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Nanotechnology Policy Across Borders: A Comparative Regulatory Analysis of the U.S., EU, China, and India

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ABSTRACT

Nanotechnology is an emerging interdisciplinary field at the intersection of science and engineering, focusing on the study and application of extremely small particles and materials that typically range from one to one hundred nanometers in order to leverage unique physical and chemical properties such as enhanced strength, chemical reactivity, and conductivity. The miniscule scale at which these nanomaterials operate unlocks quantum mechanical effects and vastly increased surface areas that enable advancements across a wide range of fields including energy, medicine, and electronics.

However, the rapid commercialization of nanomaterials has significantly outpaced the development of coherent regulatory frameworks, leading to fragmented and inconsistent policy guidelines across countries and industries.

This report aims to carefully examine the existing regulatory landscape governing nanotechnology across four jurisdictions: the United States of America, the European Union, China, and India. Focusing on four key areas - chemical manufacturing, food safety, product liability, and environmental protection - this study conducts a comparative analysis of existing regulatory frameworks, overseeing agencies, and enforcement mechanisms. This whitepaper employs a systematic qualitative review methodology that encompasses a structured search conducted with specific keywords, spanning academic databases, international law firms, official governmental regulatory agency websites, and international policy organizations.

By identifying critical gaps and inconsistencies in current approaches, this paper proposes pathways toward greater policy harmonization that would facilitate responsible innovation in nanotechnology while ensuring robust public safety.

INTRODUCTION

Nanotechnology allows for the manipulation of materials at the atomic and molecular scale to craft complex molecules that self-assemble or are precisely arranged to display particular structural and chemical properties that cannot be observed in their bulk forms. Since the turn of the century, thousands of consumer products containing nanoparticles, such as sunscreens, dietary supplements, electronics, and textiles have rapidly entered the marketplace. [1] Despite the swift integration of nanotechnology into everyday life, national governments have been slow to establish comprehensive nano-specific industry regulations. As a result, the regulatory landscape remains patched and fragmented, with varying approaches towards oversight creating critical gaps in governance and reflecting concerns regarding the unknown effects of nanotechnology.

Governments have sought to address these challenges through the development of nanolaw: an emerging field of policy and ethics tasked with tackling the unique implications posed by nanotechnology. The potential benefits of effective regulation are significant: if implemented correctly, it could lead to meaningful advancements in everyday consumer products, enhancing everyday life globally. [2]

Despite the considerable presence of nanotechnology in modern society, public understanding remains limited. This lack of awareness may provoke resistance similar to the backlash previously experienced with genetically modified crops. [3] Currently, numerous debates surround the realm of nanolaw, characterized by disputes over universally agreed definitions and a primary reliance on general industry guidelines rather than nano-specific regulations.

As a result, dedicated nanotechnology legislation remains exceedingly rare, prompting calls for more robust and unified frameworks to address potential risks.

METHODS

This whitepaper employs a structured qualitative review and a comparative policy analysis to examine how nanotechnology is regulated across four distinct jurisdictions- the United States, the European Union, China, and India. Relevant sources were identified through a structured search encompassing academic databases, international law firms, official governmental and regulatory agency websites, and international policy organizations. Articles published between 2020 and 2025 were prioritized to reflect contemporary regulatory approaches. Searches were conducted using combinations of keywords including “nanomaterial regulation”, “nanoparticle policies in [country]”, “food safety” “product liability”, “chemical manufacturing”, and "environmental health and toxicity”, as well as terms related to real-world regulatory implications and comparative studies across different countries.

Searches were limited to English-language sources focused on international nanotechnology policy and regulation across key sectors. Duplicate articles, preliminary policy briefs, and non-substantive abstracts

were removed during an initial screening process, after which full texts were systematically reviewed. Fifteen high-quality policy studies analyses and regulatory reports published between 2020-2025 were selected for inclusion in this whitepaper. References cited within selected studies, including case studies and whitepaper reviews, were also examined to identify additional relevant sources and information. Key regulatory systems and policies were verified using official government and regulatory agencies for each jurisdiction to ensure accuracy and reliability.

This methodological review is subject to certain limitations. The analysis is limited to English-language sources and databases, which may exclude relevant regulatory developments published in other languages, particularly in jurisdictions such as China or India. Additionally, the reliance on publicly available documents and secondary sources may limit the depth of insight into regulatory implementation and enforcement mechanisms that occur at the federal level.

