



Labori

Innovation Laboratory of the AGU

Regulatory Sandbox Reference Guide

MINISTRY OF
DEVELOPMENT,
INDUSTRY, TRADE
AND SERVICES



BRAZILIAN GOVERNMENT
BRASIL
UNITING AND REBUILDING



Words from Minister Jorge Messias

developing agile and efficient solutions to address societal demands.

We are in an era where technology and innovation play a central role in the effective implementation of public policies. Regulatory Sandbox stands as a pioneering instrument that reflects our commitment to the flexibility required to test new ideas, without compromising the security standards mandated by the state.

This approach ensures that Brazil remains competitive in the global landscape while safeguarding the legal certainty of state actions, focusing on the advantages a robust regulatory environment can offer to citizens and the national entrepreneurial ecosystem. Experimentation generates evidence to inform decision-making processes and fosters continuous learning among all stakeholders involved, allowing this knowledge to be shared and applied across multiple sectors.

This guide is not merely a technical document but also an invitation to a sustained dialogue among the government, the private sector, academia, and society. The Attorney General's Office, in partnership with other public and private institutions, is at the forefront of an institutional transformation that must be inclusive, ethical, and, above all, human-centered. We recognize that behind every perspective on innovation lies the tangible needs of people. It is our duty to ensure that the regulatory framework underpinning these transformations is fair, equitable, and accessible.

I am confident that this guide will serve as a strategic compass for managers and regulators throughout the country, providing guidance in navigating the complexities of regulatory innovation. Together, we advance in our mission to build a stronger, more innovative, diverse, efficient, and equitable Brazil — one that is recognized as the great nation it aspires to be.

I reaffirm that the Attorney General's Office will remain a pillar of legal certainty and innovation, ensuring that every step taken toward modernization is guided by responsibility and a steadfast commitment to the public good.

Innovation is central to the evolutionary trajectory of humanity. Knowledge, technologies, ideas, and innovative processes propel the development of nations, fostering autonomy and sovereignty while promoting inclusion, justice, and sustainability. Various economic sectors are among the principal agents driving the significant transformations demanded by the challenges of a globalized world, connecting realities that remain markedly distinct.

As the Attorney General for Brazil, I am a direct witness to the critical role played by public advocacy in this process, particularly in addressing the regulatory challenges posed by innovation. The pursuit of an effective and balanced regulatory legal environment requires the promotion of legal certainty for innovative solutions, positioning us as the driving force of change, rather than an impediment to progress.

It is within this framework that I present the Regulatory Sandbox Reference Guide, a cornerstone document for fostering innovation and enhancing the regulatory apparatus of the Brazilian state. Aligned with a forward-looking agenda, the current administration of the Attorney General's Office (AGU) has dedicated itself to expanding the adoption of advanced technologies and innovative practices, while

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Presentation

The Regulatory Sandbox Reference Guide is a document prepared by the Innovation Laboratory of the Attorney General's Office (Labori/AGU), in partnership with the Secretariat of Competitiveness and Regulatory Policy of the Ministry of Development, Industry, Trade and Services (SCPR/MDIC), which aims to facilitate the implementation of Regulatory Sandboxes in the country, harmonizing understandings and procedures and bringing legal certainty to the regulatory environment.

The use of the Regulatory Sandbox was nationally endorsed by the Startups and Innovative Entrepreneurship Legal Framework¹. This new instrument represents a set of simplified special conditions for participating legal entities to receive temporary authorization from bodies or entities with sector regulatory competence to develop innovative products, services and business models, on an experimental basis and in a controlled real environment, complying with previously established criteria and limits.

Thus, the Regulatory Sandbox is an instrument with the potential to provide new regulatory paths that adjust to the national capacity to innovate through a structured methodology that allows collaboration and learning between regulatory and regulated entities. Its adoption is an opportunity for innovation both in the designing of new business models, products and services and in the creation or improvement of the regulatory frameworks that shape markets.

The Brazilian Attorney General's Office (AGU), as the entity responsible for representing the Federal Government in judicial and extrajudicial matters; providing consulting and legal advice to the Executive Branch; and developing mediation, conciliation and arbitration activities, has a tradition of promoting broad debates about society's most pressing challenges. The innovation agenda is essential for all public sectors, but the AGU, which plays a central role in ensuring legal certainty for government action, must offer increasingly rapid and precise responses to the transformations of the various sectors essential for the common good, and to the legal and regulatory issues that guide or challenge this process.

In that sense, the AGU Innovation Laboratory (Labori) was established through Normative Ordinance No. 120 of December 18, 2023, aiming to build effective bridges between ideas, knowledge, instruments, techniques and technologies that are presented in the political, administrative and operational spaces of Public Administration and in its spheres of action, with partners from academia, the private sector and civil society. The Labori is a collaborative and multidisciplinary environment that seeks to develop innovative solutions in products, services and processes to contribute to the improvement and legal security of governmental action, focusing on Brazilian society.

One of the priorities of the laboratory is the creation of innovative legal solutions for public policies. In this context, Labori and the SCPR/MDIC have been following the discussions on regulatory challenges that impact different economic sectors. This document is part of a larger set of regulatory quality and governance review initiatives implemented by the Federal Government. These initiatives aim to reduce the asymmetry in regulatory maturity among the regulatory bodies of the Federal Executive Branch for the achievement of public policy objectives that increase the well-being and minimize the costs imposed on the productive sector and on citizens.

The debates and proposals of the Program for Strengthening Institutional Management Capacity in Regulation (PRO-REG), reformulated by Decree No. 11,738, of October 19, 2023, emphasize the need for regulatory simplification and promotion of innovation, understood in a broader context that includes well-developed and adequately implemented regulatory frameworks, capable of contributing to the effective overcoming of obstacles to economic and social development.

The expansion and improvement of the connection between the legal and regulatory agendas are also relevant to reducing the cost and legal uncertainty of the act of regulating and contribute to a greater promotion of competitiveness, productivity and innovation in the country.

Aware of the challenges inherent to the use of the Regulatory Sandbox in the different federal entities, the Labori is pleased to present the Regulatory Sandbox Reference Guide to the public, in order to facilitate the proper use of this regulatory experimentation instrument so it can positively impact society with its contributions, focusing on a regulatory approach that adapts to the evolution of markets and is able to stimulate and fast track innovation in the country, both for regulator and regulated entities.

This is a living document that aims to clarify, with simple and accessible language, important aspects about the possibilities and limitations of this experimentation for the construction of adaptive governance in the Brazilian regulatory sector, allowing for more a sustainable and harmonious relationships between regulatory entities, regulated agents and citizens.



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Introduction

Innovation plays a central role in the development of nations. New ideas, technologies and approaches can lead us to overcoming complex problems for the benefit of societies. Innovative solutions impact the economy and expand governmental capacities, driving sustainable growth; creating markets; strengthening national industries; improving public policies; and repositioning the country on the global stage.

The dynamics of innovation, however, demand either an anticipatory action or a timely reaction by the State in the construction and adaptation of public policies, especially when it comes to regulatory policy, so that the current arrangements do not represent an obstacle to the opportunities and benefits arising from the innovative process. According to the Organisation for Economic Co-operation and Development (OECD)², the traditional approach to regulation is reactive, that is, it fails to anticipate risks and identify opportunities in the existing environment. It is also not able to effectively capture and interpret the relevant demands of users.

Thus, it is necessary to think about an approach to encourage innovation in all its aspects and in the different sectors of government action, ensuring swiftness in the offer of new products and services to society while respecting the limits established by the public good and the national priorities.

Instead of trying to reach the solution for a regulatory problem through the adoption of a traditional approach, which usually includes a Regulatory Impact Analysis (RIA), a Regulatory Result Assessment (RRA), among other instruments, innovation may consider the possibility of other non-traditional approaches, including experimental ones. The Regulatory Sandbox, as illustrated in Figure 1, is one of these approaches.

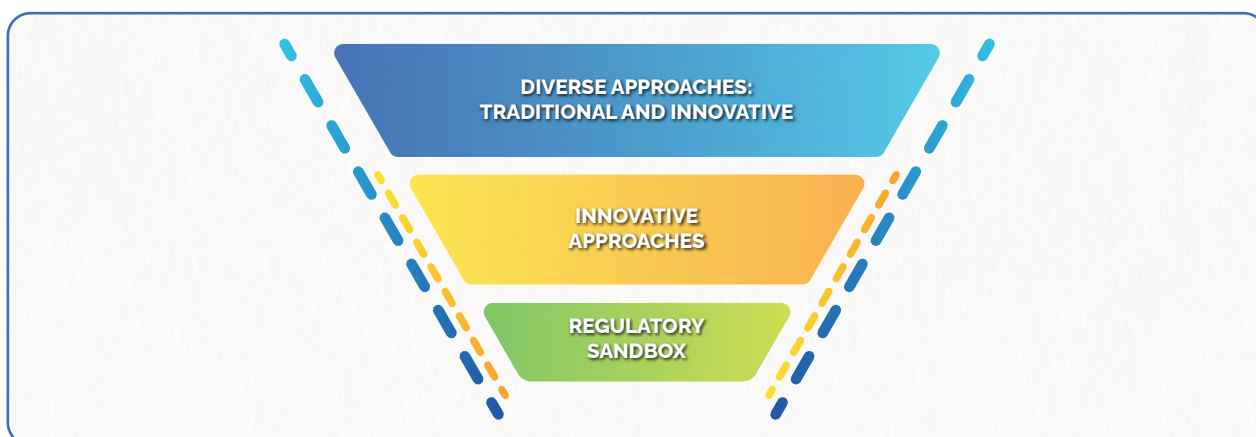


Figure 1 - Regulatory Approaches

The decision on the approach should consider, in addition to the ability of the regulator to use innovative approaches, the nature of the regulatory problem or opportunity identified.

Regulatory sandboxes are spaces in which it is possible to temporarily and under specific conditions remove the regulatory rigidity imposed on regulated agents, in order to allow experimentation and small-scale testing of innovative business models, products and services that do not fit the current regulatory standard, but that represent development opportunities for the regulated sectors. The existence of regulatory gaps for different types of innovation can also be addressed within the scope of the regulatory sandbox, in which it is possible to collaboratively build a regulation that incrementally adapts to these new scenarios. In this controlled environment, the interaction between the economic actors involved is allowed so that agile regulatory solutions can be found faster through an experimental process, considering a context of continuous social transformation.

When properly carried out, the implementation of regulatory sandboxes by the government strengthens the country's innovation strategy and takes full advantage of the diverse potential of national companies, while allowing for a greater understanding of regulatory frameworks; the behavior of markets, users and consumers; public policies; and business models in the context of innovation and uncertainty. It also expands the possibility of anticipatory or adaptive proactive and collaborative regulation. This opens space for collective learning by the various actors involved, also allowing the improvement of national regulatory practices and underlying public policies, considering real-world experiences and inducing competitiveness, productivity and innovation in the face of challenges imposed by changes and transformations inherent to a globalized world, which is exposed to new realities on a daily basis.

Complementary Law No. 182, of June 1, 2021, which established the Startups and Innovative Entrepreneurship Legal Framework in Brazil, addressed the provision contained in Article 3, item VI, of the Economic Freedom Law (Law No. 13,874, of September 20, 2019), and endorsed the implementation of regulatory sandboxes in the country. This legal framework represents an innovative solution for the national regulatory policy and is of particular relevance for the development of public intelligence, legal certainty in the business environment, and the expansion of governmental capacities. However, the lack of a harmonized understanding on the subject has hindered the proper use of this type of experimental regulatory environment, a gap that the Regulatory Sandbox Reference Guide seeks to fill.





General Goal

This document aims to provide legal certainty to the implementation and operationalization of sandboxes in the regulatory environment, based on an agenda to improve the regulatory process and disseminate good practices throughout the country, observing the principles of transparency and social participation.

Based on federal experiences (municipal, state and federal), this practical guide is not supposed to be a fixed or definitive document. It is meant to be a living document that guides innovative actions, adapting to the scenarios shaped by new challenges imposed on regulation.

Therefore, it is not meant to be a disciplinary instrument for institutional actions in the regulatory and innovation fields, but a practical guide that understands the different local realities and proposes a safe way to use the regulatory sandbox instrument at the national level.



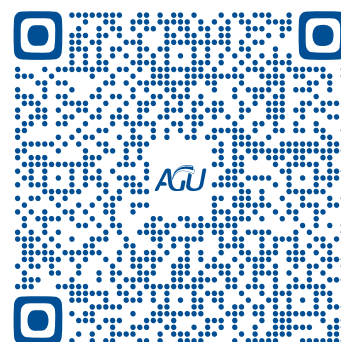
Methodology

The Regulatory Sandbox Reference Guide was developed based on three lines of action:

- i) The exploratory analysis of national regulatory experiences and/or implementation of regulatory sandboxes, mostly coordinated by the Public Administration at the federal, state and municipal levels;
- ii) The consolidation of the contributions received in the Request for Contributions on Regulatory Sandboxes made on January 2024, and collected by Labori between June 25 and July 24, 202, through the Participa Mais Brasil Platform, in the Opine Aqui tool, with the aim of promoting the participation of stakeholders and society. The initiative received 13 rich contributions that were reviewed and considered in this document;
- iii) The identification and analysis of legal opinions issued within the scope of the national experiences mapped, with the main recommendations made by the legal consultancies and specialized federal prosecutors of the General Attorney's Office (AGU) to the institutions of the direct and indirect Federal Public Administration.

The results and knowledge obtained through the lines of action listed were inspiring sources for consolidation of the step-by-step implementation of regulatory sandboxes presented in this guide. This document serves as a guideline for the creation and operation of regulatory sandboxes, offering a general framework that can be adapted to the specific needs of each sector, and the context in which it will be implemented. It is, therefore, a flexible and adjustable approach that can be modified by regulatory entities according to their reality and the particular challenges they face, thus ensuring a more effective implementation, appropriate to the diverse Brazilian regulatory environment.

Check out the **National Experience Mapping** through the QR code below:





Regulatory Sandbox

According to the Startups and Innovative Entrepreneurship Legal Framework³, a regulatory sandbox is a “set of simplified special conditions for participating legal entities to receive temporary authorization from entities with sector regulatory competence to develop innovative business models and test experimental techniques and technologies, upon compliance with criteria and limits previously established by the regulatory entity and through a facilitated procedure”.

THE OECD⁴ has stated that regulatory sandboxes create spaces in which authorities motivate companies to test innovative products and services that challenge the existing legal framework. Participating companies obtain a waiver from legal provisions or compliance processes that allows them to innovate. It adds that regulatory sandbox approaches can vary, but share some common characteristics: they are temporary, with testing periods of usually six months; they involve the joint action of regulatory entities and private companies; they dispense with legal provisions and offer personalized legal support for specific projects, usually based on trial and error; and the technical and market data they collect help regulatory authorities assess whether specific legal frameworks are suitable for the purpose of innovation or whether they need adaptations.

Thus, a regulatory sandbox allows innovative projects to be tested in real controlled environments, without the current regulatory framework representing an obstacle to their experimentation, because of the possibility of regulatory flexibility. The exception created makes it possible for selected legal entities to operate without the immediate change of the current rules for the market as a whole, allowing an evidence-based incremental adaptation of the regulation, whenever necessary.

Temporary authorization for experimentation occurs through the definition of criteria, limits and safeguards, generally established for each innovative project, as a way to protect users and consumers and to prevent or mitigate the risks of the model. It can be granted to the formally constituted legal entity (under public or private law), alone or in consortium, for a predetermined period.

The tests with users and consumers are monitored by regulatory authorities to ensure legal certainty and the identification and analysis of the advantages and disadvantages of the new approaches, their benefits to the regulated sectors and society, and the potential risks. During this process, it is possible and desirable to establish a continuous dialogue between regulator and regulated entities and to implement communication channels to collect the perceptions of users and consumers. In this context, the regulatory sandbox is a learning space for the actors involved and other stakeholders, allowing the identification of more appropriate ways to build or adapt regulatory apparatuses, as well as to improve the innovative business model or products and services offered, driving and enabling innovation at broader scales.

Scope

This document is a practical guide for the harmonization of understandings and procedures, and the provision of legal certainty to the implementation of regulatory sandboxes in the field of Public Administration.

According to the previously established Startups and Innovative Entrepreneurship Legal Framework⁵, in its article 11, the bodies and entities of the public administration with competence to regulate specific sectors may, individually or in collaboration, within the scope of the regulatory sandbox, remove the incidence of standards under their competence in relation to the regulated entity or groups of regulated entities.

