed Barakat, Benjamin Espinasse *et al*. (2014). An adaptable mesocosm platform for performing integrated assessments of nanomaterial risk in complex environmental systems. *Scientific Reports*, 4(1): 5608. https://doi.org/10.1038/srep05608.

Ávila Bernal, Alba Graciela, Ana María Ocampo Gómez, Oliver Wootton and Pablo Vieira Samper. (2015). *Nanotechnology and manufactured nanomaterials in Latin America and the Caribbean: safety issues*. ISBN e-book: 978-958-774-305-0.

Bachler, Gerald, Natalie von Goetz and Konrad Hungerbuhler. (2015). Using physiologically based pharmacokinetic (PBPK) modeling for dietary risk assessment of titanium dioxide (TiO_2) nanoparticles. *Nanotoxicology*, 9(3): 373-380. https://doi.org/10.3109/17435390.2014.940404.

Barnard, Amanda S. (2009). How can ab initio simulations address risks in nanotech? *Nature Nanotechnology*, 4(6): 332-35, June. https://doi.org/10.1038/nnano.2009.126. https://doi.org/10.1038/nnano.2009.126.

Berger, Mauricio and Airton Guilherme Berger Filho. (2022). Nano-governance, nanoregulation and nano-citizenship? An analysis of normative scenarios in Brazil and Argentina. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 15(28). https://doi.org/10.22201/ceiich.24485691e.2022.28.69659.

Bhat, Mansoor Ahmad, Tanja Radu, Ignacio Martín-Fabiani, Panagiotis D. Kolokathis, Anastasios G. Papadiamantis, Stephan Wagner, Yvonne Kohl *et al*. (2025). Safe and sustainable by design of next generation chemicals and materials: SSbD4CheM project innovations in the textiles, cosmetic and automotive sectors. *Computational and Structural Biotechnology Journal*, 29: 60-71. https://doi.org/10.1016/j.csbj.2025.03.022.

Bleeker, Eric A. J., Elmer Swart, Hedwig Braakhuis, María Luisa Fernández Cruz, Steffi Friedrichs, Ilse Gosens, Frank Herzberg *et al*. (2023). Towards harmonisation of testing of nanomaterials for EU regulatory requirements on chemical safety — A proposal for further actions. *Regulatory Toxicology and Pharmacology*, 139: 105360. https://doi.org/10.1016/j.yrtph.2023.105360.

Bonfil Olivera, Martín. (2018). Estafas y control de calidad. *Milenio*. https://www.

milenio.com/opinion/martin-bonfil-olivera/la-ciencia-por-gusto/estafas-y-control-de-calidad.

Brunner, Paul H. and Helmut Rechberger. (2016). *Handbook of material flow analysis: for environmental, resource, and waste engineers*. CRC press. https://doi.org/10.1201/9781315313450.

Bucher, Guillaume, Hind El Hadri, Océane Asensio, François Auger, Josefa Barrero and Jean-Philippe Rosec. (2024). Large-scale screening of E171 food additive (TiO_2) on the French market from 2018 to 2022: occurrence and particle size distribution in various food categories. *Food Control*, 155: 110102. https://doi.org/10.1016/j.foodcont.2023.110102.

Camarillo Abad, Eduardo, Rafael Blome Fernández, Pablo Ivan Castellanos Andrade and Jessica Campos Delgado. (2019). Mitos y realidades de la nanotecnología en México. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 12(22): 73-88. https://doi.org/10.22201/ceiich.24485691e.2019.22.65023.

Cenam. (2017). *IUPAC Workshop on safety of engineered nanomaterials*. https://www.gob.mx/cenam/articulos/iupac-workshop-on-safety-of-engineered-nanomaterials-28-29-september-2017-cenam-queretaro-mexico?idiom=es.

Chatterjee, Mainak, Arkaprava Banerjee, Priyanka De, Agnieszka Gajewicz-Skretna and Kunal Roy. (2022). A novel quantitative read-across tool designed purposefully to fill the existing gaps in nanosafety data. *Environmental Science: Nano*, 9(1): 189-203. https://doi.org/10.1039/D1EN00725D.

