DEBATE
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Nanotechnologies: evidence-based regulation

Nanotecnologias: regulação baseada em evidências

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ABSTRACT

The debate on best practices for the regulation of nanotechnologies needs to be deepened, and this still represents a challenge for Brazilian society, political authorities, and regulatory bodies. In recent years, there has been much discussion about the regulation of nanotechnologies; however, as a disruptive technology due to its complexity, limitations in the validation of analysis methodologies, and the scarcity of references on nanoparticles and nanomaterials, significant asymmetries, and difficulties in understanding the best regulatory practices persist. Due to the limited technical and scientifically validated evidence, regulatory models known as "command and control", and the precautionary principle prevent concrete/abstract but plausible dangers. As an alternative to the current regulatory model, this paper discusses the regulatory model considered the best global regulatory practice, which relies on regulatory science and evidence-based regulation. There is growing global acceptance of using technically and scientifically validated evidence to assist political and regulatory authorities in developing guidelines and regulatory standards to protect public interests and maximize new technologies' economic and social benefits. Furthermore, evidence allows for anticipating potential risks and enables proactive approaches to nanotechnologies regulation. When considering this perspective, it is essential to emphasize that implementing an evidence-based regulatory model requires political, scientific, technical, and regulatory maturity to ensure that the benefits are harnessed to provide prosperity, safety, and sustainability through disruptive technologies.

KEYWORDS: Nanoparticles; Nanomaterial; Nanosafety; Regulatory Science

RESUMO

O debate quanto às melhores práticas da regulação das nanotecnologias precisa ser aprofundado, pois ainda representa um desafio para a sociedade brasileira, autoridades políticas e regulatórias. Nos últimos anos, muito se fala na regulação das nanotecnologias, porém, como tecnologia disruptiva, pela complexidade, limitações na validação de metodologias de análise e escassas referências sobre nanopartículas e nanomateriais, ainda persistem expressivas assimetrias e dificuldades de compreensão sobre as melhores práticas regulatórias. Atualmente, pelas ainda limitadas evidências técnicas e científicas validadas, utilizam-se os modelos de regulação denominados de comando e controle e o princípio da precaução como meio de evitar o perigo concreto/abstrato, mas cuja ocorrência seja verossímil. Como alternativa ao atual modelo regulatório, no presente texto, discorre-se sobre o modelo regulatório, tratado como a melhor prática regulatória global e que se vale da ciência regulatória e da regulação baseada em evidências. Globalmente cresce a aceitação do uso de evidências técnicas e científicas validadas para auxiliar autoridades políticas e regulatórias na elaboração de diretrizes e normas regulatórias que consigam proteger os interesses públicos e maximizar os benefícios econômicos e sociais das novas tecnologias. Para além disso, evidências permitem antecipar possíveis riscos e permitem abordagens proativas para a regulação das nanotecnologias. E ao considerar essa perspectiva, é importante enfatizar que a implementação de um modelo de regulação baseada em evidências requer maturidade política, científica, técnica e regulatória, para que os benefícios sejam aproveitados de maneira a prover prosperidade, segurança e sustentabilidade pelo uso de tecnologias disruptivas.

PALAVRAS-CHAVE: Nanopartículas; Nanomateriais; Nanossegurança; Ciência Regulatória