Collaboration between regulatory authorities is especially necessary in situations where selected projects or prioritized topics impact more than one regulated sector. The bodies or regulatory entities proposing the regulatory sandbox should provide for its operation, establishing:

- I - the criteria for selection or qualification of the regulated entities;
- II - the duration and extent of the suspension of the impact of the rules; and
- III - the standards covered.

The implementation of the regulatory sandbox precludes the existence of a regulatory gap and/or the need for regulatory flexibility for the experimentation of an innovation, which occurs when the standards are not adequate or sufficient to accommodate the proposed model, creating barriers to its adoption and diffusion⁶. In addition, it is characterized by the mediation of experimentation and information gathering activities by the regulatory authority, in collaboration with other stakeholders; continuous provision of support to regulated agents, and collective learning; as well as the generation of evidence for the innovative business model and the regulatory process.

If the demand is only related to a regulatory challenge that requires guidance on standards or ways to adapt the innovative business model to the regulated market, there are alternatives capable of providing solutions, such as regulatory advisory programs⁷; or even the company's participation in innovation offices; advisory panels; incubators and accelerators; and open innovation programs. The adoption of regulatory sandboxes is not the ideal solution for all problems linked to innovation and its consequent regulatory process. It is also not synonymous with deregulation and does not take away from the regulatory mission of the regulatory entity.

Thus, this document aims to guide Public Administration in the adoption of best practices related to regulatory sandboxes, considering their experimental nature, their potential for the modernization of national regulatory policy, and their contribution to the improvement of governmental action.



Non-Scope

The Regulatory Sandbox Reference Guide does not aim to present a literature review or a historical analysis on the subject, considering existence of official documents that already meet this end by presenting the state of the art and the main concepts related to the topic, such as the technical studies of the National Data Protection Authority (ANPA)⁸; of the Inter-American Development Bank⁹; of the Court of Auditors of the European Union¹⁰; of the National Health Surveillance Agency¹¹ and of the OECD¹². It does not propose, in its first version, a reflection about sandboxes in a broader sense or address other experimentation environments without the presence of regulatory flexibility. It also does not expand on general open innovation experiences, which stimulate the engagement of different actors in the development of innovative solutions.

Ongoing legislative discussions are also not part of the scope of this document, without prejudice to future inclusions, after entry into the legal system. Some of the Bills that make express mention of the regulatory sandbox, are:

Bill No. 2,338, of May 3, 2023, which aims to regulate the use of artificial intelligence in Brazil;

Bill No. 534 of March 4, 2024 on the establishment of a legal framework for autonomous services offered via applications;

Complementary Bill No. 124, of July 16, 2024, amending complementary Law No. 182, of June 1, 2021, establishing the Startups and Innovative Entrepreneurship Legal Framework, to add measures for the inclusion of autistic and neurodivergent people and people with disabilities, to encourage innovation in the public health sector, and to add value to the Amazon region;

Bill No. 2021, of May 23, 2024, which sets the guidelines of the National Urban Infrastructure Policy, and regulates art. 182 of the Federal Constitution, as well as amends laws No. 6,766, of December 19, 1979, which provides for the subdivision of urban land, No. 10,257, of July 10, 2001 (City Statute) and No. 12,608, of April 10, 2012 (National Urban Protection Policy). and civil defense – PNPDEC) and provides for other measures;

Bill No. 5816, of December 28, 2023, which makes provisions for the low-carbon hydrogen industry, its structure and sources of resources and amends laws No. 9,427, of December 26, 1996, 9,478, of August 6, 1997, 10,438, of April 26, 2002, 11,488, of June 15, 2007, 11,508, of July 20, 2007, 12,431, of June 24, 2011 and 14,182, of July 12, 2021;

Bill No. 5751, of November 28, 2023, which establishes the legal framework for low-carbon hydrogen, provides for the National Low-Carbon Hydrogen Policy, its principles, objectives, concepts, governance and instruments, amends Law No. 9,427, of November 26, 2023, alters Law No. 9,478, of August 6, 1997, Law No. 9,991, of July 24, 2000, Law No. 10,438, of April 26, 2002, Law No. 10,848, of March 15, 2004, Law No. 11,508, of July 20, 2007, Law No. 14,182, of June 12, 2007, Law No. 14,182, of June 12, 2007, Law No. 9,478, of August 6, 1997, Law No. 9,991, of July 24, 2000, Law No. 10,438, of April 26, 2002, Law No. 10,848, of 2021, and makes other arrangements; and

Bill No. 21, of February 04, 2020, which sets the foundations, principles and guidelines for the development and application of artificial intelligence in Brazil; and makes other provisions.

As stated, this document is intended to guide the implementation of regulatory sandboxes by national institutions, listing important recommendations for each of the stages of this process, focusing on ensuring their legal certainty.





Regulatory Cycle and Regulatory Sandbox

The traditional approach usually applied in the design of the regulatory cycle, has the following stages:

- (i) regulatory planning - elaborating/reviewing the regulatory agenda;
- (ii) regulatory intervention, based on an RIA, which involves the decision to maintain the status quo or to develop a regulatory instrument;
- (iii) implementation of the intervention;
- (iv) supervision and monitoring of the intervention;
- (v) evaluation, especially of the results; and
- (vi) management of regulatory stock.

Similarly, non-traditional (innovative or experimental) approaches include:

- (i) identifying challenges or opportunities and unnecessary administrative burdens that impede innovation;
- (ii) collection of ideas, through stakeholder consultation, especially in early stages of regulation, with a focus on outcomes and values rather than compliance with the process;
- (iii) development of proposals, such as the creation of safe spaces for innovation, and clear requirements for impact assessment to ensure the achievement of the desired objectives;
- (iv) implementation of projects, with a stable regulatory framework, adequate financial incentives, and possibly with the use of behavioral science;
- (v) evaluation of projects, using appropriate documentation to verify that regulations are achieving their stated purposes and identifying corrective measures, when appropriate; and
- (vi) dissemination of lessons learned to advance the country's regulatory maturity.

Good regulatory practices lead to common recommendations for all approaches: focus on the citizen, transparency and promotion of social participation throughout the regulatory cycle. THE OECD¹³ also mentions the channeling of public resources to where they are most needed. Therefore, regardless of the approach being traditional or not, regulatory policymakers must adopt regulatory practices that aim to anticipate risks or opportunities in that specific environment and favor innovations that result in greater value for citizens. This should be the case even when innovative approaches use the steps typical of traditional regulation cycles, such as RIA. As an experimental approach, the regulatory sandbox should also incorporate the same precepts.

Regulatory Sandbox Implementation Journey

This section aims to guide national institutions in the use of the regulatory sandbox instrument to address challenges and opportunities that arise in regulated markets and have innovative potential to contribute to the modernization of regulatory policy and the development of the country. Figure 2 presents a flowchart with the main phases of the regulatory sandbox implementation process, which will be detailed and discussed in the following pages.

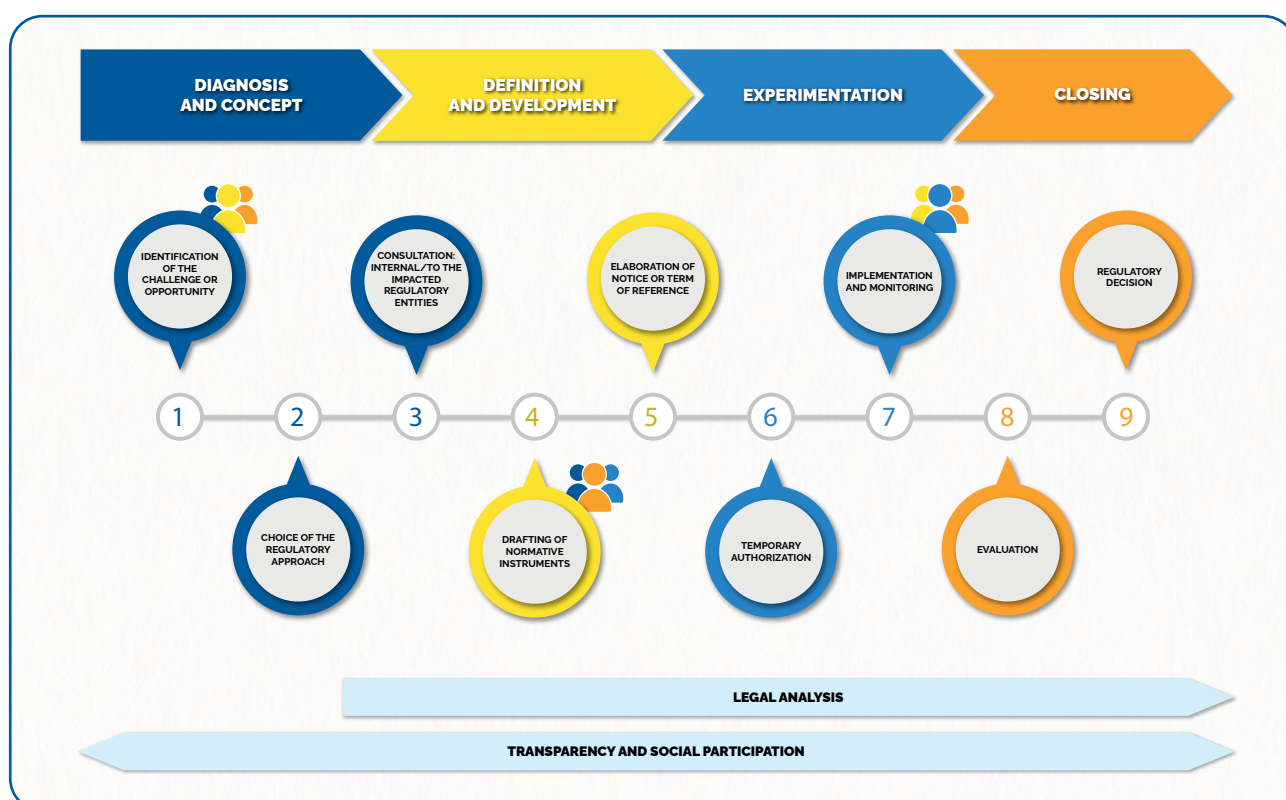


Figure 2 - Flowchart of Regulatory Sandbox Implementation

The flowchart describes the main steps for the implementation of a regulatory sandbox, organized into four main phases: **(a) Diagnosis and Design**, **(b) Definition and Development**, **(c) Experimentation** e **(d) Conclusion**. The process covers nine steps, ranging from the identification of the regulatory challenge to the final decision, with two cross-cutting elements, the Legal Analysis and the Social Participation, which are present in more than one stage of the process.

Identification of the challenge or opportunity

The identification of challenges and opportunities phase helps in the recognition of **areas or themes** require more attention from regulatory authorities. To this end, it is essential for the regulator to remain open to dialogue and consider the implementation of **social participation** to subsidize this stage. This phase also includes an analysis of **political priorities** to foster an institutional environment favorable to the development of appropriate solutions to the challenges identified.

Some of these challenges and opportunities may arise from technological, social and economic transformations that, by causing an accelerated change in the dynamics of markets, require a **proactive response from regulatory institutions**.

Thus, new roles arise in regulatory policy which, if armed only with traditional concepts, approaches and tools, lacks robust evidence both for decision-making and for achieving more assertive solutions.

POLITICAL PRIORITIES

The political priorities of a country or region play a determining role in deciding on the regulatory approach, especially in challenging situations.

In contexts where technological innovation is a **strategic priority**, regulators may be more inclined to adopt solutions focused on experimentation, as they are more adherent to scenarios of complexity and uncertainty, facilitating the obtaining of evidence for the decision-making process, based on supervised testing.

Attention to political priorities seeks to ensure the **legitimacy of the regulatory framework** and its popular acceptance, as it allows regulation to meet real and urgent demands faced by society. It also provides predictability to the regulated sector, attracts investment and encourages innovation.

In an opinion, the General Attorney's Office (AGU) highlighted that the increase in innovative businesses in Brazil should contribute to:

- Improving the competitiveness and innovation indexes in the economy;
- Strengthening the country's integration into the global economy; and
- Generating income and quality jobs.

The inclusion of sectors of society in the discussions gives more legitimacy to the political priorities, thus consolidating a **more democratic regulatory agenda**. Participation facilitates social control and open communication about the results of this process, creating collective learning opportunities and symbolizing **responsible governance**.

In this sense, keeping the regulatory agenda updated promotes the transparency and predictability of regulatory policies and encourages more engagement from actors.

In an opinion, the the General Attorney's Office (AGU) also highlighted the collaborative effort between public and private entities to improve the business environment in Brazil, increasing the competitiveness of companies through the adoption of more efficient administrative procedures. This involves the need to balance innovation and regulation, ensuring that new technologies and business models are properly tested and regulated, thus benefiting consumers, businesses and the regulatory system.

Definition of the regulatory approach

The regulatory approach definition phase is characterized by the need to determine what kind of approach will be used in face of the challenges or opportunities identified in the previous phase. The **feasibility** and the **potential for success** of each approach are analyzed, some approaches may be more traditional and rigid, others more flexible. Some examples are: traditional regulation by command and control; responsive regulation; regulation by results; regulated self-regulation; regulation by incentives; risk-based regulation; experimental regulation; co-regulation, etc.

Depending on the context, some approaches may be more appropriate than others. It is the responsibility of the regulatory authority to identify the **nature** and the **main features**, challenges or opportunities, in order to recognize demands related to deadlines and the necessary flexibility of the regulatory apparatus, as well as the risks involved and the legal certainty of the chosen approach. The regulatory authority may also draw on the experiences conducted by other institutions to deepen its understanding of the **advantages and limitations inherent to each approach**.

In an opinion, the General Attorney's Office (AGU) considered that the creation of a regulatory sandbox seeks to adapt the regulated sector to technological innovations and new business models.

This phase involves not only the mapping of regulatory approaches, but also an evaluation of the regulatory agent's willingness to experiment, when appropriate. Each of these elements plays an essential role in the creation of an **enabling environment for innovation**, as detailed below:

MAPPING OF REGULATORY APPROACHES


Mapping regulatory approaches allows regulators to identify a diverse set of approaches that may be best suited to particular situations. Not all situations require a regulatory solution based on experimentation. There are contexts in which traditional regulatory techniques may be more effective and less expensive, for example.

In an opinion, the General Attorney's Office (AGU) acknowledged that the regulatory sandbox enables the development of innovations in a controlled environment. Experimentation provides the necessary learning environment to keep regulation updated and in tune with the market, balancing innovation and regulation.

WILLINGNESS TO EXPERIMENT

The willingness and interest of the regulatory agent to allow experimentation within its domain of action are essential in the choice process. Thus, it becomes important to analyze the organizational culture and the openness of the regulator to adopt flexible approaches. Regulators in more conservative or risk-averse sectors may require greater convincing or additional guarantees to engage in experimentation.

Factors such as the complexity of the regulated sector, market pressure for innovation, and the regulatory authority's track record of adopting disruptive regulatory practices also influence this. Identifying these factors helps map the degree of openness and anticipate potential challenges.



After the political priorities analysis; when faced with a problem or opportunity for innovation, and when there is willingness for experimentation by the regulator, it is necessary that the regulatory entity chooses among the **experimental approaches** the one that is most appropriate to address that problem or opportunity.

It is possible that in some cases the regulatory sandbox will be identified as the most appropriate option.

The development of a business model, innovative products or services and the testing of experimental techniques and technologies is a legal requirement for permission to enter a regulatory sandbox and allows the granting of **flexible regulatory conditions** (cf. Art. 2, item II, of the Startups and Innovative Entrepreneurship Legal Framework).

The alignment of the project to sectoral **macroeconomic guidelines** allows it to meet the purposes of **government public policies**, making commercial and public interests compatible.

In an opinion, the General Attorney's Office highlighted that the regulatory sandbox is an exceptional situation, which requires a political-regulatory decision.

The choice of the regulatory sandbox should be guided by a careful analysis of the identified challenge or opportunity, considering whether the objective of the experimentation is to test new business models or innovative products or services in a real environment, with the participation of users and consumers. This experiment seeks to understand the behavior of the innovation, the regulated market and the users and consumers, in addition to verifying whether the regulatory framework needs adjustments to definitively accommodate the innovation.

In an opinion, the General Attorney's Office (AGU) stressed that the sandbox should prioritize indicative (rather than punitive) supervision. This premise follows the lean startup methodology, which promotes rapid development cycles and continuous interaction with customers, adjusting the product or service until it finds its optimal configuration or determines its viability in the market.

Thus, the regulatory sandbox is indicated when there is demand for **regulatory flexibility** in the implementation of an experiment, for a limited period, and under the supervision of the regulatory authority, allowing for the provision of **regulatory guidance** and **collective learning**. During the process, it is possible that gaps in existing standards may be identified, they will need to be eliminated by the collaborative and incremental creation of new rules or regulations.