Chávez-Hernández, Jorge Antonio, Aída Jimena Velarde-Salcedo, Gabriela Navarro-Tovar and Carmen González. (2024). Safe nanomaterials: from their use, application and disposal to regulations. *Nanoscale Advances*, 6(6): 1583-1610. https://doi.org/10.1039/D3NA01097J.

Chen, Qiran, Jim E. Riviere and Zhoumeng Lin. (2022). Toxicokinetics, dose–response, and risk assessment of nanomaterials: methodology, challenges, and future perspectives. *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology*, 14(6): e1808. https://doi.org/10.1002/wnan.1808.

CIMAV. *Diagnóstico y prospectiva de la nanotecnología en México*. (2008). https://www.economia.gob.mx/files/comunidad_negocios/industria_comercio/Nanotecnologia.pdf.

Clark, Nathaniel, Joanne Vassallo, Patrícia V. Silva, Ana Rita R. Silva, Marta Baccaro, Neja Medvešček, Magdalena Grgić *et al*. (2022). Metal transfer to sediments, invertebrates and fish following waterborne exposure to silver nitrate or silver sulfide nanoparticles in an indoor stream mesocosm. *Science of the Total Environment*, 850: 157912. https://doi.org/10.1016/j.scitotenv.2022.157912.

Cofepris. (2018). *Se realizará el simposio sobre ciencias regulatorias*. https://www.gob.mx/cofepris/prensa/se-realizara-el-simposio-sobre-ciencias-regulatorias

Conley, Mikaela. (2025). Titanium dioxide, banned in Europe, is one of the most common food additives in the U.S. *U.S. Right to Know*. https://usrtk.org/chemicals/titanium-dioxide/.

Creutzenberg, Otto. (2021). Nanoparticles and their regulation. *Regulatory Toxicology*, 1-17. https://doi.org/10.1007/978-3-642-36206-4_122-1.

Cross, Richard K., Dave Spurgeon, Claus Svendsen, Elma Lahive, Simon Little, Frank von der Kammer, Frédéric Loosli *et al*. (2024). An integrated approach to testing and assessment (IATA) to support grouping and read-across of nanomaterials in aquatic systems. *Nano Today*, 54: 102065. https://doi.org/10.1016/j.nantod.2023.102065.

Delgado-Ramos, Gian Carlo. (2014). Nanotechnology in Mexico: global trends and national implications for policy and regulatory issues. *Technology in Society*, 37: 4-15. https://doi.org/10.1016/j.techsoc.2013.09.005.

Devasahayam, Sheila. (2017). Overview of an internationally integrated nanotechnology governance. *International Journal of Metrology and Quality Engineering*, 8: 8. https://doi.org/10.1051/ijmqe/2017002.

EFSA Panel on Food Additives and Flavourings (FAF), Maged Younes, Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fowler, María José Frutos Fernández *et al*. (2021). Safety assessment of titanium dioxide (E171) as a food additive. *Efsa Journal*, 19(5): e06585. https://doi.org/10.2903/j.efsa.2021.6585.

Foladori, Guillermo and Edgar Záyago Lau. (2014). The regulation of nanotechnologies in Mexico. *Nanotech. L. & Bus*., 11: 164. https://heinonline.org/HOL/LandingPage?handle=hein.journals/nantechlb11&div=15&id=&page=.

Foladori, Guillermo, Edgar Arteaga Figueroa, Edgar Záyago Lau, Richard Appelbaum, Eduardo Robles-Belmont, Liliana Villa, Rachel Parker and Vanessa Leos. (2015). Nanotechnology in Mexico: key findings based on OECD criteria. *Minerva*, 53: 279-301. https://doi.org/10.1007/s11024-015-9281-6.

Fonseca, Paulo F. C. and Tiago Santos Pereira. (2014). The governance of nanotechnology in the Brazilian context: entangling approaches. *Technology in Society*, 37: 16-27. https://doi.org/10.1016/j.techsoc.2013.07.003.

