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# Toxicity and environmental persistence of nanomaterials

# Toxicidad y persistencia ambiental de los nanomateriales

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**ABSTRACT:** Nanomaterials applications are growing at an incredible pace in a wide variety of fields. Being a relatively new technological field, the safe and sustainable use of nanomaterials has not kept pace with the fast commercialization of nanotechnology products; hence, the information about the associated toxicity and persistence in the environment must be addressed to consolidate proper methodologies for assessment of toxicology as well as life cycle assessment. This review aims to give an appropriate understanding of novel nanomaterials in environmental applications, their fate in the environment, and transformations due to external factors. Finally, the efforts made by international and regional organizations in risk assessment and toxicological frameworks are addressed, emphasizing current challenges.
**KEYWORDS:** nanotoxicology, nanomaterials legislation, nanomaterials persistence.

**RESUMEN:** Las aplicaciones de los nanomateriales están creciendo a un ritmo extraordinario en una amplia variedad de campos. Al tratarse de un ámbito tecnológico relativamente nuevo, el uso seguro y sostenible de los nanomateriales no ha avanzado al mismo ritmo que la rápida comercialización de productos basados en nanotecnología; por lo tanto, es necesario abordar la información relacionada con la toxicidad y persistencia en el medio ambiente para consolidar metodologías adecuadas tanto para la evaluación toxicológica como para la evaluación del ciclo de vida. Esta revisión tiene como objetivo proporcionar una comprensión adecuada de los nanomateriales novedosos en aplicaciones ambientales, su destino en el entorno y las transformaciones sufridas debido a factores externos. Finalmente, se abordan los esfuerzos realizados por organismos internacionales y regionales en materia de evaluación de riesgos y marcos toxicológicos, haciendo énfasis en los desafíos actuales.
**PALABRAS CLAVE**: nanotoxicología, legislación de nanomateriales, persistencia de nanomateriales.

## Introduction

Over the past two decades, nanotechnology has emerged as a powerful tool in extensive environmental applications, including water purification, air remediation, contaminant sensing, and sustainable energy production. Their exceptional physicochemical properties make them ideal candidates for catal-

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ysis, adsorption, separation, and sensing processes across various environmental matrices (Saleh, 2020). However, the rising use of nanomaterials (NMs) has increased concerns about their environmental behavior and potential toxicity (El-Kady *et al*., 2023). When NMs interact with complex environmental compartments such as soils, sediments, and natural waters, they may undergo various transformation pathways, including aggregation, dissolution, redox reactions, and surface modifications (Abbas, Yousaf, Amina *et al*., 2020). These transformations can result in modified nanostructures with different physicochemical profiles and biological activities. Consequently, transformed NMs may display toxicity profiles that vary from those of their original forms, which can complicate risk assessment strategies (Ren, Hu and Zhou, 2016).

Risk assessment can be defined as a systematic process for evaluating the likelihood that exposure to a given hazard will result in adverse health or environmental outcomes. It usually comprises four steps: hazard identification, hazard characterization, exposure assessment, and risk characterization (Savolainen *et al*., 2010). However, in the case of engineered NMs, traditional risk assessment methods are deficient due to their unique transformations and size-dependent effects (Johnston *et al*., 2020). For instance, traditional mass-based dose–response assessments often fail to capture the relevance of surface area or particle number, which are more predictive of nanoscale toxicity. Similarly, standard genotoxicity assays designed for soluble chemicals are not reliably predictive for insoluble or particulate NMs, leading to inconsistent or misleading results (Savolainen *et al*., 2010). In this context, regulations such as (EC) No 1907/2006 of the European Parliament control all chemicals and their use including high-volume substances such as silicon dioxide ($SiO_2$) or titanium dioxide ($TiO_2$) fail to include NMs explicitly (Laux *et al*., 2017). These deficiencies highlight the need for more tailored approaches and improved metrics to achieve reliable and reproducible nanomaterial risk assessments.

In response, regulatory bodies and international agencies are creating guidelines to assess the safety and environmental impact of NMs. Institutions such as the European Chemicals Agency (ECHA), the U.S. Environmental Protection Agency (EPA), and the Organization for Economic Co-operation and Development (OECD) have proposed specialized protocols for hazard identification, exposure assessment, and lifecycle analysis of NMs. Efforts such as REACH, (Registration, Evaluation, Authorization, and Restriction of Chemicals), NanoFASE (Nanomaterial Fate and Speciation in the Environment), and Safe-by-Design (SbD) approaches aim to establish more predictive, standardized, and precautionary strategies for the development and use of safer nanotechnologies (Rasmussen *et al*., 2016; Schwirn *et al*., 2020; Foulkes *et al*., 2020; Lai *et al*., 2018). However, challenges remain in harmonizing regulations across jurisdictions, filling knowledge gaps in transformation kinetics, and integrating alternative testing methods that reduce reliance on animal models

(Schwirn *et al*., 2020; Garner, Suh and Keller 2017; Chávez-Hernández *et al*., 2024).

This review provides a comprehensive analysis of NMs used in environmental remediation technologies and highlights their associated risks related to environmental transformation, persistence, and toxicity. Special emphasis is placed on the influence of physicochemical properties and environmental parameters on nanomaterial fate, the role of bioavailability in determining biological effects, and the transformation mechanisms that govern their ecotoxicological behavior. Additionally, regulatory frameworks and knowledge gaps are discussed to guide future research efforts toward the safe and sustainable use of NMs in environmental systems.