In an opinion, the General Attorney's Office (AGU) highlighted that the creation of an experimental regulatory environment to overcome regulatory difficulties allows the testing of new solutions in a controlled environment, while also accelerating the approval of products and services, facilitating the entry of companies into the market and contributing to economic and social development.

RESPONSIBLE FLEXIBILITY IN EXPERIMENTAL PROGRAMS

The temporary departure from norms, which characterizes the sandbox, must be carefully justified to avoid the creation of market distortions. By allowing certain participants to operate under flexible or specific rules, there is a risk of generating undue competitive advantages in relation to other agents subject to stricter regulation. If the departure from norms is not properly underpinned and controlled, it can result in a scenario of unfair competition, in which only some actors benefit from reduced regulatory requirements, while the rest continue to comply with all applicable requirements.

One of the biggest risks of competitive problems in the regulatory sandbox is the creation of competitive obstacles for agents who do not have access to the sandbox. This scenario can discourage innovation outside the project, as traditional companies, forced to follow general norms, may see their market positions threatened by the lack of fair competition.

Thus, after the test period, it is critical to ensure that sandbox participants adapt to the full regulatory standards, adjusted or not, without maintaining individualized advantages. This process prevents companies from continuing to operate with a disproportionate competitive advantage after the period of departure from the norms has expired. General normative stability ensures that all competitors operate under fair and balanced conditions.



The questionnaire presented below is recommended to guide the decision on the adoption of the regulatory sandbox.

1. Are there regulatory obstacles that hinder the advancement of innovation?

This item identifies whether the innovation faces legal and regulatory barriers that prevent its implementation or development. In general, these barriers may relate to excessive regulatory requirements, such as limits imposed on the innovation by the existing standards, but can also refer to the insufficiency or non-existence of legislation. Thus, it is up to the regulator to reflect on the following aspects:

- **Is the current legislation insufficient to regulate the proposed innovation?**

☐ Yes: There is no regulatory framework that addresses the characteristics of the innovation.

☐ No: The legislation already provides for or covers the innovation, at least partially..

- **Do existing standards impose limitations that make the innovation unfeasible?**

☐ Yes: Current legal requirements make it difficult or unfeasible to develop or operate the new product/service or business model.

☐ No: The innovation can be implemented within the limits of current norms.

- **Are regulatory requirements, such as documentation or approvals, excessive for the test phase?**

☐ Yes: The demand to comply with all regulatory requirements makes the test phase impossible or extremely complex.

☐ No: The requirements can be met without great difficulty, even during the test period.

- **Are there explicit prohibitions or limitations in current regulation that prevent the innovation?**

☐ Yes: The laws or regulations in force prohibit the innovation or experimentation directly (and/or indirectly).

☐ No: There are no direct (and/or indirect) prohibitions that impede the implementation of the innovation.

2. Is a temporary relaxation of the rules required to enable the innovative experiment?

This item assesses whether temporary flexibility in standards is necessary to allow tests under safe and controlled conditions.

- **Does the innovation require a controlled test environment before it can be applied on a large scale?**

☐ Yes: The innovation needs to be tested in real conditions before it is fully implemented or commercialized.

☐ No: The innovation can be applied directly, without the need for a controlled experimental phase.

- **Do current regulations prevent the innovation from being tested safely and effectively?**

☐ Yes: A relaxation of the norms is necessary to ensure that testing can be done without compromising safety or regulatory compliance.

☐ No: Tests can be carried out without significant changes to the current rules.

- **Do real-world tests impose regulatory risks that need to be temporarily mitigated?**

☐ Yes: Running the tests in a regulated environment without temporary flexibility creates legal, economic or operational risks that could be mitigated by a more flexible regulatory environment.

☐ No: The test can be performed with the current standards, without the need for adjustments or flexibility.

- **Could temporary flexibility in the rules accelerate regulatory learning and facilitate the adaptation of the innovation to the market?**

☐ Yes: The innovation can benefit from temporary adjustments in an experimental phase, which will help in the assessment of how to adapt the standards in the future.

☐ No: Temporary flexibility is not necessary, as current standards already allow for testing.

- **If the innovation is implemented without temporary adjustments, will the costs and regulatory complexity be increased?**

- ☐ Yes: The current rules allow for the innovation, but at a higher cost or with increased complexity that could be temporarily alleviated.
- ☐ No: Costs and regulatory complexity are manageable within the current regulatory framework.

3. Is the project really innovative?

This item verifies whether the proposed product, service or business model actually represents an innovation in terms of technology, process or impact.

- **Does the proposal use new technologies or processes?**

- ☐ Yes: The innovation introduces new technologies or processes that have not yet been explored or widely applied.
- ☐ No: The innovation uses technologies or processes that have already been used in the past.

- **Does the innovation introduce a new approach to solving an existing problem?**

- ☐ Yes: The innovation presents a creative and effective solution to a known problem that has not been satisfactorily solved yet.
- ☐ No: The approach is similar to other solutions on the market.

- **Does the innovation significantly improve an existing product or service?**

- ☐ Yes: The proposed innovation brings clear improvements, such as increased efficiency, reduced costs or better customer service.
- ☐ No: The improvements are marginal or of little relevance to the market.

- **Does the innovation have the potential to have a large-scale impact on the market or society?**

- ☐ Yes: The innovation can significantly transform the industry or provide large-scale benefits to society.
- ☐ No: The potential impact is limited to a specific niche or on a smaller scale.

- **Is the innovation aligned with emerging or future trends?**

- ☐ Yes: The proposal is in line with emerging trends such as sustainability, digitalization or artificial intelligence etc.
- ☐ No: The proposal is not aligned with emerging technological or social trends.

4. Are there other regulatory approaches that can be used as an alternative to sandboxing?

This item evaluates whether the regulatory sandbox is the best solution or if other alternatives may be more appropriate.

- **Would immediately permanently modifying the regulatory framework to solve the impediment be unfeasible?**

- ☐ Yes: Permanent regulatory change would be time-consuming and complex and sandboxing is the best solution in the short term.
- ☐ No: Changing the regulation in a definitive manner would be more effective, which makes the sandbox unnecessary.

- **Is the sandbox the most suitable alternative among the available regulatory options?**

- ☐ Yes: The sandbox offers the right controlled environment to test the innovation.
- ☐ No: Other options, such as experimental regulations or pilot projects in specific sectors, can solve the barriers without the need for a formal sandbox.



FINAL DECISION

Figure 3 illustrates the final decision regarding the adoption of the regulatory sandbox instrument, based on the answers to the proposed questionnaire. A possible tie (yellow) usually characterizes a situation where discretion by the regulatory authority should be used to choose one path or the other, based on the organizational culture, political priorities, and the identification of viable alternatives

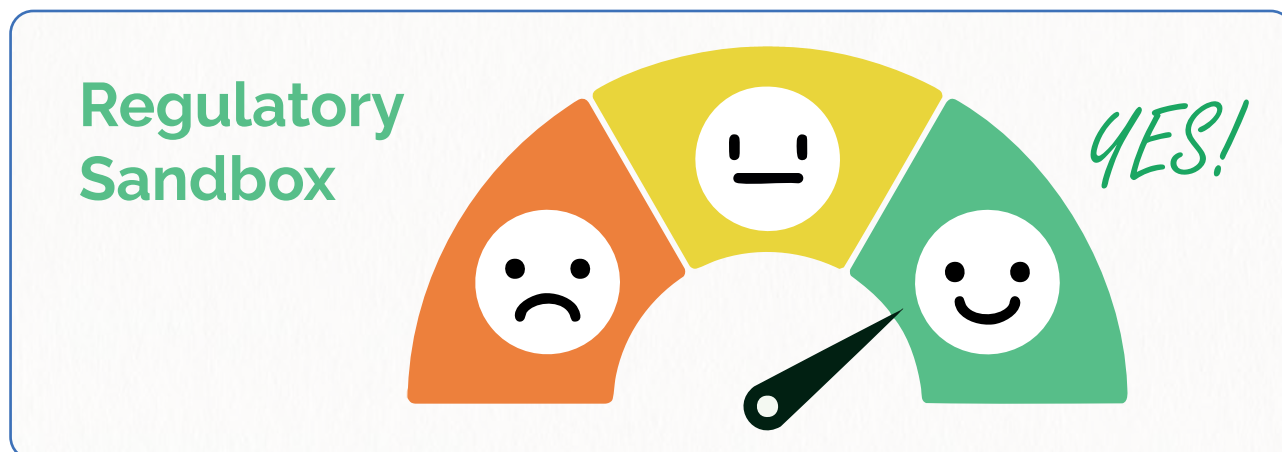


Figure 3 - Decision-making on the use of the regulatory sandbox

Table 1 presents the legend for reading the results of the questionnaire, highlighting the final result as a probability-based recommendation.

| Number of "Yes" answers | Probability of using the regulatory sandbox | Recommendation |
|---|--|---|
| The higher the number of "Yes" answers | The greater the likelihood that the regulatory sandbox is the most appropriate approach to address regulatory obstacles and allow experimentation with the innovation. | The use of the regulatory sandbox is strongly recommended. |
| Balance between "Yes" and "No" | There is a moderate probability that the sandbox will be useful, but the challenges need to be further analyzed. | A deeper analysis is recommended before deciding to implement the regulatory sandbox, considering the complexity and risks. |
| The higher the number of "No" answers | The lower the likelihood that sandboxing is required, indicating that other approaches may be more suitable. | The regulatory sandbox is probably not necessary; explore other regulatory or experimental alternatives. |

Table 1 - Legend for reading the results of the questionnaire

After these considerations, if the regulatory authority chooses to use the regulatory sandbox to deal with the challenges or opportunities identified, it is recommended that internal dialogues and discussions with society are also held, as presented below.

Internal Consultation and Consultation with Affected Regulatory Entities

The internal consultation and the consultation of other regulatory authorities seeks to promote **coordination** and **alignment** between the different agencies and departments, while also integrating the regulatory entities directly impacted by the initiative. Internal consultation allows the regulator to identify **technical gaps**, **operational challenges** and **potential synergies** between departments, contributing to the optimization of the sandbox structure and increasing the chances of **success of the regulatory experimentation**. Consultation with the impacted regulators is equally relevant, especially when regulatory challenges span across different sectors of the economy or involve **multiple regulatory competencies**.

INTERNAL CONSULTATION

The internal consultation phase aims to ensure that the design of a regulatory sandbox is well-founded and aligned with the objectives and capabilities of the regulator. This phase involves conducting internal consultations with the different departments or units of the regulatory entity, as well as a detailed analysis of the **feasibility** and the **risks involved** in the experimentation project.

The goal is to ensure that all aspects of implementation of the regulatory sandbox are considered and that the diverse perspectives of the regulatory authority's departments are integrated into the decision-making process. During these consultations, it is essential to identify **potential internal challenges** that may arise with the implementation of the sandbox, such as the need to make **adjustments to operational processes**, **the allocation of resources** or the need to develop **new skills** in the team.

The General Attorney's Office (AGU) recommends that the proposal to create the regulatory sandbox be considered in alignment with the public interest and based on relevant factual and legal grounds, emphasizing the public purpose of the normative act. Additionally, it is suggested that the compliance with formal requirements for the drafting of the normative act — including competence, purpose, form, reason and object — be preserved.

FEASIBILITY ANALYSIS

The feasibility assessment involves the verification of available resources; the **regulator's operational capabilities**; and **need for capacity-building in the department involved**. It is essential to identify the **financial**, **human** and **technological resources** required to operate the regulatory sandbox effectively. In this scenario, regulators with reduced operational capacity or limited resources should consider less costly alternatives.

In an opinion, the General Attorney's Office (AGU) recognizes that the sandbox prioritizes efficiency by allowing market activity and behavior to be evaluated in a controlled environment. If the results are positive, the regulation can be adjusted more quickly, without the need to go through the entire regulatory change process before the evaluation. Thus, the sandbox complies with the principle of efficiency, provided for in Art. 37, caput, of the Federal Constitution.

RISK ANALYSIS

The risk analysis is an indispensable tool for the implementation of a regulatory sandbox. The identification of potential risks creates a solid basis for **decision-making** ensuring that innovation and economic development take place without compromising **market and consumer security**. This diagnosis strengthens the regulator's ability to act responsibly, promoting **public trust** and ensuring the **legitimacy of the regulatory process**.

Table 2 presents the most common risk categories, their potential consequences, and possible mitigation measures.

| Risk category | Identified risks | Potential consequences | Mitigation measures |
|-------------------------------|---|---|---|
| Consumer protection | Possible technical failures, lack of transparency, risks to consumer safety. | Losses to consumers, loss of confidence in the market. | Implementation of safety requirements, exposure limits, guarantees and insurance. |
| Market stability | Disruptive innovations that cause market distortions, displacement of traditional companies, confidence crises. | Instability in the market, bankruptcies, negative impacts on the economy. | Gradual introduction of technologies, provision of equal conditions, control mechanisms and regulatory adjustments. |
| Regulator's Reputation | Failure to manage risks, criticism of the instrument's effectiveness and accountability of the regulator; damage to the regulator's reputation. | Loss of public trust, criticism of regulatory effectiveness. | Transparent communication, implementation of mitigation strategies, demonstration of diligence and accountability. |
| Technical risks | Technological failures, inadequacy of the innovation to market needs, lack of scalability. | Products or services that do not function as expected, inadvertent damage, commercial failures. | Rigorous testing, continuous feedback, scalability and feasibility evaluations. |

Table 2 - Identification of risks related to the implementation of regulatory sandboxes



CONSULTATION WITH AFFECTED REGULATORY ENTITIES

It should be first verified whether the proposing regulatory authorities have the competence to address the challenge or opportunity through the sandbox, ensuring that the projects have the necessary legal certainty.

There is also a need to verify whether other regulatory entities also have competence to address the issue or whether they will be directly or indirectly impacted.

If the answer is yes, the relevant entities should **coordinate**, so as to promote regulatory coherence and convergence. The need for coordination has become fairly common, in view of the increasing complexity of innovations and, especially, the technological convergence that usually involves more than one sector.

In an opinion, the General Attorney's Office (AGU) recommends the joint action of the regulatory authorities, including in the publishing of the public call, the issuance of authorizations, and in supervisory activities. This behavior is encouraged by the Brazilian Constitution, since the principle of cooperation, implicit in the organization of the Public Administration, contributes to the realization of the principle of efficiency, which should guide the actions of the Public Power.

The **increased complexity** in the framework of a regulatory sandbox, may result in a need for involvement of multiple regulators in the planning, execution, and evaluation of the experimentation. In cases where innovations occur in a cross-cutting manner or when they transversely impact different regulated sectors, there may be a need for joint action by national - and possibly international - regulatory authorities throughout the experimentation process.

In an opinion, the General Attorney's Office (AGU) highlighted the importance of synchronization between regulatory authorities to facilitate the working environment for entrepreneurs. This strategy simplifies the regulatory frameworks and supports the implementation of innovation stimulus policies in line with the government's normative rationalization principles.

Based on this perception, the regulator should, as soon as possible, evaluate the **need for coordination** in the definition, development and monitoring of a regulatory sandbox, which will require a greater effort in engaging in cross-cutting **dialogue and coordination among the sectors involved**. The transversality of themes and projects may even result in the need to designate an **intersectoral governance structure** for the selection, evaluation and monitoring of experiments.

In an opinion about the multisectoral nature of some enterprises, the General Attorney's Office (AGU) considered it legally possible to adopt a joint normative act, even without express legal provision, since the very lack of such a provision allows the practice. While not mandatory, the decision to adopt a joint act is discretionary, that is, it is at the discretion of the entities involved. This flexibility allows the agencies to act together to fill legislative gaps, as long as there is no express legal prohibition to do so.

It is therefore recommended that the regulator consults with other regulatory entities in the early stages, when evaluating the implementation of a regulatory sandbox, including to analyze the possible **joint jurisdiction** for the implementation of the sandbox itself, in order to ensure dialogue and proper sectoral interaction.

Although it may not be the case of officially implementing an **intersectoral project**, consultation with other agencies and entities may prove important to ensure that the project is developed in accordance with the regulations of other sectors impacted by it, and it is a good practice that the regulator can adopt, if considered necessary.

In any case, the regulator may, at any time, urge their own legal department to issue an opinion regarding any legal doubts. The assessment of the intersectoral nature of the regulatory sandbox and/or its compliance with the standards of other sectors are eminently legal aspects that must be included

in the legal analysis for the implementation of the instrument. This analysis may even suggest a legal consultation with the other entities involved.

