REGULATORY SANDBOX TOOLKIT

A Comprehensive Guide for Regulators to Establish and Manage Regulatory Sandboxes Effectively

TECHNICAL PAPER

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Acknowledgements

Table of contents

FIGURES

TABLES

1 Introduction

About regulatory sandboxes

Regulators in today's fast-paced technological environment are confronted with the challenge of striking a fine balance between safeguarding consumer protection and market integrity while fostering innovation. Technologies such as blockchain, FinTech, and Artificial Intelligence often do not completely align with existing regulatory frameworks. This can create uncertainty, which can stifle innovation as businesses might hesitate to invest in new technologies without clear regulatory predictability. Additionally, they face the challenge of adapting their regulatory frameworks to keep pace with technological advancements.

One way to try to address and mitigate such dynamics is through "Regulatory Sandboxes" (RS), an important instrument of Regulatory Experimentation (RE). **A regulatory sandbox typically involves a temporary regulatory waiver or flexibility, allowing new products, services, or business models to be tested with fewer regulatory constraints. The purpose of sandboxes is to understand the opportunities and risks associated with specific innovations and to develop an appropriate regulatory environment to accommodate them effectively** (OECD, 2024[1]) and (Federal Ministry for Economic Affairs and Climate Action (Government of Germany), 2023[2]). RS offer a proactive solution to the problem of regulatory uncertainty by creating a controlled environment where innovators can test new products and services. They create a conducive environment for innovation by allowing businesses to test new products, services, and business models in a controlled and supervised setting. This approach fosters experimentation without the immediate pressure of full regulatory compliance and immediate generalised consequences, thereby encouraging creativity and technological advancement. Sandboxes are, for instance, considered a key tool in the development of privacy enhancing technologies (OECD, 2023[3]) and in linking more formal regulation to standards, as is important in the case of AI (Ferrandis and Perset, 2023[4]). By providing a structured yet flexible framework, RS help innovators navigate regulatory challenges and bring innovative solutions to market more efficiently.

In addition, RS allow for a more proactive and collaborative approach to regulation. Innovators gain clarity and support from regulators, which facilitates the development and deployment of new technologies. Regulators, in turn, can gain a deeper understanding of emerging trends and increased capacities for designing and implementing more informed and effective regulatory policies. This direct interaction helps them understand the practical implications of new innovations, allowing them to adapt regulatory frameworks proactively. In this way, regulators also benefit from sandboxes by gaining firsthand experience and insights into advancing technologies and business models. Further, regulators can utilise the experimental environment themselves for testing new or alternative approaches to regulation such as outcome-based regulation or negative licensing. **Sandboxes are a learning tool**, enabling regulators to identify potential risks, trial new regulatory approaches and ultimately develop informed policies that balance innovation with consumer protection and market stability.

About this Toolkit and how to use it

This Regulatory Sandbox Toolkit offers a comprehensive guide for regulators to establish and manage regulatory sandboxes effectively. The purpose of the toolkit is to help the regulator set-up and manage controlled environments where new financial products, services, or business models can be tested with real consumers under relaxed regulatory conditions, but with regulatory oversight.

The toolkit is structured into three key components, each serving a distinct purpose, ensuring a structured and effective approach to regulatory experimentation:

1. The Regulatory Sandbox Guidebook (RS Guidebook)

This first part provides a comprehensive guide for designing, executing, and evaluating a RS. It sets out the overarching concepts, methods and good practices (tips") that help regulators navigate the regulatory challenges of emerging innovations. The RS Guidebook examines three RS phases: (1) Planning and designing; (2) Executing; and (3) Closing and learning from the sandbox. Each phase contains key steps, including stakeholder engagement, risk management, regulatory flexibility, and performance measurement. Before starting, regulators should first review the "Sandbox Test" (Annex A) to determine whether an RS is the appropriate tool for their needs.

2. The Regulatory Sandbox Workbook (RS Workbook)

This part is designed as a practical fillable step-by-step guide for users that helps regulators and stakeholders document and structure their sandbox initiatives. The workbook contains RS diagnostic tests (the Legality Test and Suitability Test) that assess whether a regulatory sandbox is feasible and beneficial. It also includes blueprints or canvases for the different sandbox phases, enabling users to define objectives, identify key stakeholders, assess risks, and determine necessary resources. Users are encouraged to fill out each section sequentially, following the structure outlined in the RS Guidebook.

3. Instructions on Filling out the RS Workbook

This third component support the practical work of the user, providing explicit guidance on how to complete the RS Workbook effectively. Each instruction corresponds to a section in the workbook, ensuring that users correctly input data, define regulatory requirements, and set measurable Key Performance Indicators (KPIs). It outlines specific steps for drafting the sandbox application, mapping stakeholders, setting up data collection processes, and developing an evaluation strategy. The instructions ensure consistency in regulatory experimentation and provide clarity on how to structure sandbox activities for maximum impact. Regulators and participants are encouraged to refer to these instructions at each phase of the sandbox lifecycle to ensure alignment with best practices.

> *NOTE:* Is a regulatory sandbox the right tool? The steps outlined in this Toolkit take for granted the decision to launch and run a RS. However, a RS is not a silver-bullet solution, and it might not adequately address the regulatory challenges regulators might face, or it might not be necessary. Regulators should therefore consider the "Sandbox Test" outlined in Annex A (attached to the toolkit) before embarking in the RS process.

Inspired by and building upon good practices in developing agile and future-proof regulatory frameworks in the OECD countries, the toolkit also closely aligns with the Recommendation of the OECD Council for *Agile Regulatory Governance to Harness Innovation* (OECD, 2021[5]) and the OECD Framework for the Anticipatory Governance of Emerging Technologies (OECD, 2024[6]). It promotes forward-looking governance by helping regulators anticipate and monitor the implications of high-impact innovations, fostering continuous learning and adaptation. It is designed to encourage outcome-focused regulatory

approaches, supporting experimentation and testing under regulatory supervision to ensure a structured and safe environment for innovation.

> *TIP:* Ensuring the legality of Regulatory Experimentation. The most explicit way to ensuring RE legality is through regulatory experimentation clauses, legal provisions allowing temporary exemptions from current legal rules. Annex B. provides guidance on how to formulate an experimentation clause. It also lists examples of experimentation clauses introduced across various sectors in selected countries.

2 The steps of a sandbox

Step 1. Planning and designing the sandbox

Creating a regulatory sandbox is a strategic step towards fostering innovation and testing new technologies under a controlled regulatory framework. This chapter guides the reader through the crucial phases of conceptualising and structuring a regulatory sandbox that effectively supports innovation while managing risks.

Planning and design are foundational to the success of the sandbox. It involves critical decisions about the scope, objectives, and operational mechanisms of the sandbox, including eligibility criteria, and the envisaged regulatory flexibilities. Additionally, this chapter will discuss the importance of establishing robust governance structures and transparent processes that ensure fairness and accountability.

What to find in this step

- Designing and launching the application process
- Prototyping the sandbox
- Consulting on the sandbox design

1.1 Designing and launching the application process

Regulatory sandboxes are controlled experiments with selected participants over defined periods of time. They can be triggered through two different approaches:

- **"Innovator-driven RS":** this scenario assumes that it is a (private sector) entrepreneur and innovator that prompts the regulator about the opportunity to run a RS, in the light of perceived or real regulatory barriers hampering the scaling and diffusion of its innovation. Accordingly, the regulator launches a time-defined or open call for interested parties to submit proposals.
- **"Regulator-driven RS":** in this alternative scenario, it is the regulator that initiates a RS, for instance, if it decides to test an alternative (simplified) regulatory design or enforcement regime and appraise its validity over the current requirements and practices. In this instance, the regulator must first "make the case" for a RS and then open the possibility to interested parties (businesses and stakeholders) to participate.

Figure 2.1. Steps of a sandbox
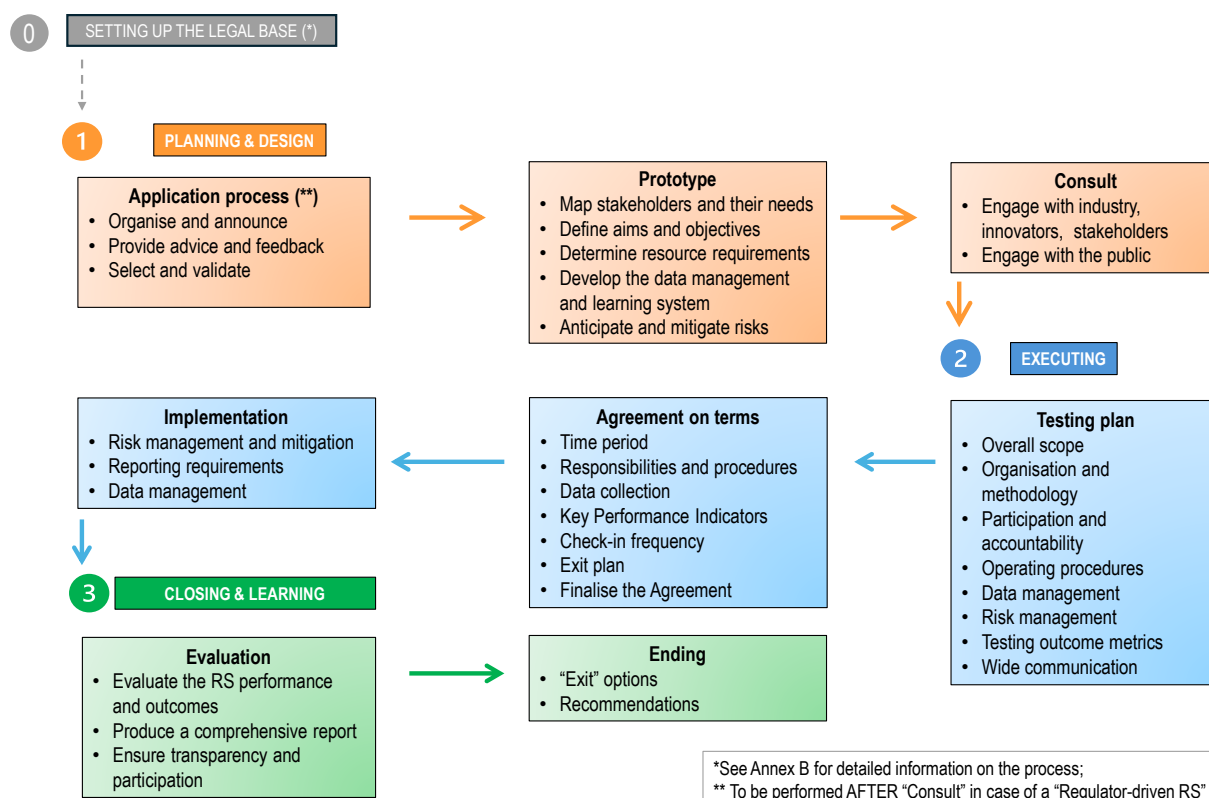
NOTE: This Toolkit considers the "innovator-driven RS" scenario as the standard scenario. The designing and launching of the application process is therefore the first stage of Step 1. Should regulators instead be in the "regulator-driven RS" scenario, then this stage should be considered after Step 1.3 Consulting on the sandbox design

In this early stage, potential applicants have a high demand for advice for the application, the eligibility and assessment criteria, which the regulator has to fulfil by providing information material, but also providing informal support via phone. Other target groups have to be contacted directly and motivated convincingly, if their involvement is necessary for the success of the regulatory sandbox.

The potential stakeholders interested in participating in a regulatory sandbox have to apply. In order to assure the success of a regulatory sandbox and to select the most promising participants, eligibility criteria have to be defined. The type of innovation, but also of the company has to fit to the scope and focus of the regulatory sandbox. There should be a sufficient level of innovativeness, which goes beyond the already existing products and services in the targeted market. However, also the consumers or the society as such should benefit. Very important is to identify the barriers caused by the current regulatory framework, such as administrative burdens and overlapping legal frameworks. Finally, the innovators have to disclose a plan for testing their new product including clear objectives, parameters and success criteria, but also risk mitigation strategy.

→ See **Instruction 1** for more details.

1.2 Prototyping the sandbox

Once regulators have decided that a regulatory sandbox is an appropriate instrument for their objective and is a good fit for their regulatory context and needs, they can start to design it. This process begins with creating an initial sandbox design proposal – a first version, or 'prototype' of the sandbox that explains the essentials of what it will do and how it will work.

To create the prototype, begin by identifying stakeholder and their needs and learning from other sandbox implementations (see references and additional resources) and from any stakeholder engagement to date, before defining aims and objectives, specifying design parameters, determining resource requirements, and anticipating and mitigating risks - see Box 2.1.

Box 2.1. How to create a sandbox prototype

- Map stakeholders and their needs: Identifying stakeholder needs helps to understand who should be involved in a sandbox, what their roles would be and how they might interact. One approach of clarifying the relevant stakeholders is to perform a mapping exercise differentiating between the core stakeholders, other active or occasional participants and groups in the surrounding environment. Regulators have to clarify the aims and goals of the sandbox by identifying how it could address the needs, interests, challenges, and uncertainties surfaced through ongoing informal engagement with key stakeholders, particularly industry and innovators, but also consumers and other societal groups, and extract key points indicating stakeholder needs and challenges. → *See **Instruction 2** for more details.*

- Define aims and objectives: Before developing the different elements of the sandbox, regulators have to define its objectives. This step is necessary to shape what the sandbox has to look like in practice. The objectives should be identified and elaborated in collaboration with the core stakeholders of the regulatory sandbox. It is recommended to reach and codify a consensus on common aims. Although differing expectations challenge the performance and eventually the success of regulatory sandboxes, they can be also an option to clarify these differences during their performance. However, agreed objectives facilitate the evaluation of regulatory sandboxes.