Franken, Remy, Minne B. Heringa, Thies Oosterwijk, Miikka Dal Maso, Wouter Fransman, Tomi Kanerva, Biase Liguori *et al*. (2020). Ranking of human risk assessment models for manufactured nanomaterials along the cooper stage-gate innovation funnel using stakeholder criteria. *NanoImpact*, 17: 100191. https://doi.org/10.1016/j.impact.2019.100191.

Furxhi, Irini, Anna Costa, Socorro Vázquez-Campos, Carlos Fito-López, Danail Hristozov, Juan Antonio Tamayo Ramos, Susanne Resch *et al*. (2023). Status, implications and challenges of European safe and sustainable by design paradigms applicable to nanomaterials and advanced materials. *RSC Sustainability*, 1(2): 234-250. https://doi.org/10.1039/D2SU00101B.

Hochella, Michael F., David W. Mogk, James Ranville, Irving C. Allen, George W. Luther, Linsey C. Marr, B. Peter McGrail *et al*. (2019). Natural, incidental, and engineered nanomaterials and their impacts on the earth system. *Science*, 363(6434): eaau8299. https://doi.org/doi:10.1126/science.aau8299. https://www.science.org/doi/abs/10.1126/science.aau8299.

Hong, Hyunjoo and Bernd Nowack. (2024). Form-specific prospective environmental risk assessment of graphene-based materials in European freshwater. *Environmental Science & Technology*, 58(49): 21750-21759. https://doi.org/10.1021/acs.est.4c05153.

Hong, Hyunjoo, Véronique Adam and Bernd Nowack. (2021). Form-specific and probabilistic environmental risk assessment of 3 engineered nanomaterials (nano-Ag, nano-TiO_2, and Nano-ZnO) in European freshwaters. *Environmental Toxicology and Chemistry*, 40(9): 2629-2639. https://doi.org/10.1002/etc.5146.

Hristozov, Danail, Elena Badetti, Paolo Bigini, Andrea Brunelli, Susan Dekkers, Luisa Diomede, Shareen H. Doak *et a*l. (2024). Next generation risk assessment approaches for advanced nanomaterials: current status and future perspectives. *NanoImpact*, 100523. https://doi.org/10.1016/j.impact.2024.100523.

Hupffer, Haide María and Luisa Lauermann Lazzaretti. (2019). Nanotecnologia e sua regulamentação no Brasil. *Revista Gestão e Desenvolvimento*, 16(3): 153-177. https://doi.org/10.25112/rgd.v16i3.1792.

International ISO. (2023). *Nanotechnologies – Vocabulary. Part 1. Core vocabular*y. ISO 80004-1: 2023, July.

Isibor, Patrick Omoregie. (2024). Regulations and policy considerations for nanoparticle safety. In *Environmental nanotoxicology: combatting the minute contaminants*. Cham: Springer Nature Switzerland, 295-316. https://doi.org/10.1007/978-3-031-54154-4_14.

Isigonis, Panagiotis, Danail Hristozov, Christina Benighaus, Elisa Giubilato, Khara Grieger, Lisa Pizzol, Elena Semenzin, Igor Linkov, Alex Zabeo and Antonio Marcomini. (2019). Risk governance of nanomaterials: review of criteria and tools for risk communication, evaluation, and mitigation. *Nanomaterials*, 9(5): 696. https://doi.org/10.3390/nano9050696.

Jaya, P. (2021). NanoMalaysia to launch two initiatives to boost commercialization of nanotechnology. https://thesun.my/business-news/nanomalaysia-to-launch-two-initiatives-to-boost-commercialisation-of-nanotechnology-YL8148320.

Karlaganis, Georg, Rachel Liechti, Sirasak Teparkum, Pavadee Aungkavattana and Ramjitti Indaraprasirt. (2019). Nanoregulation along the product life cycle in the EU, Switzerland, Thailand, the USA, and intergovernmental organisations, and its compatibility with WTO Law. *Toxicological & Environmental Chemistry*, 101(7-8): 339-68. https://doi.org/10.1080/02772248.2019.1697878.