SPECIFIC RECOMMENDATIONS FOR MULTISECTORAL CHALLENGES

1. Mapping of relevant entities

Conduct a prior mapping of regulatory entities and other public bodies that may have competence or interest in the project. Identifying the parties that should be consulted avoids omissions that could compromise the implementation of the regulatory sandbox.

2. Use of formal dialogue mechanisms

Use formal mechanisms for consultation, such as technical chambers, intersectoral committees or working groups. These spaces can facilitate ongoing dialogue between the agencies involved and promote greater alignment between regulations.

3. Establishing of schedules

To ensure that consultation with other entities does not delay implementation, set clear timelines with deadlines for answers and opinions.

4. Joint technical and legal consultation

Promote legal and technical consultations with the entities involved, especially in projects involving technological innovations or complex regulations. The integration of these consultations results in a more complete and robust analysis, including when it comes to operational capacities.

5. Transparency in the consultation process

Maintain transparency throughout the process whenever possible, by recording the interactions and answers received.

6. Identification of potential conflicts

During the consultation, be aware of possible conflicts between regulations from different industries. Identifying these conflicts in advance allows you to seek consensual solutions before the implementation of the regulatory sandbox.

Transparency and social participation

The regulator can, at their sole discretion, assess the relevance of gathering input during the preliminary stages of the regulatory process, considering the possible need for better understanding on a particular topic. The data and information collected in that process can be used as subsidies in the development of studies and proposals for regulatory and administrative acts by the regulator.

The following are some forms of social participation that can be adopted during all phases of the regulatory sandbox and, in particular, in the identification of the challenge or opportunity, the elaboration of normative instruments, and/or during implementation and monitoring:

GATHERING OF INPUT

EAt an initial stage, the regulator may, at its discretion, assess the relevance of conducting a public consultation procedure, which takes place during the preliminary phases of the regulatory process and arises from the need for a better understanding of a specific subject. The data and information collected during this procedure can be used as input in the development of studies and proposals for regulatory and administrative acts by the regulator.

PUBLIC CONSULTATION

The public consultation is a social participation instrument widely used in the definition and formulation of public policies. It gives legitimacy and transparency to administrative deliberations. The submission of a matter of collective interest to a public consultation allows participation to take place in an organized and timely manner, within appropriate timelines.

In an opinion about a regulatory sandbox project, the General Attorney's Office (AGU) highlighted the importance social participation and control, emphasizing that public participation must be transparent and responsive, ensuring that the contributions of society are properly considered in the development of the project.

The discussions between the various economic actors, the government and society that take place in a public consultation – an institutionalized space for the voicing of opposing interests – allows opinions, criticism and suggestions to be effectively considered in the design of public policies and regulations.

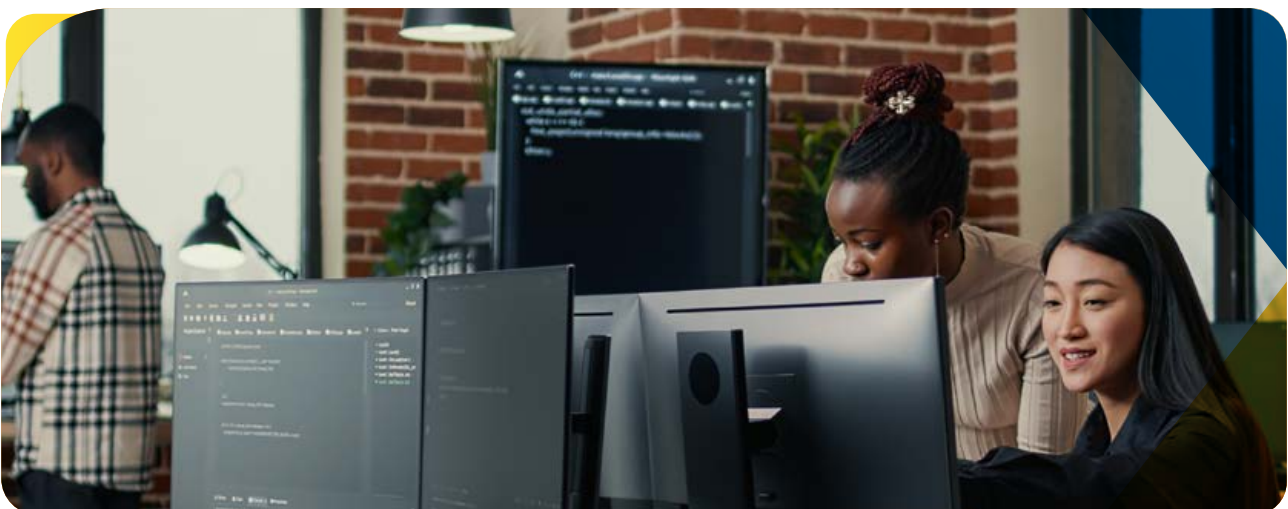
In an opinion, the General Attorney's Office (AGU) has deemed it pertinent to hold public consultations to collect input to be later considered in the preparation of the final minutes.

The public consultation legitimizes the decision-making and is considered as the appropriate mechanism for receiving considerations made by stakeholders. This process reveals the permeability that should be present in all instances of public decision-making, by establishing a space for exchanges between society and the Public Power. Thus, the implementation of a public consultation configures a good practice and reduces the democratic deficit of the regulatory activity.

Mandatory public consultation.

In the sphere of the functioning of Federal Regulatory Agencies, the Law provides for the holding of public consultations prior to decision-making on amendments to regulatory acts of general interest for economic agents, consumers or users of a service, in accordance with Article 9 of Law No. 13,848, of 2019.

In an opinion, the General Attorney's Office (AGU) has highlighted that public consultation is essential to mitigate the risks of the regulatory practice. The lack of transparency compromises the independence of the regulator and can result in an unacceptable democratic deficit. Public participation through consultation ensures that regulatory decisions are transparent and democratic, promoting an open and institutionalized dialogue between regulators and economic agents.



The legal provisions about the implementation of public consultations include:

- (a) a minimum period of 45 (forty-five) days to receive contributions;
- (b) the publication of an official public consultation notice, both in the Official Diary of the Union and on the website of the Regulatory Agency;
- (c) the provision of the RIA report and other documents necessary to understand the proposal to all interested parties, with the exception of confidential documents;
- (d) the publication of the contributions sent by society in the context of the public consultation, within 10 (ten) working days after the end of the consultation, both at the headquarters of the Agency and on its website;
- (e) the publication of the answers given to the contributions received, also at the headquarters of the regulatory authority and on its website, within 30 (thirty) working days after the meeting of the collegiate that materialized the final decision on the matter.

If the implementation of a regulatory sandbox is regulated by a normative act, this act must be subjected to criticism and suggestions from the general public through a public consultation, in compliance with the conditions provided for in Article 9 of Law No. 13,848, of 2019.

Non-mandatory public consultation.

The holding of a public consultation, or the use of any social participation tool, is considered a good practice, even when there is no legal obligation to do so. Opening a decision-making process to public scrutiny gives transparency to governmental activity, since public officials should not adopt secrecy as a decision-making practice. Therefore, regulators must also assess the appropriateness of carrying out a public consultation even when implementing regulatory sandbox programs through non-normative acts.

The incorporation of social participation mechanisms in the implementation of the regulatory sandbox should preferably occur in the initial phases, during the setting of rules, objectives and criteria. However, **participation can be distributed in different stages of the process of experimentation**, at the discretion of the regulator.

It is up to the decision-making authority to observe the need to establish a deadline for receiving contributions, in line with the complexity of the topic under discussion.

The related documents necessary to understand the proposition should also be published at least on the website of the agency or entity involved, with the exception of legally confidential documents. This will result in the expanded and informed participation of actors and stakeholders.

In an opinion, the General Attorney's Office (AGU) stresses the importance of ensuring that the regulatory process is conducted in accordance with applicable legal standards and good transparency and public participation practices.

Lastly, the publication of the administrative documents that formalize the analysis and the answers to the contributions received (in the website of the competent agency or entity) is fundamental, since it shows that the decision-making authority considered the criticism and suggestions received from society in the decision-making process.

PUBLIC HEARING

Another mechanism that can be used to increase social participation in the scope of regulatory sandbox proposals is the public hearing, which, in the same way as the public consultation, allows society in general to have an opinion on collective issues, with the difference that it is characterized by orality and debate.

This instrument can also be used together with the public consultation to increase social participation in the implementation of experimental environments, especially in matters that have greater technical, social, environmental, economic and/or legal complexity.

Within the framework of the decision-making process of the regulatory agencies, the adoption of public hearings shall comply with the provisions of Article 10 of Law No. 13,848, of 2019.

The following is a summary of the recommendations about the holding of public consultation and the incorporation of other social participation mechanisms in regulatory sandbox proposals, to be evaluated by the regulator:

- a) Evaluation of the relevance of the collection of input during the preliminary stages of the regulatory process.
- b) The holding of public consultations by federal regulatory agencies in the implementation of the regulatory sandbox through a normative act must comply with the provisions made in Article 9 of Law No. 13,848, of 2019.
- c) Evaluation of the implementation of a public consultation as a good practice, even in cases where there is no legal obligation to do so.
- d) Setting of a deadline to receive the contributions, in line with the complexity of the topic.
- e) Publication of the public consultation notice, at least on the website of the agency or entity involved.
- f) Recommendation that the consultation takes place as soon as possible, usually at the stage of setting the rules, objectives and criteria of the regulatory sandbox, with submission of the draft act that will incorporate these guidelines to the public. However, it is possible to carry out consultations in several phases of the experimentation, at the discretion of the regulator.
- g) Publication of administrative documents that contain the analysis and the answers to the contributions received on the website of the agency or entity.
- h) Evaluation of the desirability of increasing social participation through the use of other mechanisms, such as public hearings, especially in matters involving greater technical, social, environmental, economic and/or legal complexity.

TRANSPARENCY AND ACCOUNTABILITY

Transparency allows the communication of Public Administration with society, promoting a more integrated participation of citizens in public processes. For this reason, it is a central element for the generation of public value, the strengthening of trust in public management, the promotion of citizen participation, the guarantee of legal certainty and the identification of areas that need to be improved to guarantee a more responsible public management.

In the context of the regulatory sandbox, it is recommended that as much of the actions involved as possible are disclosed, allowing the active participation of stakeholders and society. This includes the provision of information such as the knowledge generated, reporting on activities, and publication of the regulatory results achieved.

ACTIVE TRANSPARENCY

Active transparency refers to the voluntary disclosure of information by the regulator or participating companies without the need for a formal request. This practice is proactive and aims to make the information widely available and accessible.

Examples in the Regulatory Sandbox:

- Disclosure of sandbox objectives, rules and criteria;
- Publication of periodic reports on the progress and results of the project;
- Dissemination of knowledge generated, impacts and accountability;
- Transparency in decisions on the exclusion of data or the protection of confidential information, with public justifications.

In compliance with the principle of transparency, it is important that all information about the sandbox experience be disclosed, including the results, even those that may be statistically less significant. The data excluded or protected by **legal secrecy** should also be mentioned, accompanied by **clear justifications** for the exclusion or restriction of access.

Transparency can be operationalized through **communication channels** made available specifically for this purpose on institutional platforms and websites, through an ombudsman, and in the form of documents, guides, informative links with open and concluded notices, reports of completed experiences, collection of input, and public consultations.

The **on-line availability**, of **simple and free access** information, including information on how the experiment was designed, analyzed and interpreted is recommended¹⁴.

PASSIVE TRANSPARENCY

Passive transparency refers to the availability of information after a formal request made by citizens, organizations or companies. In this case, the regulator will only make the data available upon specific request.

Examples in the Regulatory Sandbox:

- Provision of information on less publicized results or technical details of experimental projects upon formal request;
- Answers to access requests about deleted or protected data;
- Clarification of doubts or requests for reports not previously disclosed.

The **sharing of information** on the development of a project with the regulator is in accordance with the overarching objective of the regulatory sandbox: to allow regulatory improvement and added-value to society in the form of **results-based public policies**.

Parts of the information from these experiences are subject to specific rights safeguarded by the legal system, which is why it is necessary to seek a balance between the interests of actors and knowledge production and sharing, without prejudice to the **protection of the rights of the actors involved**.¹⁵

In regulatory sandbox projects, the sharing of the experiences among the actors in the sector and the wide dissemination of the results of tests benefit innovation in the regulated sector and in the market in general. However, it is necessary that the official notice provides for specific measures regarding **confidential information**, such as those applicable to **personal data**, in the form of Law No. 13,709, of August 14, 2018, and **intellectual property law**, especially when it comes to trade secrets.

The wide dissemination of the results and procedural acts related to regulatory sandbox projects is, as a rule, a legal requirement¹⁶. Publicity and transparency, in compliance with all legal requirements, contribute to the development of innovative solutions in a **continuous learning** environment. The benefits of broad access to test data are invaluable for both industry players and potential entrants who may use this information to develop new solutions or simply discontinue failed projects.

Intellectual property rights, such as **trade secrets** for example, are explicitly exempted from disclosure¹⁷ and their secrecy is ensured. Furthermore, the lack of adequate protection of sensitive and strategic information such as trade secrets or information covered by other intellectual property rights, shared by agents of the sector with public authorities within the scope of regulatory sandbox projects, may discourage participation in these projects.¹⁸

Thus, it is recommended that, in the implementation of a sandbox, legal requirements related to secrecy and confidentiality are considered and balanced in the face of the legal requirements of publicity, and the ideals behind sharing experiences and learnings achieved with the tests. The **protection of sensitive information** shared in the context of a regulatory sandbox is also recommended, in order to ensure legal certainty, convey confidence, and stimulate the participation of companies and other stakeholders in these projects¹⁹.

Legal analysis

The legal analysis ensures control of the legality of the regulatory and administrative acts to be issued in the context of experimental programs, such as regulatory sandboxes. The scope of this analysis varies according to the proposed experimental environment in question. Although the object of the legal piece is not exhausted, it is essential that some points receive special attention.

First, it is necessary to check the formal meeting of **requirements for editing the normative act**. It is important to assess the existence of competing assignments and possible intersectoral nature of the project, especially with regard to competence. In this case, the need to initiate intersectoral dialogue through consultation with other entities involved should be emphasized, if appropriate. This may even require the institution of a joint governance structure, which may be recommended in the opinion, if applicable.

Legality control also requires a **project compliance** analysis to be developed according to the standards of other sectors. At this point, it is possible to recommend consultation to other bodies and entities to inform the process.

Another important aspect to consider when preparing legal opinions in the context of experimental programs is the suggestion of including **participation** and **social control mechanisms** throughout the process. It should be noted that the use of these mechanisms must be effective, the regulator may also add the analysis of contributions and the justifications for their consideration or non-consideration to the records.

It is also relevant to observe whether there is a need for clarification and justification regarding the proposed regulatory sandbox, and, if appropriate, the suggestion of measures for informing and substantiating the files. Clarifications may involve aspects related to security, the appropriateness of the deadline for the tests and the protection of data and the rights of users, just to name a few examples.

The process must be properly informed in relation to the **regulatory obstacles** for its development and, consequently, the standards that will be departed from or relaxed in the regulatory sandbox. A **technical analysis of possible competitive impacts** of approval that could affect the isonomy of the regulated sector must also be included, since the regulatory sandbox should not create regulatory asymmetries. In the absence of a competitiveness assessment, the adoption of measures for the purpose of procedural motivation may be recommended.

Another point of attention relates to the possibility of the regulatory sandbox causing **legal doubts** in relation to other regulations, including from different fields. The national experiences analyzed include the case of the National Oil, Natural Gas and Biofuels Agency, which, from a legal standpoint, involved the analysis of Article 1, item II, of Law No. 8,276, of 1991 that provides for the use of LPG, in disagreement with the norms established by law (which was precisely the goal of the implementation of the experimental environment)²⁰ as a crime against the economic order²¹.

In the hypotheses of a formal selection process, the convergence between the content of the selection notice and regulatory acts and temporary authorization should be considered and, if appropriate, suggestions for editorial and legal improvements may be made.

On the other hand, when the regulatory sandbox is implemented through **description of the object regulated**, it will be necessary to verify whether this regulatory option is properly substantiated. In addition to adhering to the principles that govern Public Administration, the exemption from a formal selection process must be justified by the characteristics intrinsic to the proposal of an experimental environment, and by the project itself. In this hypothesis, the suggestion of incorporating social participation mechanisms throughout the decision-making process for the implementation of the regulatory sandbox is even more relevant.