- Determine resource requirements: Once the aims, objectives, and design parameters of the regulatory sandboxes have been specified, it is important to assess the required resources to perform it. The resources cover physical and digital infrastructure, data, experts for the focused technology, and the derived innovations, but also for stakeholder engagement and eventually of its evaluation. Furthermore, operational capabilities, like communication, legal capacities, and IT infrastructure are needed, as well as support for the participants of regulatory sandboxes, via trainings and other support. → *See **Instruction 3** for more details.*

- Identify and mitigate risks: When designing the regulatory sandbox, it is very important to elaborate an initial profile of the potential risks that may be experienced in implementing. This needs not to be exhaustive, but should allow for the identification of "red flags". Regulators should already consider countermeasures that can be deployed to mitigate those risks. → ***Instruction 6** can guide this exercise.*

- Develop a data management and learning system: Regulatory sandboxes can be a crucial learning opportunity for regulators, but also the other involved stakeholders, and sector and society as such. However, it is important to set-up a specific strategy to capture all experiences, but also to disseminate them. For example, data collection and analysis has to be planned,

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including the definition of key performance indicators and their measurement, as well as the dissemination strategy. The level of detail and frequency of formal monitoring depends on the complexity of the products and services covered by the regulatory sandboxes, their life cycles, but also by the potential risks generated. The gained insights have to be shared among the participants of the regulatory sandbox, but also other impacted stakeholders including other regulators and policymakers. Finally, the reporting responsibilities have to be determined. →
*See **Instructions 7 and 8** for more details.*

*TIP: **How many discussions should be organised?** If planning to launch a sandbox, regulators should have already engaged with industry, innovators, and the public to help determine whether a sandbox is the appropriate instrument. If discussions have already been conducted, consider whether there is a need to speak with more or different types of stakeholders at this stage. If regulators are already in close interaction with them, they can perhaps revisit their previous insights by adjusting key ideas that should inform the redesigned sandbox. An understanding of stakeholder needs, interests, and challenges will evolve over time; therefore it should be documented and continuously revised.*

*TIP: **Where to get inspiration from?** Learning from other regulatory sandboxes can be very helpful. In order to not start from scratch, try to contact other regulators, who might have dealt with similar objectives and learn from them in setting up the regulatory sandbox. This step could also include conducting desk research to review descriptions of already performed regulatory sandboxes. Learning from these examples can help in the design process by providing typical models of regulatory sandboxes on which to base the design of the one being developed. Particularly, they can help to identify critical parameters where the design of the sandbox needs to be adjusted, or to show difficulties where other regulatory sandboxes failed or performed unsatisfactorily.*

1.3 Consulting on the sandbox design

Consulting widely is vital not only to validate and enrich the sandbox design, but also to inform and address perceptions, concerns and expectations. After determining the objectives of the regulatory sandbox with the input from the core stakeholders, they should be shared and disseminated among a broader set of stakeholders, even via a formal consultation to collect further feedback. This feedback will help to assess the general interests in the regulatory sandbox, but also to shape its feature, to eventually validate it, and to anticipate its possible impacts.

The consultation process should be shaped along two axes:

- *Engaging with industry, innovators and other stakeholders* – The interaction with industry in general, the innovators in particular, but also other stakeholders interested in participating or contributing to the regulatory sandbox will reveal its relevance. It is also crucial for its success to eventually define its scope and focus and to align its purpose and functionality between the regulator and industry, but also other stakeholders. The success of the regulatory sandbox will become more likely, the more that is known about the motivations of the participants, the support needed and opportunities to get users involved. Overall, an open and transparent engagement with industry and innovators and all other relevant stakeholders will not only ensure that the regulatory sandbox considers users' needs, but it will also demonstrate regulators' commitment in promoting innovation.

- ***Engaging with the public*** – The public is also an important stakeholder, which will be impacted by the regulatory sandbox. For example, individuals can participate as users or consumers, but this requires their consent. For the success of other regulatory sandboxes, general support by the public can be helpful. Within a collaborative process, the interaction with the public can help to elaborate on the scope of the regulatory sandbox, identify the preferred design option, and also its likely or expected impacts. However, engaging the general public can often be a difficult process—including the identification of the right stakeholders and how they are engaged. Employing a clear structure for engagement, and associated principles, provided in the workbook are critical to mitigating these challenges to engagement.

→ See **Instruction 2** for more details.

Step 2. Executing the sandbox

Implementation of a sandbox is not "execution in auto-pilot". Because the sandbox is about learning, not everything can be set up ex-ante. It could still be the case that after the design phases, based on consultations and processes, the sandbox is not pursued for various reasons. Learning is an ongoing process that can also imply adaptation and change when things get operational.

Generally, the implementation of a sandbox takes the form of running one or more simulations, or "tests". A Sandbox Test is generally a practical exercise set in real or realistic circumstances, which allow the regulator to observe the implications of the impact of the tested innovation and / or the envisaged regulatory changes and draw the appropriate conclusions. In certain cases, the Sandbox Test may be executed virtually.

What to find in this Step

- Designing a testing plan
- Getting agreement on the terms of the sandbox
- Implementing the sandbox test

2.1. Designing a Testing Plan

Regulators should work closely with all the entities participating in the test to draw up the "Testing Plans". In essence, a Testing Plan outlines what will be tested, how it will be conducted, and why the test is designed in a particular way. ***Each Testing Plan is ad hoc – designed, executed, managed and supervised on a case-by-case basis.*** While the Plan differs in content from one sandbox to the other, it should include standard elements – see Box 2.2.

The preparation of a Testing Plan is usually quite intensive. To develop the testing agreements and exemptions usually requires a few dedicated staff.

→ See **Instruction 4** for more details

> **TIP: *When is the Testing Plan a good plan?*** As a basic rule, after having elaborated the plan, one should feel confident that, if the test is conducted as planned, it will be possible at the end to decide on the next steps will be and choose one of the envisaged "Exit Options" (see Point 3.2 below). In reviewing a draft Testing Plan, one should confirm that the plan is comprehensive and clear.

> **Box 2.2. What the Testing Plan should include**
>
> As a minimum, the Testing Plan should:
>
> - **Overall scope:** Describe precisely what is being tested, how it is being tested, and why the test takes the shape it does. Define also the overall timeline and budget of the testing phase.
> - **Organisation and methodology:** Describe each testing stage (i.e. when and where the test is run and how it unfolds) and the test iterations (i.e. if and how many times a test is repeated).
> - **Participation and accountability:** For each stage and iteration, identify the staff needed and all other participating actors and service partners, their roles and their responsibilities.
> - **Operating procedures:** Establish rules of engagement for each actor participating in the test, covering the launch, execution, data collection and monitoring, evaluation and reporting stages; as well as communication channels and protocols among the participants throughout the test.
> - **Data management:** Agree data collection, validation, processing and storage protocols, including requirements and standards for data and cyber-security; Intellectual Property Rights (confidentiality and transparency) regimes; fundamental rights (privacy, personal data protection, anti-discrimination and hate speech, etc.)
> - **Risk management:** Define the risks that may emerge during the execution of the test and the related mitigating measures (e.g. limited test duration, safety and security of participants and third parties, environmental protection, dispute resolution and compensation plans, remediation measures). Include also plans for exiting or winding down the test in the event of failure or unanticipated risks.
> - **Testing outcome metrics:** Develop an Evaluation Plan. Set out Key Performance Indicators and evaluation criteria, including conditions and standards of "success".
> - **Wide communication:** Elaborate a communication strategy for the wider public, before, during and after the testing phase.
>
> Note: Testing Plans are normally developed under conditions of strict confidentiality between the authorities and the sandbox participants.

2.2. Draw up a legal document on the terms of the sandbox

It is important to develop an legal document with each participant that outlines the terms of the sandbox as a whole, and/or of the individual tests. The legal document (e.g. agreement, contract, license, protocols) formalises the commitments (obligations) and expectations derived from the Testing Plan. The legal document is built upon the Testing Plan – while the Testing Plan defines the operational and evaluation aspects of the RS, the Agreement adds a governance framework. The following items should be endorsed and written into the legal document before beginning the sandbox:

Elements of the legal document	Description
Time period	If the time limit of each test hasn't been established by the overall design of the sandbox or by the wording of an exemption clause, regulators will want to confirm this with each participant depending on what they are testing. The time available for testing varies significantly and can be anything from eight to ten weeks to several years. Longer testing arrangements tend to be used to investigate less mature technologies such as autonomous vehicles
Responsibilities and procedures	Each agreement should also include stipulations on responsibilities and procedures over the course of testing (e.g. how often the innovator will need to share information and in what form) and what should happen if a particular incident should occur (i.e. how and when the test would be stopped). Risk and impact assessments should be done upfront and can help identify areas that will need closer monitoring by the regulator or its agents
Data collection	In order to measure these outcomes, participants and regulators need to identify what kind of data is needed, how this will be collected and by whom. Participants will be expected to provide data through reports, e.g., on the number of complaints or safety-related incidents, and to share raw data where possible
Key Performance Indicators (KPIs)	At this stage, participants should be asked to identify any Key Performance Indicators (KPIs) related to their business objectives (e.g. customer satisfaction), while also working with the regulator to identify other key outcomes that need to be assessed (e.g. environmental impacts in the form of emissions)
Check-in frequency	Regular, informal meetings should be arranged with participants to identify areas of potential concern before issues arise.
Exit plan	Sandbox agreement should also include an exit plan to avoid disruption at the end of the sandbox or if the participant should exit part way through the testing phase. Parties should be given the option to terminate the test at any time.

*TIP: **Have expectations, rights and obligations been clarified?*** The participation in a sandbox does not guarantee a license to operate. It is important that to ensure that all the parties involved understand the purpose and scope of the exercise, along with each respective roles and responsibilities. That is why the agreement is drawn up and signed before beginning any testing. Moreover, since regulatory sandboxes have an experimental character, they might fail. However, what constitutes "failure" can differ for the regulator and for the participants. Therefore, all parties should have the opportunity to terminate or leave the sandbox. Both the conditions must be defined as well as the exit procedure including its ex-ante agreed termination.

2.3. Consider risk management and mitigation measures

The identification of risks, their management, and the elaboration of related mitigation measures are crucial for several reasons – the protection of the safety and security of participants and third parties; the preservation of physical and intellectual property; compliance with standards and rights; the preservation of reputational and integrity assets.

At this stage of the process, the initial risk assessment exercise undertaken in Step 1 must be enriched and completed with more details and rigor, defining the likelihood of risks to occur; their potential impacts; and the resulting priority given to them. Further, there are certain strategies that can be employed to help manage and build a robust system to respond to unforeseen or unknown risks that may not be identifiable ex-ante.

→ *See **Instruction 6** for guidance.*

2.4. Collect and manage data

Running a well-functioning data management system is a critical success factor for a RS because it allows for robust analytics and reporting, helping all actors involved understand patterns, and performance metrics. Good data management reduces redundancies and errors, streamlining operational processes and workflows, making it easier to prepare for and pass audits, demonstrating transparency and accountability

A fundamental activity during the implementation period is the collection and monitoring of the test, according to the performance indicators set out in the plan – see Box 2.3.

Box 2.3. Reporting requirements and data management

Data and information collection should begin as soon as the testing phase begins. Remember to collect relevant baseline data prior to testing. Throughout the testing phase, innovators are expected to communicate and share data with the regulator and bring attention to any issues as soon as they arise. The mechanisms for doing this will have been agreed in the previous phase. Information should be recorded in a standardised way so lessons and insights can be compared. Where resources allow, a dedicated contact person may be appointed for each participant.

The amount of monitoring required will be specific to each sandbox plan and will depend on the level of risk involved in the development of the product or service. High-risk plans will require more frequent monitoring. Accordingly, meetings may be set up or reporting scheduled on a weekly, monthly, or on an ad-hoc basis, whether in person or online.

The regulator will convene regular supervisory and co-ordination meetings with the participants – both bilaterally and together – to share progress reports and updates. Incidents jeopardising safety and protection, data breach, mismanagement or fraud, or other issues leading to potential risks must be identified timely and immediately addressed. On the other hand, a two-way flow of information should be nurtured, providing timely advice and relevant guidance to the participants - from the design phase over the whole performance period of the sandbox. This holds particularly for the detection of possible risks and the elaboration of mitigation measures. The regulator can also oversee the testing of products and services to suggest their further development.

→ *See **Instructions 7 and 8** for more details.*

Step 3. Closing and learning from the sandbox

Upon completion of the tests, an evaluation of what was delivered through the sandbox exercise should be carried out (or, in case: co-ordinate). The objective is to recommend specific courses of actions for the further management of the innovation being experimented, by drawing specific as well as more general lessons. Lessons should address all regulators and public administrations involved or affected by the sandbox; the participants in the sandbox (industry and experts); wider stakeholders who may be affected by the sandbox results; as well as the general public.