Keller, Arturo A., Alex Ehrens, Yuanfang Zheng and Bernd Nowack. (2023). Developing trends in nanomaterials and their environmental implications. *Nature nanotechnology*, 18(8): 834-37. https://doi.org/10.1038/s41565-023-01409-z.

Keller, Arturo A., Yuanfang Zheng, Antonia Praetorius, Joris T. K. Quik and Bernd Nowack. (2024). Predicting environmental concentrations of nanomaterials for exposure Assessment – A review. *NanoImpact*, 33: 100496, January. https://doi.org/https://doi.org/10.1016/j.impact.2024.100496.

Kumari, Ritika, Kalpana Suman, Swagata Karmakar, Vandana Mishra, Sameer Gunjan Lakra, Gunjan Kumar Saurav and Binod Kumar Mahto. (2023). Regulation and safety measures for nanotechnology-based agri-products. *Frontiers in Genome Editing*, 5: 1200987. https://doi.org/10.3389/fgeed.2023.1200987.

Lai, Racliffe W. S., Katie W. Y. Yeung, Mana M. N. Yung, Aleksandra B. Djurišić, John P. Giesy and Kenneth M. Y. Leung. (2018). Regulation of engineered nanomaterials:

current challenges, insights and future directions. *Environmental Science and Pollution Research*, 25: 3060-3077. https://doi.org/10.1007/s11356-017-9489-0.

Landeros, Abisai. (2008). Normas Oficiales Mexicanas (NOM) y Normas Mexicanas (NMX). https://www.academia.edu/33326779/Normas_Oficiales_Mexicanas_NOM_y_Normas_MN.

Lazos-Martínez, Rubén J. and Norma González-Rojano. (2013). Nanometrology in emerging economies: the case of Mexico. *Mapan*, 28(4): 299-309.https://doi.org/10.1007/s12647-013-0083-8.

Lebre, Filipa, Nivedita Chatterjee, Samantha Costa, Eli Fernández-de-Gortari, Carla Lopes, João Meneses, Luís Ortiz, Ana R. Ribeiro, Vânia Vilas-Boas and Ernesto Alfaro-Moreno. (2022). Nanosafety: an evolving concept to bring the safest possible nanomaterials to society and environment. *Nanomaterials*, 12(11): 1810. https://doi.org/10.3390/nano12111810.

Luizink, Miriam. (2009). NMP4-CT-2006-032155. Nanoforum EULA. Nanoforum EU Latin America. https://cordis.europa.eu/docs/results/32/32155/123545511-6_en.pdf.

Malsch, Ineke, Martina Lindorfer, Isabella Wagner and María Lima-Toivanen. (2016). International cooperation on nanosafety between Europe and Latin America. *Managing Risk in Nanotechnology: Topics in Governance, Assurance and Transfer*, 71-92. https://doi.org/10.1007/978-3-319-32392-3_5.

Malsch, Ineke, Vrishali Subramanian, Elena Semenzin, Danail Hristozov, Antonio Marcomini, Martin Mullins, Karena Hester, Eamonn McAlea, Finbarr Murphy and Syed AM Tofail. (2015). Empowering citizens in international governance of nanotechnologies. *Journal of Nanoparticle Research*, 17 (2015): 1-19. https://doi.org/10.1007/s11051-015-3019-0.

Mancardi, Giulia, Alicja Mikolajczyk, Vigneshwari K. Annapoorani, Aileen Bahl, Kostas Blekos, Jaanus Burk, Yarkın A. Çetin *et al*. (2023). A computational view on nanomaterial intrinsic and extrinsic features for nanosafety and sustainability. *Materials Today*, 67: 344-370. https://hal.science/hal-04227136v1/file/MATTOReviewPartnersFinal.pdf.

