GOVERNANCE AND SANDBOX: BUILDING SELF-REGULATION MODELS FOR NANOTECHNOLOGIES

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ABSTRACT

The 21st century is marked by the emergence of a new Industrial Revolution, the fourth, which is characterized by speed, systemic impact, in addition to breadth and depth. Nanotechnologies are born from the human possibilities of accessing the so-called nano scale: the scale that is equivalent to a billionth of a meter. When it comes to nanotechnologies and products generated from this scale, there is something new in research and production, which can generate effects that are still little known by human beings, especially through the interfaces with the human body and the environment. There is an openness to formulating regulatory environments, structured from a varied set of principles and designing agile, flexible and adequate "regulated self-regulation" models. The choice of the structuring principles of these directives must take into account the guidelines of ethics and be enriched with dimensions coming from the environment where these scientific-technological innovations. The governance of the various stakeholders in nanoscale regulation and the combination of principles, to be tested in Regulatory Sandbox, as real laboratories for improvements in normative models that are structured from principles sought in national and international organizations.

KEYWORDS: Agile Regulation; Governance; Nanotechnologies; Principles; Regulatory Sandbox; Regulated Self-Regulation.

1 INTRODUCTION

This article aims to address the importance of revising the General Theory of Legal Sources, shifting the primacy of legal texts as sources in order to create more prominent spaces for other constructions. It seeks to highlight the role of creatively using the regulatory architecture of the so-called "regulated self-regulation." The problem that guides this research is: What are the structural elements of a regulatory sandbox to test models of "regulated self-regulation" to regulate advances in nanotechnologies? The provisional answer points to the importance of governance among various legal sources and public and private actors to guide the development of regulatory models, given the absence of a state normative framework.

To achieve this goal, bibliographic and documentary research will be conducted, using the keywords indicated in this article, in order to compile a survey of sources from the CAPES Periodicals Portal accessed through the main page of the Unisinos Library, using the researcher's institutional password, with a focus on publications since 2015.

2. THE WORLD OF NANOPARTICLES

The hierarchical structure of legal sources still dates back to the period of legal positivism, notably the legalistic bias associated with the contributions of Thomas Hobbes (Engelmann, 2001). While the perspective that legal texts could capture and regulate life's facts was valid, nowadays, this approach is no longer sufficient or appropriate to encompass the richness of the characteristics brought about by the Fourth Industrial Revolution, namely, speed, systemic impact, as well as breadth and depth (Schwab, 2016). These characteristic elements promote the "convergence of a group of technologies," among which nanotechnologies can be highlighted. This term encompasses various productive areas that operate at the billionth part of a meter, or in scientific notation: 10-9. It represents a very small measurement, the nanometer, which gives rise to new physicochemical characteristics of materials and products containing any nanoparticle. How can this phenomenon be defined on the nanoscale? On June 10, 2022, the European Commission published a recommendation, revising its own previous definition of nanomaterial (dated 2011), considering it as a natural, incidental, or manufactured material consisting of solid particles that are present, either isolated or as identifiable constituent particles in aggregates or agglomerates, and in which 50% or more of these particles by number-based size distribution meet at least one of the following conditions: a) one or more external dimensions of the particle are in the size range of 1 nm to 100 nm; b) the particle has an elongated shape, such as a rod, fiber, or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm (European Commission, 2022). Several elements can be observed in the conceptualization of nanomaterials. Even considering this definition, numerous possibilities arise for different presentations of materials at the nanoscale. This is one of the main points that complicates legislative-state regulation. If this definition and its implications were taken seriously, there would have to be a law for each type of nanomaterial. However, this is impractical. In addition to this difficulty, the time it takes for a bill to be passed should be noted. By the time all the formalities prescribed from Article 61 of the Brazilian Federal Constitution are fulfilled, that nanomaterial may have already undergone some mutation or combination with another particle, giving rise to a new nanomaterial.

Adding to these two difficulties is the following observation: a significant change is underway, with a large number of products from various sectors already containing some nanoparticles. Despite this, there is still no regulatory framework in place. This is a striking characteristic of technologies within the context of the Fourth Industrial Revolution (Schwab, 2016 and 2018), which compels the legal and regulatory field to seek normative formulas that are more agile and flexible.