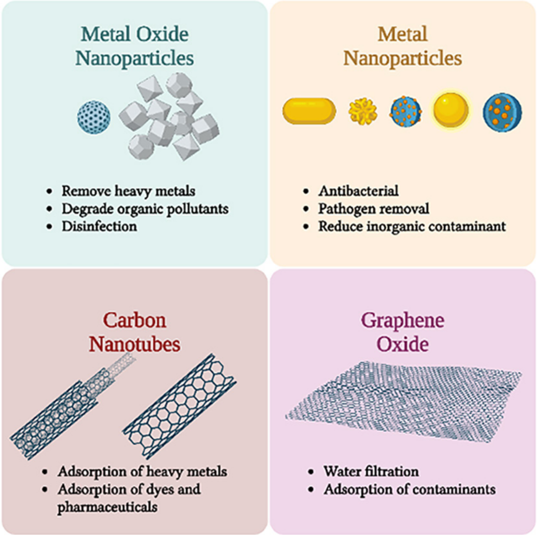
## Types of nanomaterials and their physicochemical properties

The study of different types of NMs is conducted from various perspectives, depending on their intended applications. Synthesis methods, as well as chemical, physical, optical, and mechanical properties are essential for their application in environmental remediation (Saleh, 2020; Paramasivam *et al*., 2021; Al-Khayri, Ansari and Singh, 2021). A variety of synthesis approaches are available, including chemical, physical, and biological methods (Wang *et al*., 2021). Chemical synthesis techniques, such as sol–gel and co-precipitation, provide precise control over nanoparticle size and morphology (Khan *et al*., 2018). In contrast, physical methods like laser ablation and ball milling are advantageous for producing high-purity nanoparticles (Koul *et al*., 2021; Pandit *et al*., 2022).

A wide range of NMs, including carbon-based NMs (CNMs), metal oxides, quantum dots, and other materials based on organic or inorganic compounds, have been used for application in environmental remediation or energy production and are shown in figure 1 with its main applications (Zhang *et al*., 2022).

Due to population growth and accelerated global industrialization, water quality has been affected, detecting the presence of heavy metal ions, radionuclides, and organic pollutants (S. Yu *et al*., 2022). New techniques such as advanced oxidation processes (AOPs) have been studied to develop strategies to resolve this issue, including NMs, which have significant potential for use as catalysts, adsorbents, and antimicrobial agents useful in removing contaminants from wastewater. These remediation technologies (AOPs) typically employ three mechanisms: adsorption, oxidation, and contaminant degradation (Singh and Singh, 2022). Its efficiency largely depends on the reactivity of each material, the adsorption capacity of porous structures and surface properties, as well as the modification of area and surface area (Lu and Astruc, 2020; El-sayed, 2020). In this context, the photocatalytic oxidation and degradation of organic contaminants in water have been demonstrated using

**FIGURE 1.** Nanomaterials for water treatment and their main applications.



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$TiO_2$ and ZnO, which are highly efficient in self-cleaning coatings, achieving a maximum dye degradation of 83.6% (Kumar *et al*., 2024; Pedroza-Herrera *et al*., 2019; Medina-Ramírez *et al*., 2022).

Furthermore, nano adsorbents have been synthesized, tested, and used for the removal and separation of contaminants such as radionuclides, heavy metals, dyes, and pharmaceutical compounds, including microplastics or nano plastics. Among the most notable are inorganic NMs (metals or metal oxides), CNMs (carbon nanotubes or graphene), and nanocomposites with polymer matrices (Pan *et al*., 2020; Bodzek, 2023). Magnetic NMs have been studied as efficient adsorbents thanks to their ability to separate easily from the process through the application of a magnetic field, in addition to their advantageous surface charge and good redox activity (Abdel Maksoud *et al*., 2020). Furthermore, systems that adsorb, degrade, and filter various pollutants are being considered. Their effectiveness is expected to be improved through structural modifications, such as metal doping or the formation of heterostructures, which expand their light absorption capacity and improve charge separation (Saleem *et al*., 2022). Some bismuth (BiOX) materials with significant adsorption characteristics and a wide band gap have been used as candidates for indoor air disinfection and purification with good results, showing a removal of airborne microorganisms greater than 79%. (Jiménez-Relinque *et al*., 2024; Martínez-Montelongo *et al*., 2024).

The phenomenon of increasing pollution implies a potential risk to human health, which highlights the need to develop monitoring systems that allow for the timely and accurate detection of toxic agents in different environments (Seesaard, Kamjornkittikoon and Wongchoosuk, 2024; X. Yu *et al*., 2025). Nanomaterial-based sensors have proven to be an important alternative in the field of real-time detection and monitoring, thanks to their optical, luminescent, catalytic, magnetic, and electrical properties, in addition to their manufacturing simplicity, sensitivity, selectivity, and variety (Rohilla, Chaudhary and Umar, 2021; Fazio *et al*., 2021). Among the NMs used for the detection of $NO_2$, $H_2S$, and $NH_3$ gases in air are carbon nanotubes, metal oxides, quantum dots, graphene, and hybrid composites, all different sizes, which present specific advantages in terms of sensitivity, selectivity, and response time (Lun and Xu, 2022). Quantum dots based on carbon, noble metals (Au, Ag, and Pt), metal oxides, and other metallic nanoparticles have been used to detect harmful metal ions leached from heavy metals such as Hg, Pb, and Cd in water bodies (Rohilla, Chaudhary and Umar 2021). The flexibility of nanomaterial-based sensors enables the development of portable systems or monitoring stations in harsh environments, such as for the detection of toxic gases and subsurface water pollutants, while their high sensitivity allows real-time monitoring essential for rapid detection and timely environmental protection (X. Li, Zhang and Li, 2025).