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INTRODUCTION

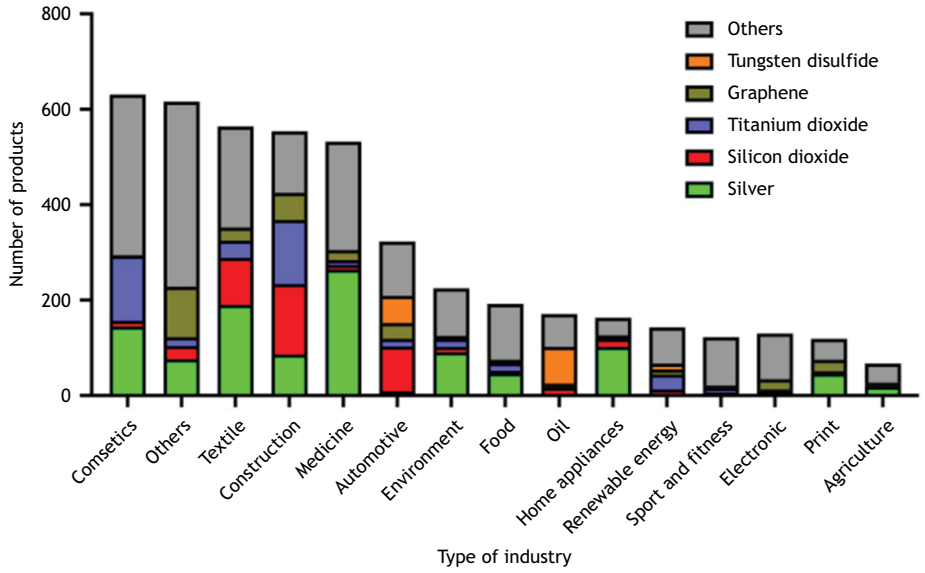
Nanotechnologies are at the basis of the main scientific and technological changes in recent years, which is opening up a new technological cycle called the "nanotechnologies age" with important repercussions on society, work, the environment, and other areas (such as the war industry). These technologies have a transversal, disruptive, and pervasive scientific-technological character, which requires understanding, governance, control, and the safe and responsible use of the particular properties of matter on a nanometric scale[1].

Manufacturing matter on a nanometric and molecular scale produces nanoparticles, which, in turn, make up nanomaterials (NM), which can have different properties from the original material. For many years, discussions about nanoparticles have considered their size rather than their properties, but it is now understood that this definition is not specific enough. Notably, nanoscale refers not only to size but mainly to the unique physical, chemical, biological, and optical properties that arise naturally in nanoparticles or the ability to modulate such effects. The specific properties of NM, in turn, are of great interest for driving innovation and offering innovative products. Although these properties may also be responsible for NM's adverse effects or toxicity. This is why differentiated safety assessment procedures are needed so as not to repeat the damaging global history of asbestos and the ethical use of technologies, which is why nanotechnologies require specific regulation[2,3]. It is also interesting to note that the marketing of manufactured products containing NM (produced with manufactured nanoparticles) is growing rapidly (Figure 1).

According to records in the StatNano database, in 2023, more than 11,000 consumer products were already found on the market containing NM, including pharmaceuticals, cosmetics, sanitizers, textiles, paints, biocides, sports products, electronic products, energy conversion products, construction materials, particles with applications in life sciences, solar cells, catalysis, and new compounds, to name just a few[4].

Still, regarding consumer products on the market containing NM, it is worth mentioning that they have enormous potential for new technological solutions, considering the current society challenges. However, the speed of innovation and development of nanotechnologies have created asymmetries between innovative products and the ability of regulatory authorities to govern the potential associated risks. This asymmetry is exacerbated by the need to develop new reference standards and specific nanotechnological analytical methodologies. However, although there have been advances in analytical capacity, there is a pressing need to improve analytical methodologies and regulatory mechanisms at national and international levels to ensure the quality and safety of nanotechnologies[5].

Returning to the initial concepts, it can be seen that, despite various initiatives to increase research, regulatory debates on the safety of nanotechnologies are still primary, and there is still limited validated knowledge and information. This suggests an urgent need for action in the production of technical and scientific evidence that considers interaction with cells, the behavior of nanoparticles and NM on the health of consumers and workers, as well as environmental behavior and toxicological effects, primarily since the tests described in the international literature are often carried out at the beginning of the product development process, and the NM in the final product may behave differently[6,7,8].



Source: StatNano, 2023.

Figure 1. Number of manufactured products containing nanomaterials in their formulation, considering the different industrial segments.