What to find in this Step

- Evaluating the sandbox
- Ending the sandbox

3.1 Evaluating the sandbox

The regular monitoring and reporting carried out throughout the testing period facilitates the final evaluation of the sandbox. The evaluation should use the parameters set out at the start of the sandbox to assess the outcomes of each test.

The evaluation should investigate both the process of setting up and running the sandbox and the outcomes from it.

The evaluation should provide transparent and objective information on the following:

Elements of the evaluation report	Description
Introduction	Clearly articulated goals are a fundamental starting point for effective evaluation. This section is a narrative describing the objectives of the sandbox, its timing, the number / duration / location of the tests, as well as the parties participating in the exercise. This part should mirror the Testing Plan, outlining all the procedural steps and the measures undertaken to execute the sandbox.
Assessment	Several points should be elaborated in the appraisal of the exercise, including both results and process considerations: • The extent to which the right data was collected and utilised to evaluate the exercise against the Evaluation Plan • The extent to which all key stakeholders were involved • The appraisal of the efficiency of the exercise in terms of resources • The extent to which the sandbox has achieved its aims and objectives, based on the selected criteria and KPIs • Whether the results of the exercise are sufficiently robust to validate/partially support/disprove the hypothesis and, by extension, to inform the next steps, including potential adjustments to the innovation, additional testing, or moving towards full market entry • What insights emerged during the exercise and how do they relate to the planned outcomes - what was learned from the experiment, including informing future sandboxes • Whether and why the possible risks identified have materialised or not; how they have been addressed and mitigated • Whether the experiment generated additional positive outcomes • Whether it has generated unexpected / unintended consequences, and how these can be avoided.
Conclusions	The conclusions from the sandbox exercise should indicate (as a minimum): • The potential expected public value of the innovation tested, and where further uncertainties may remain • The viability / acceptability of introducing the innovation, under existing regulations • In case, which changes should be made to the regulatory framework to overcome any barriers to authorisation and marketing and to upscale the innovation
Recommendations	The final part of the evaluation report should indicate the follow-up actions stemming from the exercise – see "Exit" below.

TIP: How to maximise learning? Following the spirit of experimenting with all parties involved in the exercise, the evaluation should be carried out in a transparent and participatory manner. The evaluation step is important and adequate time and resources should be devoted to it. Depending on the length of the testing phase and amount of data available, these evaluation reports can take anywhere from a matter of weeks to a few months to complete. In some cases – particularly for complex, larger-scale sandboxes or where the regulator wants to employ a rigorous experimental methodology – it will be valuable to commission an independent evaluator, such as a consultancy, NGO or academic institution, in order to benefit from deeper methodological knowledge and experience. Standardising any information collected and publishing all data and reports in a transparent manner can also benefit other regulators and parts of government.

→ See **Instruction 9** for more details.

3.2 Ending the sandbox exercise ("Exit")

How can the sandbox end? Figure 2.2. illustrates possible exit options.

Figure 2.2. Sandbox exit options
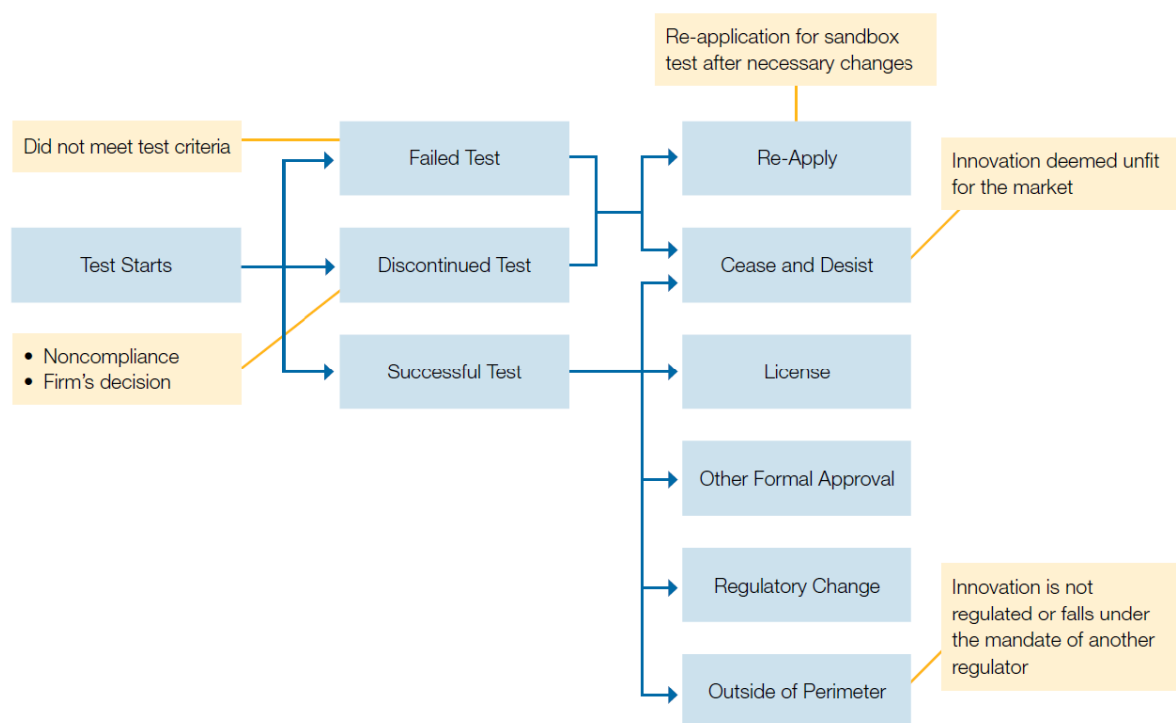
Source: (Jenik and Duff, 2020[7]).

The completed sandbox test may be deemed successful or unsuccessful. However, a successful test means that the test ran as planned, but it does not mean that the sandbox participant will be allowed to bring the innovation to market. That happens only when the sandbox participant wants to proceed, and the regulator considers the innovation subject to its mandate and market worthy.

Even further to a successful testing phase, therefore, possible sandbox outcomes may take the form of a recommendation for:

- **Prohibition to operate** – The sandbox participant is prevented from marketing their innovation because of wider considerations by the regulatory authorities about the overall adverse effects of it onto society and / or the environment.

- **Approval to operate under current licensing regimes** – This corresponds to the regular formal market authorisation procedure. The sandbox participant can fully roll out the innovation in the market in compliance with the regulatory requirements currently in force.

- **Approval to operate conditioned upon modifications** – Such modifications may refer to the need by the regulator to grant exemptions and / or waivers, or to adopt legal amendments; or they may refer to the obligation for the sandbox participant to correct certain elements of the tested innovation.

*TIP: **How to best prepare for an Exit outcome?*** Regulators should carefully map their own regulatory framework against each of the possible outcomes (as shown in Figure 2.2) to determine whether and how easy it would be to implement each. They should avoid setting up a sandbox without having legal clarity on each of the potential exit options. This appraisal is part of the design phases (see Step 1 above).

*TIP: **How prescriptive must the sandbox results be?*** The cases in which the exercise leads to immediate new regulation are rare. The relevant minister should review and approve or modify the recommendations, before engaging in deliberations within the Government. Most sandboxes therefore leave open the possibility of regulatory change, but in practice the resulting changes tend to be to guidance and advice rather than the regulation itself. Proposed regulatory changes will have to go through the formal drafting and consultation process

Annex A. The "Sandbox Test"

Despite being potentially applicable to various policy areas, regulatory regimes and industries, Regulatory sandboxes are just one of the tools available to regulators to pursue overarching societal objectives, amongst regulatory impact assessments, stakeholder engagement and other regulatory management tools covered in the OECD Recommendation on Regulatory Policy and Governance (OECD, 2012[8]). **RS should not be understood as a regulatory approach "by default".**

Prior to embarking on a RS, therefore, the regulator should "make the case" for it. This annex provides some guiding questions – the Regulatory Sandbox Test – assisting with this preliminary consideration. Before running the test, it is opportune to recall what a RS is, and what is not (see Box A.1).

Box A.1. What is and what is not a regulatory sandbox

While there are many different definitions of a regulatory sandbox, the term is here defined as a controlled environment established by regulators to allow businesses to test innovative products, services, or business models with real consumers under relaxed regulatory conditions.

A typical definition of RS include the following elements:

- **Control and testing:** A RS provides a controlled and supervised space where businesses can test new products, services, or business models with real consumers.
- **Regulatory flexibility:** A RS offers temporary regulatory relief, allowing innovators to experiment without immediately needing to comply with all existing regulations.
- **Facilitates learning and adaptation:** A RS helps regulators communicate and explain legal regimes as well as gain insights into advancing technologies, enabling them to adapt regulations based on empirical evidence and real-world data.

To fully grasp the concept of a RS, however, it is equally important to understand what it is not:[1]

- **A permanent regulatory framework:** A RS is not a permanent change to the regulatory environment; it is a temporary, experimental setup. It serves as an environment where digital innovators connect with regulatory frameworks to explore compliance and identify adjustments.
- **A free-for-all:** A RS does not mean a complete absence of regulation; participants must still adhere to certain safeguards and oversight measures.
- **A guarantee of success:** A RS does not guarantee that all tested innovations will succeed or be approved; it is a space for trial and learning.
- **No silver bullet**: While the current practice, indeed, suggests strong benefits from implementing a RS, they do not come without costs. These include both direct time and monetary costs, as well as indirect costs and potential trade-offs; these span from distortion to markets and competition to, in some cases, perceived reduced legal certainty and flexibility, and even adding regulatory burdens as sandboxes come with their own share of rules.

1. See, for an illustrative summary, (Undheim, Erikson and Timmermans, 2022[9]),

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Issues for consideration

A sandbox must respond to a real demand, it should not be a solution in search of a problem. If wondering whether to set up a RS or not, four core issues should be considered, as illustrated Figure A.1 (Jenik and Lauer, 2017[10]).

Figure A.1. Issues to consider before launching the RS process
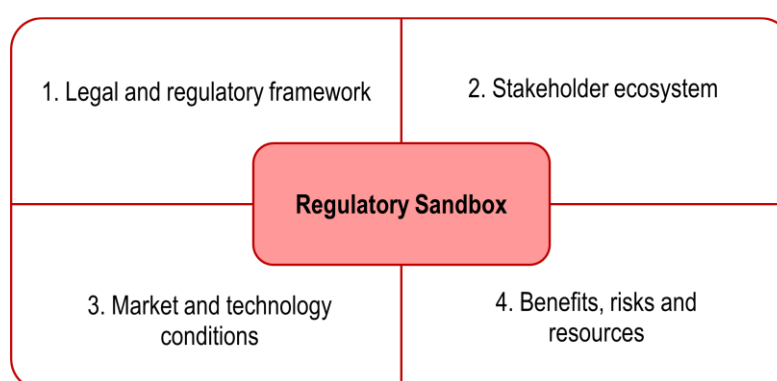
Source: Adapted from (Jenik and Lauer, 2017[10]).

1. **Legal and regulatory framework** – This determines the statutory mandate and hence the legality to set up a RS; the associated discretionary authority; and the overall scope and purpose of the RS.
2. **Stakeholder ecosystem** – Intelligence and an accurate analysis of the socio-economic context is key. This implies actively involving stakeholders both internal to the ministry and the government, as well as external from it including actors in the private sector and the wider public.
3. **Market conditions** – These are defined through the maturity of the technological frontier, the access to (a variety of) R&I investment sources, the demand for innovation and the potential spill-over effects generated from it.
4. **Benefits, risks and resources** – A RS can seldom be run in low-capacities / low-resource contexts. Financial and human resources as well as expertise are indispensable factors. These costs are relevant constraints to setting up a RS, alongside its ancillary risks. Appraising the overall benefits from the experiment as early as possible becomes all the more important.

The Checklist

Accordingly, the Sandbox Test consists of the following **5-tiered checklist**:

1. Is there legislative authority and is regulatory flexibility (exemption) possible?

It is essential to understand the current legal regime and the regulator's room for manoeuvre. This includes

- clarifying that the service or product under consideration for a RS falls under the regulator's regulatory portfolio; and
- ascertaining that the regulator has the authority to issue an exemption (typically, the latter is temporary and ad hoc).

- If existing authorities are not sufficient, applying for a legislative change to enable a sandbox. In such cases, legal teams should be consulted for options on how to achieve exemptions, waivers and/or legislative change.

NOTE: In some cases, RS may require exemptions from multiple legal bases and the involvement and co-ordination of several regulators operating also at different levels of government. All required regulatory exemptions must therefore be identified and confirmed as secured.

→ *For further considerations on regulatory derogations, see Annex B. Also check out the **Preliminary Legality Test** in the Regulatory Sandbox Workbook for further guidance.*

2. Is there sufficient buy-in for a RS?

A sandbox may be initiated in response to requests from individual innovators. However, beware of regulatory capture by individual actors. Do not go ahead without first completing detailed background research and engage as widely as possible with industry and the public. It is important to establish sectorial interest in the RS—shaping the core objectives of the regulatory sandbox, then engaging more widely to generate interests and shape the features of the RS so that they are inclusive of, and useful to, a broad range of relevant actors.

- Consider which stakeholders to consult, why they are being selected (and why others are not), and what the engagement aims to uncover.