Although many nanoparticles possess physicochemical properties ideal for specific environmental applications, their significant impact on the environment must also be considered (Bilardo *et al*., 2022; Jayawardena *et al*., 2021). Interactions with systems and the environment are crucial in defining the biological and environmental behavior of NMs. The dimensional characteristics of NMs directly affect their biodistribution, stability, and cellular internalization (Anastasiadis *et al*., 2022). Studies suggest that sizes smaller than 100 nm and surface functional groups affect the transport of nanoparticles through the soil, in addition to considering the conditions and characteristics of the environment (Shaniv, Dror and Berkowitz, 2021).

In summary, synthesis methods must consider the physical and chemical approaches of each material for its final application (Wang *et al*., 2021). NMs must have practical and efficient applications, in addition to being cost-effective, biocompatible, and presenting lower environmental toxicity (Koul *et al*., 2021; Pandit *et al*., 2022). Understanding the NMs' fate, bioavailability, and transformation pathways in terrestrial and aquatic environments is essential for assessing environmental and health risks, as well as for informing regulatory frameworks (Besha *et al*., 2020).

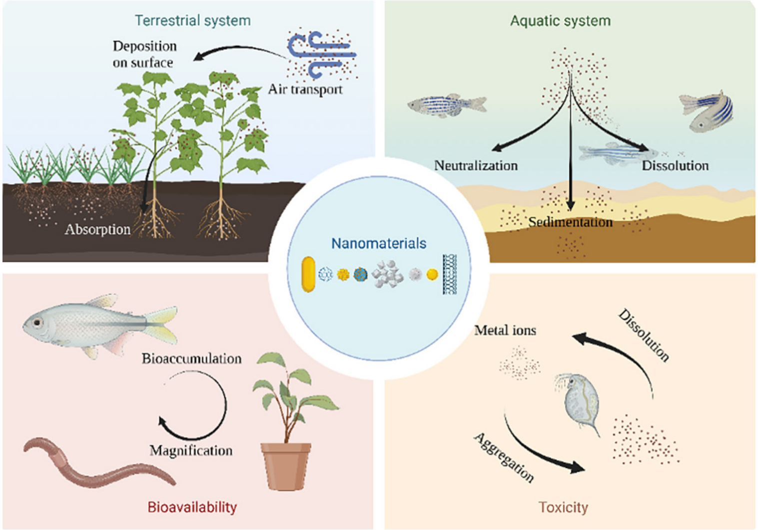
## Environmental behavior and fate of nanomaterials

Industrial activities —including manufacturing chemicals, coatings, construction materials, metallurgy, mining, textiles, electronics, cosmetics, and agriculture— are widely recognized as the main sources of engineered NMs emissions into the environment. These sectors contribute to the release of

NMs during production, use, and disposal, with emissions entering air, water, and soil systems. It is estimated that 63 – 91% of NMs will likely be disposed in landfills, with an 8 – 28% going to soils, 0.4 – 7% to water, and lastly 0.2 – 1.5% to the atmosphere (Keller *et al*., 2013; Ding *et al*., 2017). Although NMs offer significant advantages over traditional materials for technological applications, their behavior in natural systems is highly complex and dynamic (Deng *et al*., 2022).

NMs can accumulate, transform, and increase their concentration in biological systems, leading to bioaccumulation and subsequent biomagnification in the predatory organism. Furthermore, biotransformation, which can be defined as a bioactivation process which could produce reactive metabolites that are more toxic, is the final stage, in which the chemical concentration of toxins in the organism exceeds that of the environment (Uddin, Desai and Asmatulu, 2020). In terrestrial systems, NMs can go through several pathways (figure 2, top-left), including atmospheric deposition, the land application of biosolids, and their use in agriculture (nano fertilizers and pesticides) (Wahab *et al*., 2024). In these environments, fate and transport are affected by soil properties such as pH, organic matter content, cation exchange capacity, and redox conditions (Rawat *et al*., 2018). Furthermore, NMs can undergo various environmental transformations, such as redox reactions, aggregation, agglomeration, dissolution, and interactions with organic and inorganic ligands, sedimentation, adsorption, and sulfidation, which can alter their surface chemical composition, influence their transport, bioaccumulation, and toxicity (Spurgeon, Lahive and Schultz, 2020).

**FIGURE 2.** Behavior and fate of nanomaterials.



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In the aquatic environment, NMs can undergo transformations involving physical, chemical and biological processes causing sedimentation, dissolution or neutralization (figure 2, top-right). As a result of these transformations, NMs can interact with other dissolved substances or organisms, forming new complexes that alter the chemical dynamics of the aquatic environment (Kansara *et al*., 2022; Harrison *et al*., 2023). Water characteristics, such as pH and temperature, can influence ionic strength and alter surface charges, promoting aggregation or sedimentation (Dai *et al*., 2022). NMs can even become more stable and disperse more efficiently, increasing their potential to cause harm to living organisms (Swirog *et al*., 2022) (figure 2, bottom right).