Thus, being aware of this complexity, it is essential to note that in Brazil, there is still limited availability of technical guidelines and norms and a lack of specific regulation for nanotechnologies[9]. In this scenario, considering the technical complexity of regulating nanotechnologies, as well as the limited engagement in the debate on regulatory models, this article aims to present concepts, the meaning, and debate the importance of regulatory science for the evidence-based regulation model as a way of improving the regulatory process and increasing assertiveness in the drafting of regulatory guidelines and standards by the responsible authorities.

Regulatory science

Regulatory science is currently receiving more and more attention. It is a field of knowledge that focuses on applying scientific principles and technical evidence to help define mechanisms for the drafting, implementation, and evaluation of regulatory guidelines and standards by the competent authorities. It is also the science of developing new tools and standards with a scientific and interdisciplinary approach to assessing the safety, quality, and efficacy of regulated products, processes, and services, such as nanotechnologies[10].

Regulatory science aims to develop and qualify the regulatory mechanisms that guide the development, production, use, and marketing of products and services, always focusing on promoting the protection of society's health, safety, and well-being and the protection of the environment. Regulatory science is applicable in many fields, such as health, food safety, occupational and environmental safety, chemicals, medicines, medical devices, energy, and telecommunications[11].

Regulatory scientists play a key role in using scientific methods and analytical approaches to assess risks, set limits, and establish compliance standards. They carry out experiments, establish standards, data analysis, epidemiological studies, systematic literature reviews, and other scientific methods to support the rationale for making regulatory decisions[12].

Another aspect worth highlighting is that regulatory science must consider interaction and collaboration between governments, the legislature, the judiciary, regulatory agencies, academic experts, industry, civil society, workers, consumers, and other stakeholders[13]. In addition to the emphasis on regulatory science, the participation of society is increasingly important through public consultation. In this context, the Council on Regulatory Policy and Governance of the Organization for Economic Cooperation and Development (OECD)[14] established 12 specific recommendations for member countries, such as regulatory impact analysis, emphasizing the need for public consultation[13]. In Brazil, 90% of regulatory agencies hold public consultations before publishing new regulations[15]. This interaction makes it possible to speed up the dissemination and exchange of information and consolidate knowledge to base decisions on evidence, making them more effective and assertive.

Finally, regulatory science plays a crucial role in protecting society and the environment, balancing the interests of different stakeholders, and promoting safety, quality, and compliance in various regulated sectors, considering best practices and technical and scientific knowledge.

Evidence-based regulation

Evidence-based regulation (EBR) is a principle that seeks to base regulatory decisions on the best available and validated scientific evidence. Data and information are the lifeblood of modern regulation. This process involves collecting, analyzing, and interpreting relevant scientific data and information (evidence) to assess the risks and benefits of certain products, technologies, or processes that are regulated. Regulatory science plays a key role in implementing EBR, as it involves using scientific data and information to inform and support regulatory decision-making[10,16].

In addition, the EBR follows a similar approach, which seeks to base professional interventions and decisions on technical and scientific evidence. To illustrate this approach, in health, such as medicine, nursing, and psychology, the aim is to make clinical and healthcare decisions based on the best technical and scientific evidence available. The same principle applies to the EBR, in which scientific data and information are the basis for regulatory decisions, with a pre-defined emphasis on the safety, quality, and efficacy of regulated products and technologies[10,17].

However, while on the one hand, EBR seems to be essential and represents a step forward in terms of qualifying regulatory mechanisms, on the other hand, there is growing pressure to treat EBR as a global best practice, with clear political interests in the hope of overcoming barriers and curbing the "regulatory state, regulatory bodies, and multilateral mechanisms", as well as technical limitations, such as in the case of innovative technologies, where there is a lack of technical references and validated methodologies for the full use of EBR.

These considerations indicate that EBR still has limitations in terms of application, and there are certain conditions under which this decision-making practice is likely to be less viable than the command-and-control model or the application of the precautionary principle itself. Table 1 summarizes the main limiting conditions that impact the viability of EBR. These conditions are present in varying forms, with greater or lesser complexity at national and transnational levels, with effects accentuating economically less favored countries[16].

