Council of the
European Union

Brussels, 26 July 2023
(OR. en)

12199/23

RECH 366
COMPET 794
IND 419
ENER 457
BETREG 17
ECOFIN 805

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	25 July 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2023) 277 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Regulatory learning in the EU *Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy*

Delegations will find attached document SWD(2023) 277 final.

Encl.: SWD(2023) 277 final

EUROPEAN
COMMISSION

Brussels, 25.7.2023
SWD(2023) 277 final

COMMISSION STAFF WORKING DOCUMENT

Regulatory learning in the EU

Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy

Glossary

Term or acronym	Meaning or definition
AI	Artificial intelligence
AnMBR	Anaerobic membrane bioreactor
BIM	Business information modelling
BIPV	Building-integrated photovoltaics
CAPEX	Capital expenditure
CCAM	Connected, cooperative and automated mobility
CECs	Citizen energy communities
CEER	Council of European Energy Regulators
CSC	Collective self-consumption
DER	Distributed energy resources
DLT	Distributed ledger technology
DSO	Distribution system operator
EBP	European Blockchain Partnership
EBSI	European Blockchain Services Infrastructure
EHDS	European Health Data Space
EIT	European Institute of Innovation and Technology
ETIP SNET	European Technology Innovation Platform - Smart Networks for Energy Transition
FE	France Expérimentation
GHG	Greenhouse gas
IED	Industrial Emissions Directive
INCITE	Innovation Centre for Industrial Transformation and Emissions
IIoT	Industrial Internet of Things
IoT	Internet of things
JRC	Joint Research Centre
LCA	Life cycle assessment
LL	Living lab
NRA	National regulatory authority
OITB	Open innovation test bed
OPEX	Operating expenditure
PCM	Phase change materials

PLL	Policy learning labs
PV	Photovoltaics
R&D	Research and development
R&I	Research and innovation
RECs	Renewable energy communities
REFIT	Regulatory fitness and performance programme
RES	Renewable energy sources
SME	Small and medium-sized enterprises
TRL	Technology readiness level
TSI	Technical support instrument
TSO	Transmission system operator
TUoS	Transmission-network-use of system
ULabs	User validation laboratories

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT FOR EXPERIMENTATION

Innovation is a key driver of economic growth, progress and prosperity. The ability to create innovative products, services and business models creates societal value and is essential for staying competitive. At the same time, the impact of innovation on the economy and society is often unpredictable. Innovations can disrupt existing markets, networks and products by delivering new value propositions, creating new markets or displacing established market leaders. Current examples of the most disruptive technologies and data-driven innovations in the digital field are artificial intelligence, blockchain and the 'internet of things' (IoT). These innovations are quickly spreading across sectors and jurisdictions, spurring new interactions between innovations and their users. Similar developments are occurring in many other areas (e.g. environmental and climate technologies, mobility and the pharmaceutical sector). As a result, innovations push the boundaries of existing regulatory, economic, and societal arrangements, with sometimes unintended consequences. Innovation developments require the constant attention of policymakers in order to anticipate them and adapt existing legislation and policies.

This Staff Working Document is one of the deliverables of the New European Innovation Agenda[1] and of the REPowerEU Plan[2]. It clarifies relevant use cases of regulatory sandboxes, testbeds and living labs in order to support regulators and innovators in their approach to experimentation in the EU.

Innovators face the challenge of fitting their innovative solutions into relevant laws, policies, standards, rules and specifications set by regulatory authorities (i.e. 'regulatory frameworks') during the development and deployment phase. For example, EU-funded R&D projects must consider existing regulation during development. Understanding and complying with regulations layered across EU, national and regional/local levels requires time and resources. Start-ups and smaller companies may not know how to do this. Disruptive innovations can be subject to outdated regulatory frameworks or fall outside them altogether. Outdated regulatory frameworks may slow down the development and deployment of innovation and may undermine investor and consumer confidence.

Regulators establish and enforce policies and legislation, and balance different objectives. These objectives include environmental, social and fundamental rights protection, addressing market failures, competitiveness and meeting international commitments. The speed and nature of innovation pose multiple challenges because regulators need to keep pace with innovation and understand its impact in order to ensure that regulation remains fit for purpose. Put simply, the public sector faces two main welfare-decreasing risks when it comes to innovation: under- and over-regulation. Lenient legal frameworks (under-regulation) can leave society and the environment vulnerable to the moral hazards of market players. Overly stringent regulation (over-regulation) and regulatory uncertainty can deter investment and stifle innovation and

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'A New European Innovation Agenda', COM(2022) 332 final, in particular *Flagship 2: Enabling deep tech innovation through experimentation spaces and public procurement*. For further details, see The New European Innovation Agenda (europa.eu).
[2] REPowerEU Plan COM(2022) 230 final, Brussels, 18.5.2022.

business activity. Furthermore, regulators have to be mindful of the need to create and maintain a level playing field for innovators and to mitigate market fragmentation risks.