→ *For further considerations on Stakeholder Engagement, see **Section 1.3** above and **Instruction 2 – Mapping and Consulting Stakeholders (Step 1)** below.*

3. Is there alignment between the technology readiness and the regulatory timeframe?

If the aim of the RS is to determine regulatory change (either by updating existing provisions or by adopting novel regulation), then it should ensure that advances in the technological frontier, market conditions and regulatory outputs can be aligned within a reasonable and useful timeframe. There is little added value to test early-stage innovations if their actual application to services and products are unclear, or if their actual impacts remain highly volatile and uncertain despite the experimentation. By the same token, as stressed above, it is important that the innovation tested in the RS is widely accepted by society in principle, and does not clash with long-lasting values and beliefs.

NOTE: Comparing technology readiness or innovation maturity with levels of regulatory uncertainty helps. As a guide, regulatory sandboxes are recommended for technologies at Technology Readiness Levels 7-9, however this is very dependent on the situation. Broadly speaking, a RS can be more useful if innovations are still immature but a high degree of regulatory uncertainty. This way, the RS helps develop the technology and regulation in parallel, and by the time the innovation is ready to be deployed, adequate regulations are in place. Similarly, if the novel products and services are market-ready, it is preferable to launch a RS if there is little regulatory uncertainty to deal with. That way, the experiment can be tailored to relatively narrow, technical aspects.

4. Are the overarching benefits from the RS significant (compared to the risks and the available resources)? Is the public interest principle respected?

RS are resource intensive. One of the objectives of engaging with stakeholders and the public is to gauge whether the RS is worth (e.g. in promoting innovation) and determine that the exemption is in the public interest. In this respect, consider "public interest"

- not only as mere compliance with minimum health, safety and security standards,
- but as encompassing a general public benefit, need or welfare as defined with regard to the overall purposes of the main Act,
- and as respecting general procedural an substantive fairness.

At this stage, also determine a preliminary risk-benefit ratio. By their nature, RS require a different approach to risk management and rest on trust and positive perceptions to experimenting. Therefore,

- define the highest levels of accepted risks and set out the conditions required to mitigate risks to safety or security associated to the RS.

NOTE: Set up an advice centre or create better mechanisms to engage directly with industry, consumers and public authorities might be enough to resolve any reported regulatory issues.

→ *For further considerations on Managing risks, see **Instruction 6.** below.*

If any of the above questions have been answered with "NO", the RS should NOT be launched at this stage.

Even if all answers are positive, two additional interlinked conditions should be considered to determine the opportunity to launch a RS (Question 5).

5. Have the innovators' bottlenecks been clearly attributed to regulatory barriers? Is live-testing truly necessary, or could other regulatory tools and methods be used instead?

Remember that RS typically seek to address regulatory barriers to innovation. These are of three types: i) costly compliance, ii) uncertainty created by regulation, and iii) innovation prohibited by regulation. Barriers related to low levels of capital, expertise and ideas available in the market are not adequately solved through a RS.

Existing tools such as administrative simplification analysis and Regulatory Impact Assessment (RIA) already allow for the identification and resolution of many regulatory bottlenecks. The key factor in deciding whether to establish a regulatory sandbox is the **added value** of conducting a live experiment—specifically, whether it will generate unique, actionable evidence to improve the design of formal regulation. This should be weighed against alternative approaches such as co- and self-regulatory regimes, standardisation, or rule-making informed by RIA, risk analysis, or enhanced guidance.

→ *Check out the **Preliminary Suitability Test** in the Regulatory Sandbox Workbook for further guidance.*

Annex B. Legal bases for regulatory experimentation

Regulatory sandboxes include a derogation component. The process is grounded on an explicit legal provision (so-called "experimentation clauses"), which is often be time-bound and ad-hoc. The main aim of these clauses is to introduce legal flexibility enabling the conduct of innovative projects, which may subsequently become a permanent part of the governance framework. Clauses may take various forms and modalities. They may provide for an exemption from a "prohibition"; from an "approval requirement"; or again from "requirements to provide documentation or deploy certain equipment" (Council of the EU, 2020[11]).

NOTE: Some types of sandboxes do not necessarily involve legal exemptions. Instead, they rely on supervision, collaboration and enhanced dialogue, e.g. to provide innovators with certainty on the legal classification of the innovation at hand. In addition, regulators can also allow these exemptions "implicitly" by adopting a wait-and-see approach when tabling new policy or regulatory initiatives. It should be noted that all these approaches are not mutually exclusive, and a country may deploy them jointly or in sequence.

When to formulate an experimentation clause

If focusing on setting a general experimentation clause as part of the legal framework, this step should occur **before** the sandbox planning and design process begins. Specifically, it fits into the pre-regulatory phase, where foundational legal provisions are established to enable regulatory sandboxes or other experimental regimes.

How to formulate an experimentation clause

Formulating an experimentation clause builds on four sets of considerations. Accordingly, the experimentation clause's legal text could be organised along four sections, as illustrated in Table B.1.

Table B.1. Sections of the experimentation clause text

SECTION 1:	Purpose of the testing
SECTION 2:	Institutional, legal and procedural provisions
General part:	Competence; authorisation of authority; Operative part of decision; Object of testing and material limitation
Special part:	Procedural requirements for application; Scope (material and spatial) of the testing; Accompanying obligations; Time limit of permission/approval; Other ancillary provisions; Possibility of revocation
SECTION 3:	Evaluation including transfer; Time limit for the clause
SECTION 4:	Authorisation to issue ordinances or naming of the legal basis

Source: Adapted from (Federal Ministry for Economic Affairs and Climate Action (BMWi), 2021[12]),

Annex B offers guidance on drafting the various sections.

Section 1: Purpose of Testing

The first section guides the competent authority in its decision-making and is an important basis for the way in which the clause is interpreted. The purpose of the testing must be defined and specified clearly, preferably emphasising practical testing and regulatory learning.

- *Example of possible wording:* "The purpose of this rule is to provide for the practical testing of innovation [xyz] and for learning towards the potential development of the regulation for [...]."

Section 2: Institutional, legal and procedural provisions

Section 2 forms the core of the experimentation clause. It consists of a general part that provides the basis for the decision by the competent authority as well as a special part regulating the specific design of the testing.

Section 2a (General part) – First a respective competent authority in consensus with other related authorities must be designated that decides whether and how the testing of an innovation can be carried out and whether it is possible to deviate from specialist legal requirements for this purpose.

- *Example:* "Innovation [xyz] which are not yet recognised by a regulation can be recognised by the [...] agency for a period of up to two years [...]."

The competent authority may **be empowered** in different ways:

- **Binding decision ("must"):** The authority must grant its approval as soon as the requirements of the individual case are met.
- **Simple discretion ("can", "may", "is entitled to", "decides according to due discretion"):** The authority is given room to make decisions. It does this on the basis of due discretion within an expedient scope. As a rule, it has the discretion to decide (the "whether") and to act (the "how"). Such discretionary decisions are subject to judicial review for discretionary errors.
- **Intended discretion ("should"):** The discretion of the authority "should" generally be exercised in the manner specified, unless there are circumstances involved that are atypical. Such a regulation is more innovation-friendly, and it is particularly useful if the risks associated with the testing are expected to be low.
- *Example: "In order to allow for the practical testing of innovation [xyz], the licensing authority may, upon request on a case-by-case basis, authorise exemptions [...].*

Legally, it must be specified in concrete terms **what decision the authority may make**. This is based on three in-depth analyses:

- Where are there legal barriers to innovation [xyz]?
- Where are deviations and exceptions unable to be made due to superior law (e.g. EU law)?
- Does the regulation contain any exceptions that are in contradiction to one another?

The following options can be used to determine the **type of deviation**:

- **Approval or licensing (rule):** The experimentation clause contains the deviations from applicable legal provisions and provides for public space to be temporarily opened up for testing.
- **Mere option for deviation:** Derogations from certain legal provisions are granted without directly conferring any power to the innovator, e.g. empowerment of an authority to issue deviating legal ordinances.

The following options can be used to define the **specific deviations**:

- **Narrow variant:** specific designation of the provisions from which deviations can be made.

  Example: "In justified cases, the competent authority can permit exemptions from the prohibitions of operation pursuant to subsection [abc] if specific preconditions are met. [...]."

- **Broad variant:** It can also be further regulated in law that deviations from the requirements of the respective specialist legislation may be made.

  Example: "[...] authorise exemptions from the provisions of this Act or from provisions adopted on the basis of this Act for a maximum period of four years, [...]."

The key element within the experimentation clause is the **definition of what is to be tested**, formulated in such a way that there is an appropriate balance between specificity and flexibility. **Specificity** ensures legal certainty (e.g. the requirement for certainty under the rule of law, general requirement for equal treatment, right to review and redress) and effectiveness (transparent decision, uniform and targeted application). The authority must be put in a position whereby it is able to decide on the basis of plausible and reliable criteria which innovations are to be tested. **Flexibility** is needed to ensure that there is sufficient openness for innovation and consideration of the given context.

In order to strike the right balance between specificity and flexibility, it is preferable to describe what is to be tested rather than to provide a detailed definition. This specification can be provided in the following ways:

- Use of recognised generic terms for definable subject areas.

  Example: "In order to allow for the practical testing of innovation [xyz]."

- Material limitation serves to balance the advantages of testing with the conflicting interests and concerns. Firstly, material limitation filters out innovations for which testing is non-justifiable due to the fact that it would involve significant risks, i.e. which are therefore not eligible for testing ("whether"). Secondly, this element also specifies the scope within which testing is justifiable ("how"). This scope is then specified by the rules in the special part of Section 2 (see below).

  Example: "Permission shall be granted if the intended operation, if innovation [xyz] does not lead to a danger to the safety of consumers, to a violation of the regulations on data protection, and to nature conservation."

Section 2b (Special part) – In cases where innovators are required to file an application to make use of an experimentation clause, specifications need to be set for the application procedure at the competent authority.

When it comes to **licensing for testing**, it is useful to set **spatial and material limitations** for each of the stages involved as appropriate. This element is optional as it is not required for all types of testing. In addition, the competent authorities will also decide on the permissible scope of testing at the approval or licensing stage. The wording should depend on the level of risk involved.

An open wording may be used when the legislation provides a broad framework for the authorities to exercise discretion. The competent authority is responsible for defining the specific parameters that will apply for an individual case of testing.

- *Example:* "[...] the Ministry can issue ordinances to provide for materially and spatially limited derogations from the following provisions: [...]".

However, it is often useful to set as different spatial and material limitations for each stage of testing as necessary. In many cases, the actual risks associated with testing are not fully known until after testing begins. It is therefore useful to initially set narrower limits, which can then be gradually relaxed if the testing proves safer in practice.

In order to fulfil the government's duty to protect third parties, especially in high-risk areas, and to evaluate the legislative rules, it may be necessary to issue **accompanying obligations** for the innovator, third parties, or for the competent authority. These might particularly include monitoring or reporting obligations and the obligation to participate in scientific studies. Since accompanying obligations may interfere with the fundamental rights of economic operators, they must be justified and proportionate, and their scope must be based on the duty to protect and the legitimate interest in evaluation. The more high-risk an innovation is or the earlier the stage of testing, the more extensive and detailed the monitoring and reporting obligations should be.

- *Example of evaluation:* "Innovation [xyz] may only participate in the market if they are contributing to scientific testing by a research institute."
- *Example of government monitoring:* "The governmental agency shall supervise the suitability of innovation [xyz] during the entire period of the provisional recognition. If the supervision identifies security-relevant risks […], the supervisory body can […] take additional measures to remedy these risks […]."

The **time limit** should be stated clearly, taking into due account both the actual testing phase as well as the associated regulatory learning process. The duration of the time limit can be structured in different ways, and is a prerogative of the competent authority, in close consultation with the parties involved in the sandbox. Both the minimum and maximum amount of time for testing should be indicated, including options for extension.

- *Example:* "In order to allow for the practical testing of innovation [xyz], the competent authority may, upon request on a case-by-case basis, authorise exemptions […] for a period of no longer than four years […]."
- *Example:* "The testing shall be limited to an appropriate period of time. As a general rule, a period of no less than two years and no more than five years is appropriate."
- *Example:* "In the event that an action is brought or an objection filed against the licence, the duration of the time limit shall be extended accordingly." [The process through which the extension is granted could also be set out in the provision.]

Section 3: Evaluation including Transfer

Once an experimentation clause has started to be used in practice, regulatory learning requires it to be evaluated to provide information on whether and to what extent the objectives of the provision are being achieved, how it needs to be improved, and whether and to what extent it can be transferred into standard practice.

The evaluation looks whether the experimentation clause serves to determine whether its individual elements are correctly designed, whether the individual regulatory sandboxes, which are implemented on the basis of the experimentation clause, summarises the experience gained in practice, and whether the law in which the experimentation clause is enshrined needs to be adapted.

It makes sense for the experimentation clause to offer several components and variants such as participation in scientific research and reporting obligations, both for the innovator to the administration, and for the administration to the legislator.

- *Example:* "The Ministry will evaluate the application of the provisions [...] on a scientific basis. The Government shall inform the Parliament of the results of the evaluation."

It is recommended to assign the evaluation to an institution or authority that is superior to the authority responsible for licensing the testing and that can collect information from several authorities.

- *Example:* "The Parliament shall evaluate the law on a scientific basis one year before it expires."

It is advantageous for the experimentation clause to stipulate that the licensee clearly designate the unit responsible for the evaluation of the regulatory sandbox and for transmitting all of the necessary information to the competent governmental agency.