According to data collected on July 13, 2023, from the *Nanotechnology Products Database*, there are 10,860 products manufactured by 3,674 companies located in 68 countries. These products are found in the following productive segments: electronics, medicine and related fields including pharmaceuticals, construction, cosmetics, textiles, automotive, environmental, renewable energies, food and packaging, household appliances, oil, agriculture, printing, sports, and fitness. Considering that these products can be purchased, mostly online, deliveries do not always undergo health surveillance by countries, including Brazil. People are consuming and disposing of packaging and remnants of products with nanoparticles without knowing the real effects on the health of living organisms (not only humans) and the environment. This is a serious issue that is being overlooked due to the absence of a regulatory framework and the lack of specialization and analytical categories in ANVISA (Brazil's National Health Surveillance Agency), for example.

3. REGULATED SELF-REGULATION AS AN AGILE REGULATORY MODEL

In order to use scientific research and help mitigate the effects of this situation, the possibility of constructing a model of "regulated self-regulation" is proposed. This term is connected to the transformation of the regulatory role of the State, especially through the Legislative branch, presenting itself as its new form of action, developed through networks for the description of a certain phenomenon that needs to be regulated, combined with the perspective of governance over the regulatory structure (Franzius, 2015, p. 217). What is proposed in this article is linked to these three inherent characteristics of the Fourth Industrial Revolution: the necessary reshaping of legislative action, driven by the aforementioned structural elements of technologies present in the Fourth Industrial Revolution. How can this be done? Without abandoning state participation, a new role is assigned to it, ensuring that self-regulation models developed by nanotechnology-based organizations can be designed, but with the observation of components that exist outside the organizations: this is where the State comes in, overseeing, for example, respect for human rights or, rather, the protection of human rights in the development and advancement of nanotechnologies, in order for them to effectively serve to improve the lives of living beings in society (Engelmann, 2022). This movement will be realized through governance among the involved parties, including the State, but without the latter's prevalence. Hence, the adjective "regulated" applied to self-regulation. Instead of normative imposition and coercion, it emphasizes governance and the combination of efforts and scientific knowledge in *normative-regulatory design*. Therefore, rather than "government" as an institution, it is about "governance" as a process (Berger Filho, 2018). The use of the World Economic Forum's (WEF) guiding principles in this regard proves to be suitable and they are referred to as the "foundations of good regulatory practice," namely: a) transparency and broad participation, including public and private actors, whereby all stakeholders involved in the regulation of a specific matter can be considered. However, the involvement of stakeholders should not be seen as a checkbox to be ticked, but as a process through which regulators can gain continuous learning on how to design and manage regulation more effectively. As regulation becomes more agile, it is important for regulators to find more flexible ways to support the understanding, participation, and oversight of citizens and stakeholders (WEF, 2020, p. 7); b) proportionality among regulatory forms, incorporating alternative regulatory models alongside the traditional legislative approach; attention should also be given to the design of transaction costs that may arise from regulation, attempting to minimize them, particularly through regulatory testing during the regulation creation process; c) justice is an essential foundation of the law. Regulatory decisions should be made objectively, impartially, and consistently, without conflict of interest, bias, or improper influence. This allows companies and other stakeholders to compete on equal terms and helps ensure that the best ideas, products, and business models that have emerged during the Fourth Industrial Revolution are those that have the best structural conditions to achieve success in their implementation (WEF, 2020).

These foundations supporting "good regulatory practice" also align with a shift in the temporal dimension of regulating "new technologies." Instead of regulating after the occurrence of events, there is a move towards "anticipatory regulation," which is projected in parallel with technology development. Anticipation should not be seen as a race to regulate. Instead, early identification of problems allows for a more informed and open dialogue with citizens and stakeholders about how the opportunities and risks of innovation should be managed, as well as the collection of better evidence to assess the impact of a range of policy options. The result should be a more timely and proportionate response, supported by stakeholder engagement (WEF, 2020). In particular, regulators need to exercise careful judgment regarding when to intervene. Acting too late, regulators may fail to seize economic opportunities or address emerging risks. However, intervening too early, regulators may stifle innovation or develop ineffective rules based on an incomplete understanding of emerging technology. This is the famous "Collingridge Dilemma" that illustrates the difficulties and challenges of regulating the so-called "new technologies" (Collingridge, 1980).

4. NEW REGULATORY STRUCTURES TO KEEP UP WITH ADVANCES IN NANOTECHNOLOGIES: THE CASE OF THE "REGULATORY SANDBOX"

In this regard, it is useful to shift from a mindset of "regulate and forget" to one where regulation is seen as a cycle of continuous learning and adaptation as technology develops. In this approach, soft law mechanisms such as regulatory guidance, codes of practice, and voluntary standards are used to guide technological development, with regulation codified as the technology reaches full maturity (Zwanenberg, Ely, & Smith, 2011).