Thus, when considering these limiting conditions, it is essential to emphasize that the EBR model aims to make informed decisions based on validated technical and scientific information. Given this concept, it is necessary to remember that EBR cannot represent an imposition dressed up as "best regulatory practice and global harmonization" by the economic domain.

Evidence-based regulation in nanotechnologies

EBR in nanotechnologies involves making regulatory decisions based on validated scientific data, standards, and information for nanoparticles and NM. However, as this technology has disruptive, complex characteristics, limitations in the validation of analysis methodologies, and scarce references on nanoparticles and NM, there are still significant challenges to the application of EBR. In this sense, in many cases, the command and control model and the precautionary principle are still used to avoid concrete/abstract danger, but whose occurrence is likely. This practice is still vital to ensure the safety and efficacy of nanotechnologies products due to the lack of validated evidence[16,18].

When considering these aspects, it is also important to point out that, concerning EBR for nanotechnologies, it is necessary to fulfill some basic requirements, highlighted in Table 2.

Global regulatory developments in nanotechnology

The regulation of nanotechnologies is a complex issue that requires a regulatory policy focused on products and their application based on scientific evidence that proves their safety, guided by ethical and legal principles. The regulatory approach must be based on the best available science and ensure transparent and predictable regulatory pathways[19]. There is a significant debate about the responsibility and scope of nanotechnology regulation, and currently, regulatory models worldwide seek to assess the safety of new substances or manufactured products on a case-by-case basis before allowing them onto the market[20].

Aware of this complexity, although there are still several limiting conditions, regulatory agencies worldwide seek to follow good regulatory practices by establishing guidelines and standards based on the best scientific evidence available to assess the safety of nanotechnology products. It is essential to emphasize the example set by the US government, which funds various research projects through the US National Nanotechnology Initiative (NNI) to understand the economic, ethical, social, legal, and cultural implications of using nanotechnology[21]. This example is being followed by some other governments, including concerns about using these technologies for war purposes.

Still, on the regulatory front, it is worth mentioning that regulatory agencies such as the U.S. Food and Drug Administration (FDA) regulate these products according to specific standards that apply to each type of product under their jurisdiction[19]. At the same time, the Occupational Safety and Health Administration (OSHA) has established some standards applicable to nanotechnology activities in industry in general[22]. In the European Union, the existing standards essentially deal with NM, with specific standards for products, including the safety assessment of these materials and the obligation to label, i.e., they follow a safety regulatory principle that applies to all chemical products and mixtures which are the regulations for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP)[23]. In Australia, seven separate bodies regulate nanotechnology and the use of NM in commercial products[24]. China invests in standards and

Table 1. Limiting conditions under which, currently, the practice of evidence-based regulation (EBR) is not always viable, requiring the application of the command-and-control model or application of the precautionary principle (2023).

Order	Limiting conditions
i	Global political interests
ii	Protectionism
iii	Technical barriers
iv	Lack of standards, data, and validated information
v	Asymmetry between the development of innovative technologies and security assessment methodologies
vi	Decision makers have limited technical capacity to evaluate technologies at the speed of their advancement.

Source: Prepared by the authors, 2023.

Table 2. Basic requirements necessary to advance evidence-based regulation (EBR) in nanotechnology considering the current stage (2023).

Item	Stage description
i	Identify and collect validated scientific evidence regarding the safety of nanoparticles or nanomaterials for different uses, as well as measuring impacts throughout the cycle
ii	Develop and validate technical standards to be used as comparative references
iii	Identify risks associated with nanotechnology, including possible adverse effects on human health, worker health, and the environment, as well as develop mitigation measures necessary to minimize risks
iv	Develop regulatory guidelines and standards focusing on risk assessment
v	Implement mechanisms for monitoring and updating guidelines and standards
vi	Cooperation between different stakeholders, including government, regulatory authorities, research institutions, industry, civil society, among others
vii	Stimulate promotion, education, and awareness about the risks and benefits of nanotechnologies, including training in regulatory sciences for health professionals, scientists, and regulators

Source: Prepared by the authors, 2023.

reference materials, and the first regulations relating to the laboratory use of NM were published by the Chemical Abstracts Service (CAS) in 2007[25,26].