Mech, Agnieszka, Stefania Gottardo, Valeria Amenta, Alessia Amodio, Susanne Belz, Søren Bøwadt, Jana Drbohlavová *et al*. (2022). Safe-and sustainable-by-design: the case of smart nanomaterials. A perspective based on a European workshop. *Regulatory Toxicology and Pharmacology*, 128: 105093. https://doi.org/10.1016/j.yrtph.2021.105093

Mendoza Cantú, Ania and Irina Ana Rosa Ize Lema. (2017). Las sustancias químicas en México. Perspectivas para un manejo adecuado. *Revista Internacional de Contaminación Ambiental*, 33(4): 719-745. https://doi.org/10.20937/rica.2017.33.04.15.

Metreveli, George, Sandra Kurtz, Ricki R. Rosenfeldt, Frank Seitz, Samuel K. Kumahor, Alexandra Grün, Sondra Klitzke *et al*. (2021). Distribution of engineered Ag nanoparticles in the aquatic-terrestrial transition zone: a long-term indoor floodplain mesocosm study. *Environmental Science: Nano*, 8(6): 1771-1785. https://doi.org/10.1039/D1EN00093D.

Miernicki, M., Hofmann, T., Eisenberg, I., von der Kammer and Praetorius, A. (2019).

Legal and practical challenges in classifying nanomaterials according to regulatorty definitions. *Nature Nanotechnology*, 14(3): 208-216. https://doi.org/10.1038/s41565-019-0396-z.

Mishra, Mansi, Kavya Dashora, Ayushi Srivastava, Vinayak D. Fasake and Ramineni Harsha Nag. (2019). Prospects, challenges and need for regulation of nanotechnology with special reference to India. *Ecotoxicology and Environmental Safety*, 171: 677-682. https://doi.org/10.1016/j.ecoenv.2018.12.085.

Mundo Nano (Revista). (2014a). Lineamientos para regulaciones sobre nanotecnologías en México. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 5(9). https://doi.org/10.22201/ceiich.24485691e.2012.9.45193.

Mundo Nano (Revista). (2014b). Lanzamiento de LABnano-Laboratorio Socioeconómico en Nanociencia y Nanotecnología. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 5(9). https://doi.org/10.22201/ceiich.24485691e.2012.9.45228.

Mundo Nano (Revista). (2010). Red Temática de Nanociencia y Nanotecnología. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnolog*ía, 3(2). https://doi.org/10.22201/ceiich.24485691e.2010.2.52224.

Nielsen, Maria Bille, Anders Baun, Aiga Mackevica, Amalie Thit, Inger Odnevall Wallinder, Julián A. Gallego *et al*. (2021). Nanomaterials in the European Chemicals Legislation – Methodological challenges for registration and environmental safety assessment. *Environmental Science: Nano*, 8(3): 731-747. https://doi.org/10.1039/D0EN01123A.

Nielsen, Maria Bille, Lars Skjolding, Anders Baun and Steffen Foss Hansen. (2023). European nanomaterial legislation in the past 20 years – Closing the final gaps. *NanoImpact*, 32: 100487. https://doi.org/10.1016/j.impact.2023.100487.

Nymark, Penny, Martine Bakker, Susan Dekkers, Remy Franken, Wouter Fransman, Amaia García-Bilbao, Dario Greco *et al*. (2020). Toward rigorous materials production: new approach methodologies have extensive potential to improve current safety assessment practices. *Small*, 16(6): 1904749. https://doi.org/10.1002/smll.201904749.

Ochoa López, Héctor Eduardo. (2021). *Integración de los datos de identidad química de las nuevas sustancias a incluir en el catálogo nacional de sustancias químicas*. https://www.gob.mx/cms/uploads/attachment/file/688885/Reporte_Final_CNSQ_6-12-2021_8_.pdf.

OECD. (2023). (Q)SAR Assessment framework: Guidance for the regulatory assessment of (quantitative) structure – Activity relationship models, predictions, and results based on multiple predictions. *Series on Testing and Assessment*, 386. https://one.oecd.org/document/ENV/CBC/MONO(2023)32/en/pdf.