Section 4: Authorisation to Issue Ordinances

Not all requirements for testing innovations need to be regulated in an act of parliament. Instead, there is often the possibility of stipulating the experimentation clause in whole or in part by means of an ordinance, which does not have to go through the parliamentary procedure in order to be enacted. The use of secondary regulation by the Executive is particularly recommended where the elements aimed at reducing risk need to be formulated flexibly, e.g. with regard to procedural requirements such as material limitation, scope, or accompanying obligations. The advantage is that ordinances can be amended more easily if key assumptions, such as risk assessments, change during the course of the testing. This ensures more effective control and increased agility. It can also serve to provide greater administrative guidance, ensure uniform practice among the authorities and accelerate procedures.

The more complex the regulatory area, the more specific the administrative guidance needs to be in the form of secondary legislation. In some cases, an experimentation clause may be stipulated entirely in an ordinance. This is particularly useful for complex and rapidly changing matters.

However, there are limits to what can be regulated by ordinances. Ordinances function within the boundaries set by the separation of powers, the requirement of parliamentary approval, the principle of democracy, and fundamental rights. The basis for these is always an authorisation to issue ordinances enshrined in a parliamentary act. In the event that the experimentation clause is placed in an act, and then further specified in an ordinance, the experimentation clause itself must contain an authorisation to issue ordinances. This authorisation to issue ordinances must satisfy the requirement of parliamentary approval and the relevant constitutional and legal requirements.

- *Example:* "The Ministry shall be authorised to issue ordinances with the approval of the Parliament on […]."

Examples of experimentation clauses

When it comes to explicit legal provisions, it can be useful to distinguish between general laws or provisions enabling regulatory experiments on the one hand, and experimentation-enabling clauses integrated into legislation (either in a given law or in a specific sector).

- **France**, for instance, falls in the first, since the possibility of resorting to experimentation there is enshrined in the Constitution.[1] This provision is the basis for "France Experimentation", an inter-ministerial mechanism in place since 2016, which allows companies to derogate from any legislation or regulation that restricts an innovative project subject to approval (Interdepartmental Directorate for Public Transformation, 2024[13]). Applicants eligible for France Experimentation benefit from tailor-made guidance and support from the predisposed organs; and legal and

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[1] See Article 72 of the French Constitution.

technical expertise by the various ministries concerned. On the basis of the analyses and opinions rendered, each case is submitted to the Prime Minister's Office for deliberation.

- **Italy** adopted "*Sperimentazione Italia*", a general legal provision that seeks to offer companies, universities, research bodies, university start-ups and spin-offs from any sector (except for some excluded areas of application) the opportunity to conduct pilot projects in the fields of digitalisation and technological innovation by derogating regulatory constraints (Department for Digital Transformation, 2020[14]). Temporary regulatory exemptions (sandboxes) may be conceded jointly by the Minister of Technological Innovation and Digital Transition and the Ministry of Economic Development, in conjunction with other relevant authorities, after an ex-ante evaluation based on pre-established criteria. Within 90 days from the date of the positive certification of the experimentation report, the President of the Council of Ministers or the delegated Minister, in agreement with the Minister responsible for the matter, will promote the necessary regulatory measures for the experimentation activity to be carried out. Authorities involved will also subsequently decide whether to introduce permanent revisions to the temporarily derogated regulation—data gathered through allowed experimentations will be presented in a report with a view to informing decisions in that respect.

- Currently, **Germany** does not enjoy a general experimentation clause at the federal level, although it has been on the agenda of the government since 2019 (e.g. a commitment is specified in the regulatory sandbox strategy of the Federal Ministry of Economic Affairs and Climate Action). The draft of the regulatory sandbox law is under preparation by the Ministry and is expected by be released by the end of 2024. Only, the Federal Ministry of Transport and Digital Infrastructure is authorised, under the Road Traffic Act, to issue ordinances with the approval of the Bundesrat on the "licensing of vehicles for road traffic, including exemptions from admission, the characteristics, equipment and testing of vehicles, in particular requirements for the licensing of motor vehicles and their trailers, in particular on the construction, characteristics, inspection and approval, equipment and operation". In addition, there is an experimentation clause in the Carriage of Passengers Act and the Road Vehicles Registration and Licensing Regulations, which allow for the practical testing of new modes or means of transport, like self-driving vehicles, for a maximum period of four years.

- In the **United Kingdom**, the Financial Services and Markets Act 2023 (FSMA 2023) generally empowers HM Treasury to establish sandboxes specifically for financial market infrastructures (FMIs) through regulations called "Statutory Instruments" (SIs). The latter require approval by Parliament. Each SI may establish a specific sandbox with its own legal basis, modifications to existing laws for participants (temporary disapplication, modification, or application) and wider framework (eligible participants and any restrictions on activities). This flexible approach allows for testing different technologies and practices in separate sandboxes. Finally, the learnings from these sandboxes can be used to make permanent changes to UK legislation. HM Treasury will report to Parliament on each sandbox and propose these permanent changes through additional SIs requiring parliamentary approval. Under that regime,[2] the UK is launching a new initiative called the "Digital Securities Sandbox" (DSS) to explore the potential of the novel blockchain technology, also known as Distributed Ledger Technology (DLT). This program aims to revolutionise the way securities are issued, traded, and settled. The DSS aims to address possible current regulatory barriers by allowing companies to test their DLT-based solutions in a real-world setting for five years, albeit under a modified regulatory regime. To implement the sandbox effectively, DSS

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[2] Sections 13 to 17 of, and Schedule 4 to FSMA 2023, give HM Treasury the power to create Financial Market Infrastructure (FMI) sandboxes through Statutory Instruments (SIs) (Government of UK, 2025[23]):

Regulations were adopted introducing targeted modifications to existing UK legislation that impacts the sandbox environment.[3] The DSS Regulations also grant the FCA and BoE specific powers for managing the sandbox effectively. These powers include establishing an application process for participation, implementing joint supervision of the DSS, overseeing participating entities, creating, modifying, or waiving rules for participants, and setting limits on the overall activity level within the DSS (UK Government, 2023[15]).

- **Spain** launched in 2020 a financial sandbox establishing its legal framework through a legislative initiative aimed at fostering the digital transformation of the financial sector. This sandbox aims at pointing out regulatory barriers or uncertainties that may hamper innovation in the financial sector, thus dragging financial entities' efficiency and the improvement of financial services that consumers have access to. The financial sandbox is managed by Spain's Treasury while three sectoral supervisory authorities participate in the oversight of participants as well as in the definition of test protocols and the execution of the projects' tests. In addition, AML/CFT, privacy and data protection authorities take part in the sandbox's activity to ensure compliance. The tests carried out in the sandbox environment can involve real customers and/or dummy ones; while the success of these tests does not represent an automatic authorization to develop licensed activities, it can help to fast track the participant's application for authorization through the usual channels. The activity of Spain's financial sandbox has c shaped regulatory changes in order to adapt the existing financial legal framework to the use of new technologies such as Distributed Ledger Technology.

- **Austria** established and implemented a regulatory sandbox by means of a dedicated legislative amendment in the underlying legal framework of the Financial Market Authority (FMA). By virtue of that amendment, the FMA is granted the necessary competence to establish the framework for the sandbox and implement it. The FMA is only allowed to act on the basis of this law, and not allowed to use free discretion to decide about a participant in the regulatory sandbox. Thus, in the Austrian case, the relevant clause can be categorised as specific experimentation-enabling clause.[4]

- Several countries, including **Denmark**, **Lithuania** and others, have inserted experimentation clauses in their sectoral legislative framework, for instance in relation to energy, health, mobility and financial services.[5]

- **Israel,** for example, have a regulatory clause enabling experimental activities in the field of autonomous vehicles, embedded in 2018 in the Israeli Traffic Regulations, 1961. This clause enables the National Traffic Supervisor to grant an exemption to a subset of provisions for the purpose of conducting an experiment, and in consultation with the Licensing Authority. This decision needs to be made with consideration to potential impacts of the experiment such as road safety, disruptions and providing for emergencies. More generally, Israel has a legal guide to regulatory sandboxes that supports the legal establishment and operations of a sandbox (Roitman, Kaufman and Gedaliahu, 2024[16]).

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[3] Concerned legislation includes the UK Central Securities Depositories Regulation (UK CSDR), the Financial Services and Markets Act 2000, the Uncertificated Securities Regulations 2001 (USRs), and the Companies Act 2006.

[4] Cfr. Article 23a of the Financial Market Authority Act (*Finanzmarktaufsichtsbehördengesetz*, FMABG), entered into force on 1 September 2020 (Austrian Financial Market Authority, 2021[24]).

[5] See (OECD, 2024[1]), esp. Box 1.4. On the energy sector specifically, see (ENTEC, 2023[19]), *Regulatory Sandboxes in the Energy Sector*, Study prepared by Fraunhofer ISI for the European Commission (DG ENR) (ENTEC, 2023[19]).

- A further example from the **United Kingdom** is worth reporting. The UK Financial Conduct Authority (FCA) launched a sandbox in 2016 providing an environment for firms to test innovative products and services in the real market with real customers (Financial Conduct Authority UK, 2024[17]). This initiative has not granted a regulatory exemption, since applicants still need to be appropriately authorised or registered first before carrying out an activity regulated by the FCA. To ensure a fair and competitive environment that protects consumers, the FCA has established clear "conduct of business" guidelines serving as a roadmap for companies participating in the sandbox. A FCA Handbook details the Authority's expectations on compliance and provides practical guidance on how to conduct business within the sandbox, for instance in terms of customers relationship, disclosures and overall transparency. Companies must implement robust systems and controls to guarantee adherence to these regulations, and the FCA has the right to request proof of compliance at any time. Furthermore, companies must have a well-defined complaint handling process in place, and any significant complaints need to be reported to the FCA. To ensure accountability, the FCA may also conduct regular supervisory visits and request reports on business operations. Finally, the FCA reserves the right to impose additional conduct of business criteria on participating companies as they see fit, all with the ultimate goal of safeguarding consumers and fostering a healthy competitive market within the sandbox.

Annex C. Regulatory Sandbox Workbook

The Preliminary Legality Test

The Legality Test *Enter Project Name Here*		*This test is used to determine whether the RS is an appropriate tool for addressing your regulatory challenge – cfr. Question 1. of the Sandbox Test (Annex A)*	
Regulatory diagnostics			
The baseline – AS IS situation		**Desired state – TO BE situation**	
Strengths - What is currently permitted by the legislation?	Constraints - What is currently not permitted by the legislation?	Opportunities - What needs to be changed?	Actions - How do we change it?
Possibilities and opportunities that the current legal framework provides for experimentation within the sandbox. Example; Croatian financial regulations already permit limited-time trials of new digital payment systems under certain conditions. This affordance could allow a fintech company to test a blockchain-based payment system within the sandbox without needing to undergo full regulatory approval beforehand.	Legal or regulatory limitations that might restrict what can be done in the sandbox. Example: In the same fintech scenario, if existing regulations prohibit the use of cryptocurrencies for transactions, this constraint would need to be considered and potentially addressed through temporary exemptions within the sandbox.	Identify specific regulatory or operational aspects that must be modified to make the sandbox feasible or effective. **Example**: If current regulations prohibit any form of digital-only identity verification for financial transactions, this would need to change to allow fintech companies to test new digital ID methods within the sandbox.	Propose solutions or steps to overcome the identified constraints or regulatory barriers. Example: To enable digital identity verification in the sandbox, a possible change could involve granting a temporary exemption or modifying the relevant regulation to allow a pilot program for digital ID verification, with strict oversight to ensure security and compliance during the trial period.