It is also worth highlighting the initiatives and efforts of the International Organization for Standardization (ISO) and the Organization for Economic Cooperation and Development (OECD) in establishing benchmarks for advancing nanotechnology EBR. The complementarity of initiatives in nanotechnologies between ISO and the OECD can be seen in the references and technical documents for NM, which, in practice, are essential references for regulatory authorities focused on EBR.

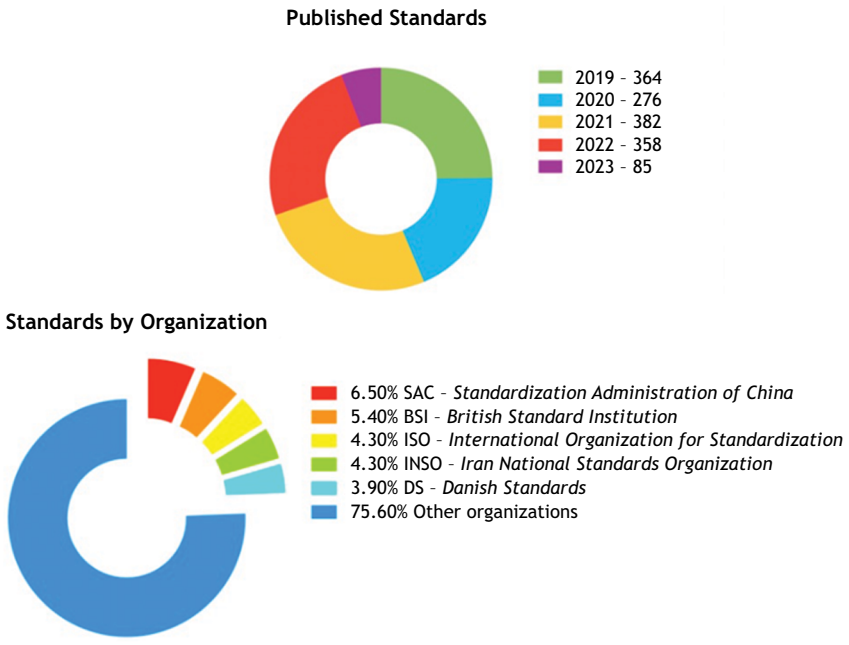
A summary of global regulatory developments is shown in Figure 2, which shows that 1,465 standards were published between 2019 and 2023. However, 3,683 guidelines and standards have already been published by 56 regulatory authorities or organizations in 44 countries, according to a survey on the StatNano platform in September 2023[4]. These statistics point to a significant increase in the number of guidelines and standards over the last five years, although it is impossible to make any inferences about the quality and effectiveness of these regulatory instruments. This is a positive development, considering that the regulatory authorities and national and international organizations are deepening the debate to overcome limiting conditions and with a growing focus on the EBR[3,4].

In Brazil, the regulatory development of nanotechnologies is slow, punctual, and still entirely restricted to a limited circle of authorities[9]. Some initiatives, such as the collaboration between Brazil and the European Union, aim to establish nanotechnological safety standards, particularly the NANoREG consortium[27]. In a recent publication, Oliveira Figueiredo and Assis Figueiredo[28] analyzed Brazil's legal framework for nanotechnology. They emphasized the need to adopt governance policies and regulatory strategies in line with environmental sustainability, economic, ethical, and social responsibility while also considering the protection of the professionals involved in the production chain.