OECD. (2021). *Evaluation of tools and models for assessing occupational and consumer exposure to manufactured nanomaterials – Part I: Compilation of tools/models and analysis for further evaluation*. https://doi.org/10.1787/43273e0a-en.

OECD. (2022). *Important issues on risk assessment of manufactured nanomaterials*. https://doi.org/10.1787/2f6e7c61-en.

Oomen, Agnes G., Eric A. J. Bleeker, Peter M. J. Bos, Fleur van Broekhuizen, Stefania

Gottardo, Monique Groenewold, Danail Hristozov *et al*. (2015). Grouping and read-across approaches for risk assessment of nanomaterials. International *Journal of Environmental Research and Public Health*, 12(10): 13415-13434. https://doi.org/10.3390/ijerph121013415.

Ortiz-Galvez, Luis Mauricio, Alejandro Caballero-Guzmán, Carla Lopes and Ernesto Alfaro-Moreno. (2024). Probabilistic material flow analysis of released nano titanium dioxide in Mexico. *NanoImpact*, 35: 100516. https://doi.org/10.1016/j.impact.2024.100516.

Ozbek, Ozlem, Destina Ekingen Genc and Kutlu O. Ulgen. (2024). Advances in physiologically based pharmacokinetic (PBPK) modeling of nanomaterials. *ACS Pharmacology & Translational Science*, 7(8): 2251-2279. https://doi.org/10.1021/acsptsci.4c00250.

Park, H. G., Yeo, M. K. (2016). Nanomaterial regulatory policy for human health and environment. *Mol. Cell. Toxicol*., 12, 223-236. https://doi.org/10.1007/s13273-016-0027-9.

Porcari, Andrea, Elisabetta Borsella, Christina Benighaus, Khara Grieger, Panagiotis Isigonis, Somik Chakravarty, Pete Kines and Keld Alstrup Jensen. (2019). From risk perception to risk governance in nanotechnology: a multi-stakeholder study. *Journal of Nanoparticle Researc*h, 21(11): 1-19. https://doi.org/10.1007/s11051-019-4689-9.

Ramadan, Qasem, Roa Saleem Fardous, Rana Hazaymeh, Sultan Alshmmari and Mohammed Zourob. (2021). Pharmacokinetics-on-a-chip: *in vitro* microphysiological models for emulating of drugs ADME. *Advanced Biology*, 5(9): 2100775. https://doi.org/10.1002/adbi.202100775.

Rasmussen, Kirsten, Eric A. J. Bleeker, James Baker, Jacques Bouillard, Wouter Fransman, Thomas A. J. Kuhlbusch, Susanne Resch *et al*. (2023). A roadmap to strengthen standardisation efforts in risk governance of nanotechnology. *NanoImpact*, 32: 100483. https://doi.org/10.1016/j.impact.2023.100483.

Rasmussen, Kristen, Riego, S. J. and Rauscher,H. (2024). How nanoparticles are counted in global regulatory nanomaterial definitions. *Nature Nanotecnology*, 19: 132-138. https://doi.org/https://doi.org/10.1038/s41565-023-01578-x.

Rauscher, Hubert, Vikram Kestens, Kirsten Rasmussen, Thomas Linsinger and Elzbieta Stefaniak. (2023a). Guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial. https://data.europa.eu/doi/10.2760/143118.

Rauscher, Hubert, Andrej Kobe, Vikram Kestens and Kirsten Rasmussen. (2023b). Is it a nanomaterial in the EU? Three essential elements to work it out. *Nano Today*, 49: 101780. https://doi.org/10.1016/j.nantod.2023.101780.

Saldívar-Tanaka, Laura. (2024). El principio de precaución ante los posibles riesgos de la nanotecnología y sus derivados. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 17(33). https://doi.org/10.22201/ceiich.24485691e.2024.33.69762.

Saldívar-Tanaka, Laura. (2022). Recomendaciones de política pública de nanociencia y nanotecnología en México: privilegiar el bienestar humano y ambiental.

Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología, 15(28): 1e-23e. https://doi.org/10.22201/ceiich.24485691e.2022.28.69655.