RESULTS

The United States

The United States regulates nanotechnology through a fragmented, sector-based framework that adapts existing chemical, food safety, consumer protection, and environmental laws rather than enforcing nano-specific legislation. [4] Oversight is distributed among national agencies such as the Food and Drug Administration, Environmental Protection Agency, and Consumer Product Safety Commission, which oversees nanomaterials based on product utility rather than nanoscale properties. While recent reforms—particularly within the EPA—have shifted toward mandatory reporting as a risk management strategy, U.S. nano-policy remains largely reliant on voluntary compliance and post-market surveillance to regulate the nanotechnology industry. [5] Across sectors, a recurring challenge is the absence of standardized methods for evaluating nano-specific risks such as bioaccumulation and toxicity. As a result, nanomaterials often enter commerce before their long-term impacts are fully analyzed and understood, revealing structural limitations that will be critical for comparison in other regulatory regimes. [6] Figure 1 compares the regulatory framework governing nanotechnology in the United States across the chemical manufacturing, food safety, product liability, and environmental protection industries.

Industry	Key Laws/Policies	Agencies	Regulation of Nanomaterials	Key Gaps/Challenges

Chemical Manufacturing	-Federal Insecticide, Fungicide, and Rodenticide Act: regulates antimicrobial chemicals nanomaterials such as nanosilver used to destroy, mitigate, or repel microorganisms and pests. Frank R. Lautenberg Chemical Safety for the 21st Century Act: Updates chemical safety rules to protect human health and exposure to chemical substances.	EPA (Environmental Protection Agency): *EPA is a member of the National Nanotechnology Initiative	Significant New Use Rule (SNUR): Requires companies to notify EPA at least 90 days before using a chemical in a "significant new use" to allow risk assessment and potential chemical exposure risks. Mandatory reporting rule for nanomaterials: production volume, manufacturing methods, exposure, and release information must be submitted to EPA.	The U.S. regulatory framework is evolving from voluntary to mandatory reporting, but struggles to keep pace with diverse ENMs (engineered nano-materials) ENMs are difficult to evaluate due to variation in shape, size, coatings, and elemental chemical composition. Standard testing may fail because ENMs agglomerate or will potentially react with test materials.
Food Safety	Federal Food, Drug, and Cosmetic Act regulates food, drugs, cosmetics, including nano-products Premarket review for drugs and color additives required safety and efficiency data for nano-engineered products.	FDA (Food and Drug Administration) *FDA is a member of the National Nanotechnology Initiative	Nanoproducts are regulated under existing frameworks, depending on the utility of the product rather than the nature of the nano-material itself. Only products subject to pre-market review require nano-specific regulatory	With no specific law targeting nano-material presence in food, most nano-engineered products enter the market with a lack of rigorous, targeted safety. Risk assessment tools

			data Mostly relies on industry compliance and voluntary reporting rather than mandatory pre-market approval.	for foods, cosmetics, and drugs containing nanomaterials are extremely limited. Guidance is non-binding and voluntary, creating huge gaps in oversight and prior approval.
Product Liability	Consumer Protection Safety Act (CSPA): Manufacturers, retailers, and distributors must report if they have information regarding if a nano-engineered product fails a safety rule or creates a substantive hazard to customers. Federal Hazardous Substances Act (FHSA): Requires precautionary labeling of hazardous substances to help customers safely store and utilize those products and to give them information about immediate first aid steps if an incident occurs.	CPSC (Customer Product Safety Commision) *CPSC is a member of the National Nanotechnology Initiative	Nanomaterials are regulated through existing customer-protection laws, focusing on default identification and risk. CPSC requires manufacturers to report defects and align to safety standards established by the CPSA and FHSA. A product is not evaluated by the CSPC for potential risk until it has entered the marketplace and has been distributed for commerce.	Neither the Consumer Protection Safety Act nor the Federal Hazardous Substances Act requires the pre-market registration or the approval of products, so issues may not arise until release to the public via commerce. No uniform method for assessing nano-specific risks in products (toxicity at the nanoscale, bioaccumulation, etc) Nano-materials are increasingly used in components and mixtures, making it difficult to track and assign liability across manufacturers, suppliers, distributors.