The dissolution process of NMs is influenced by the chemistry of the environment and the characteristics of the NMs; for instance, decreasing size increases the active sites for dissolution (Kansara *et al*., 2022). In stratified water bodies, the dissolution of NMs is affected by redox gradients; anoxic zones promote reductive transformations that affect interactions with organisms (Harrison *et al*., 2023). Iron-based NMs can dissolve in anoxic sediments, releasing ferrous ions ($Fe^{2+}$) that can interact with various nutrients, pollutants, and microorganisms. This interaction can increase the mobility and bioavailability of contaminants, further complicating the assessment of nanomaterial toxicity in such environments (Weng *et al*., 2023)

Bioavailability is a critical factor influencing their uptake and efficacy in both terrestrial and aquatic environments (figure 2, bottom left). In both, NMs can be absorbed by plants, invertebrates, and microorganisms through various mechanisms, such as endocytosis, membrane transport proteins, or passive diffusion (Mintis *et al*., 2024; Mateos-Cárdenas *et al*., 2021). Due to aquatic environment diverse conditions, nanoparticles can induce oxidative stress, cellular and genetic damage in fish, algae, and crustaceans, altering the ecological balance, biogeochemical cycles, biodiversity, and the food chain (López *et al*., 2022; Valerio-García *et al*., 2021). In terrestrial ecosystems, earthworms play a crucial role. They have been observed to bioaccumulate metallic NMs present in the environment (Baccaro *et al*., 2021). Bioaccumulation affects their physiological health and survival and has implications at all trophic levels (Adeel *et al*., 2021). Earthworms are consumed by predators such as birds, mammals, and invertebrates, which increases the ecological risks associated with nanomaterial contamination in terrestrial systems by producing biomagnification (Dodds *et al*., 2021; Gambardella and Pinsino, 2022).

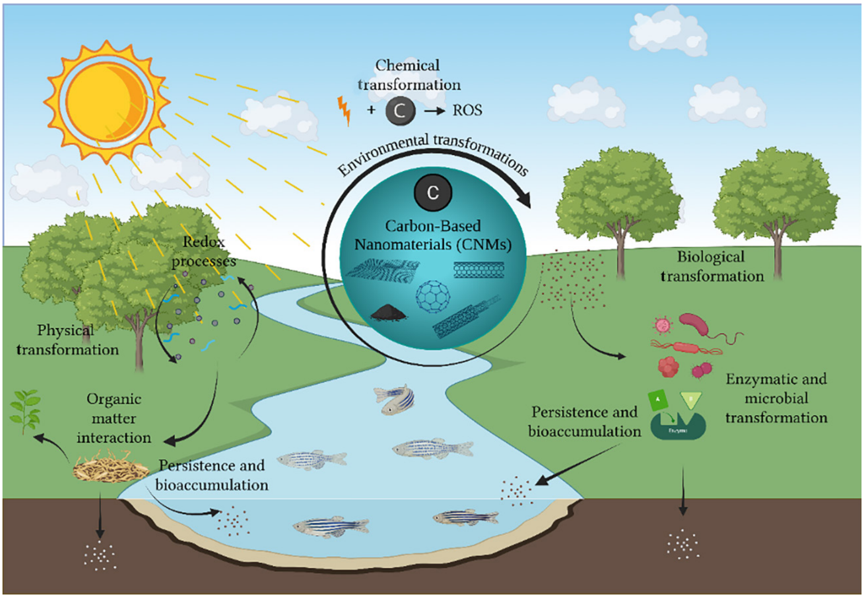
On the other hand, plants can absorb nanoparticles through roots or leaves and, in some cases, translocate them to aerial tissues (Garcidueñas-Piña *et al*., 2016). In the root system, nanoparticles can enter through apoplastic or symplastic spaces, overcome the endodermal barrier, and be transported by the xylem to aerial organs. Within the plant, these particles can accumulate, transform, or generate positive or negative physiological effects, such as oxidative stress, alterations in photosynthesis, germination, or growth, depending on their physicochemical properties and the dose used (Lv, Christie and Zhang, 2019).

In summary, NMs exhibit complex behaviors in the environment, characterized by their ability to transform, accumulate, and generate adverse ecological and trophic effects. Their presence not only highlights their ecotoxicological impact but also the need to understand their persistence in ecosystems. Therefore, analyzing the environmental persistence and degradation processes of NMs becomes a fundamental step in assessing their risks, defining their life cycle, and establishing effective mitigation strategies.

## Environmental persistence and degradation

Depending on the specific chemical and environmental conditions, NMs exhibit slow degradation kinetics in environmental matrices, leading to their prolonged persistence and accumulation, which can pose significant ecological and health risks. Their stability facilitates interactions with both biotic and abiotic components of ecosystems. In this context, metal and metal-oxide nanoparticles such as Titanium dioxide ($TiO_2$ NPs), zinc oxide (ZnO NPs), and silver nanoparticles (Ag NPs), are widely used in various industries including cosmetics, food packaging, coatings, electronics, and biomedicine (Khan *et al*., 2018), leading to their increasing release into the environment. Their persistence in the environment is a growing concern due to their widespread application and potential ecological impacts. For instance, ZnO NPs have been reported to influence the growth and reproduction of aquatic organisms and alter soil microbial communities (Khan *et al*., 2018). $TiO_2$ NPs can generate ROS under UV light, damaging cells, and act as carriers for co-contaminants such as polycyclic aromatic hydrocarbons, thereby affecting toxicity (Mbanga *et al*., 2022). Likewise, Ag NPs have been shown to persist in aquatic systems, where they undergo transformations such as sulfidation or chlorination that reduce solubility and contribute to long-term accumulation in sediments (Furtado *et al*., 2014). Overall, these nanoparticles strong interactions with natural organic matter (NOM) and sediments, which hinder their natural degradation and make their removal from the environment particularly challenging (Donia and Carbone, 2019). In addition to metal-based nanoparticles, CNMs have garnered particular attention due to their widespread use and unique properties. Their use has expanded across various industries, such as energy storage, biomedicine, electronics, photonics, analytical chemistry, and catalysis (J. Wang *et al*., 2020). Nevertheless, their inherent resistance to degradation and increasing environmental prevalence have raised critical concerns regarding their potential toxicity (Chen *et al*., 2017). Moreover, due to their elevated specific surface area and strong adsorption capacity, CNMs can act as vectors for co-transporting environmental pollutants, thereby exacerbating the overall toxicological burden (Peng *et al*., 2020).