Saldívar-Tanaka, L., Hansen, S. F. (2021). Should the precautionary principle be implemented in Europe with regard to nanomaterials? Expert interviews. *J Nanopart Res*, 23, 70. https://doi.org/10.1007/s11051-021-05173-w.

Saldívar-Tanaka, Laura. (2020). Regulación blanda, normas técnicas y armonización regulatoria internacional, para la nanotecnología. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 13(24). https://doi.org/10.22201/ceiich.24485691e.2020.24.69621.

Saldívar-Tanaka, Laura. (2019). Regulando la nanotecnología. *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 12(22): 37-57. https://doi.org/10.22201/ceiich.24485691e.2019.22.63140.

Sayes, Christie M., Rajeev Wahi, Preetha A. Kurian, Yunping Liu, Jennifer L. West, Kevin D. Ausman, David B. Warheit and Vicki L. Colvin. (2006). Correlating nanoscale titania structure with toxicity: a cytotoxicity and inflammatory response study with human dermal fibroblasts and human lung epithelial cells. *Toxicological Sciences*, 92(1): 174-185. https://doi.org/10.1093/toxsci/kfj197.

Shandilya, Neeraj, Effie Marcoulaki, Sven Vercauteren, Hilda Witters, Eric Johansson Salazar-Sandoval, Anna-Kaisa Viitanen, Christophe Bressot and Wouter Fransman. (2020). Blueprint for the development and sustainability of national nanosafety centers. *NanoEthics*, 14: 169-183. https://doi.org/10.1007/s11569-020-00364-6.

Sørensen, Sara Nørgaard, Anders Baun, Michael Burkard, Miikka Dal Maso, Steffen Foss Hansen, Samuel Harrison, Rune Hjorth *et al*. (2019). Evaluating environmental risk assessment models for nanomaterials according to requirements along the product innovation stage-gate process. *Environmental Science: Nano*, 6(2): 505-518. https://doi.org/10.1039/C8EN00933C.

Sørensen, Sara Nørgaard, Henning Wigger, Alex Zabeo, Elena Semenzin, Danail Hristozov, Bernd Nowack, David J. Spurgeon and Anders Baun. (2020). Comparison of species sensitivity distribution modeling approaches for environmental risk assessment of nanomaterials — A case study for silver and titanium dioxide representative materials. *Aquatic Toxicology*, 225: 105543. https://doi.org/10.1016/j.aquatox.2020.105543.

Stone, Vicki, Stefania Gottardo, Eric A. J. Bleeker, Hedwig Braakhuis, Susan Dekkers, Teresa Fernandes, Andrea Haase *et al*. (2020). A framework for grouping and read-across of nanomaterials-supporting innovation and risk assessment. *Nano Today*, 35: 100941. https://doi.org/10.1016/j.nantod.2020.100941.

Subhan, Md Abdus, Tahrima Subhan, Kristi Priya Choudhury and Newton Neogi. (2024). Safety measures, regulations, ethical, and legal issues for nanomaterials. In *Handbook of Nanomaterials*, vol. 2, 791-828. Elsevier. https://doi.org/10.1016/B978-0-323-95513-3.00006-X.

Teunenbroek, T. V., Baker, J. and Dijkzeul, A. (2017). Towards a more effective and efficient governance and regulation of nanomaterials. *Part Fibre Toxicol*, 14, 54. https://doi.org/10.1186/s12989-017-0235-z.

Tsang, Michael P., Danail Hristozov, Alex Zabeo, Antti Joonas Koivisto, Alexander Christian Østerskov Jensen, Keld Alstrup Jensen, Chengfang Pang, Antonio Marcomini and Guido Sonnemann. (2017). Probabilistic risk assessment of emerging materials: case study of titanium dioxide nanoparticles. *Nanotoxicology*, 11(4): 558-568. https://doi.org/10.1080/17435390.2017.1329952.

UIN (Unidad de Inteligencia de Negocios, ProMéxico). (2018). El mundo de la nanotecnología. Situación y prospectiva para México. https://es.scribd.com/document/485569847/El-mundo-nanotecnologia-Situacion-prospectiva-Mexico-pdf.