Environmental Protection	Frank R. Lautenberg Chemical Safety for the 21st Century Act: Updates chemical safety rules to protect human health and exposure to chemical substances. -Federal Insecticide, Fungicide, and Rodenticide Act: regulates antimicrobial chemicals nanomaterials such as nanosilver used to destroy, mitigate, or repel ecological microorganisms and pests in the biosphere.	EPA (Environmental Protection Agency): *EPA is a member of the National Nanotechnology Initiative	In order to ensure a more comprehensive understanding of nanomaterials and their potential effects of the environment, the EPA mandates that chemical and manufacturing companies to inform the agency of certain information such as: chemical identity, production volume, health and safety data, etc Following premature notifications, EPA will determine whether action is warranted for nanomaterials that may pose an unreasonable risk to the environment.	Traditional toxicity methods may not capture nano-specific effects, which precedes the development of new approaches such as nanosensors. The proper disposal of projects containing nanomaterials, such as consumer goods or medical goods, are not fully covered by current environmental guidelines. Nanomaterials possess dynamic properties, meaning that they may change under environmental or biological conditions, which further complicates standards for efficient regulation.

Table 1: Regulatory frameworks governing nanotechnology in the United States

The European Union

Compared to the United States, the European Union regulates nanotechnology through a more formalized framework that incorporates nano-specific guidelines within existing chemical, food, product safety, and environmental laws. Oversight is handled by the European Chemicals Agency and the European Food Safety Authority, with additional monitoring from the European Commission and the European Union Observatory for Nanomaterials. [7] Despite these measures, EU policy struggles to address the unique properties of nanomaterials under pre-existing sector laws, particularly in regards to REACH

(Registration, Evaluation, Authorization, and Restriction of Chemicals). [8] Many consumer products face health and safety challenges due to logistical and legal barriers that make it difficult to link defects to specific risks. Consequently, even with comprehensive reporting and labeling requirements, nanomaterials can evade fully standardized risk assessment, revealing regulatory gaps that are important when comparing the EU's approach to other international frameworks. [9] Figure 2 compares the regulatory framework governing nanotechnology in the European Union across the chemical manufacturing, food safety, product liability, and environmental protection industries.

Sector	Key Laws/Policies	Agencies	Regulation of Nanomaterials	Key Gaps/Challenges
Chemical Manufacturing	REACH Regulations (Registration, Evaluation, Authorization, and Restriction of Chemicals) CLP Regulations (Classification, Labeling, Packaging) European Commission (The executive body of the EU)	European Chemicals Agency (ECHA) *Developer of the European Union Observatory for Nanomaterials (EUNO)	REACH Regulations: Companies who manufacture or import nanoforms (substances with specific nanoparticles) above 1 tonne/year must submit dossiers to ECA with nano-specific data. REACH Annexes now introduce nano-explicit requirements for chemical safety assessments and registration information Nanomaterials fall under the REACH's general classification of chemicals but are subject to specific laws depending on their size. CLP Regulations: Requires the classification, labeling,	The definition of a nanomaterial has been updated frequently, citing the need for a standardized definition that is homogenous across the EU's jurisdiction. Even though dossiers containing nano-specific data is a requirement under REACH regulations, there is a severe lack of comprehensive toxicological data, especially long-term effects, from nanomaterials utilized in chemical manufacturing, as testing is costly and complex. Adapting current chemical laws and regulations such as REACH to unique

			and packaging of nanomaterials based on their hazards rather than utility. European Commision: Provides the official EU Definition of a nanomaterials based on particle size.	nanomaterial properties poses a challenge as they often exhibit different physical and behavioral properties than their bulk counterparts.
Food Safety	Novel Foods Regulation (defines and regulates the safety of food products that weren't largely consumed from May of 1997) FIC Regulations (Food Information to Customers)	European Food Safety Authority (EFSA) European Commision	Requires pre-market authorization under the Novel Foods Regulation (must provide detailed physical/chemical and toxicological data for safety assessment by the EFSA). A safety dossier including all assessment data must be submitted to EFSA for approval. Mandatory labeling for all ingredients that are engineered nanomaterials, requires the word "nano" in brackets after listing ingredient names.	-Measuring the presence of specific nanoparticles from contact with food materials is a major challenge, especially with organic nanomaterials. -There is limited knowledge of the potential toxicological effects of nanoparticles, such as their risk for harmful bioaccumulation in organs and tissues. -Many regulatory reassessments are often based on volume production size rather than unique nano-properties, which creates gaps in standardized safety assessments.
Product Liability	REACH Regulations	ECHA (European Chemicals Agency)	Manufacturers are liable for damages if a	There is a significant reliance on