Finally, the information to be shared with the regulator and the standards that will be temporarily departed from must necessarily appear in the temporary authorization act, conferring **legal certainty** to the project. The legal analysis should pay particular attention to the **departure from normative incidence in the concrete case**, to avoid possible use of the proposed regulatory sandbox as a mechanism to replace the regulatory process.

Table 3 reflects the essential elements of a legal analysis in the regulatory sandbox.

| Element | Description | Recommendations |
|---------------------|---|--|
| Jurisdiction | Verifying whether the regulator has the legal authority to implement the regulatory sandbox and whether there is a need for involvement of other regulators, in case of intersectoral aspects. | To make sure that the responsible entity has the appropriate competence to act. To assess whether it is necessary to establish intersectoral governance in cases of projects involving more than one regulated sector. To recommend consultation to other regulating entities when necessary. |
| Object | Analyzing the content or subject matter of the normative or administrative act. Assessing compliance with existing standards and whether the proposed flexibilities are necessary to execute the project. | To ensure that the sandbox object is compliant with current standards and that the proposed regulatory flexibility is justified. To avoid regulatory asymmetries that preclude isonomy and competition. To ensure that the regulatory barriers to be removed or made flexible are proportionate and justified. |
| Motive | Identifying facts that justify the creation of the sandbox and the need to make regulatory standards more flexible. | To identify reasons that demonstrate that regulatory flexibility is necessary and justified based on concrete facts. The reasons must be clearly described and based on data that supports the need to create the experimental environment. To recommend, if necessary, that the records be informed with additional information that emphasizes the reasoning behind the act. |
| Purpose | Recognizing the public objective that the administrative act intends to achieve, focusing on benefits for the market and for consumers. | To verify if the regulatory sandbox is in the public interest and if the purpose of the innovation is beneficial to the market and consumers. To ensure that the purpose is compatible with the objectives established by the regulator and that there is no favoring of specific entities to the detriment of fair competition. |
| Form | Observing the necessary formalities for the establishment of the regulatory sandbox, including official publication, consultations and social participation. | To ensure that the process meets the formal requirements laid down by law, such as public consultation and transparency. To verify that the act of temporary authorization is formally correct and that it contains all the necessary information, such as standards made flexible and conditions to be met by sandbox participants. To recommend clarity and precision in regulatory provisions and sandbox governance tools. |

Table 3 – Suggested elements for the legal analysis of regulatory sandboxes

Elaboration of normative instruments for the implementation of the regulatory sandbox

The normative instruments of a regulatory sandbox establish the **guidelines for operationalization of experimental environments**, in addition to providing transparency for formalization procedures. In the **federal sphere**, for example, the use of **Resolutions** to establish the rules of the constitution and operation of a sandbox, allows a detailed and specific setting of the criteria and procedures necessary for the experimental development of projects, also allowing greater flexibility and adaptability to emerging regulatory needs. These resolutions usually establish the governance structure of the regulatory sandbox, to be operationalized through **Ordinances**.

In the **state and municipal spheres**, experience has shown a preference for the use of **Laws and/or Decrees** to regulate experimental regulatory environments. These normative instruments formally adopted through a legislative process, provide a robust legal basis that can facilitate acceptance and foster the implementation of sandboxes at the infra-national level, while also giving more stability and predictability to initiatives.

In summary, a well-designed regulatory instrument makes it possible to establish a transparent experimental regulatory environment, promoting an innovation that is safe and aligned with existing standards. It is also able to protect the **public interest** and ensure the **integrity of the regulated market** and of the **public-private relations**. To that end, social participation mechanisms should be provided in the elaboration of these normative instruments, seeking to guarantee the legitimacy, representativeness and **democratization of the experimentation process** with the regulated sectors and society.

Table 4 presents a summary of the main elements to be considered in the elaboration of the normative instruments for the operationalization of regulatory sandboxes.

| Element | Description |
|--|--|
| Governance | Defines the governance structure, responsibilities and supervisory functions, including the possible participation of third parties. |
| Scope | Defines the scope of the regulatory sandbox, as well as the areas and sectors of application. |
| Objectives | Specifies the objectives of the regulatory sandbox, outlining the goals and outcomes expected from regulatory experimentation. |
| Departures and flexibility of standards | Sets out the standards that can be simplified, relaxed or departed from in the regulatory experimentation. |
| Selection Process | Determines the need to open a selection process for the submission of projects for the regulatory sandbox. |
| Receipt of proposals | Defines the procedure for receiving proposals, which may be continuous or have a specific duration period. |
| Eligibility criteria | Specifies the eligibility criteria for the participation of projects and/or entities in the regulatory sandbox. |
| Safeguards | Establishes protective measures to mitigate potential risks associated with regulatory experimentation activities. |
| Risk and responsibilities management | Sets the basis for risk management and accountability within the regulatory sandbox. |
| Temporary authorizations | Sets out the procedures for granting temporary authorizations to participants. |
| Supervision and monitoring | Describes a procedure for evaluating the results of the regulatory sandbox, based on the information and evidence collected in the supervisory and monitoring phase. |
| Review and adjustment mechanisms | Establishes the structure for periodic review and adjustments in the standards for the regulatory sandbox. |
| Discontinuation plan | Establishes a detailed plan for the possible discontinuation of experimental activities. |
| Evaluation | Describes a procedure for evaluating the results of the regulatory sandbox, based on the information and evidence collected in the supervisory and monitoring phase. |
| Definitive authorizations | Defines the procedures for the transition from temporary to permanent authorizations, if innovations are approved for large scale implementation. |
| Transparency and accountability | Defines the mechanisms of active and passive transparency and regulatory sandbox accountability procedures. |

Table 4 - Elements to be considered in the normative instruments

Recommendations on the governance structure, scope, objectives, departure and relaxation of standards, as well as eligibility criteria, safeguards and risk management can be found below.

GOVERNANCE STRUCTURE

In the context of regulatory sandboxes, governance refers to the **set of structures, processes, rules and mechanisms that are established to ensure the coordination, supervision and operation of experimentation initiatives**. Governance involves defining who is responsible for the different stages

and activities of the regulatory sandbox, how decisions will be made, what rules and procedures will be followed, and how conflicts will be resolved.

A governance structure for regulatory sandboxes includes the following:

Organizational structure: identification of the entities and committees responsible for conducting the regulatory sandbox, such as deliberative committees, operational groups or specific units within the regulatory authority.

Coordination and supervision: definition of mechanisms that ensure collaboration between different stakeholders such as regulators, regulatory sandbox participants, and other stakeholders.

Transparency and accountability: implementation of practices that ensure transparency in the operations, allowing stakeholders and society to monitor the progress and results of the initiatives.

Conflict resolution: creation of channels and processes to resolve disputes that may arise between participants or between them and the regulator during the implementation of projects.

Monitoring: definition of metrics and criteria to monitor the initiatives of the regulatory sandbox, collection of evidence for the assessment.

Assessment: Analysis of the data collected in the previous phases, allowing evidence-based regulatory decision-making.

GOVERNANCE MODELS

The following are different governance models that can be adapted according to the specific needs of each project.



SECTORAL APPROACH

Sectoral governance

Sectoral governance refers to the elaboration and implementation of projects restricted to a specific sector, that is, developed in a way that tackles the challenges of a particular sector. In this model, there is no need for direct interaction with other regulated sectors, which allows a more focused and specialized approach in the regulation and supervision of innovation projects.

Multisectoral governance

Multisectoral governance is essential for the coordination of innovative projects that cover more than one regulated sector. In this model, the governance structure involves multiple actors and sectors, ensuring integration and collaboration between different regulatory areas. The National Data Protection Authority (ANPD), for example, has proposed the creation of the Multisectoral Advisory Committee of Experts (CCME) to monitor the implementation of experimental regulatory environments, given the transversality of the topic under its competence – privacy and protection of personal data. This committee includes experts, academics, representatives of industry and civil society and other relevant stakeholders.

TEMPORALITY

Permanent governance

In this model, governance instances operate continuously, managing different cycles of experimentation in the regulatory sandbox. Collegiate bodies and standing committees are responsible for overseeing all stages of the process, from the selection to the final assessment of innovations. The Central Bank of Brazil (BCB) uses a Strategic Management Committee for the Regulatory Sandbox, established by BCB Resolution No. 77/2021, which operates indefinitely, with one of its members assuming the presidency of the committee at each call for applications.

Temporary governance

Temporary governance is formed specifically for each cycle of experimentation. After the end of the cycle, the work of the collegiate is concluded. This model is useful for experimental regulatory environments that have a well-defined scope or that operate in cycles of experimentation with different designs. The Superintendency of Private Insurances (SUSEP) adopts specific commissions for each public notice, according to Susep Ordinance No. 7661/2020.

FUNCTIONALITY

Governance by deliberative and operational committees


Some governance models involve the creation of committees with deliberative and operational functions that work together to manage and oversee the experimental regulatory environment. These committees can be thematic or operational, depending on the specific needs of the project. In the model of the Securities and Exchange Commission (CVM), CVM/PTE Ordinance No. 75/2020 establishes a sandbox committee with a strategic core and an operational core. The strategic core has a rotating coordination, while the operational core is composed of representatives with two-year mandates, with the possibility of renewal.

Governance integrated in the regimental structure

In this model, the governance of the experimental regulatory environment is integrated into the existing regimental structure of the regulatory body or entity. Project management is conducted by the regulator's own internal sectors, without the need to create additional committees or structures. The National Telecommunications Agency (ANATEL) uses its own regimental structure to manage the regulatory sandbox through the involvement of the Board of Directors for approval and specific departments for evaluations.

Localized governance in development programs by federated entities

Some city and state administrations use broader development program frameworks to manage experimental regulatory environments. In these cases, project governance is linked to innovation



or economic development programs by the federated entities. Sandbox.Rio, managed by the undersecretary of regulation and business environment of the Municipal Secretariat of Economic Development of Rio de Janeiro, and the InovaTerê Sandbox, managed by the Municipal Secretariat of Science and Technology of Teresópolis, exemplify this model.

Governance with shifting participation

In this model, in addition to the regulatory entity, there is also participation of representatives of other public, private or expert bodies, which collaborate with the governance process through partnerships or cooperation agreements. In the experience of Jaraguá do Sul, in the state of Santa Catarina, the Sandbox Committee is composed of permanent and shifting members, and specific members are chosen according to the activity to be developed in the sandbox.

The choice of a governance model for the regulatory sandbox should be carefully considered, taking into account the specific needs of the project, the regulatory context and the resources available. Whether the governance is multi-sector, permanent, temporary, integrated into the regimental structure, or with shifting participation, it is essential that the governance structure offers transparency, efficiency and flexibility, ensuring that the objectives of the sandbox are aligned with the public interest.

In short, to overcome the challenges and ensure the effectiveness and legitimacy of regulatory sandbox initiatives, it is recommended that a solid governance structure is adopted. This structure is essential to create a normative-institutional framework that promotes effective coordination between institutions, defines precise strategies for data management and establishes adequate supervision and communication mechanisms, thus ensuring the integrity and success of the experiments.

SCOPE

The scope of a regulatory sandbox is a critical component that helps define the boundaries and parameters within which innovations can be tested. This scope includes not only the **application areas** and the **economic sectors** involved, but also the relevant stakeholders, such as investors, consumers, and regulatory authorities.

A well-defined scope provides an objective view of what to expect from the regulatory process, facilitating strategic and operational planning. The design of the project scope also seeks to safeguard the integrity of the sandbox, ensuring that it is used exclusively for the central purpose of experimentation and development of innovations, avoiding misuse as a means of moving away from stricter standards applicable outside this controlled environment.

The setting of a scope subsequently allows the detailed definition of the objectives of the regulatory sandbox, the flexibilities allowed, the eligibility criteria and the necessary safeguards to mitigate potential risks.

OBJECTIVES

The objectives serve as the backbone of the entire process, ensuring that the sandbox is able to generate **measurable results**. Here we highlight the importance of creating well-defined objectives and recommend their inclusion in the structure of any regulatory sandbox.

Strategic direction

The objectives establish the core purpose of the regulatory sandbox, acting as a strategic guide that guides all activities and decisions within this controlled environment. They also help determine which innovations will be prioritized for testing, which regulatory standards can be made more flexible, and what results are expected.

Measuring success

The ability to measure the success of a regulatory sandbox directly depends on the objectives set at the beginning of the process. They allow the assessment of the results and impact of the tested innovations and the identification of regulations that may eventually need adjustments or improvements.

Justification for flexibility

The objectives justify the need for regulatory simplifications, departures or flexibility in the sandbox. They justify, therefore, the need for the temporary suspension of certain norms in order to allow

experimentation, ensuring that these exceptions are properly motivated and aligned with the expected results.

Table 5 lists the main objectives related to the implementation of regulatory sandboxes.

| Main objective | Regulatory implication | Recommended actions |
|---|---|--|
| 1. To increase benefits for users | Improvements to existing services: Current services are improved in aspects relevant to customers, providing tangible improvements in convenience and quality. New services for underserved segments: Introduction of innovative services to serve unmet or under-served customer segments, filling gaps in the market. | <ul style="list-style-type: none"> - To develop and test technological solutions to enhance customer experience. - To continuously monitor the impact of innovations. |
| 2. To promote competition | Licensing of new entrants: New entrants become licensed and new services are offered in the market, increasing diversity and competitiveness. Stimulation of competition: An environment of healthy competition between new entrants and established entities is fostered. | <ul style="list-style-type: none"> - To create an agile and efficient licensing process for new entrants. - To implement policies that encourage fair competition. - To monitor the competitive impact and adjust regulations as necessary. |
| 3. To stimulate innovation | To give support for emerging innovations: to provide a safe space to test new ideas and pioneering technologies. Fostering creativity: To encourage startups and companies experimenting with creative and disruptive solutions. | <ul style="list-style-type: none"> - Disponibilizar suporte e recursos, como consultoria técnica e orientação regulatória. - Facilitar testes rápidos e de baixo custo em um ambiente controlado. |
| 4. To reduce barriers to entry | Facilitated access: Complexity is simplified and costs are reduced so new entrants can enter the market and effectively compete. Equity in the market: Companies of different sizes have a fair opportunity to participate. | <ul style="list-style-type: none"> - To implement simplified regulatory procedures. - To identify regulatory processes and costs from the perspective of the company. |
| 5. To test the effectiveness of the regulatory framework to accommodate innovation | Practical assessment: Impact and applicability of regulations to the experimentation of innovation is tested, in a controlled environment, generating evidence for its maintenance or definitive change. Adjustments and fine-tuning: Regulations are adjusted and fine-tuned based on the results obtained during the test. | <ul style="list-style-type: none"> - To perform tests within the sandbox to generate evidence. - To collect feedback and adjust the regulations as needed. |
| 7. To verify and mitigate risks | Identification of risks: The risks associated with new technologies and business models are assessed in a controlled environment. Risk mitigation: Strategies to mitigate risks before large-scale adoption are developed. | <ul style="list-style-type: none"> - To conduct risk management for each innovation proposal. - To implement and monitor risk mitigation plans. |
| 8. To improve regulation and supervision | Regulatory enhancement: Regulatory and supervisory practices are improved based on the results and experiences gained during the sandbox. Skills development: More effective regulatory skills are developed. | <ul style="list-style-type: none"> - To evaluate and improve regulatory and supervisory processes. - To provide continuous training for regulators based on sandbox experiences. |

Table 5 - Main objectives for the implementation of regulatory sandboxes

DEPARTURES AND RELAXATIONS

The departure from or relaxation of the norms offered in a regulatory sandbox are valuable tools to **encourage innovation**, allowing new ideas to be tested in a **controlled environment**, with less **legal barriers**. However, the implementation of these measures requires **caution and responsibility**, ensuring that the stimulus to innovation is balanced with protecting consumers and preserving market integrity²².

In the context of a regulatory sandbox, “departures “and” relaxations” of norms may have close connotations, but are not exact synonyms.

DEPARTURES

Meaning: Refers to temporary suspension or the non-application of certain standards or regulatory requirements which, under normal circumstances, would be in effect.

Objective: To allow sandbox participants to act without being bound by certain rules that could make it difficult to experiment with innovations.