Vermoolen, Ruby, Remy Franken, Tanja Krone, Neeraj Shandilya, Henk Goede, Hasnae Ben Jeddi, Eelco Kuijpers, Calvin Ge and Wouter Fransman. (2025). The nano exposure quantifier: a quantitative model for assessing nanoparticle exposure in the workplace. *Annals of Work Exposures and Health*, wxae104. https://doi.org/10.1093/annweh/wxae104.

Villa Vázquez, Laura. (2022). *Programas educativos en nanotecnología en México*. Proyecto Conacyt Ciencia de Frontera 2019 No. 304320 (fordecyt-pronaces/304320/2020). https://relans.org/wp-content/ uploads/Produccion-Cientifica.pdf.

Williams, Richard J., Samuel Harrison, Virginie Keller, Jeroen Kuenen, Stephen Lofts, Antonia Praetorius, Claus Svendsen, Lucie C. Vermeulen and Jikke van Wijnen. (2019). Models for assessing engineered nanomaterial fate and behaviour in the aquatic environment. *Current Opinion in Environmental Sustainability*, 36: 105-115. https://doi.org/10.1016/j.cosust.2018.11.002.

Wohlleben, Wendel, Nathan Bossa, Denise M. Mitrano and Keana Scott. (2024). Everything falls apart: how solids degrade and release nanomaterials, composite fragments, and microplastics. *NanoImpact*, 34: 100510, March. https://doi.org/https://doi.org/10.1016/j.impact.2024.100510. https://www.sciencedirect.com/science/article/pii/S245207482400020X.

Wohlleben, Wendel, Thomas A. J. Kuhlbusch, Jürgen Schnekenburger and Claus-Michael Lehr (eds.) (2015). *Safety of nanomaterials along their lifecycle: release, exposure, and human hazards*. CRC Press, 2014. ISBN 9781032236469.

Wu, Jimeng, Govind Gupta, Tina Buerki-Thurnherr, Bernd Nowack and Peter Wick. (2024). Bridging the gap: innovative human-based *in vitro* approaches for nanomaterials hazard assessment and their role in safe and sustainable by design, risk assessment, and life cycle assessment. *NanoImpact*, 36: 100533. https://doi.org/10.1016/j.impact.2024.100533.

Yu, Qilin, Honggang Wang, Qi Peng, Ye Li, Zhe Liu and Mingchun Li. (2017). Different toxicity of anatase and rutile TiO_2 nanoparticles on macrophages: involvement of difference in affinity to proteins and phospholipids. *Journal of Hazardous Materials*, 335: 125-134. https://doi.org/10.1016/j.jhazmat.2017.04.026.

Záyago Lau, Edgar, Guillermo Foladori, Stacey Frederick and Edgar Ramón Arteaga. (2016). Researching risks of nanomaterials in Mexico. *Journal of Hazardous, Toxic, and Radioactive WasteV*, 20(1): B4014001. https://doi.org/10.1061/(ASCE)HZ.2153-5515.0000247.

Záyago-Lau, Edgar and Guillermo Foladori. (2010). La nanotecnología en México: un desarrollo incierto. *Economía, sociedad y territorio*, 10(32): 143-178. http://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S1405-84212010000100006&lng=es&tlng.

Zheng, Yuanfang and Bernd Nowack. (2021). Size-specific, dynamic, probabilistic material flow analysis of titanium dioxide releases into the environment. *Environmental Science & Technology*, 55(4): 2392-2402. https://doi.org/10.1021/acs.est.0c07446.

Zolkipli, Maryam, Nurul Izza Shamsul Kamal and Noor Ashikin Basarudin. (2024). Regulating sustainable nanomaterials in Malaysia based on mandatory registration of selected eu countries. *e-book of extended abstract*, 54. https://www.researchgate.net/publication/390793339_comparative_study_on_the_legality_of_dog_and_cat_meat_consumption_under_malaysia_animal_welfare_laws#pf36.