The Preliminary Suitability Test

The Suitability Test *Enter Project Name Here*		*This test is used to determine whether the RS is an appropriate tool for addressing your regulatory challenge – cfr. Question 5. of the Sandbox Test (Annex A).*	
Regulatory diagnostics			
The regulatory challenge		**Desired state – TO BE situation**	
What is the challenge?	Why is it a challenge?	What are the benefits from addressing it?	How do you address it with a regulatory sandbox? Are there alternatives?
Identify the specific issue that the sandbox is intended to address. **Example**: A regulatory authority notices that current financial regulations are too rigid to accommodate rapidly evolving digital banking technologies. The problem might be defined as "Inability of current regulations to support innovation in digital banking, affecting fintech startups' ability to scale."	Explain the underlying reasons why the identified issue is significant and needs to be addressed. It explores the impact of the problem on stakeholders, the market, or broader societal goals. **Example:** In the case of digital banking, the problem might be that existing regulations are too rigid, preventing fintech startups from introducing innovative digital services quickly. This rigidity stifles competition, limits consumer choice, and may lead to the market being dominated by a few large players who can better navigate the complex regulatory environment.	Identify specific regulatory or operational aspects that must be modified to make the sandbox feasible or effective. **Example**: If current regulations prohibit any form of digital-only identity verification for financial transactions, this would need to change to allow fintech companies to test new digital ID methods within the sandbox.	Explains the urgency of addressing the problem, highlighting any immediate threats, opportunities, or timing considerations that make it critical to act quickly. **Example**: In the context of digital banking, the need to solve the problem now could be due to the rapid growth of fintech startups that are outpacing traditional banking regulations. Without timely updates to regulations, these startups may either be forced to operate in a legal gray area or move their operations to other jurisdictions, leading to a loss of innovation and competitiveness in the domestic market. **Are there better options than the RS to address the challenge? If the answer is YES, the RS is not the right approach in this case.**

The Regulatory Sandbox Blueprint – Step 1: Planning and design

The RS Blueprint: *Enter Project Name Here*		This section provides a detailed roadmap for setting up and executing the regulatory sandbox, including steps for design, stakeholder engagement, risk management, resource allocation, and monitoring progress to ensure the sandbox achieves its intended goals.		
	STEP 1: Planning and Design			
Stage	**1.1 Design and launch the application process**	*1.2 Map out and engage the RS stakeholders*	**1.3 Define aims and objectives**	**1.4 Determine the needed resources**
Consider	*What are the criteria applicants must meet to participate in the RS? Is your application process, including the testing plan instructions, well-structured and easy to understand? Is your onboarding process efficient?*	*Who are the key stakeholders? What are their key needs and constraints?*	*What is your key objective? What are you aiming to achieve??*	*What resources do you need to run the RS effectively?*
Action points	**#1 Create a structured application process** that is easy to understand and complete. This should include application forms, guidelines, and submission deadlines. **#2 Establish criteria** that applicants must meet to participate in the sandbox, such as industry focus, innovation type, and regulatory relevance. **#3 Require applicants to submit a detailed testing plan as part of their application**. The plan should outline their objectives, methodologies, success criteria, and how they will collect and manage data. **#4 Launch the application process** and promote it through relevant channels to attract qualified participants. **#5 Set up a review process to evaluate the applications** based on the eligibility criteria and the quality of the submitted testing plans. Example: For a fintech regulatory sandbox, eligibility criteria might include being a registered financial service provider, having a viable digital payment solution and demonstrating the potential for regulatory impact. Develop an online application portal where applicants can fill out their details, upload necessary documents, and submit their applications. A testing plan could include a pilot program with a specified number of users, metrics for assessing loan processing speed and accuracy, and strategies for data security.	**#1 Identify and map key stakeholders.** Identify key stakeholders, and clearly define their roles and responsibilities. **#2 Address key stakeholder needs.** Document specific unmet needs: clearly outline the business, regulatory, and policy gaps that your regulatory sandbox (RS) is designed to address. Pinpoint and analyse key areas of regulatory uncertainty: determine the areas where current regulations are unclear, and develop strategies within the RS to explore and clarify these uncertainties. Define and target desired benefits: specify the benefits you intend to achieve through the RS for industry players, innovators, regulators, consumers, and society as a whole. **#3 Consult and engage key stakeholders**: develop a plan to actively involve and gather input from all relevant stakeholders, ensuring their contributions shape and support the RS.	**#1 Clearly define the primary goal or purpose of your sandbox initiative**. Articulate the main outcome you want to accomplish through the sandbox, whether it's testing a new technology, refining regulatory frameworks, or driving innovation in a specific sector. Example: The key objective of the sandbox might be to evaluate the viability and safety of using AI-driven algorithms for automated loan approvals in the financial sector. The aim is to gather data on how these algorithms perform under various conditions, assess their impact on decision-making accuracy and fairness, and ultimately inform new regulations that balance innovation with consumer protection.	**#1 Assess the resources—time, people, and funding.** Time: Running a sandbox takes time, but it yields higher quality evidence. Consider if you need quick answers or if thorough, slower results are more valuable. People: Evaluate if your team has the capacity and skills needed or if you'll need additional staff to manage and analyse the sandbox. Funding: Determine your budget constraints and weigh the costs of experimenting versus the risks of not gaining critical insights through a sandbox.
Inspiration	To establish the eligibility criteria for your RS and appraise applications, see **Instruction 1 – Application and Participant Selection Process (Step 1)**	For detailed instructions on stakeholder identification and engagement, see **Instruction 2 – Mapping and Consulting Stakeholders**	See **Box 1.1** of this Toolkit for more information on defining aims and objectives	For detailed instructions on how to determine resources and create a needs assessment,, see **Instruction 3 – Resources Assessment.**

Instruction 1 – Application and participant selection process (Step 1)

RS run over defined periods and engage a limited number of innovators. While RS might be repeated and hence there may have an open, ongoing application process, the eligibility criteria and the selection period should be standardised. This allows regulators to better manage resources and adapt each iteration of the RS, while the open approach allows firms to engage with the regulator at any time when they are ready to test an idea without giving preferential treatment to one entity.

During the process, regulators often provide informal advice to applicants on what they might need to consider when completing applications, explain the eligibility and assessment criteria and what is required from applicants.

Eligibility criteria
Potential participants in RS are typically required to submit applications that are judged on specific eligibility criteria. Eligibility criteria will depend on the scope and focus of the RS but generally will cover five dimensions
Innovativeness – Participant must demonstrate one of the following forms of innovations in its proposed solution: • Innovative products, services, processes, and business models: companies proposing a new business model that leverages emerging or advancing technologies • Scale-up of solution: significantly scale-up of an existing emerging or advancing technology
Need for Regulatory Amendment – Regulation can also be a driver of innovation by providing important preconditions such as a general framework for competition, consumer protection and business processes. Regulatory amendment in many cases may be required due to: • Achieving regulatory compliance takes time and might need to be done gradually • Uncertainty about regulations • Need for waiver, administrative simplification, or deregulation • As a guarantee that controlled risks can be taken without any backlash
Technological Readiness – Participant should ensure that the technology readiness of their business model, products and services fall under one of the following categories: • Fully commercial system that is readily available for customers • First-of-a-Kind commercial system complete and qualified • Demonstrated system operating near commercial scale (advanced prototype)
Societal Benefits – Participant must produce sufficient evidence showing that: • The innovation proposed offers an identifiable and direct benefit (e.g., reducing cost or improving quality of service) or indirect benefits to consumers (e.g. increasing competition), but also society as such (e.g. green innovation) • It has adequately identified and addressed any risks for consumers, markets, and society resulting from its proposed innovation • It has put in place a suitable mitigation plan to manage those risks and ensure protection to consumers throughout the testing
Commercial Potential – Participant must provide prove that the innovation proposed has strong commercial viability with: • A commercial presence with one or more successfully marketed products and solutions; and • A robust business plan • Proof of business financial viability / funding (including with regard to the capacity to sustain the costs linked to the participation in the sandbox)
Testing and Exit Plan – Participant must produce a well-developed testing and exit plan (exit after successful testing and for the event of discontinued testing) that contain: • A comprehensive testing plan with key milestones and detailed timelines • A clear methodology of the testing and controls required • Test team named with details of their roles in the test and within the overall organisation • Reporting schedule stating the format and content (e.g. KPIs) of the report to be submitted to the regulator throughout the testing • Plans to scale-up its innovation to a larger market should the testing be successful • Clear and measurable consumer safeguards

The appraisal of the applications varies from one RS to the other and the criteria and scoring systems should therefore be designed on a case-by-case basis. Nonetheless, one can make reference to broad positive and negative indicators that can guide the selection process:

Positive Indicators in Applications	Negative Indicators in Applications
Innovativeness	
Few or no comparable offerings in the national market.	Several examples of similar technologies already deployed in the national markets
Offering / solution leverages emerging or advancing technologies	Offering / solution only leverages conventional technologies
Participant produces a comparison of key features of business model, product or service highlighting where it is differentiated vs. competitors	Participant is not able to prove that their offering is significantly different from the existing ones in the market
Need for regulatory amendment	
Participant proves that there is a need for regulatory waivers or revisions to be able to commercialise their offering / solution	Participant is unable to establish that there is any scope for regulatory reform or need for waivers
Offering the solution outside of the RS carries a significant risk of incurring penalties or facing regulatory / legal action	Offering the solution outside of the RS bears no risk of incurring penalties or facing regulatory / legal action
Technological readiness	
Participant successfully proves that full commercial system is readily available for customers	Participant is only able to demonstrate an intermediate prototype or a pilot prototype
Participant has successfully demonstrated a First-Of-A-Kind commercial system that is complete and qualified	Participant is only able to demonstrate small scale system tested in a laboratory
Participant has successfully demonstrated a system operating near commercial scale (advanced prototype)	Participant is only able to demonstrate basic function or formulate the technological concept
Commercial potential	
Participant has a commercial license for one or more successfully marketed offerings	Participant has no commercial licence or partnership agreement with national authorities licenced business
Participant has a strong business track record	Participant has a commercial licence, but shows no or limited commercial activities
Participant has a robust and promising business plan	Participant has an unproven or unviable business plan
Participant is adequately capitalised on their balance sheet or agreed available funding (debt or equity or corporate budget)	Participant has limited evidence to show how they will fund tests
Societal potential	
Participant provides research or simulation results showing potential benefits such as reducing cost, customer experience, efficiency, quality of product, lower prices, environmental footprint, etc.	Participant is unable to articulate how the innovations that are proposed can result in a clear benefit, whether direct or indirect, for consumers or society as large
The participant can produce a comprehensive assessment of risk to consumers and other societal stakeholders, including the environment as well as a mitigation plan to ensure consumer protection, but also other societal concerns, e.g. environmental protection	Participant is unable to provide a detailed set of risks including a set of mitigants that will ensure an adequate degree of consumer protection and the protection of other societal objectives.
The participant has sufficient resources in place to provide appropriate redressal to consumers and other societal stakeholders if required	Participant cannot deploy resources proportional to the risks identified in case a redressal is required
Testing and exit plan	
Participant produces a comprehensive testing plan that identifies key milestones, a timeline, and likelihood of achieving target outcomes	Participant is not able to provide CST with the results of any previous research or results of lab simulations carried out prior to the submission of the application

Participant can demonstrate that the resources and test team credentials required to start testing can be successfully mobilised	The participant cannot demonstrate that the test team has the skills or ability to mobilise the resources required to conduct the testing
Participant proposes key metrics and parameters to be used and methodology for their analysis	No clear description around on metrics that will be measured, or the tools used to capture information
Participant produces an exit strategy that clearly identifies the various possible endgames of the testing exercise (incl. discontinued testing)	The participant's existing strategy is inconclusive with no provisions for settlement of obligations (if any)
The participant's exit strategy contains details on resources needed to scale-up the technology to serve a larger market and estimated timelines	The participant's exit strategy provides simplistic description to scale-up the operation, but with no detail around how it will seek to achieve it

Instruction 2 – Mapping and consulting stakeholders (Step 1)

When mapping and consulting stakeholders related to RS, several key considerations must be addressed to ensure effective engagement and collaboration. Here are the primary aspects to consider:

- **Identification of key stakeholders, their roles and their relationships** – Understand who will need to be involved in carrying out the RS from within the regulatory organisation and its close circle of collaborators. Define roles and responsibilities for each.

- **Address key stakeholder needs.** A regulatory sandbox must address the unmet needs of key stakeholders, including industry players (startups, SMEs, and incumbents), government regulators, and civil society. It should focus on resolving areas of regulatory uncertainty, such as compliance barriers, liability concerns, and policy gaps, by providing a controlled environment for experimentation. The RS aims to generate benefits for all participants—offering innovators a pathway to test new solutions, regulators the insights to refine policies, and consumers greater transparency and protection. Ensuring active stakeholder involvement through structured consultations, partnerships, and iterative feedback mechanisms is essential for maximising the RS's effectiveness and fostering long-term regulatory improvements. Use the table below (Box C.1) to systematically implement this step.

Box C.1. Addressing key stakeholder needs

What are the specific unmet needs (business, regulatory, policy, etc.) that the RS will aim to address?

- Industry: Incumbent players, startups, SMEs, innovators and non-traditional players.
- Other government departments and regulators (local municipal, provincial/territorial and federal level).
- Civil society organisations and the public (may be more relevant at a later stage, once a RS design is ready to be proposed).

Stakeholder 1	
Stakeholder 2	
Stakeholder 3	
....	

What are the key areas of regulatory uncertainty and how will the RS aim to address them?

Stakeholder 1	
Stakeholder 2	
Stakeholder 3	
....	

What benefits are intended to be achieved for industry? Innovators? Regulators? Consumers? Citizens? Society as such?

Stakeholder 1	
Stakeholder 2	
Stakeholder 3	
....	

How will involvement and contributions from these stakeholders to the regulatory sandbox be ensured?	
Stakeholder 1	
Stakeholder 2	
Stakeholder 3	
....	

- **Engage and involve key stakeholders.** Once priority stakeholders have been identified, the means of engagement can be designed. To effectively engage and involve stakeholders in a regulatory sandbox, it is essential to follow a structured plan that ensures their contributions shape and support the sandbox (see table below). Start by identifying priority stakeholders, including industry innovators, regulators, and policymakers, and determining the most effective ways to engage them. Hold informal conversations with key industry stakeholders and innovators to identify non-regulator perspectives on regulatory and wider industry challenges, and by testing out the high-level RS idea. Nonetheless, introduce others to the concept of a RS and observe how it is received. This helps keep decision-making aligned with industry needs, interests, expectations, readiness, and appetite. This process can also offer opportunities to soundboard an early-stage sandbox concept before committing to a particular approach to design and implementation. Involving relevant stakeholders at all stages of the experimentation design and implementation helps to ensure that it runs smoothly, is fit-for-purpose, and can provide valuable feedback for a better decision making. For some groups, seek their direct input into the design. For others, keep them informed to build engagement and support for the experiment's outcomes.