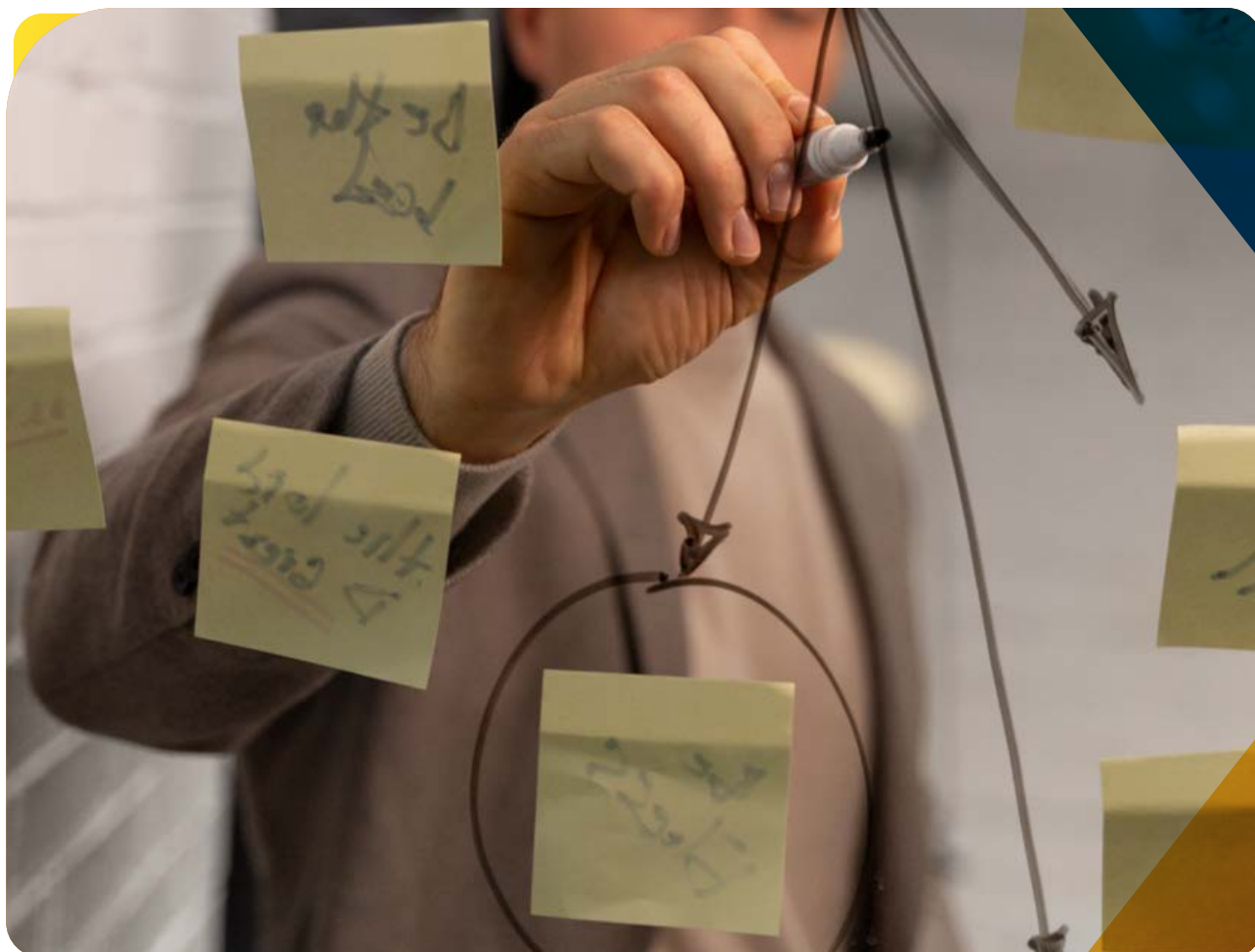
Example: A company may be temporarily exempted from complying with certain legal requirements such as specific licensing rules for testing new products or services.

RELAXATIONS

Meaning: Implies a temporary change or adaptation of standards, to be applied less rigidly or adjusted to the needs of sandbox participants.

Objective: To allow participants to follow standards, but in less rigid way, facilitating innovation without entirely removing regulatory obligations.

Example: A regulator may allow a company to meet a safety standard with less stringent criteria or with extended adequacy deadlines during the sandbox period.



The goal is to create a safe **space for experimentation**, without compromising the stability of the regulatory system. Thus, it is essential that this space be structured in a way that **minimizes risks**, ensuring that the benefits of innovation are manifested without compromising the safety and well-being of society.

In an opinion, the General Attorney's Office (AGU) stated that sandbox participants can be exempted from some regulations as long as they comply with the conditions of that authorization. However, regulators may maintain essential requirements, such as suitability rules, to ensure that products are compatible with the customers' risk profile.



In the context of Brazilian administrative law, **the regulatory sandbox, by itself, does not have the power to deter the enforcement of laws**. However, it allows the operation of innovative projects within a legal framework that enables regulatory flexibility under specific conditions. In order for a regulatory sandbox to offer departures or relaxations from certain rules, the following are recommended:

- **Legal authorization:** the creation and operation of a regulatory sandbox must be supported by an objective legal basis, such as the authorization provided for in Article 11 of complementary Law No. 182, of June 1, 2021, Startups and Innovative Entrepreneurship Legal Framework, which gives the regulatory agency the power to remove the incidence of standards under its competence. This basis may be supplemented by other laws, decrees or regulations specifying the powers and limitations of the regulator.
- **Discrecionariade reguladora:** deriva do poder normativo dos órgãos e entidades reguladoras para que possam responder às especificidades e dinâmicas de seus setores de atuação.
- **Revisibilidade e reversibilidade:** as flexibilizações concedidas devem ser sujeitas a revisões periódicas e reversíveis, permitindo que o regulador reimplente as regras originais, caso surjam problemas.

Thus, the creation and operation of a regulatory sandbox requires a careful balance between fostering innovation and ensuring compliance with the current legal framework.

Table 6 presents examples of departures and relaxations in a regulatory sandbox, with description, objective and expected impact:

| Type of Relaxation | Description | Objective | Impact | Example |
|---|--|---|---|---|
| Departure from licensing requirements | Allows companies to operate without the need to obtain full licenses during the test period. | To facilitate the entry of new companies into the market without the administrative and financial burden of full licensing. | Reduces time and cost to start operations, encouraging experimentation and innovation. | A fintech can launch a payment application without a full banking license, but under regulatory supervision. |
| Dispensation of minimum capital requirements | Temporarily reduces minimum capital requirements required for operation. | Allows startups and small businesses to participate in the market, even without the typical financial resources required. | Increases competitiveness and diversity in the market, allowing new ideas to be tested. | A loans startup can operate with less initial capital than usually required. |
| Relaxation of compliance norms | Allows companies to ignore some compliance rules or administrative procedures. | To facilitate the testing of new business models or technologies that do not fit the existing regulatory structures. | Stimulates innovation by removing barriers for new technologies while maintaining a certain level of supervision. | A blockchain company may be exempted from following some traditional banking compliance rules. |
| Dispensation of operational requirements | Allows companies to operate without meeting certain operational requirements. | To provide flexibility to test new operational processes or technologies without the need to immediately meet all regulatory standards. | Helps companies to develop more efficient or innovative solutions, while they gradually adjust to the established norms. | A delivery drone company can operate without initially complying with all aviation regulations, but with controlled safety. |
| Dispensation of interoperability requirements | Allows companies to test systems or technologies that are not compatible with the existing interoperability standards. | To facilitate the development of new technologies that can set new standards or improve interoperability in the future. | Promotes innovation in technology and systems, by allowing the evolution to new standards. | A financial technology company can test a system of payment that does not fully integrate with the existing networks. |
| Temporary dispensation with quality certifications | Temporarily reduces minimum quality requirements for innovative products in the test phase. | Allows companies to introduce new products for assessment, without the need of full certifications. | Reduces the time it takes to enter the market and encourages innovative products. | A manufacturer of medical devices can test new equipment without initial full certification, but under supervision. |
| Relaxation of safety testing requirements | Allows new technologies to be tested with less rigorous safety protocols, but under controlled conditions. | To facilitate innovation in safety, allowing new approaches to be quickly evaluated. | Startups and small businesses can redirect resources to other critical areas for development, such as research and designing of products. | A company can test a new encryption algorithm in a controlled and supervised environment before full implementation. |

Table 6 - Types of regulatory relaxation

RECOMMENDATIONS FOR THE SCOPE OF REGULATORY DEPARTURES AND RELAXATIONS

To ensure that regulatory departures and relaxations promoted by a regulatory sandbox are responsibly implemented, it is critical to respect the **hierarchy of legal norms**. Hierarchically inferior normative instruments, such as ordinances and resolutions, cannot contradict provisions established by law or by the Federal Constitution. Therefore, any proposed relaxation or departure should be carefully evaluated to ensure that it complies with the **legality principle**.

Relaxations involving infra-legal norms, such as resolutions or normative instructions, should be managed in the **scope of competence of the regulator or group of regulators involved**. On the other hand, the removal or relaxation of norms provided for by law requires an express modification or exemption through a norm of equal or higher hierarchy. Compliance with the regulatory framework is key to ensuring that the experimental regulatory environment operates within a solid legal framework, preserving the legitimacy of regulatory initiatives and the protection of the rights of those involved.

INTERACTION BETWEEN DIFFERENT SECTORS

The multisectoral approach seeks to ensure the harmonization of standards and the feasibility of experimental projects that involve the departure or relaxation of regulations from different bodies or regulatory entities.

Steps for multisectoral interaction in the regulatory sandbox

- **Mapping of the bodies or entities involved**
 - To identify all regulatory entities that have standards applicable to the project.
 - To assess the need for temporary departure from standards in different industries.
- **Interinstitutional consultation**
 - To initiate dialogue with regulatory bodies whose standards will be impacted by the sandbox.
 - To explain the objectives of the sandbox and the need for regulatory flexibility.
 - To define the criteria and limits for the temporary departure from or relaxation of standards.
- **Legal analysis**
 - To consult the legal department of the entities involved to ensure that the relaxation of the rules is in accordance with current legislation.
 - To identify the best legal instrument to formalize the departure from the norms (joint resolution or technical cooperation agreement).

Legal instruments to formalize multisectoral interaction

Joint resolution

A joint resolution is a normative act issued by two or more regulatory bodies. In this case, it would be used to temporarily suspend a rule of one of the bodies in the context of a regulatory sandbox.

Greater legal certainty, since all the entities involved participate in the decision.

Clearly defines the limits and deadlines for regulatory departure/relaxation.

Technical cooperation agreement

A technical cooperation agreement is a formal legal instrument that establishes collaboration between different regulatory bodies, defining conditions and deadlines for the suspension or relaxation of standards.

Flexible, allowing adaptation to the specific needs of the sandbox.

Facilitates collaboration and exchange of information between agencies.



ELIGIBILITY CRITERIA

The structured definition of eligibility criteria seeks to ensure the **qualification of participants and projects** to conduct the tests safely, efficiently and with tangible benefits for society and the market. These criteria aim to promote the creation of solutions that can effectively transform the sector and contribute to economic and social progress.

The following are examples of criteria that can be considered in an experimental regulatory environment project, including the regulatory sandbox.

INNOVATION

Innovation is the cornerstone of regulatory sandboxes, requiring companies to come up with solutions or new technological approaches that represent significant advances if compared to the status quo. To be eligible, proposed innovations must demonstrate overt use of new technologies or an innovative application of existing technologies, providing differentiated benefits such as improvements in efficiency, consumer experience or cost savings.

READINESS

The readiness of the participants assesses the level of preparedness to conduct the proposed test. Companies must demonstrate that their innovations are at an advanced stage of development, ready to be tested in real market conditions. This criterion includes the presentation of a detailed test plan, methodology, success criteria, as well as the resources available for the implementation of the project.

RELEVANCE

The proposed innovations must be relevant to the current challenges and needs of the regulated sector. This criterion requires that the solutions presented are directly aligned with significant market challenges or opportunities, offering effective responses that can generate positive impacts on the regulated environment.

ALIGNMENT WITH PUBLIC GOALS

Innovations should be aligned with strategic public goals, such as promoting financial inclusion, environmental sustainability or strengthening the economy. Proposals should demonstrate how they will contribute to the achievement of public policy goals, benefiting the collective interest and going beyond individual commercial interests.

TECHNICAL CAPACITY

The companies' technical capacity is the guarantee that participants have the necessary skills and knowledge to implement and test their innovations efficiently. Companies must demonstrate that they have a qualified team with relevant experience, as well as adequate technological infrastructure to support testing activities.

FINANCIAL CAPACITY

To join a regulatory sandbox, companies need to prove that they have sufficient financial stability to develop their innovations. It is essential that a financial plan be presented, demonstrating how the resources will be distributed during the test and how the company intends to continue operating after the end of the test period. Sound financial capacity reduces the risk of disruptions and ensures that testing is continuously conducted generating consistent results.

SCALABILITY

The scalability potential is a criterion that evaluates the ability of the innovation to be expanded on a larger scale after testing in the regulatory sandbox. Proposals should include a scalability plan, addressing how the innovation can be implemented in a broader market while maintaining its effectiveness and quality.

ETHICS

The ethics criterion assesses whether the company and its innovation adhere to ethical principles, including fairness, transparency and social responsibility. Business practices must be ethical at all stages of innovation development and testing, so the proposal must demonstrate a commitment to social responsibility, avoiding any form of exploitation or collective damage. Ethical considerations ensure that the innovations are not only technologically advanced, but also contribute to a fairer and more responsible society.

COMPLIANCE WITH SOCIAL, FISCAL, AND ENVIRONMENTAL STANDARDS, DATA AND INTELLECTUAL PROPERTY PROTECTION

This criterion covers compliance with social regulations, tax and environmental obligations, data protection and intellectual property. Innovations must comply with all relevant laws and regulations.

Table 7 summarizes the main criteria to be observed in the eligibility of companies and projects for regulatory sandboxes.

| Criterion | Definition | Interoperability (requirements) |
|---|--|---|
| Innovation | Innovation is the foundation of any regulatory sandbox. It requires companies to come up with products, services, or processes that genuinely offer something new or significantly improved. | <ul style="list-style-type: none"> - Technological innovation - Differentiated benefit |
| Readiness | Refers to the level of preparedness of the company to test the innovation in the sandbox. | <ul style="list-style-type: none"> - Technological maturity - Test plan - Available resources |
| Relevance | Innovation must be aligned with the needs and challenges of the sector, offering meaningful and impactful solutions. | <ul style="list-style-type: none"> - Alignment with industry challenges - Potential impact |
| Alignment with public goals | Innovation must be aligned with the needs and challenges of the sector, offering meaningful and impactful solutions. | <ul style="list-style-type: none"> - Public policy objectives - Social benefits |
| Technical capacity | It assesses whether the company has the necessary skills and knowledge to develop, implement and test its innovation. | <ul style="list-style-type: none"> - Team experience - Technological infrastructure |
| Financial capacity | Refers to the company's ability to sustain the development and testing of the innovation during the sandbox period. | <ul style="list-style-type: none"> - Financial health - Financial planning |
| Scalability | Assesses whether the innovation has the potential to be expanded on a large scale after sandbox testing. | <ul style="list-style-type: none"> - Financial health - Financial planning |
| Ethics | Evaluates whether the company and its innovation adhere to ethical principles, including fairness, transparency, and social responsibility. | <ul style="list-style-type: none"> - Ethical practices - Social responsibility |
| Compliance with social, fiscal, and environmental standards, data and intellectual property protection | Abrange a conformidade com as regulamentações sociais, fiscais, ambientais, proteção de dados e propriedade intelectual property protection. | <ul style="list-style-type: none"> - Compliance environmental and social standards - Data protection - Intellectual property |

Table 7 - Eligibility criteria for regulatory sandboxes

SAFEGUARDS

Safeguards, in the context of a regulatory sandbox, refer to protective measures and security mechanisms designed to mitigate risks during the experimentation of innovations. These measures seek to ensure that, even in the face of regulatory flexibility, consumer safety and market integrity are preserved. Safeguards are essential to ensure that innovations can be tested responsibly and safely, without compromising public interests or consumer rights.

Some examples of safeguards that can be fixed according to the concrete situation are listed below.

TIME LIMITATION

Time limitation refers to the period during which innovations can be tested in the regulatory sandbox. Based on national experiences, this period usually varies between six months and two years, with the possibility of extension based on results and periodic evaluations. This safeguard must ensure that tests are evaluated in sufficient time to provide meaningful results, but without indefinitely prolonging experimentation. The possibility of extension should be duly justified by the need for more time to fully assess the impacts of the innovation or by the identification of new challenges that require additional time to be resolved²³.

In an opinion, the General Attorney's Office (AGU) points out that the sandbox program has a certain term, and ends with the obtaining of definitive authorization by the participant or with its exit from the market, upon expiration of the term of the initial authorization.

LIMITATION OF THE NUMBER OF PARTICIPANTS

The number of participants should be manageable, to allow regulators to properly monitor and control all activities in the regulatory sandbox. The administrative capacity of the regulator and the need to ensure equal opportunities for all eligible applicants are factors that influence this limitation.