	(Registration, Evaluation, Authorization, and Restriction of Chemicals) CLP Regulations (Classification, Labeling, Packaging) European Commission (The executive body of the EU)	*Developer of the European Union Observatory for Nanomaterials (EUNO) Product Liability Directive (PLD) General Product Safety Regulation (GPSR)	nano-engineed product is found to be harmful or defective Products must meet the level of safety a user is entitled to expect, taking into account unique nanoparticle risks such as increased reactivity or penetration. Courts may now presume a stated nano-engineered product is defective if the claimant faces extensive difficulties obtaining the burden of proof, particularly if the damage is consistent with the suspected defect.	nanomaterial thresholds that look at volumes rather than potential risk-based. Proving a direct causal link between a nano-specific defect in a customer product because the health effects may be delayed. Difficulties to define a "safe" or "unsafe" nanoparticle that constitutes a particular product defect.
Environmental Protection	REACH Regulations (Registration, Evaluation, Authorization, and Restriction of Chemicals) CLP Regulations (Classification, Labeling, Packaging) European Commission (The executive body of the EU): sets standards for nanoparticle	ECHA (European Chemicals Agency) *Developer of the European Union Observatory for Nanomaterials (EUNO) European Commision	Water Framework Derivative "Watch It" List contains potentially harmful nanoparticles in nano-form. The Precautionary Principle aims to prevent environmental harm from unknown long-term effects of nanotechnology. Explicit legal requirements demand that registration dossieres are present and updated for chemicals that possess nanoforms including	Existing REACH thresholds possess a lack of stringent requirements which allow many nano-enabled products to bypass certain safety assessments. Traditional environmental toxicological tests often fail to capture the unique size-dependent properties of nano-materials such as agglomeration/dissolu tion, which dictates

	definition and recognition.		characterization, safety assessment, and risk management measures for environmental toxicity measures.	their environmental consequences.

Table 2: Regulatory frameworks governing nanotechnology in the European Union

China

China's regulatory approach to nanotechnology relies on sector-specific chemical, food, product safety, and environmental regulations, coordinated by agencies such as the Ministry of Ecology and Environment (MEE), the Standardization Administration of China (SAC), and the Ministry of Industry and Information Technology (MIIT). [10] Nanomaterials are generally treated as chemical substances, requiring pre-market registration, safety data sheets, and controlled production practices, yet regulation often relies heavily on adapting existing chemical standards to nanoscale level materials. As a result, the unique properties of nanomaterials are often not fully addressed, particularly in long-term toxicity, agglomeration, and environmental behavior. [11] Consequently, nanomaterials may be approved without specialized, validated evaluation, reflecting regulatory constraints that remain significant when examining China's framework in a broader global context. [12] Figure 3 compares the regulatory framework governing nanotechnology in China across the chemical manufacturing, food safety, product liability, and environmental protection industries.

Sector	Key Laws/Policies	Agencies	Regulation of Nanomaterials	Key Gaps/Challenges
Chemical Manufacturing	MEE Order 12: Requires the registration of new nanomaterial chemicals prior to production or importation if they aren't already included in the Inventory of Existing Chemical Substances. Requires the production, storage,	Standardization Administration of China (SAC) Ministry of Emergency Management (MEM) Ministry of Industry and Information Technology (MIIT) Ministry for	Nanoparticles and NMs are currently treated as chemical compounds under pre-existing regulations. National standards are kept in place in regards to detailed safety assessments before utility or production, terminology, and testing methods. New nano-ingredients require safety	While the current regulatory landscape is evolving, many Chinese standards are mostly voluntary. Specific occupational exposure limits for a variety of nano-materials and chemicals they may be present in are still in early development stages.