**FIGURE 3.** Environmental transformation of carbon-based nanomaterials.



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Once released into the natural environment, NMs can undergo a variety of transformation processes, including physical changes, (photo)chemical redox reactions, biological interactions (Sigmund *et al*., 2018), and associations with environmental constituents such as NOM (figure 3). These processes alter significantly the NMs physicochemical properties leading to their degradation or biodegradation. For example, ZnO NPs dissolve under acidic conditions, releasing $Zn^{2+}$, which represents their primary degradation pathway and source of toxicity. ZnO NPs can also undergo chemical transformations, such as formation of zinc phosphates in soils and sludge, which influence their mobility and toxicity (S. Wang *et al*., 2022). Ag NPs degrade through oxidative dissolution, releasing $Ag^+$ that are quickly transformed into less soluble forms ($Ag_2S$ or AgCl) in natural waters, contributing to long-term accumulation in sediments (Furtado *et al*., 2014). In contrast, $TiO_2$ NPs exhibit high stability and low solubility; their environmental transformations are mainly driven by photoactivation under UV-light, leading to the ROS generation and surface modification rather than true degradation (Mbanga *et al*., 2022). For CNMs the main degradation process is photo-degradation; this process is predominantly driven by UV radiation, which promotes the generation of ROS and electron-hole pairs that facilitate the carbon framework oxidative degradation, resulting in the cleavage of carbon-carbon bonds and the eventual formation of low-molecular-weight compounds and $CO_2$ (T. Li *et al*., 2017; Hou *et al*., 2015). The efficiency of this process is regulated by several environmental parameters such as the presence of auxiliary chemical oxidants, pH, ionic strength, and particle size (Freixa *et al*., 2018). Moreover, the limited penetration of UV radiation in natural environments, along with the complex interactions between CNMs and co-existing organic and inorganic species, may significantly reduce the efficiency of photodegradation (Peng *et al*., 2020).

Due to their small size, persistence, and partial dissolution, NMs are taken up by primary producers and passed along the food chain. $Zn^{2+}$ ions released from ZnO NPs can be assimilated by algae and aquatic plants, allowing direct transfer to herbivores and subsequently to consumers at higher trophic levels (Khan *et al*., 2018). Ag NPs, in both particulate and ionic or sulfurized forms, have been detected in plankton and may transfer to fish, raising concerns about bioaccumulation (Furtado *et al*., 2014). For $TiO_2$ NPs, their stability generally limits systemic assimilation; however, ingestion by suspension feeders shows they remain a viable exposure route within aquatic chains. CNMs, with their high surface area and strong sorption capacity, can bind co-existing contaminants and facilitate their co-transfer across trophic levels, even when the NMs themselves undergo minimal degradation (Peng *et al*., 2020). Trophic transfer constitutes a significant ecological exposure pathway, shaped by both intrinsic material properties and complex food web interactions.

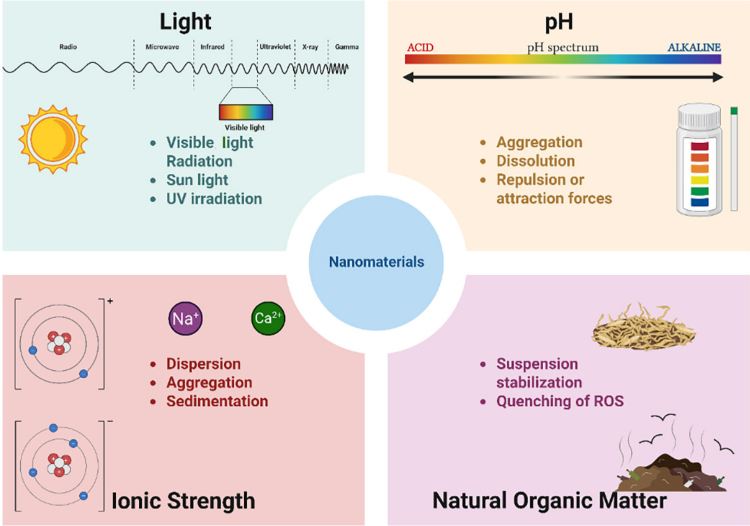
Another key factor in the environmental fate of NMs is their potential for biodegradation. While biodegradation refers to the breakdown of substances by biological organisms into simpler products, metal and metal-oxide nanoparticles usually undergo only partial biotransformation. For instance, ZnO NPs dissolve to release $Zn^{2+}$, while $TiO_2$ NPs remain highly resistant and interact mainly through surface processes. Ag NPs release $Ag^{+}$ ions that bind to biomolecules or transform into insoluble species, maintaining long-term persistence. CNMs are also structurally stable, typically experiencing only surface modifications. However, biodegradation via enzymatic, microbial, and cellular pathways —particularly through oxidoreductase enzymes— has been explored for CNMs, where these catalysts can cleave the carbon backbone, promoting oxidative breakdown into low-molecular-weight compounds and $CO_2$ (Peng *et al*., 2020). This biological approach offers specificity and minimal secondary pollution, making it a promising strategy for mitigating CNM accumulation in ecosystems.

The environmental fate of NMs is driven by their high stability, slow degradation rates, and complex interactions with environmental matrices, which together contribute to their persistence and bioavailability. Metal- and carbon-based nanoparticles not only undergo diverse transformation pathways but also retain the capacity for trophic transfer and pollutant co-transport, amplifying ecological and health risks. Although partial dissolution and biotransformation processes occur, the limited extent of natural degradation highlights the urgent need for effective strategies to mitigate their long-term accumulation and impacts in ecosystems.