GEOGRAPHICAL LIMITATION

The geographical limitation defines the territorial scope within which the innovation can be tested. This limitation ensures that testing is conducted in areas where regulators have administrative competence and monitoring capacity. Geographical limitation also takes into account regional needs and regulatory differences, allowing tests to be adapted to local conditions and but avoiding unwanted impacts in places that are not prepared for that innovation.

LIMITATION OF THE OPERATIONAL SCOPE

This safeguard involves restricting the functional scope of the innovations tested. For example, a sandbox may only allow testing of certain aspects of a product or service, such as specific features or development phases. The limitation of the operation scope ensures that innovations are tested in a controlled environment, minimizing risks and allowing for a more accurate assessment of the impact of each tested feature.

LIMITATION OF VOLUME AND SCALE

Limiting volume and scale restricts the number of operations or the reach of the test. This restriction may include limiting the number of end users, transactions, or volume of data used during testing, ensuring that testing is performed at a scale that allows for risk control. This avoids complications that could arise from large-scale implementation without proper supervision and prior evaluation.

CONSUMER PROTECTION

Consumer protection should be a top concern in a regulatory sandbox. This safeguard includes the implementation of security measures to protect consumers during the test period, as well as ensuring that they are fully informed about the experimental nature of the products or services. Compensation and dispute resolution mechanisms can also be established to deal with potential damages or dissatisfaction, ensuring that consumers' rights are preserved at all stages of the test.

RISK MANAGEMENT

Risk management provides the appropriate space to identify and mitigate potential threats during testing. This safeguard involves establishing continuous monitoring processes to track innovation performance and implementing contingency plans to deal with unexpected problems. Risk management helps ensure that even in the case of failures, impacts are minimized and participants can quickly act to correct any problems that may arise.

The safeguards presented here are suggestions that the regulator may consider when designing a regulatory sandbox. They therefore serve as guidelines to help create a safe and controlled testing environment, but should not be seen as mandatory or applicable for all projects. Each innovation and regulatory context are unique and it is up to the regulator to carefully assess the specific case to decide which safeguards are appropriate. The regulator must adapt the safeguards suggested to the specific needs of each project, thus ensuring a balance between innovation and safety.

Preparation of the Notice or Term of Reference

The Startups and Innovative Entrepreneurship Legal Framework allows public bodies and entities with sector regulation competence to establish the criteria for selection or qualification of the regulated actors, for the purpose of participation in a regulatory sandbox program (cf. Article 11, paragraph 3, of complementary Law No. 182, of 2021). The regulator, while observing the specificities of the regulated sector and the established experimental environment itself, must first choose if they want to adopt a **formal selection process** or a **regulated qualification process**.

The preference for a formal proposal selection process has several advantages. First, it allows the prioritization of viable initiatives, considering technical, economic and social aspects. It also contributes to the mitigation of risks related to the creation of regulatory and competitive asymmetries, lack of transparency, and possible subjectivity in the choice of projects.

Although regulatory sandboxes may have distinct characteristics depending on the regulated sector and the specific regulatory objectives pursued by the experimental environment, the inclusion of the following stages in the proposal selection process is generally recommended:

- a) Public consultation prior to the preparation of the public call for proposals, to define the priority themes, objectives and rules of the regulatory sandbox;
- b) Publication of the public call for proposals to be evaluated and selected;
- c) Receipt of proposals;
- d) Public consultation about the proposals received, if relevant;
- e) Evaluation and selection of projects by the technical area responsible;
- f) Disclosure of approved projects.

Since **there is no one way to implement a regulatory sandbox**, the regulator will be constantly urged to make a series of administrative choices throughout the proposal selection process. In addition to defining whether or not there will be the adoption of a formal selection process, it will be necessary to establish the moment(s) in which social participation will be allowed in an institutionalized manner, the legal and regulatory implications of the public call and the form in which the proposals will be received and publicized.

The public call notice may choose to list the specific needs of the regulator (**internal impulse**); or to allow the voicing of specific demands for an experimental environment by the regulated actors (**external impulse**); it can also opt for a **hybrid model**.

The **receipt of proposals** may be **continuous** or divided into **periodic cycles**, according to the regulator's choice, taking into account aspects like institutional capacity, and specificities of the regulated sector.

The evaluation and selection of projects by the responsible technical area must take place in an isonomic and transparent manner, with observance of compliance or non-compliance with the eligibility criteria to select participants in the project.

Finally, the **publicizing of projects** approved for the regulatory sandbox is a transparency measure that must be adopted by the regulator, allowing the joint action of civil society with the Public Administration,

as well as social control and monitoring of the project selected by the stakeholders.

In an opinion, the General Attorney's Office (AGU) recommends the wide publicizing of the initiative and the conditions for participation, with clear information for the submission of proposals, ensuring transparency and impersonal treatment.

STRUCTURE OF THE SELECTION NOTICE

Within the scope of the gathering of contributions, it was agreed that the selection notice must, at a least, contain the following information:

- vii. regulatory sandbox objectives and maximum test period;
- viii. eligibility criteria;

In an opinion, the General Attorney's Office (AGU) highlighted that the sandbox normative instrument must define its objectives, focusing on promoting innovation in the sector and collecting information for a faster update of the regulation. The document can also provide for sandbox editions, with priority themes and specific deadlines for submission and evaluation of projects.

- ix. schedule for submission and selection of proposals; and
- x. evaluation criteria for projects.

The call for proposals must therefore provide for the **maximum regulatory sandbox duration**, ensuring that the test environment is temporary. It is also possible to provide for the possibility to **extend of the test period** in the notice, this should be viewed as an **exceptional situation**, to be duly justified by the regulator, arising from the need for additional time to assess the impacts of the project under development or in the case of unforeseen events or force majeure.

The **eligibility criteria** for proponents and projects to join a sandbox also aims to ensure the isonomy of the participants throughout the process. In this scenario, the call for proposals must list the criteria to be met by both the **proponents** and for the **project** to be tested.

The **schedule** should set the dates for the submission, evaluation, and selection phases, allowing interested parties to prepare their applications within the allotted time. This structure helps to avoid delays and ensure an orderly assessment.

The **evaluation criteria** should establish objective standards that guide the selection of proposals. When these criteria are well defined and there is a deadline for the **receipt of appeals**, proponents can check whether their proposals have been properly assessed, giving more transparency to the process.

The notice must be written in **plain language**, and can also mention a deadline for receiving requests for clarification from interested parties.

Depending on the form of selection of proposals chosen by the regulator, the notice may indicate in its text the regulatory standards to be departed from in the development of the project, which should also be provided for in the temporary authorization act. Any need for the individualized indication of **departure from a normative incidence**, linked to specificities of the project under development, may also be evaluated on the occasion of the temporary authorization for the development of the project.

The notice may also provide for **governance** mechanisms for the monitoring of activities in the framework of the sandbox, as well as mechanisms for reviewing and adjusting the operation of the sandbox based on feedback, without excluding the possibility of recognizing other forms of implementing this structure.

The selection notice and the authorization term are documents that can provide for the conditions that ensure the protection of users, the establishment of a safe testing environment and the soundness of the public and private interests involved. Thus, they should provide for **risk management** mechanisms and respect for **consumer rights**, as well as **transparency** and **publicity** and ensure the dissemination

of information related to the experimental environment and the projects tested to society, with the exception of the information covered by **legal secrecy**.

The prior establishing of the hypotheses of exit from the regulatory sandbox is also a strongly recommended measure. It is important that the notice provides for situations that may cause **exclusion from the experimental environment** due to: expiration of the period established in the temporary authorization; request by the participant; cancellation or suspension provided for in the instrument; recognition of excessive risks arising during the development of the activity; non-compliance with eligibility criteria or obligations established in the experimental environment, among other examples.

QUALIFICATION PROCESS

Complementary Law No. 182, of 2021, in its article 11, paragraph 3, item I, allows participation in a regulatory sandbox to be authorized due to the specific qualifications of the regulated actor, **without the need for a formal selection process**. This flexibility, however, requires greater attention on the part of the regulator, since the absence of a selection process can bring some risks.

Among the **associated risks** there is the possibility of creating regulatory asymmetries, the inclusion of projects without technical feasibility due to the lack of a clear screening process, and the perceived lack of impersonality and transparency in the choice of projects. These factors may raise questions about the validity of the admission of participants to the experimental environment.

Therefore, when choosing to waive a formal selection process, the regulator must present **relevant justifications** aligned with the principles that govern Public Administration, the specific objectives of the regulatory sandbox and the particularities of the project that justify this choice.

The **term of reference** can be used in the qualification process to formalize participation in a regulatory sandbox. This document should include all essential information related to the project, such as the proposed object, work plan and applicable legislation. In addition, it should detail the obligations of the parties involved, the capacity-building necessary for the regulated agents and how the sandbox will be managed.

Other important points to include in the term of reference are the guidelines on active transparency, the technical specifications of the project, the rights of users and consumers and the accountability criteria. It is also essential to provide for a communication and dissemination plan, the requirement of partial and final reports by the regulated actor and the definition of performance and impact indicators.

The term of reference must also include the changes that can be made to the sandbox, the term of validity and authorization, the forms of terminating one's participation, the exemption from some applicable standards, among other information that the regulator considers necessary for the proper functioning of the experimentation.

In this context, it is even more advisable that **transparency** and **social control mechanisms** be applied in the early stages of creating the regulatory sandbox. The inclusion of these mechanisms contributes to give greater democratic legitimacy to the administrative decision to waive the selection process.

The General Attorney's Office (AGU) recommends that the term of reference be revised focusing on legal aspects, clarity and coherence. The preparation of the document must follow technical and administrative criteria to ensure compliance with the principles of administrative merit, expediency and timeliness. It is suggested that the observations made during the analysis be incorporated to optimize the text and ensure alignment with the legal and operational requirements necessary for the effective implementation of the project

Temporary authorizations

Temporary authorizations are essential to promote a **controlled experimentation environment**, giving companies the flexibility to innovate while keeping them under **regulatory oversight**, so as to ensure safety and compliance.

Temporary authorizations allow companies to operate under a set of **relaxed rules** for a limited period. During this timeframe, companies can test their innovations in a less restrictive regulatory environment, which facilitates experimentation and adaptation, before wider implementation.

Thus, the temporary authorization act must necessarily make reference to the regulations that will be relaxed during the development of the project.

The restricted period in which these authorizations are valid allows regulators to closely monitor companies' operations and intervene if necessary. During the test period, both regulators and participants have the opportunity to assess the impacts of innovations. This **continuous monitoring** provides essential data for future regulatory decision-making, enabling evidence-based adjustments.

In an opinion, the General Attorney's Office (AGU) acknowledged that temporary permits are seen as a way to eliminate legal risk for entrepreneurs engaged in regulated activities, as well as reassure investors that their resources are safe.

GRANT PROCEDURES

The request to participate in the regulatory sandbox can be made either through a selection notice or a qualification process. In both cases, the submitted projects undergo an evaluation before the temporary authorizations are granted.

EVALUATION AND APPROVAL

The evaluation of each proposal is conducted by a regulatory committee or another designated governance body, following the eligibility criteria previously defined in the normative instrument that structures the operation of the sandbox. These criteria - which may include technical feasibility, potential market impact and innovation - will guide the evaluation process. Only projects that satisfactorily meet the set criteria receive temporary authorization, to ensure that the experimentation is carried out within the established regulatory and safety parameters.

SUSPENSION AND TERMINATION

Although temporary authorizations are designed to promote innovation for a certain period of time, there are situations in which the suspension or termination of the project may be required. These cases include serious operational failures, excessive or unforeseen risks, deviations from the agreed scope or indication of irregularities. Before a final decision is made, the participant must be notified and given the opportunity to correct its conduct. The participant must also be able to defend the continuity of their participation and have the right to present a defense, thus ensuring the legality of the process.

In an opinion, the General Attorney's Office (AGU) points out that, although it does not constitute a penalty, a termination is an unfavorable measure that must be preceded by the right to a defense, to guarantee that the participant has the opportunity voice their opinion about the decision.

In an opinion, the General Attorney's Office (AGU) recognizes that regulators have the option to terminate the activity developed at any time in the case of non-compliance with the terms of the authorization, serious flaws in the business model, or if the risks associated with the activity are not compatible with the temporary authorization regime.



EXPERIMENTAL REGULATORY RELAXATION PROTOCOL

The temporary authorization constitutes the approval of the project to participate in the regulatory sandbox, allowing the innovation to be tested under special conditions and in a controlled environment. Once the temporary authorization is issued, a **custom document** referred to as the experimental regulatory relaxation protocol, is produced.

This protocol details all the operating conditions of the sandbox project, lists the regulations that will be relaxed, describes the scope of the activities, deadlines, monitoring obligations, risk mitigation measures and other fundamental aspects to ensure that the experiment takes place in a controlled and safe manner. The protocol is therefore an **operational guide** that defines the limits and responsibilities of each party involved, serving as the formal framework for implementing the approved project.

In practice, both the temporary authorization and the experimental regulatory relaxation protocol may contain detailed information about the operation of a regulatory sandbox project. However, there are advantages to separating these two documents:

Temporary authorization: This document formalizes the approval of the project to operate in the experimental regulatory environment and grants the necessary permissions to test the innovation. It usually mentions, in a summarized way, the scope of the project, the regulatory relaxations and the main conditions such as duration and general objectives.

Experimental regulatory relaxation protocol: this document, in turn, can be more detailed and further describe all operating conditions. It must include information such as the phases of the experiment, timelines, monitoring responsibilities, safeguards and procedures for dispute resolution, as well as clearly establish the specific rules of operation and the limits of the regulatory relaxations.

Table 8 shows the recommended items that can be included in the experimental regulatory relaxation protocol.

| Item | Description |
|--|--|
| 1. Project identification | Name of the participating company or entity. Name of the project or innovation to be tested. Contact information and legal representatives. |
| 2. Project objectives | Detailed description of the objectives of the experiment. Problems that the project seeks to solve or innovations that will be tested. Results expected at the end of the test period. |
| 3. Scope of experimentation | Sectors or areas of activity where the innovation will be tested. |
| 4. Regulatory flexibilities | Rules or regulations that will be suspended or relaxed during the test period. Justification for these flexibilities. Scope of the regulatory relaxation. |
| 5. Test methodology | Description of the testing process, including detailed schedule. Implementation, development and monitoring phases. Tools or technologies used in the experiment. |
| 6. Duration and deadlines | Period of validity of the temporary authorization. Deadlines for the start and end of experimental activities. Possibility of extension of the deadline if necessary. |
| 7. Evaluation criteria and indicators | Performance indicators to assess the success of the innovation. Evaluation criteria to measure the impact on the market, consumers and regulatory environment. Data collection mechanisms. |
| 8. Periodic reports | Frequency and format of reports submitted to the regulator. Content, progress of the experiment, results and challenges. Mechanisms for adjustments based on reports. |
| 9. Risk mitigation plan | Identification of potential risks associated with the experiment. Mitigation measures to deal with risks. Emergency Response Plan. |
| 10. Safeguards | Geographic and operational limitations to control the scope of the test. Measures to protect consumers, the market and the environment. Data protection and Privacy. |
| 11. Supervision and monitoring | Administration for continuous monitoring. Definition of responsibilities. Supervisory mechanisms, which may include audits and verifications. |
| 12. Discontinuation plan | Conditions for the interruption or suspension of the experiment. Strategy to end activities at the end of the test. Reinstatement of suspended regulatory standards. |
| 13. Transparency and Publicity | Procedures for resolution of disputes between participants and regulators/third parties. Mediation or arbitration mechanisms. Deadlines and mediation responsibilities. |
| 14. Dispute resolution | Procedimentos para resolução de disputas entre participantes e reguladores/terceiros. Mecanismos de mediação ou arbitragem. Prazos e responsáveis pela mediação. |
| 15. Transition to full regulation | Conditions for the conversion of temporary authorization into definitive authorization. Procedures of transition to the full regulatory regime. |

Table 8 - Recommended content of the experimental regulatory relaxation protocol

Implementation and monitoring

In a regulatory sandbox, participating companies operate under a **intensified supervisory regime** that goes beyond the monitoring practices applied to companies outside the experimental environment. This closer supervision regime is essential to ensure that, despite the exemptions and flexibilities granted, the activities of companies are constantly evaluated for compliance with the **regulatory objectives** and the **risk mitigation**.