Anticipatory and concurrent regulation embodies a more agile approach. Anticipation allows regulators to adopt a more agile approach to regulation based on continuous adaptation and learning (Doménech-Pascual, 2021). A combination of outcome-focused regulation and industry self-governance, coupled with insights from ongoing regulatory experiments and data-driven monitoring and evaluation, can be used to create a governance framework capable of continuous improvement in response to intelligence gained through anticipation. In turn, this more responsive regulatory system can provide vital information about future innovations and disruptions that can be integrated into ongoing prospective activities (WEF, 2021; OECD, 2022).

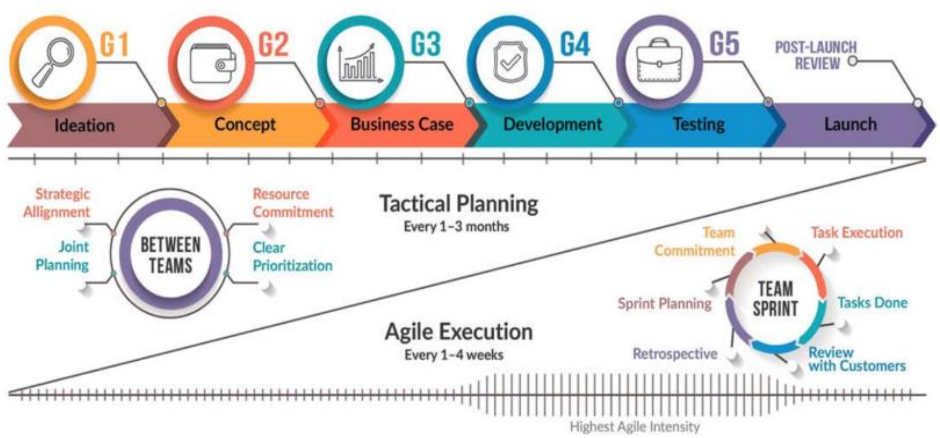
Within this context, the research conducted by the author of this article in the Postgraduate Program in Law—Master's and Doctorate, and in the Professional Master's in Business and Corporate Law, both at the University of Vale do Rio dos Sinos—UNISINOS, Brazil, points to the importance of building goal-focused regulatory models, specifically for the safe development of nanotechnologies, with control over the potential risks that access to the nanoscale may pose to living beings and the environment. The aim is to build non-state regulatory structures such as regulatory guidance, codes of practice, and voluntary standards, including the adoption of ISO standards. The construction of these non-dependent regulatory structures on the Legislative branch is based on principles. The principles studied by NanoAction (2007) are selected: precaution, nano-specific mandatory regulation, protection of health and safety for the public and workers, environmental sustainability, transparency, public participation, consideration of broad impacts, and producer responsibility. This article focuses on the "precautionary principle," which has the following structure: "when an activity threatens human health or the environment, precautionary measures should be taken, even when cause and effect relationships are not scientifically established" (NanoAction, 2007). From this conceptual presentation, the following elements are derived: an activity that can generate harmful effects not yet fully known or characterized by scientific knowledge on human health and all living beings, potentially causing harmful impacts on the environment. Why is this highlighted? Nanoparticles and nanomaterials are still being explored by humans, as a recent study (Li, Liu, Chen et al., 2021) found that exposing certain nanomaterials to light can influence their environmental transformation and toxicity. This discovery provides new insights into the behavior of human-made nanomaterials and how they can be better designed for numerous commercial applications without affecting the environment or human health.

The impacts of nanoparticles in their various uses still raise many questions, especially their behavior in the environment when they interact and produce various effects. According to research by AVICENN, a French non-profit environmental organization, when household utensils coated with nanoparticles are washed, recycled, or discarded, synthetic nanos are released into the environment—reaching the soil and sea in ways that are not yet fully understood. Some scientists believe that nanoparticles may pose an even greater threat than microplastics. Synthetic plastic nanoparticles have been found in the ocean and ice at both poles. Nanoparticles from socks and sunscreens have been found to pollute water, and some nanos have been shown to negatively affect marine wildlife, including fish and crustaceans. Little is known about the whereabouts of nanoparticles, let alone their effects on the environment. According to an article published in *The Guardian*: because they are so small, most experiments are conducted in laboratories, and it can be difficult to determine where they are being applied. "The main problem with these substances is that they cannot be measured—we know they are there, but they are so small that they are hard to detect, and that's why we don't hear much about them," says Nick Voulvoulis, a professor of environmental technology at Imperial College London. He is concerned about the uncontrolled use of nanos in consumer products. "If nanos are used properly in useful or beneficial applications, that is justified, but if they are used everywhere just because they have certain properties, that's madness" (Turns, 2022). This is the scenario that regulatory initiatives need to consider and a conducive environment for applying the precautionary principle as a guiding principle for normative-regulatory governance between Science and Law in the context of scientific uncertainty still present in research, development, and innovations in nanotechnology (Esteve Pardo, Tejada Palacios, 2013; Esteve Pardo, 2016).