	and transport of hazardous nano-chemicals to be filled out with mandatory Chinese Safety Data Sheets.	Ecology and Environment (MEE)	assessments including particle size, surface area, and specific toxicity properties. Guidelines recommend using specialized methods such as filter vacuums and fume hoods in order to reduce potential exposure harm.	
Food Safety	The Food Safety Law requires safety, toxicity, and risk assessments for any food additives in food products that may contain traces of nanomaterials. General Standards for the Use of Food Additives: Offers strict regulations for the permitted scope and dosage suggestions for additives, including those utilizing nanotechnology.	National Health Committee (NHC) (State Administration for Market Regulation) SAMR Chinese Food Safety Authority Ministry of Agricultural and Rural Affairs (MARA)	Any nano-based food sustained must be treated and viewed as a "new" substance Additives must be strictly controlled in regards to plastic, paper, and other materials to ensure that those nanomaterials do not impeach the boundaries of the packaging towards the interior of the food itself. The hygienic aspect and quality of nano-materials that are currently present in food products must meet requirements set by the Good Manufacturing Practices.	Heavy reliance of traditional chemical assessments because of lack of standardized national-level toxicological procedures for nanoparticles in food products specifically. Lack of supervision and voluntary reporting schemes decrease the effectiveness of the surveillance for the use of nanotechnology in food products.
Product Liability	The Provisions of the Management of Cosmetic Registration and Notification Dossiers requires that the term	National Medical Properties Administration (NMPA) Standardization	Use of nanomaterials in children's cosmetics products or products with high inhalation rates is strongly discouraged and in some cases prohibited	Rather than a single overarching law for all products containing traces of nanomaterials, China applies regulations

	"nano-scale" must be added after nano-ingredients on the ingredients list. SAC establishes mandatory nation-wide standards for the testing of nanoparticles and nanomaterials in products before they reach the consumer market.	Administration of China (SAC) Ministry of Emergency Management (MEM)	entirely. For medical products, comprehensive risk assessments are made on behalf of dosage and related rate of injection into the body.	based on the utility and type of product. China, who has the largest amount of nanotechnology patents, is moving increasingly towards a reliance on international standards for regulating nanomaterials put one of the most pressing challenges standing in their way is that there are extremely few, if none, internationally validates standards the measure and track the toxicity of nanoparticles over time.
Environmental Protection	MEE Order Number 12 governs the regulation, importation, and usage of new chemical substances (in products such as fertilizers or pesticides) SAC Technical Committee 279 spearheads the development of national standards for the testing, terminology, and safety of	Ministry of Ecology and Environment (MEE) Standardization Administration of China (SAC)	If a chemical substance is not already included in the Existing Chemical Substances of China, it will be treated as a "new substance' by MEE The manufacturing or importation of such new substances requires pre-market approval and registration that follows the principles set by SAC. Nanomaterials that are already present in the	There is a lack of standardized methodology systems for assessing the hazardous and potentially long-term behavior of nanomaterials exposed to the environment. Despite strong ideal policies, efforts for nation-wide coordination, supervision, and institutional capacity still greatly impeded

	environmental nanomaterials.		Existing Chemical Substances of China may be subject towards further registration if they exhibit properties such as bioaccumulation or persistence.	efforts. The unique changing properties of NMs make predicting their environmental effects, persistence, and eco-toxicity difficult.

Table 3: Regulatory frameworks governing nanotechnology in China

India

The regulation of nanotechnology in India is characterized by adaptive strategies that are fragmented across sectors such as food safety, chemical manufacturing, product liability, and environmental protection. Agencies including the Bureau of Indian Standards (BIS), the Food Safety and Standards Authority of India (FSSAI),, and the Indian Pharmacopoeia Commission provide regulatory guidance for the nanotechnology industry. [13] Many evaluations of nano-products are conducted on a case-by-case basis, which weakens the development of a unified framework with binding nano-specific risk assessments. Recent initiatives, such as BIS guidelines, have begun establishing standardized testing, research, and safety protocols for the handling of nanomaterials. [14] However, unlike the U.S. and China, which are moving toward mandatory testing and reporting, India still lacks a binding regulatory assessment, leaving critical gaps in monitoring, labeling, and evaluation of long-term nanoparticle effects- comparable with other jurisdictions facing similar regulatory challenges. [15] Figure 4 compares the regulatory framework governing nanotechnology in India across the chemical manufacturing, food safety, product liability, and environmental protection industries.