Template for stakeholder engagement plan						
Stakeholder	**Role in RS**	**Engagement Methods**	**Communication Channels**	**Feedback Mechanisms**	**Evaluation Metrics**	**Next Steps**
....						
Ministry of Transport	Regulator overseeing transport laws and ensuring policy alignment for APS deployment.	Regular working group meetings, policy briefings, and participation in sandbox design.	Monthly reports, regulatory workshops, email updates.	Formal policy consultations, legal framework reviews, direct ministerial input.	Number of policy adaptations informed by the RS, regulatory feedback received, alignment of legal framework with project goals.	Define policy recommendations for broader APS deployment and update relevant transport laws based on sandbox findings.
....						
....						

Principles for the stakeholder engagement

Engagement strategy

1. Objectives: Clearly define the objectives of stakeholder engagement, such as gathering input, building support, or addressing concerns.
2. Communication Channels: Determine the most effective communication channels for reaching different stakeholders (e.g., workshops, surveys, meetings).

Consultation process

1. Transparency: Maintain transparency throughout the consultation process to build trust and credibility.
2. Inclusiveness: Ensure that the consultation process is inclusive, giving all stakeholders an opportunity to participate and voice their opinions.
3. Feedback Mechanisms: Implement mechanisms for collecting and incorporating stakeholder feedback into the sandbox design and operations.

Information sharing

1. Clear Information: Provide stakeholders with clear, concise, and relevant information about the RS, including its objectives, scope, and potential impacts.
2. Regular Updates: Keep stakeholders informed with regular updates on the progress and outcomes of the sandbox activities.

Risk and impact assessment

1. Identify Concerns: Identify and address potential concerns and risks raised by stakeholders, including those related to consumer protection, market integrity, and regulatory compliance.
2. Impact Analysis: Conduct impact analyses to understand how the RS might affect different stakeholder groups.

Collaboration and partnerships

1. Build Partnerships: Foster collaboration and partnerships with key stakeholders to leverage their expertise and resources.
2. Joint Initiatives: Explore opportunities for joint initiatives and projects that can enhance the sandbox's effectiveness and reach.

Legal and ethical considerations

1. Regulatory Compliance: Ensure that the stakeholder consultation process complies with relevant regulations and legal requirements.
2. Ethical Standards: Adhere to high ethical standards in stakeholder engagement to maintain integrity and trust.

Monitoring and evaluation

1. Track Engagement: Monitor the effectiveness of stakeholder engagement activities and make adjustments as needed.
2. Evaluate Outcomes: Evaluate the outcomes of stakeholder consultations to measure their impact on the RS design and implementation.

Instruction 3 – Resource assessment (Step 1)

Time

Running a RS can take time, but this time investment may result in higher quality evidence. Before considering a RS further, think about how quickly an answer is needed to a question, and how likely it is that a RS will deliver this information by the time needed to act on it.

- Would any of the other approaches you have considered provide you with information more quickly?
- On the other hand, is a RS more likely to give you enough and quality evidence to proceed with and influence further action?
- If you must trade off time against confidence, which is your priority?

People

RS also require people. For example, designated or additional staff may be needed to co-ordinate implementation, and specialists may need to be brought in to support experimental design, evidence gathering, and analysis.

- What skill sets are already represented on your team, and what capacity do you have?
- What competing priorities would have to be balanced in order to take on the work associated with running a RS?

Consider future staffing costs as well. For example, how might a RS reduce administrative costs over the long term?

Funding

Given the time and people they require, RS may also need funding. Establish what budgetary constraints the RS is working within, and how these interact with timelines. Importantly, the potential costs and impacts of not experimenting should be considered.

- Which future scenarios are possible if you experiment, and which are not?
- What implications would each of these scenarios have for the public, industry, and your regulatory organisation?

Consider the risks and costs associated with implementing at scale based on alternative approaches, versus testing through an experiment first.

Use the Resource Needs Assessment template below to create an overview of the needs assessment for the RS.

Resource needs assessment						
Resource	What we have today	What we need	Priority level	Source	What risks we face not having these resources	Deadline
Time						
People						
Funding					I	

The Regulatory Sandbox Blueprint – Step 2: Executing the RS

	The RS Blueprint: *Enter Project Name Here*	This section provides a step-by-step guide for executing the regulatory sandbox. It covers the design of a testing plan including objectives, criteria, and methodologies for the sandbox. It outlines drawing up an agreement on terms, where all stakeholders align on roles, responsibilities, and expectations. It addresses risk management and mitigation strategies. Finally, it offers guidance on collecting and managing data, establishing robust systems for secure data handling, and ensuring accurate and actionable decision-making.		
	STEP 2: Executing the RS			
Stage	**2.1 Design the Testing Plan**	**2.2 Draw up an Agreement on Terms**	**2.3 Risk management and mitigation**	**2.4 Collect and manage data**
Consider	What is the scope of our RS? What are the testing stages and methodologies you will use? What are the rules of engagement? Who will be involved?	What is the time horizon of our RS? Who is responsible for what? How do we collect date and keep track of progress?	What are the potential risks involved? How will you mitigate those risks?	Set-up robust data management system
Action points	**#1 Develop clear guidelines to help the participants structure a testing plan** to evaluate innovation within the RS. Each testing plan should be proposed by RS participants and evaluated by the RS team on a case-by-case basis. The testing plan should, at minimum, contain the following key elements: (1) Objective and Scope – Clearly define the goal of the sandbox test, specifying the technologies, geographical coverage, scaling potential, and participants involved (2) business-related KPIs; (3) Data Collection – outline what data is required, who will collect it, and how it will be reported (4) Time Period – Establish a testing duration; (5) Responsibilities and procedures (6) Check-ins to monitor progress and address emerging risks. . **#2 Onboard the participants.** Inform successful applicants of their selection and guide them through the onboarding process ensuring that approved participants are formally confirmed, aligned on testing and exit plans, complete administrative and regulatory requirements, set up their testing environment, and receive ongoing support Example: testing a new AI-driven loan approval process, the testing plan might include setting up a pilot with a limited number of users, defining key metrics such as approval accuracy and processing time, and comparing these against the current system. The plan would specify the duration of the test (e.g., three months), detail the data collection methods, and outline how you will analyse the results to determine if the AI system is both effective and compliant with existing regulations.	**#1 Draw up the RS Agreement on Terms** The Agreement formalises the commitments and expectations derived from the Testing Plan. Clearly outline the specific terms and conditions that will govern the operation of the RS including roles, responsibilities, and expectations. **#2 Negotiate and Finalise Agreements**: Engage with all relevant stakeholders to discuss, negotiate, and reach consensus on the agreed-upon terms, ensuring alignment with the RS objectives. **#3 Document the Agreed Terms:** Create a formal, written agreement that captures all the negotiated terms, ensuring clarity and mutual understanding among all parties involved.	**#1 Conduct a thorough risk analysis** to pinpoint all possible risks associated with the regulatory sandbox (RS), considering operational, financial, regulatory, and reputational factors. **#2 Evaluate each identified risk** in terms of its potential impact and the likelihood of occurrence, prioritising those that could significantly affect the RS. **#3 Develop Risk Mitigation Strategies.** Create specific plans and actions to reduce or eliminate the identified risks, ensuring that these strategies are practical and effective in minimising potential negative outcomes. **#4 Implement and Monitor Risk Mitigation Measures**	**#1 Ensure high quality of collected data** through data management processes and criteria. **#2 Establish a reliable and efficient system to collect, store, and manage the data** generated during the RS. A robust data management system ensures that all data is securely stored, easily accessible, and properly organised for analysis. Example: RS testing a new fintech application, you'll need a data management system that securely stores transaction data, user interactions, and compliance logs. It allows easy access for analysis while ensuring that sensitive information is protected in line with data privacy regulations.
Inspiration	For detailed guidance on typical elements of a testing plan, see **Instruction 4 – Testing Plan** To successfully onboard participants, **see Instruction 5 – Onboarding of participants (Step 2)**		For detailed instructions on risk management, see **Instruction 6 – Risk Identification, Management and Mitigation**.	For detailed guidance on ensuring data management, see **Instruction 7 – Data Management System (Step 2)** and **Instruction 8 – Data Collection and Monitoring Arrangements (Step 2).**

Instruction 4 – Testing Plan (Step 2)

It is important to develop a contract or other type of agreement with each participant that outlines the terms of the RS. Testing plans typically are proposed by RS participants and evaluated by the RS team on a case-by-case basis. Testing plans should be customised to develop evidence on the regulatory questions presented by the specific innovation.

As a basic rule, the regulator must feel comfortable that, once the testing is conducted as planned, the regulator will be able to decide what the next steps will be and choose an exit option. In reviewing a proposed testing plan, the regulator must confirm the plan is comprehensive and clear.

The following items should be confirmed and written into the agreement before beginning the RS:

Objective and scope of the RS

In a first, step, an agreement on the terms of the sandbox have to be reached. Here, the general objective has to be agreed on, then the technologies or innovations has to be defined, then the geographical coverage, and further aspects related to scaling. Here, the potential participants also have to be identified.

Key Performance Indicators (KPIs)

At this stage, participants of the RS have to identify any Key Performance Indicators (KPIs) related to their business objectives (e.g. customer satisfaction), while other key outcomes that need to be assessed (e.g. environmental impacts in the form of emissions).

Data collection

In order to measure these outcomes, participants and regulators need to identify what kind of data is needed, how this will be collected and by whom. Participants will be expected to provide data through reports, e.g., on the number of complaints or safety-related incidents, and to share raw data where possible.

Time period

If the time limit of each test hasn't been established by the overall design of the RS or by the wording of an exemption clause, each participant depending on what they are testing has to provide a schedule for his test. The time available for testing varies significantly and can be anything from several weeks to several years in case of less mature technologies.

Responsibilities and procedures

Each agreement should also include stipulations on responsibilities and procedures over the course of testing (e.g. how often the innovator will need to share information and in what form) and what should happen if a particular incident should occur (i.e. how and when the test would be stopped). Risk and impact assessments should be done upfront and can help identify areas that will need closer monitoring by the regulator or its agents.

Check-in frequency

Regular meetings with participants have to be defined to identify areas of potential concern before issues arise. Before testing begins, other relevant stakeholders should be consulted and together regulators and innovators should disclose the nature of products and services to any customers or members of the public that will be involved or affected during the testing phase.

Box C.2 lists guiding tips and questions the help prepare the plan.

Box C.2. How to Develop the Testing Plan

1. Describe the test you are proposing to carry out in the regulatory sandbox, including the regulatory tool(s) required (e.g. restricted authorisation).
2. Describe the timeline and key milestones of your proposed test
3. What are your outstanding dependencies to finalise before testing (e.g. finalising an agreement with a partner)?
4. What are your key testing objectives?
5. Outline your quantitative and qualitative measures of success.
6. What type of customers will participate in your test and how do you intend to source these?
7. How many customers will participate in your test?
8. Summarise the key risks (to both consumers and your business) your proposition and the proposed test may involve, and the safeguards in place to mitigate these.
9. What is your exit plan (i.e. how will you wind down your test) if it is forced to end earlier than anticipated?
10. What are your next steps upon conclusion of the test?

Note: The UK FCA Guide provide additional guidance on how to address the prompts and questions listed above.
Source: UK Financial Conduct Authority, FCA Regulatory Sandbox Application Guide, at https://www.fca.org.uk/publication/information-sheets/fca-regulatory-sandbox-application-guide.pdf.

Instruction 5 – Onboarding of participants (Step 2)

This stage is broken up in the following activities:

1. **Confirm and announce participants** – The RS Team sends a confirmation of acceptance to the RS to the applicant, and subject to the applicant accepting entry, publishes their name on the a RS webpage.

2. **Finalise testing plan and exit plan** – The RS Team in collaboration with relevant regulatory stakeholders and the participants, conducts meetings to have a final view on the testing plan including timeline, criteria, milestones, safeguards, and performance metrics. This step is to ensure that all stakeholders (regulators, participants and other involved stakeholders) have everything in place, delivered and considered and are ready for testing (readiness checklist).

3. **Administrative processing of participants** – The RS Team helps the participant with administrative processing and documentation before the start of testing where applicable.

4. **Provide required inputs or approvals (if needed)** – The RS Team ensures that the participants meet regulatory and administrative requirements for the testing phase (e.g. enrolling the necessary staff, providing copies of existing permits or licenses, providing details of customers, partners, and suppliers).

5. **Prepare testing set-up and onboard participants** – The RS Team ensures that participants have configured and set up their product or service offering in the testing environment and after the initial window of testing preparation officially onboards the participant in the sandbox.

6. **Provide support** – The RS Team can assist the participants in case of any initial RS hurdles or challenges.

Instruction 6 – Risk Identification, Management and Mitigation (Step 2)

Before developing a sandbox, identify the potential risks involved in testing different innovations and put in place adequate safeguards to mitigate any risks.