The *regulatory sandbox* is envisioned as a real laboratory for bringing together stakeholders in the development of responsible and ethically committed nanotechnologies for the well-being of human beings and the preservation of the environment. With this concept, an attempt is made to broaden the conceptual spectrum of the *regulatory sandbox* presented by Feigelson and Leite (2020), which still requires a complex formalization for the structure of the experimental environment. The scientific research supporting this book chapter envisions the regulatory sandbox as a real experimental environment for testing *regulation models engineered* based on principles, as mentioned above, with a focus on the applied exercise of the precautionary principle. The architecture of these regulation models, referred to as *regulated self-regulation*, is developed based on the results obtained at various stages that integrate the agile method (Engelmann, 2018). It is worth mentioning that within the composition of a regulatory environment involving various stakeholders linked to the application and use of the nanoscale, the creation of principled regulatory structures is promoted, under the leadership of the precautionary principle, without neglecting the other principles presented by the NanoAction research. This legal creation should be guided by international documents and judicial decisions that apply these Human Rights standards, which are the regulated guidelines for self-regulation models. These elements characterize global legal pluralism, considering that principles are accepted forms of expression in many countries, both in Civil Law and Common Law traditions (Herberg, 2008).

The regulatory environment established within the *regulatory sandbox* framework is developed using agile methodology, as shown in Figure 1. It encompasses various entry and exit points at different stages of construction, prototyping, testing, and continuous experimentation in the daily activities of the actors involved in *this experimental regulatory environment*. Due to the absence of nano-specific regulation, the tested regulatory model, considered suitable for addressing research, development, and innovation processes, and aligning with the selected principles and applicable normative rules such as the Federal Constitution, becomes part of the routine of the stakeholders who contributed to the model's development process. From this stage, these models can be expanded to other public and private organizations interested in developing their activities on the nanoscale within an appropriate regulatory context that allows for constant review and updating (Hunt, 2021). The following image illustrates the functioning of the various possible movements within the regulatory sandbox environment:

FIGURE 1: Stages of the agile method.



SOURCE: Cooper; Sommer, 2018.

Figure 1 shows that gates or doors (G1, G2, etc.) and stages (ideation, concept, concrete case, development, etc.) are important steps in this hybrid model. The gates provide vital decision points to proceed or interrupt the design of the regulatory model—eliminating weak projects, providing focus on the development pipeline, and allowing top management to review projects at important transition points. The stages provide a high-level overview of the main project phases and a guide for the required or recommended activities and expected outcomes for each stage. However, the specified deliverables for each gate are leaner, less granular, and more flexible than in the classic gate model, and they are more tangible—product projects or prototypes instead of reports or slide presentations (Cooper, 2017). Each gate may have representatives from various segments (stakeholders), and one of these representatives accompanies the proposal to the next gate, and so on. If it is necessary to go back to a previous gate or stage, there will always be a member from the previous stage to provide the memory of the discussions.

5. FINAL CONSIDERATIONS

The conjugation between gates and stages represents the inner workings of the regulatory environment, specifying the movement of activities within a *regulatory sandbox*, with methodological aspects focused on constructing a normative model based on the principles outlined by *NanoAction*'s research, with an emphasis on the precautionary principle. The research question that guided the study was: What are the structuring elements of a regulatory sandbox to test "regulated self-regulation" models for governing advancements in nanotechnologies? The confirmed provisional answer points to the importance of governance among various sources of law and public and private actors to guide the development of regulatory models, given the absence of a state normative framework.

From the data presented, it is evident that there is already a wide range of products in various sectors developed at the nanoscale available in the consumer market. Despite this, there is still no regulatory structure in place. To address this challenge, innovation in law will also be necessary, valuing other sources of law, especially principles, which open up possibilities for structuring models of regulated self-regulation. This does not mean transferring regulatory capacity exclusively to business organizations operating at the nanoscale. In addition to this new characteristic, there is a need for this regulatory model to be in line with and respect standards that exist beyond these organizations. This opens up a renewed space for human rights, especially those concerned with respect for human beings and the environment.

Future research should test the hypothesis that these human rights can be structured based on the framework developed by John Gerard Ruggie (2011): protect, respect, and remedy human rights. Based on this three-pillar approach, Ruggie developed 31 principles that are applicable, with some adaptations, to nanotechnology-based companies.

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