Sector	Key Laws/Policies	Agencies	Regulation of Nanomaterials	Key Gaps/Challenges
Chemical Manufacturing	Manufacture, Storage, and Import of Hazardous Chemical Rules Quality Control Orders (QCOs)	Nano Mission Bureau of Indian Standards (BIS) National Chemical Authority (NCA)	Nanomaterials are regulated under existing chemical safety rules when they meet the definition of a hazardous chemical. QCOs are used to require Indian standards for certain chemicals, including nano-enabled materials, to prevent unsafe or low-quality products from entering the market. The Bureau of Indian Standards has developed guidelines and standards related to nanomaterials, focusing on terminology, testing methods, and material characterization.	No mandatory nano-specific registration system for chemical manufacturing. The regulation is categorized by traditional chemical classifications, which may not accurately reflect risks that are present at the nano-scale.
Food Safety	Food Safety and Standards Act	Food Safety and Standards Authority of India (FSSAI) Department of Biotechnology	Nanomaterials that are utilized in food products or packaging are treated as new or novel substances. For food additives, pre-market registration and approval is required before it is released into the	No clear legal definition of the presence of nanomaterials in food packaging and products. Heavy reliance on voluntary disclosure of nanoparticle data by manufacturers and

			consumer marketplace. FSSAI evaluates safety data on a case-by-case basis, not a standardized regulatory system.	importers. There is very limited monitoring of nano-engineered food products that have crossed the post-market stage.
Product Liability	Guidelines For the Evaluation of Nanopharmaceu-ticals. The Occupational Safety, Health, and Working Conditions Code	Indian Pharmacopoeia Commision	The product regulation of nanomaterials focuses on the intended utility and usage of the product rather than nano-specific risks. Nanopharmaceuticals in particular are subject to additional evaluation based on particle size, toxicity, and exposure.	There is no unified product liability law that specifically addresses the unknown effects of nanomaterials. Difficulties in proving harm that directly stems from nano-specific properties. No general labeling requirements for nanomaterials in consumer products demonstrate limited awareness.
Environmental Protection	Guidelines For Safe Handling of Nanomaterials	Ministry of Environment, Forest, and Climate Change Central Insecticides Board and Registration Committee	Environmental regulation of nanomaterials focuses primarily on the safe handling, storage, and disposal of nanomaterials. Pre-existing chemical laws relating to pesticides, fertilizers, etc apply to nanomaterials instead	Regulatory oversight relies on precautionary handling rather than the examination of long-term environmental impacts. Limited monitoring of nanomaterials in soil, water, and air.

			of nano-specific risk evaluations and thresholds. Nanomaterials utilized in pesticides must be registered and evaluated for approval before use.	There is no binding environmental risk assessment specific towards nanoparticles themselves.

Table 4: Regulatory frameworks governing nanotechnology in India

CONCLUSION

The regulation of nanotechnology remains a critical stepping stone for ensuring safe, responsible, and innovative applications across global industries. This study demonstrates that while all four jurisdictions- the United States, the European Union, China, and India- have developed regulatory frameworks to provide oversight over nanotechnology, significant differences and gaps persist. The United States relies primarily on existing chemical and product safety laws with voluntary compliance; the EU has begun to incorporate nano-specific guidelines but faces challenges in enforcement and toxicological data collection; China adapts traditional chemical standards to nanomaterials but often lacks validated evaluation methods; and India manages nano-products on a case-by-case basis with limited binding regulation.

These findings underscore the fragmented nature of global nanotechnology governance and highlight the risks associated with inconsistent oversight, including potential safety hazards, delays in international regulatory standardization, and additional hurdles for industry innovation. The path forward demands the reimagining of regulatory cooperation- where nations transcend competitive interests to build a unified governance framework capable of matching the transformative scale of nanotechnology itself. Ultimately, effective governance of nanotechnology will depend on balancing scientific progress with precautionary oversight, ensuring that regulatory frameworks evolve along with the rapid expansion of nanoscale innovation.

Further research should examine the regulatory challenges at the intersection of nanotechnology and artificial intelligence, particularly in areas such as AI-driven nanomaterial design or autonomous biomedical applications, where existing governing frameworks remain significantly undeveloped and difficult to align across jurisdictions.