## Impact of environmental factors on nanotoxicity

The fate and toxicity of NPs are influenced by their interactions with environmental factors such as sunlight, ionic strength, temperature, and the characteristics of the surrounding medium (Harrison *et al*., 2023). Transformed NMs can exhibit different, and sometimes opposite, biological responses when compared to their pristine forms (Ren, Hu and Zhou, 2016). Specific environmental parameters that affect the transformation and toxicity of NMs are outlined and visually summarized in figure 4.

**FIGURE 4.** Environmental factors affecting the transformation and toxicity of nanomaterials.



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- Radiation effect: when NMs enter the environment, they encounter sunlight or artificial light. Although many NMs are non-toxic or less toxic, their toxicity can increase with light exposure. Photoactive NMs can generate ROS or release metal ions under sunlight, with photo-oxidation and photo-reduction affecting coatings and oxidation states (Ren, Hu and Zhou, 2016). A well-known example is $TiO_2$, a widely utilized photoactive nanomaterial. Under UV light, $TiO_2$ becomes highly reactive, producing ROS that can harm cellular components in non-target organisms, thereby increasing the material's toxicity (Gomes *et al*., 2018). On the other hand, light exposure can also decrease NMs toxicity through processes like passivation, altering properties such as surface charge and aggregation behavior, leading to increased stability and reduced reactivity in biological systems (Naasz, Altenburger and Kühnel, 2018).

- Ionic strength (IS) influences nanoparticle aggregation, dispersion, and bioavailability, affecting their toxicity. Higher IS promotes particle aggregation and sedimentation. ZnO NPs aggregate more as IS increases, especially with divalent cations like $Ca^{2+}$ and $Mg^{2+}$, which destabilize suspensions more effectively than monovalent ions due to stronger electrostatic interactions (X. Wang *et al*., 2020). Similarly, CuO NPs show increased aggregation and altered zeta potential with higher IS, reducing colloidal stability and increasing particle size when exposed to calcium chloride ($CaCl_2$) in comparison to sodium chloride (NaCl) (C. Peng *et al*., 2017). High IS can reduce NPs' immediate toxicity by limiting dispersion and cellular uptake, but sedimented aggregates may still pose long-term risks. For Ag NPs, high IS can promote aggregation and affect their transformations, leading to the formation of smaller and more reactive nanoparticles, which may increase toxicity in organisms like *Caenorhabditis elegans* (Yang *et al*., 2019). Although initial sedimentation might reduce acute exposure in the water column, these aggregates can settle in benthic zones, where they remain bioavailable to deposit-feeding or burrowing organisms, potentially maintaining or increasing ecological risk over time (Chambers *et al*., 2013).
- pH effect: pH regulates the particle's surface potential or zeta potential. Theoretically, when the pH of a colloidal suspension approaches the point of zero charge or isoelectric point, the system becomes unstable, as electrostatic repulsions are minimized and aggregation is favored (Abbas, Yousaf, Ullah *et al*., 2020). For instance, the aggregation behavior of CuO NPs is strongly pH dependent. At low pH (< 5), particles carry a higher surface charge, leading to a stronger electrostatic repulsion and the formation of smaller aggregates. Conversely, near neutral pH (~6), larger aggregates form, increasing the sedimentation (C. Peng *et al*., 2017). pH also affects the solubility of metal-based NMs, which in turn impacts their toxicity. Acidic conditions generally enhance the dissolution of these materials, increasing the release of free metal ions that may be toxic to biological systems. For example, ZnO NPs tend to dissolve under acidic conditions, increasing $Zn^{2+}$ release and therefore their toxicity. At pH < 7, dissolution is enhanced, while aggregation is promoted near the isoelectric point (pH ~ 8.7) due to reducing electrostatic repulsion (X. Wang *et al*., 2020).
- Organic matter effect: NOM includes a wide variety of organic compounds from macromolecules (humic acid, fulvic acid, and extracellular polymeric substances) to small carbon-based compounds and ligands present in natural soils and waters (Abbas, Yousaf, Ullah *et al*., 2020). The presence of NOM influences the fate and toxicity of NMs by affecting charge, surface potential, and steric orientation, redu-

cing agglomeration rates, and enhancing particle stability in suspension (Liu *et al*., 2018). High-weight fractions of NOM provide steric stabilization to ferrihydrite nanoparticles, preventing aggregation, while low molecular weight shows the opposite effect (Z. Li *et al*., 2020). In summary, NOM can reduce the environmental and biological risks of NMs through surface passivation, which involves adsorption onto NMs surfaces. This process creates dynamic coatings that change surface charge, hydrophobicity, colloidal stability, ROS quenching, and aggregation behavior. The nature of these interactions varies according to species, NMs type, and environmental conditions.

## Risk assessment and regulatory challenges

As observed from the previous sections, it is clear that NMs in the environment can persist and exhibit toxicity depending on several external factors. Therefore, risk assessment and regulatory frameworks are key elements to portray the effects of environmental interactions (Rehman and Moore, 2021).

Risk assessment focuses on evaluating the potential hazards and exposures associated with the use of NMs in several environments, considering their unique physicochemical properties, including nanoscale dimensions and increased reactivity, which may result in biological and environmental interactions significantly different from their bulk counterparts (Rehman and Moore, 2021). Traditional risk assessment methodologies fail to assess the complexity of NMs' physicochemical properties and environmental transformation since they were primarily designed for bulk materials (Johnston *et al*., 2020). Hence, there is a need for standardized protocols that assess the safety of NMs. In this context, regulatory agencies have emerged as potential solutions to this challenge, providing regulatory frameworks for NMs. Some of these regulatory agencies are mentioned in figure 5, and the main frameworks are listed in table 1.