What are the potential risks involved?	How will those risks be mitigated?
Markets • Market Integrity: If companies in the RS engage in unethical or risky behaviour, it could undermine market integrity. • Distorted Competition: RS might create an uneven playing field, giving an unfair advantage to companies within the sandbox over those that follow standard regulations.	
Consumers • Consumer Protection: Reduced regulatory oversight might lead to products or services that are not adequately tested, potentially harming consumers. • Lack of Recourse: Consumers might have limited options for recourse if something goes wrong with a product or service developed in a RS.	
Environment • Environmental Oversight: Reduced regulation might lead to less stringent environmental checks, potentially resulting in harmful environmental practices. • Sustainability Risks: Companies focusing on short-term innovation within the RS might neglect long-term sustainability considerations.	
Society • Social Inequality: Benefits of innovation within RS might not be evenly distributed across society, potentially widening social inequality. • Public Trust: Failures within a sandbox can erode public trust in both the regulatory system and the technologies.	
Others • Please specify:	

During the RS, ensure a continuous monitoring for compliance with regulatory requirements and RS guidelines. Incidence reporting has also to be established. To that end, develop protocols for addressing any incidents or breaches that occur within the sandbox, including data breaches or regulatory violations.

Finally, unexpected risks may emerge during the RS implementation. There are several strategies that can be utilised to minimise the impact of these unknown risks, should they emerge. This includes:

- Adopting a precautionary approach: During the design and implementation process, including where there are uncertainties or changes to the regulatory approach, it is recommended that regulators apply general precautionary principles and ensure that there are response processes and mechanisms in place that enable the relevant regulator to respond swiftly.

- Define clear stop-loss or escalation triggers: Sandbox terms can specify the conditions under which trials may be paused, modified, or terminated to prevent or limit harm. This can include thresholds for indicators such as consumer complaints, adverse environmental impacts, or market distortions that are not necessarily known at the outset.

- Establish rapid response protocols: Regulators should set out clear internal procedures for investigating and responding to emergent issues, including lines of responsibility, decision-making timelines, and communication plans with participants and stakeholders.

- Ensure clear channels for continuous feedback loops: Ensure clear and accessible channels are in place for continuous feedback loops among sandbox participants, regulators, and relevant stakeholders, enabling timely sharing of potential emerging risks and dynamic monitoring.

Instruction 7 – Data Management System (Step 2)

The RS must rest on a sound Data Management System that complies with relevant legal requirements and good practices.

EU-level requirements

The EU has developed a robust legal framework governing the collection, management and use of data. Relevant legal bases include:

- The **General Data Protection Regulation** (GDPR, Regulation (EU) 2016/679) is technologically neutral and applies to the processing of personal data, also in virtual worlds.

- The **Data Governance Act** (Regulation (EU) 2022/868) and **Data Act** (Regulation (EU) 2023/2854) establish horizontal rules for data-sharing and give users control over the data generated by their connected devices. The **AI Act** (Regulation (EU) 2024/1689) tackles risks emerging from artificial intelligence (AI) and will promote innovation in trustworthy AI.

- For the protection of intellectual property rights and industrial property rights, consider the **Directive on Copyright in the Digital Single Market** (Directive (EU) 2019/790), the **Regulation on the EU Trade Mark** (Regulation (EU) 2017/1001) and the **Directive on the Protection of Trade Secrets** (Directive (EU) 2016/943).

- In relation to the protection and enforcement of the rights of individuals and companies operating in virtual worlds, the **Digital Services Act** (DSA, Regulation (EU) 2022/2065) and the **Digital Markets Act** (DMA, Regulation (EU) 2022/1925) introduce a comprehensive system of accountability and obligations for online platforms.

- RS participants are also protected by EU consumer law, in particular the **General Product Safety Regulation** (Regulation (EU) 2023/988), as well as the **Unfair Commercial Practices Directive** (Directive 2005/29/EC), which provides protection against misleading marketing practices.

- The **European Digital Identity** will give users full control over their digital identities (European Commission, 2025[18]).

- Access by persons with disabilities to key digital services is addressed by the **European Accessibility Act** (Directive (EU) 2019/882) and the **Web Accessibility Directive** (Directive (EU) 2016/2102).

Data quality management

An important element when running a RS is to make sense of the evidence and data collected. Data quality applies to the whole Data Management System, from the source to the usage of data – see Table C.1. Good quality data determines the usefulness and reliability of the RS.

Table C.1. Ensuring data quality through data management processes and criteria

Data Management System Processes	Data Quality System Criteria
Source	Validity
Collection	Reliability
Collation	Precision
Analysis	Timeliness
Reporting	Integrity
Usage	

Source: Elaborated by the authors.

Validity – This criterion ensures that data actually measures what we intended to measure. To control for validity, check definitions and assumptions; proxy measures; the data sources, the completeness of the samples, the criteria used for including and excluding entry points.

Reliability – This criterion considers whether the data consistently measures what we intended to measure. Data should reflect stable and consistent data collection processes and analysis methods over time. To control for reliability, check the methodologies and instruments deployed in the collection phase; whether significant time-, site-dependent variations can be observed; whether personal issues may affect data quality (e.g. the expertise of the data collector or those who process the data; or the existence of bias and conflict of interests). Cases in which there is direct manipulation of the data, for instance through extrapolation or aggregation methods, should be particularly reviewed.

Precision – This criterion ensures that the data is both accurate (in terms of bias) and precise (in terms of error). Precise data has a sufficient level of detail to present a fair picture of performance and enable management decision-making. It is important to ascertain that the margin of error in the data is less than the expected change being measured, and whether it is acceptable. To control for precision, check the source of data (e.g. whether it is an official database, whether it is primary data or secondary data, etc.); the type of instruments and methods that are used; whether the data is being checked for transcription error and the measurement has been subject to manipulation error or bias.

Timeliness – This criterion ensures that the data has still relevance and informative value when it is used (although this should be expected, since the RS is a live testing exercise). Check the frequency with which data is collected and reported, and whether data is time-dependent (for instance, it refers to specific, temporary data collection contexts) – and make adjustment as needed.

Integrity – This criterion focuses on whether there is improper manipulation of data. It ensures that the data is trustworthy. To ascertain this, control for intentional fabrications and falsity or unconscious mis-information (e.g. transcription errors, rounding, etc.); investigate contexts and "agendas" characterising those generating, collecting, processing and reporting data, in particular by reviewing research practices and ethics and managing conflict of interests and value-based biases.

The following worksheet helps operationalise the data quality assessment:

Indicator			Date reviewed	
Reviewer(s)			Data source	
Criterion	**Definition**		**Yes/No**	**Explanation**
Validity	Do the data clearly and adequately represent the intended result? Some issues to consider are: • Face Validity. Would an outsider or an expert in the field agree that the indicator is a valid and logical measure for the stated result? • Attribution. Does the indicator measure the contribution of the project? • Measurement Error. Are there any measurement errors that could affect the data? Both sampling and non-sampling error should be reviewed.			
Reliability	Do data reflect stable and consistent data collection processes and analysis methods over time?			
Precision	Are data sufficiently precise to present a fair picture of performance and enable management decision-making at the appropriate levels?			
Timeliness	Are data timely enough to influence management decision-making (i.e., in terms of frequency and currency)?			
Integrity	Do the data collected, analysed and reported have established mechanisms in place to reduce manipulation or simple errors in transcription?			
Key issues and recommendations (summary):				

Instruction 8 – Data Collection and Monitoring Arrangements (Step 2)

Data and information collection should begin as soon as the testing phase of the RS begins, with any baseline data being collected prior to testing particularly if a pre-post experiment, i.e. a comparison before and after the introduction of the RS to identify statistically significant differences, is planned. Where resources allow, consider appointing a dedicated contact person for each participant of the RS.

The data collection should comply with the following requirements:

- Complying with relevant data protection regulations (e.g., GDPR) to protect consumer privacy, but also ensuring high-quality and accurate data to ensure reliable analysis and decision-making – see Instruction 7. above.

- Clearly informing participants and stakeholders about what data is being collected, how it will be used, and who will have access to it.

- Obtaining explicit consent from participants for data collection and use, ensuring they understand the implications.

- Collecting only the data that is necessary for the sandbox objectives to reduce risks associated with data storage and processing.

- Drawing up a Data Collection Plan, along the template below:

Data source What? Where?	Data collection strategy Who? When? How?	Data analysis strategy Who? When? How?
Guiding questions: • What data will be gathered? • Where will the data be sourced from?	Guiding questions: • Who will collect the data? • When are the different points at which data will need to be collected? • How will the data be collected – for example through questionnaires, expert assessment or other methods?	Guiding questions: • Who will complete the data analysis and do they have the right skills? • When will the analysis take place, including the final and any intermediate analysis? • How will the data be analysed and used to prove or disprove the hypothesis, or to yield the learning sought?

The Regulatory Sandbox Blueprint – Step 3: Closing and learning

	The RS Blueprint: *Enter Project Name Here*	*This section provides a comprehensive guide for closing and learning from the regulatory sandbox, detailing the steps required to evaluate outcomes, finalise the project, and apply insights gained. It includes guidance on compiling and analysing data, making informed decisions about the future of the innovation, sharing findings with stakeholders, and planning the transition out of the sandbox. Additionally, it outlines how to address any remaining risks, ensure compliance, and establish frameworks for ongoing monitoring if the innovation is implemented more broadly, ensuring that the lessons learned continue to inform regulatory practices and innovation efforts.*
	STEP 3: Closing and learning	
Stage	*3.1 Closing and learning: Evaluation*	*3.2 Closing and Learning - Ending the RS*
Consider	Have you defined the evaluation criteria for your sandbox? How do you know if the test failed or succeeded? Have you developed a clear and concise evaluation against a set of pre-determined KPIs testing the results of the implemented RS? Have the findings been well-analysed, systematised and structured in a comprehensive RS report that provides solid evidence to support decision-making?	Have you decided on the RS outcomes (e.g. scaling the innovation, make regulatory changes, discontinue the RS)? Have you shared the results with the key stakeholders? Do you have a clear transition plan out of the RS? Have you set-up mechanisms to make sure that the knowledge produced by the RS is captured?
Action points	**#1 Assess the performance and outcomes of the regulatory sandbox (RS)** against predefined criteria. **#2 Create an evaluation plan with a set of well-defined KPIs.** **#3 Compile the evaluation findings into a report**, summarising the results and making recommendations for next steps based on the data. The evaluation helps gather insights on the effectiveness, efficiency, and overall impact of the innovation being tested. It provides evidence to support decisions on whether to scale the solution, make regulatory changes, or refine the approach before wider implementation. **#4 Follow-up on the RS - plan and execute the recommendations** Example: In the fintech cryptocurrency payment system, the evaluation plan might include tracking KPIs such as security performance (e.g., no breaches), transaction speed, user satisfaction, and compliance with regulatory requirements. The final report might show that the cryptocurrency system achieved fast transaction times and high user satisfaction but revealed minor security vulnerabilities. The report would include recommendations for refining the system and enhancing security measures.	Having crafted the evaluation report, assess the results against the initial objectives and criteria, and decide whether to scale the innovation, make regulatory changes, or discontinue the project. Share findings with stakeholders - present the final report and findings to all relevant stakeholders, ensuring transparency and collaboration on the next steps. Plan for transition or implementation. Develop a clear plan for transitioning out of the sandbox, whether that involves scaling the innovation, integrating it into existing systems, or concluding the project. Identify and mitigate any remaining risks, ensuring that all regulatory and compliance issues are resolved before concluding the sandbox. If the innovation is to be implemented more widely, establish ongoing monitoring and evaluation frameworks to track its long-term performance and impact.
Inspiration	For detailed guidance, **see Instruction 9 – RS Evaluation and Follow-up Worksheet (Step 3)**	

Instruction 9 – RS Evaluation and Follow-up Worksheet (Step 3)

Both the compliance with the agreed procedural standards and the quality of the findings from the RS is the responsibility of the regulator in charge of the RS. Effective quality control benefits from intensive co-operation and systematic expertise.

The evaluation of a RS is conducted by a lead expert. The latter may proceed to a **self-evaluation**, receiving (non-binding) methodological advice and / or analytical support from **internal peers** or **expert panels**. These could also be involved in the review and validation of the RS evaluation report.

The RS evaluation report is not the end of the evaluation process. Appropriate follow-up actions must be identified and fed into the decision-making cycle. To that end, the regulator must consider the findings and recommendations of the evaluation and drawn its assessment on whether and what further action is needed.

The consideration and, if appropriate, implementation of the evaluation recommendations are guided by a process of **management response**, which takes the form of "Follow-up Worksheet" – i.e. a table listing all recommendations. The top management comments on every recommendation and establishes whether they are fully, partially or not accepted at all. For recommendations having been accepted, steps for implementing them need to be noted – see Box C.3.

The Follow-up Worksheet is prepared by the lead evaluator, in close co-ordination with the RS team. It should be revised regularly, for instance once a year at least, in order to see to what extent the recommendations have already been implemented.

Box C.3. RS follow-up Worksheet: Possible template (with example)

Conclusion from the RS evaluation

e.g. Type A drones proved to be suitable to safely dispatch drugs and other parcels of up to 1.5 kg in weight and over a 15 km distance for commercial purposes.

Related recommendation

e.g. Regulatory amendments should be introduced to allow the use of air space over settlements for these drones, between 50 and 100 meters above ground.

Deliberation by the management (regulator)

e.g. "Agreed"

Measure	Responsibility	Deadline	Controlling
Prepare legal amendments, incl. technical standards	Ministry of transport	6 months	Ministerial procedure
Adoption and entry into force of the regulation	Ministry of Transport	9 months	Ministry of Transport GLO
Enforcement of the regulation and reporting	Municipal police	12-24 months	Ministry of Transport
…			

Note: (1) The Follow-up Worksheet should include as many sections as there are relevant / actionable conclusions and recommendations. (2) The example used here is fictional and purely illustrative.

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