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REFERENCES

Rodríguez-Gómez, Francisco D, et al. "Regulatory Pathways and Guidelines for Nanotechnology-Enabled Health Products: A Comparative Review of EU and US Frameworks." *Frontiers in Medicine*, vol. 12, 5 Mar. 2025, https://doi.org/10.3389/fmed.2025.1544393. [1]

Lin, Albert. *SIZE MATTERS: REGULATING NANOTECHNOLOGY*. 2020. [2]

Allan, Jacqueline, et al. "Modi, Jay. "Navigating Nanotechnology Regulation: A C-Suite Guide - Brightpath Associates." *Brightpath Associates*, 16 Jan. 2026, brightpathassociates.com/navigating-nanotechnology-regulation-a-c-suite-guide/. Accessed 7 Feb. 2026. [3]

Regulatory Landscape of Nanotechnology and Nanoplastics from a Global Perspective." *Regulatory Toxicology and Pharmacology*, vol. 122, June 2021, p. 104885, https://doi.org/10.1016/j.yrtph.2021.104885. [4]

Wood, Rob. "Understanding Chemical Regulatory Frameworks in the U.S. - Brightpath Associates." *Brightpath Associates*, 24 Dec. 2025, brightpathassociates.com/understanding-chemical-regulatory-frameworks-in-the-u-s/. Accessed 7 Feb. 2026. [5]

Office of the Commissioner. "Nanotechnology Programs at FDA." *U.S. Food and Drug Administration*, 2019, www.fda.gov/science-research/science-and-research-special-topics/nanotechnology-programs-fda. [6]

Bergeson, Lynn L. "ECHA Updates Report on Key Areas of Regulatory Challenge, Addresses Micro- and Nano-Sized Materials." *Bergeson & Campbell, P.C.*, Bergeson & Campbell, P.C., 17 June 2024, www.lawbc.com/echa-updates-report-on-key-areas-of-regulatory-challenge-addresses-micro-and-nano-sized-materials/. Accessed 7 Feb. 2026. [7]

European Commission Joint Research Centre. "New Guidance Supporting Safety Testing of Manufactured Nanomaterials." *Joint Research Centre*, 16 Dec. 2025, joint-research-centre.ec.europa.eu/jrc-news-and-updates/new-guidance-supporting-safety-testing-manufactured-nanomaterials-2025-12-16_en. Accessed 7 Feb. 2026. [8]

Von Burgsdorff, Christoph, and Luisa Kramer. "Increased Liability due to the New EU Product Liability Directive: What Does This Mean for the Medical and Pharmaceutical Industry?" *Ibanet.org*, 2025, www.ibanet.org/increased-liability-eu-product-directive. [9]

Wang, Yawei, et al. "Emerging Chemicals in China: Historical Development, Current Situation, and

Future Outlook." *Environment & Health*, vol. 2, no. 4, 19 Mar. 2024, pp. 180–188, https://doi.org/10.1021/envhealth.3c00126. Accessed 19 Aug. 2024. [10]

Yue, Paolo. "Chemicals Management in China: Overview - Cobalt Institute." *Cobalt Institute*, 18 Nov. 2024, www.cobaltinstitute.org/news/chemicals-manageent-in-china-overview/ [11]

Keller & Heckman. "Breaking News: China Publishes Revised Food Labeling Requirements." *Keller and Heckman*, 16 Apr. 2025, www.khlaw.com/insights/breaking-news-china-publishes-revised-food-labeling-requirements. [12]

Department of Biotechnology of India. *DBT-DRAFT 1 GUIDELINES for EVALUATION of NANO-AGRIINPUT PRODUCTS and NANO- AGRIPRODUCTS in INDIA*. [13]

King Stubb and Kasiva. "Implementing Nanotechnology Regulations in India: Importance." *King Stubb & Kasiva*, 2 May 2023, ksandk.com/information-technology/nanotechnology-regulations-in-india/ [14]

Singh, Ragini, and Santosh Kumar. "Regulatory and Safety Concerns Regarding the Use of Active Nanomaterials in Food Industry." *Researchgate*, 1 Jan. 2023, pp. 269–306, https://doi.org/10.1007/978-981-99-5045-4_8. Accessed 27 July 2024. [15]

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