As observed from table 1 and figure 5, the main frameworks concerning NMs can be classified as international regulation and regional regulation. International organizations actively work to produce risk assessment frameworks for NMs. For instance, the OECD has initiated several test guidelines to standardize NMs hazard identification along with the creation of the WPMN. Furthermore, regulatory agencies in regions including Europe, North America, and South America collaborate with international agencies to promote NMs legislation (Rasmussen *et al*., 2016; Rehman and Moore, 2021).

At the international level, in addition to the regulatory frameworks developed by the European Union, the United States, Canada, Mexico, Brazil, and other countries, the initiatives coordinated by the United Nations (UN) are particularly relevant. The World Health Organization (WHO) has recognized the need to evaluate the potential impacts of nanomaterials on human health, especially in biomedical, pharmaceutical, and food applications. These actions

**Table 1.** Summary of international and regional regulatory frameworks for nanomaterials.

| Regulatory agency | Acronym | Example of the regulatory framework | Reference |
|---|---|---|---|
| International Organization for Standardization | ISO | – ISO/TS 12901-1:2024 Series – Occupational risk management applied to engineered nanomaterials<br>– ISO/TR 16197:2014 – Compilation and description of toxicological screening methods for manufactured nanomaterials<br>– ISO/TC 229 Working groups | ISO (2024)<br>ISO (2014)<br>Saleh (2020) |
| Organization for Economic Co-operation and Development | OECD | – OECD Series on the safety of manufactured nanomaterials<br>– Guidance documents<br>– Working party on manufactured nanomaterials (WPMN) | Rasmussen *et al.* (2016)<br>OECD (2025) |
| United Nations Institute for Training and Research | UNITAR | – Guidance document titled "Developing a national nanotechnology policy and programme."<br>– Nanomaterials safety e-learning course | UNITAR (2011); UNITAR (2025) |
| United Nations Environment Programme | UNEP | – Frontiers 2017: emerging issues of environmental concern<br>– Assessment report on issues of concern: chemicals and waste issues. Posing risks to human health and the environment | UNEP (2017); UNEP (2020) |
| European Chemicals Agency | ECHA | – EU Registration evaluation and authorisation of chemicals – REACH, 2006<br>– EU Observatory for Nanomaterials – EUON, 2016<br>– NanoCRED – 2017<br>– LICARA NanoSCAN – 2016<br>– Nanomaterial fate and speciation in the environment, NanoFASE – 2015<br>– NanoRiskCat, NRC – 2011 | Moermond *et al.* (2015); Hartmann *et al.* (2017); Van Harmelen *et al.* (2016); Garner, Suh and Keller (2017); Hansen, Jensen and Baun (2014) |
| European Medicines Agency | EMA | – Data requirements for intravenous iron-based nano-colloidal products developed concerning an innovator medicinal product - Scientific guideline<br>– Data requirements for intravenous liposomal products developed concerning an innovator liposomal product - Scientific guideline<br>– Development of block-copolymer-micelle medicinal products<br>- Surface coatings: general issues for consideration regarding parenteral administration of coated nanomedicine products - Scientific guideline | EMA (2025) |
| US Environmental Protection Agency | EPA | – US Toxic Substances Control Act (TSCA) | EPA (2025) |
| US Food & Drug Administration | FDA | – Final guidance for industry - Assessing the effects of significant manufacturing process changes, including emerging technologies, on the safety and regulatory status of food ingredients and food contact substances, including food ingredients that are color additives<br>– Final guidance for industry - Considering whether an FDA-Regulated product involves the application of nanotechnology<br>– Final guidance for industry - Liposome Drug – Products: chemistry, manufacturing, and controls; | FDA (2018) |

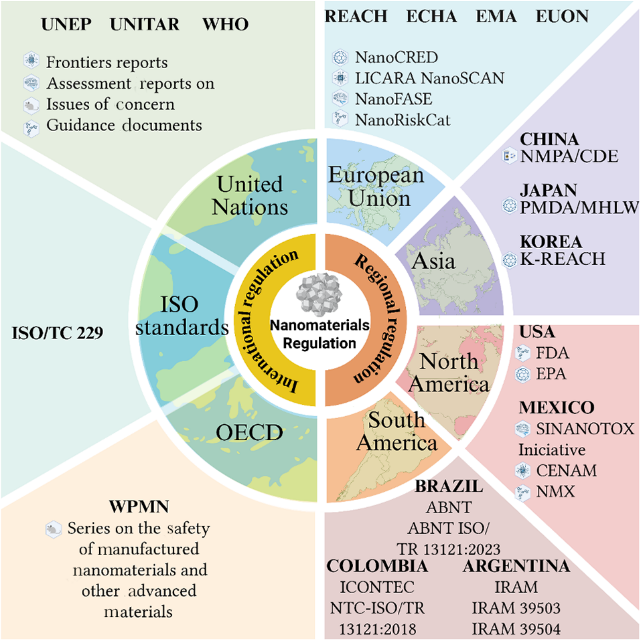
Continue ▶

**Table 1.** Summary of international and regional regulatory frameworks for nanomaterials (continuation).

| Regulatory agency | Acronym | Example of the regulatory framework | Reference |
|---|---|---|---|
| US Food & Drug Administration | FDA | Human pharmacokinetics and bioavailability; and labeling documentation<br>– Final guidance for industry - Safety of nanomaterials in cosmetic products<br>– Final guidance for industry - Use of nanomaterials in food for animals<br>– Final guidance for industry - Drug products, including biological products, that contain nanomaterials | FDA (2018) |
| Argentine Institute of Standardization and Certification | IRAM | – IRAM 39503 – Methodology for risk assessment of nanomaterials<br>– IRAM 39504 – Occupational risk management applied to engineered nanomaterials | IRAM (2019) |
| Mexican Norms | NMX | – NMX-R-13121-SCFI-2019 Nanotechnologies – Risk assessment on nanomaterials | DOF (2020) |
| Brazilian Association of Technical Standards | ABNT | – ABNT ISO/TR 13121:2023 – Nanotechnologies – Nanomaterial risk evaluation | ABNT (2023) |
| Colombian Institute of Technical Standards and Certification | ICONTEC | - NTC-ISO/TR 13121:2018: Nanotechnology. Risk assessment of nanomaterials | ICONTEC (2018) |

Source : Author's elaboration.