The main benefit of subjecting companies to stricter oversight is ensuring that the regulatory relaxations are not unduly exploited. These flexibilities are granted to allow companies to experiment with new ideas and business models. However, without proper oversight, there is a risk that such relaxations will be used

as a way to avoid fulfilling key regulatory responsibilities.

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In an opinion, the General Attorney's Office (AGU) highlighted the importance of maintaining oversight power to ensure transparency and efficiency of operations in the regulatory sandbox

Close supervision also brings benefits to companies by offering **continuous feedback** and **regulatory guidance**. The stricter supervisory regime not only protects the regulatory system and consumers, but also underpins the success of experimental sandbox initiatives.

It is up to the regulatory sandbox participant to contribute to the regulatory authority by providing information throughout the experimentation. National experiences indicate that it is the responsibility of the participants:

- I. to give access to relevant information, documents and other materials related to the experimentation, such as those relating to its development and the results achieved;;
- II. to cooperate in discussing solutions for the improvement of the business model, product and service or regulatory solution;
- III. to communicate the materialization of foreseen and unforeseen risks in the course of the development of activities;
- IV. to communicate the intention to make the relevant changes or readjustments in the provision of the service or product, as a result of the progress of the tests;
- V. to demonstrate, from time to time, compliance with established conditions, limits and safeguards; and
- VI. to inform the authority of any user complaints and measures to mitigate frequent and/or significant cases.

REVIEW AND ADJUSTMENT MECHANISMS

Periodic reviews in the standards for regulatory sandbox operations involve a systematic and scheduled evaluation of the tests, considering both compliance with the initially established conditions and performance in relation to the regulatory objectives.

Periodic reviews are conducted at regular intervals, which may vary depending on the nature of the innovation being tested and the associated risk. During these reviews, regulators examine various aspects of the companies' operations, including project management, compliance with safety and consumer protection standards, and the effectiveness of safeguards in place to mitigate risks.

In addition, the reviews also consider the impact of innovation on the market and consumers, as well as the progress of enterprises towards the goals set at the beginning of the experiment. Periodic review is an opportunity for regulators to adjust their expectations and, if necessary, reset the parameters of the experiment to ensure that the sandbox objectives are achieved in a safe manner.

The main benefit of periodic reviews is that they provide an empirical basis for making decisions about whether to continue, modify or revoke the flexibilities granted to companies in the sandbox. Based on the results observed during the reviews, regulators can adjust the operating conditions of companies to ensure that the relaxations do not result in unacceptable risks or negative impacts on the market.

For example, if a periodic review reveals that a particular waiver is leading to greater financial risk than initially anticipated, regulators may impose new restrictions or require the implementation of additional safeguards. Alternatively, if the results indicate that the company is operating without incident, regulators



may consider even more flexibility or allowing a larger scope of operation, encouraging the continuity of the innovation.

The revisions also allow rapid adaptation to changes in the external environment or in the market itself. For example, if new information emerges about risks associated with the technology or business model being tested, regulators can promptly act to adjust sandbox rules, thereby protecting both the public interest and the innovation process.

Evaluation

The evaluation phase in the experimental regulatory environment will determine the feasibility, safety and impact of the innovations on the market. Successful evaluation is a necessary step towards granting definitive authorizations, allowing the transition of the tested innovations to the large-scale market. Below are some recommendations for the evaluation stage.

DEVELOPMENT OF INDICATORS

Operational indicators: Indicators should be developed to measure innovation performance in terms of operational efficiency, service quality, cost savings and response times.

Regulatory indicators: In addition to operational efficiency, it is critical to measure the impact of regulatory relaxations. These indicators should assess how the temporary suspension of certain norms impacted the market, consumers and the competitive environment.

Social and environmental indicators: It is recommended to include indicators that measure the social and environmental impacts of innovation, such as the reduction of carbon emissions, the impact on employment or the effect on vulnerable populations.

Examples of indicators:

- Success rate of experimental operations.
- Reduction in operational costs compared to traditional methods.
- Level of satisfaction of consumers or users involved in the experiment.

DOCUMENTATION OF THE EXPERIMENT CYCLE

Regular and detailed reports: Participating entities should be responsible for providing continuous and detailed data throughout the experiment, in mid-term reports, in addition to a comprehensive final report that documents the complete cycle of the experiment.

The final report should include:

- Description of the activities carried out.
- Results obtained compared to the established indicators.
- Challenges encountered and how they were overcome.
- Proposals for future adjustments to the tested model.

Standardization and consistency of data: The standardization of the data is fundamental so that the regulator can compare different projects and efficiently analyze the results. The data collected must follow the formats established by the regulator, including metrics, calculation methods, and reporting templates comparable between different entities and projects.

Data collection can be done through digital platforms that automate the submission process, minimizing errors and maximizing efficiency. Software solutions can be used to ensure continuous real-time data collection, allowing the regulator to monitor the experiment as it progresses.

Accountability and commitment to transparency: Entities must be committed to the transparency and accuracy of the information provided. This can be reinforced by **legal or regulatory agreements** that hold the parties accountable for incorrect or incomplete data. It is important that the sandbox protocol provides for **sanctions** for the provision of incorrect or incomplete data by the participating entities.

TRANSFORMING RESULTS INTO REGULATORY POLICIES

Guidelines for new regulations: The results obtained at the evaluation stage can be used to improve the existing regulatory framework. The sandbox works as a **learning platform**. Regulators can test new approaches, assess the impact of relaxations and, from this, formulate regulations that are more effective and adjusted to market realities.

In an opinion, the General Attorney's Office (AGU) highlighted that the sandbox approach is a response to the challenges imposed by rapid technological change, offering flexibility to regulators and allowing regulatory adjustments based on the results of the tests carried out.

Applicability of results to other sectors: Innovations and flexibilities tested in one industry can provide guidance that can be applied to other industries. For example, the success of a technological innovation in the transportation can inspire new regulations in sectors such as health or energy.

Evidence-based regulation: The evaluation phase of the sandbox allows the collection of real data on the performance of innovations, their interactions with the market and the impact of regulatory relaxations. This empirical data provides a solid basis for the creation or adaptation of regulations.

Transition to final authorization: After the completion of the evaluation phase, if the experiment is considered successful, the results obtained should justify the granting of definitive authorizations. This process involves formalizing the conditions under which the innovation will be integrated into the market.

It is essential to determine which temporarily relaxed regulatory norms will become permanent or will be adjusted. This transition seeks to ensure that innovation is implemented in a safe and efficient manner, aligned with a regulatory framework that balances the promotion of innovation with the protection of consumers and the market.

KNOWLEDGE MANAGEMENT

Creation of a knowledge database: The evaluation phase should also include a knowledge management process, in order to gather the lessons learned during the experiment. This stage includes the creation of an accessible database so that the information collected during the sandbox can be consulted in future projects, subject to the provisions of the General Data Protection and the Intellectual Property Law. It is important to highlight the failures and successes of the operation of the regulatory sandbox, so that the lessons learned can foster new uses for this instrument.

Sharing of good practices: Good practices identified during the sandbox should be systematically documented and shared, both with regulators and the private sector. The replication of successful approaches should be facilitated and the creation of safer and more efficient innovations encouraged.

Other recommendations for the evaluation phase:

- Regulators and participating entities should ensure active transparency by sharing clear and accessible information about the progress and results of the experiment.
- Implement mechanisms for public disclosure of intermediate and final reports, whenever possible, to allow monitoring by society.
- Establish open communication channels between sandbox participants and consumers, allowing for the consideration of user feedback for adjustments and improvements.
- Create dedicated communication platforms, such as customer service systems, ombudsmen and satisfaction surveys, under the supervision of regulators.
- Regulators should adopt legal standards that require transparency during the sandbox, including sanctions in cases of noncompliance.

- The absence of transparency should be treated as a violation of administrative and regulatory principles, impacting the experiment and its credibility.
- Ensure the balance between transparency and secrecy by protecting sensitive information about business models or proprietary technologies without compromising security or the public interest.
- Establish confidentiality agreements that define the boundaries of secrecy and ensure that it is not used to hide operational risks or failures.

Regulatory decision

The regulatory decision is the **final act** where the regulatory authority assesses the results obtained during the experimentation phase and defines the **fate of tested innovations**. At this point, the test period is concluded and the authority may decide whether the innovation will be implemented on a large scale or if the project will be discontinued, based on the results achieved.

The closing of a regulatory sandbox project must ensure that innovations are successfully integrated into the market or responsibly terminated. A well-planned closing allows regulators to make a full assessment of the results obtained during the experiment if compared to the goals set at the beginning of the sandbox.

In an opinion, the General Attorney's Office (AGU) has already analyzed the introduction of a "regulatory holiday" to allow the entity to operate while sector regulation is not updated to incorporate the innovative business model. This period would serve to define which norms could be temporarily suspended for the entity, prioritizing the necessary regulatory update and evaluating possible impacts on competitors.

However, this option should be evaluated with caution and on a case-by-case basis, to avoid any competitive damages related to the regulatory holiday.

EXTENSION OF THE TEST PERIOD

If the innovation shows promising results, but still requires adjustments or more time for a full evaluation, the regulator may choose to **extend the test period**. This scenario occurs when there is progress, but refinements in the business model or technology are still necessary.

TERMINATION OF EXPERIMENTATION WITHOUT IMPLEMENTATION

The termination of the experimentation without implementation occurs when the regulator assesses that the experiment was not effective or could not be adopted on a large scale. It can happen when the tested innovation does not meet the established criteria or presents **significant risks** that prevent its adoption in the market. In this case, the temporary authorization granted during the sandbox does not become permanent. Despite this, the knowledge gained during the process can be useful to guide future initiatives and new projects in other sectors.

TRANSITION TO DEFINITIVE AUTHORIZATION

The transition to a definitive authorization occurs when the experiment in the sandbox is considered successful. There are three possible scenarios:

Market launch with full compliance and no change in regulatory rules: the tested innovation is considered successful and is ready to be integrated into the market on a large scale. The regulator grants a definitive authorization, allowing regular operation under the permanent rules, without the need for changes in current standards.

Temporary flexibilities are removed and the innovation is broadly implemented, offering benefits such as increased efficiency, cost savings or new services to consumers, in full compliance with the existing regulatory standards.

Adjustment in the permanent regulation rules: based on the results of the sandbox, the regulator adjusts the norms that were relaxed during the experiment. Some flexibilities can be maintained

or adjusted to benefit the industry as a whole, thus adapting the regulatory environment to the innovation tested. In this scenario, **it is essential that the entity responsible for relaxing the standards is one of the participants or managers of the sandbox.** The market starts to operate under new rules, improving regulatory efficiency and promoting an environment that is more favorable to innovation. Thus, the regulatory sandbox serves as an input to the traditional regulatory process, supporting regulatory decision-making and the enactment of normative changes.

Among the national experiences, a concrete case is the sector regulated by the National Agency of Petroleum, Natural Gas and Biofuels (ANP), on the occasion of an experimental environment established for testing a regular direct delivery service for fuel consumers. The agency began to allow the innovative business model previously prohibited by Art. 21, item VII, of ANP Resolution No. 41, of 2013, by permanently incorporating the permission to exploit this service in its regulations, through ANP Resolution No. 858, of 2021, as a result of the regulatory sandbox.

In an opinion, the General Attorney's Office (AGU) stated that there is no impediment, with the occasional exception of any prohibitive rules, for the regulatory authority to use an experimental project to study the improvement of a regulation. On the contrary, empirical testing based on experience and observation should be encouraged, due to its potential contribution to regulatory efficiency, provided it is carried out in a controlled manner.

Partial incorporation of innovation: : some parts of the tested innovation are considered successful and can be implemented immediately, while other parts require additional adjustments or are discarded because they do not meet the necessary criteria. Partial incorporation can occur with or without modifications to regulatory rules, depending on the need to adapt standards for the full integration of the innovation. In this case, the regulator approves only aspects of the innovation for immediate application.

DISCONTINUATION PLAN

The main objective of the discontinuation plan is to ensure that the regulatory sandbox termination process is carried out in a structured and safe manner, protecting the rights of participants and consumers, as well as maintaining data integrity and ensuring that all legal and contractual commitments are fulfilled. This plan should provide guidelines for the completion of activities, minimizing negative impacts and preserving market stability.

In an opinion, the General Attorney's Office (AGU) suggests the presentation of a discontinuation plan to outline how activities would be terminated if the experiment is not successful or if the regulatory authority decides not to authorize the continuity of operations under the innovative model after the end of the experiment. If a discontinuation plan is not adopted, the opinion recommends the definition of clear criteria for the termination of activities.

PLANNED DISCONTINUATION

A detailed plan should be created to outline the steps required for discontinuation, including resource management, resolution of outstanding issues, and provision of ongoing support for participants. This plan should be reviewed and adjusted as necessary to ensure that it meets the termination objectives and the needs of those involved.



EMERGENCY TERMINATION

Contingency measures should be established for emergency situations, such as unexpected failures or legal problems. These measures should include immediate actions to mitigate negative impacts and ensure that key commitments are met. A crisis management plan should also be in place to deal with any serious issues that may arise during the termination process, ensuring that the transition is as smooth as possible and that consumers are protected.

DISCONTINUATION PROCEDURES

Early warning: One of the pillars of the discontinuation plan is clear and early communication. Participants and stakeholders should be informed of the decision to discontinue the sandbox sufficiently in advance to allow for preparation and adaptation. This notice must include details about the discontinuation schedule and the reasons that led to the termination.

Efficient communication: The information provided should be transparent and detailed, explaining the reasons for termination and giving guidance on the next steps to be taken, both for participants and for the consumers impacted.

Fulfillment of obligations: It is essential that all contractual and regulatory obligations are met by the closing date, as well as the completion of any ongoing testing and the delivery of final reports, as required by the regulator.

Conclusion of tests: All tests must be completed in an orderly manner, ensuring that participants can complete their activities and report their results in accordance with the requirements set by the sandbox.

Data protection and destruction: During the closing of the project, strict measures must be implemented to protect confidential data and personal information. If necessary, this data should be disposed of in accordance with data protection laws and regulations, avoiding any risk of privacy violation.

Data transfer: when appropriate, the secure transfer of data to participants or another designated entity should be facilitated, ensuring that data is maintained in compliance with regulations and that continuity of services to consumers is preserved.

Participant support: During the closing of the project, participants should receive support and guidance to help them finalize their sandbox activities, including information on how to end operations and how to fulfill all contractual obligations.

Consumer assistance : Consumers impacted by the discontinuance should be informed about how to continue using alternative services and receive compensation, if applicable. Ensuring that consumers are adequately assisted is critical to preserving trust in the system and minimizing negative impacts.



Final Considerations

The implementation of regulatory sandboxes represents an opportunity for innovation to drive development. The instrument has the potential to shape new regulatory paths, providing balance between consumer protection, regulatory modernization and incentive to innovation, in line with the objectives of the Regula Melhor Strategy, established by Decree No. 12,150, of August 20, 2024.

The Regulatory Sandbox Reference Guide presents the main guidelines for the harmonization of understandings and the standardization of procedures in the field of Public Administration, bringing legal certainty to the regulatory environment and contributing to the consolidation of a more efficient and adaptive regulation.

The General Attorney's Office (AGU), through Labori, reinforces its commitment to advancing the innovation agenda, playing a central role in promoting the legal certainty necessary for the transformations taking place in the various economic sectors. The Secretariat of Competitiveness and Regulatory Policy of the Ministry of Development, Industry, Trade and Services (SCPR/MDIC), in turn, strengthens its role in regulatory improvement with the coordination of a systematic improvement process. Thus, the effort in providing qualified contributions to the discussions around the complexity of regulatory challenges persists, aiming at the discovery of solutions that promote competitiveness, productivity and innovation.

It is our hope that this guide will be decisive for the transformation of markets, the modernization of regulatory actions and the strengthening of the capacity to innovate. A special invitation is extended to all stakeholders – regulators, regulated actors and citizens – to participate in the next steps of this journey. This reference guide is a living document that will be improved and updated over time, in order to contribute to a regulatory environment that adheres to the needs of a constantly transforming market.

Contributions may be sent to labori@agu.gov.br.

The team that developed this guide remains available for dialogue and partnerships in the implementation of this important instrument in all spheres of Public Administration.

Final Notes

1. BRAZIL. Complementary Law No. 182, of June 1, 2021. Establishes the legal framework for startups and innovative entrepreneurship; and amends Law No. 6,404, of December 15, 1976, and Complementary Law No. 123, of December 14, 2006. Official Gazette of the Union, Section 1, Brasília, DF, June 2, 2021. Available at: https://www.planalto.gov.br/ccivil_03/leis/lcp/lcp182.htm. Accessed on: September 15, 2024.
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