In summary, the regulation of nanotechnologies, whether in Brazil or globally, requires a comprehensive and complex regulatory approach that guarantees safety and ethical use, taking into account the best technical and scientific evidence available. However, despite efforts, the current regulation of nanotechnologies is insufficient. It is essential to question whether existing regulations can prevent damage to health and the environment, as with asbestos and microplastics. Furthermore, there are no regulations preventing leaders, states, and/or other groups from using nanoparticles or nanorobots for intentionally destructive purposes, such as the use of chemical and biological weapons.

Challenges in Evidence-Based Regulation

Although products derived from nanotechnologies and NM have already reached the global market, there is still a need to understand the impacts and effects of NM throughout their



Source: StatNano, 2023.

Figure 2. Standards published globally between 2019 and 2023 and percentage distribution of standards published by different organizations and regulatory authorities, according to the StatNano platform database records.

Table 3. Challenges related to evidence-based regulation as a convergent and protective practice against possible harm and safe and transparent practice in disruptive technologies (2023).

Order	Main challenges
i	Seek political and technological convergence between countries to overcome divergences in regulatory objectives that make evidence-based regulation unfeasible
ii	Overcome asymmetries and technical and technological barriers
iii	Overcome the lack of standardization of nanomaterial nomenclature and reference standards
iv	Overcome the lack of validated methodologies and the lack of characterization of nanomaterials
v	Overcome the lack of certified reference materials for different nanomaterials
vi	Urgent need to expand understanding of cell/nanoparticle interaction, understanding of environmental contamination, human exposure, and possible risks arising from the life cycle of nanoparticles

Source: Prepared by the authors, 2023.

life cycle, including waste in the environment in their various technological applications. There are many efforts among regulatory authorities and organizations worldwide to assess the safety of NM, such as initiatives to establish validation and standardization processes by ISO and OECD. Despite the multiple international initiatives and efforts on the subject, through research carried out by specific working groups, such as the OECD[29], many challenges remain to overcome for the effective adoption of EBR, as summarized in Table 3.

As a warning to the decision on whether or not to adopt evidence-based regulation, several factors must be taken into account, which have not been covered in depth in this article. Still, concerning EBR, it is worth mentioning that the regulation of strategic technologies and transnational businesses is associated with various economic interests and technological dominance. This illustrates the difficulty of establishing this regulation model and that full global regulatory harmonization only benefits the most privileged economies. As a result, careful reflection is needed on whether and how to use regulatory science instead of the command and control model in regulatory decision-making, assuming that the aim is to maximize regulatory effectiveness and protection from possible unfavorable impacts.

CONCLUSIONS

In recent years, much has been talked about the need to improve the regulation of nanotechnologies. However, as an innovative, disruptive, complex technology with limitations in validating analysis methodologies and scarce references on nanoparticles and NM, there are still significant regulatory challenges. Safety information throughout the nano's life cycle is vital for the governance of nanotechnologies.

The application of the precautionary principle must be properly and dynamically combined with scientific evidence in a reciprocal, mutual, and interdependent ways. All research is seen as a collective scientific construction aimed precisely at eliminating risks and uncertainties on an ongoing basis, with new scenarios and applications constantly emerging, requiring continuous risk assessments.

On the other hand, in the EBR model, regulators use validated technical and scientific evidence to draw up guidelines and standards. This model starts from a technical and scientific rationale, focusing on risk analysis rather than imposing generic rules that are not always contemplative of effective risk control. EBR requires research, continuous and dynamic vigilance to adjust guidelines and standards in line with advances based on the best available evidence.

Finally, it is essential to emphasize that implementing an EBR model requires political, scientific, technical, and regulatory maturity. It requires the promotion of regulatory science, the development of standards, analytical methodologies, characterization, and analysis of NM safety so that the model results in informed decisions with an assessment of the risks so that the benefits can be enjoyed safely and sustainably without, however, renouncing sovereignty and the principle of regulatory self-determination, which gives the country the right to freely decide the validated technical criteria to be adopted when drawing up regulatory guidelines and standards for nanotechnologies.

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Authors' Contribution

Binsfeldl PC, Granjeiro JM - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. All the authors approved the final version of the work.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.