**Figure 5.** Classification of nanomaterials regulation frameworks.



Source: Created in BioRender. Based on Rosales, A. (2025). https://BioRender.com/qd1x0t7.

are aligned with the Strategic Approach to International Chemicals Management (SAICM) led by the United Nations Environment Programme (UNEP), which aims to strengthen global governance for the safe management of chemicals, including emerging issues such as manufactured nanomaterials.

Regulatory agencies, including the EPA, ECHA, FDA, and EMA, advocate for tiered testing approaches integrating *in vitro*, *in vivo*, and computational modeling techniques. Additionally, uncertainties in the NMs lifecycle assessments, from production to disposal, necessitate precautionary regulatory strategies to mitigate unintended consequences (Chávez-Hernández *et al*., 2024; Faghih Akhlaghi *et al*.,2021).

The European Union's REACH program now includes specific provisions for NMs, emphasizing the need for physicochemical characterization, exposure assessments, and toxicity testing. The Safe-by-Design (SbD) approach has gained traction, advocating for the early integration of safety considerations into NMs development to minimize potential risks. In addition, several frameworks under the REACH legislation have gained popularity, including NanoCRED (Moermond *et al*., 2015; Hartmann *et al*., 2017), LICARA NanoSCAN (Toon van Harmelen *et al*., 2016), NanoFASE (Garner, Suh and Keller, 2017), and NanoRiskCat (Hansen, Jensen and Baun, 2014), each of which considers its factors and scale to categorize and report nanomaterial toxicity.

In Latin America, several institutions have made important progress in adopting international standards and developing regulatory frameworks. Mexico has published official norms (NMX) aligned with ISO standards, covering risk assessment and occupational safety for nanomaterials. Brazil, through ABNT, has adopted ISO/TR 13121, while Colombia's ICONTEC has incorporated NTC-ISO/TR 13121:2018. Argentina's IRAM has established nanotechnology-related standards (IRAM 39503/39504). These efforts demonstrate an increasing commitment to harmonize national regulations with international best practices and to promote regional governance of nanomaterials under sustainability principles.

Despite all the current efforts made by international organizations to assess and legislate NMs fate and toxicity in the environment, several challenges persist. Characterization techniques, ecotoxicity tests, and even synthesis methods that are still not homologated among countries, hinder the application of current legislation. Furthermore, due to its unique properties, new approaches to effectively manage NMs must be adopted. In this context, we can list the main drawbacks found to date:

- Incomplete data and methodologies: There is a lack of comprehensive data and standardized methodologies for assessing the risks of NMs. Life cycle assessments (LCA) are not fully adopted, and public databases lack inventory data for NMs, complicating risk evaluations (Chávez-Hernández *et al*., 2024).
- Biological and environmental impact: NMs can disrupt biological sys-

tems, such as the intestinal barrier, through mechanisms like lysosomal disruption and mitochondrial dysfunction. However, evidence is inconsistent, highlighting the need for harmonized methodologies in safety assessments (Baccaro *et al*., 2021; Blázquez Sánchez *et al*., 2021).

- Standardization issues: Consistency in nanomaterial production, including size, shape, and purity, is crucial for safety and efficacy. However, establishing appropriate standards remains a challenge, both nationally and internationally (Chávez-Hernández *et al*., 2024).

To sum it up, the future direction of research in terms of legislation of NMs will try to standardize the main definition of NMs and nanoparticles to enable their global application along with a comprehensive, multi-perspective framework that includes standardized methodologies. Future risk assessment and regulatory frameworks for NMs must address data gaps, standardize testing methods, and develop specific guidelines that consider the unique properties of NMs.

## Conclusions

As we have seen from the previous analysis on NMs, although the advantages of the use of nanotechnology in several sectors have enabled significant advancements, their environmental behavior and potential toxicity are concerning. Combined with its persistence in terrestrial and aquatic ecosystems, the interaction with biotic and abiotic components potentially leads to bioaccumulation, biomagnification, and ecological disruption. Furthermore, the interactions between NMs and the environment can be mediated by several factors such as pH, ionic strength, light exposure, and presence of organic matter, significantly influencing transformation, bioavailability, and toxicity of NMs.

Lastly, the existing risk assessment frameworks, although evolving, still face limitations due to methodological gaps, lack of standardized protocols, and insufficient data on NMs life cycles and environmental concentrations. Therefore, there is an urgent need for harmonized international regulations, improved characterization techniques, and predictive models to ensure the safe design, use, and disposal of NMs.

## Authors contribution

*I. E. Medina-Ramírez*: concept and design of the article.
*J. Martínez, M. Jiménez-González, R. Hernández*: methodological development.
*J. Martínez, M. Jiménez-González, R. Hernández, I.E. Medina-Ramírez*: data mining, analysis, and interpretation
*J. Martínez, M. Jiménez-González, R. Hernández*: original draft writing.
*I.E. Medina-Ramírez*: final review and editing of the text.

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