Citizens and consumers play a key role in the acceptance and uptake of innovative solutions. However, there is increasing concern about the lack of public scrutiny of emerging technologies, their impact and governance mechanisms. This may undermine the legitimacy of innovation policies and consumer acceptance.

Box 1: EU policy context

EU innovation policy builds on multi-stakeholder participation, citizen engagement, testing and experimentation to generate wider and more diverse insights and real-world evidence, thereby improving the effectiveness and uptake of innovative solutions in line with EU policy objectives.

Horizon Europe, the EU's current framework programme for research and innovation aims at fostering citizen engagement in the green and digital transitions, open innovation and real-world experimentation. The **European Research Area** has citizen participation at its core to promote trust and facilitate the acceptance of science, technology and innovation.

The **New European Innovation Agenda** includes a flagship area on enabling deep tech innovation through experimental approaches to regulation, including the use of regulatory sandboxes, testbeds, living labs and innovation procurement.

The **Innovation Principle**[*] aims to ensure that all new EU policy and legislation supports innovation, and that the regulatory framework in Europe is innovation-friendly.

The **European Commission's Better Regulation Agenda** ensures more evidence-based and transparent EU policymaking, involving citizens, businesses and other stakeholders. **The Better Regulation Toolbox** includes regulatory sandboxes and other forms of experimentation as instruments of adaptive regulation.

The **Council Conclusions on Regulatory Sandboxes and Experimentation Clauses** of 16 November 2020 note that regulatory sandboxes can provide significant opportunities for SMEs to innovate and grow, and for regulators to find the best means to regulate innovations based on real-world evidence. Regulatory sandboxes are an important part of recent proposals in the digital field, such as the **AI Act** and the **Interoperable Europe Act** (both currently under negotiation).

Supporting innovation and an innovation-friendly approach to regulation in line with EU policy objectives, is also key to preserving the **long-term competitiveness of the EU** beyond 2030. As explained below, the Commission has also proposed regulatory sandboxes on net-zero industries (the **Net Zero Industry Act**) and the pharmaceutical sector. This can be extended to other sectors.

[*] For further reference see Council of the European Union, *Research and Innovation friendly regulation* - Council conclusions (adopted on 27/05/2016); Council of the European Union, *Better Regulation to Strengthen Competitiveness*, Press release (25/06/2016), and Better Regulation Tool #22.

The above challenges may create a **gap between innovators and regulators**. Innovators need up-to-date and predictable regulation to develop and deploy their solutions. They may find it hard to understand existing requirements and to establish whether and how these apply to their specific case. Regulators need to guarantee that regulation simultaneously encourages innovation, steers it towards desired policy objectives (e.g. safety, the green and digital transitions) and delivers public and market value. In some cases, **reconciling the needs of innovators and regulators requires a degree of flexibility or space to experiment** subject to appropriate safeguards where the regulatory frameworks may be less stringent under certain circumstances. New tools and approaches are therefore being developed in the EU and beyond to narrow the gap between innovation and regulation, and to foster **regulatory learning**. The latter occurs whenever regulators derive insights into the risks and opportunities associated with specific emerging technologies and innovations, as well as into any gaps or deficiencies in the applicable regulatory and supervisory frameworks. It is especially relevant in areas where disruptive technologies can address societal challenges. Regulatory learning enables competent authorities to gain better knowledge and understanding of the risks and opportunities as well as the need for possible changes to or new interpretations of existing legislation to effectively address new technological developments and enable innovation. The goal of regulatory learning can either be to initiate processes to gather the evidence needed to propose new or revised measures (top-down) or to gain insights from emerging innovation activity in an experimentation space (bottom-up). This process can therefore improve the regulatory governance of innovation by incorporating a wider evidence-base and agile, participatory and anticipatory elements.

Regulatory learning is increasingly organised in 'experimentation spaces' to gather evidence in a more systematic and structured manner on the need to adapt or introduce regulation, while ensuring a level playing field and competitive developments[3]. In an EU context, all forms of experimentation will be in line with existing Treaty rules.

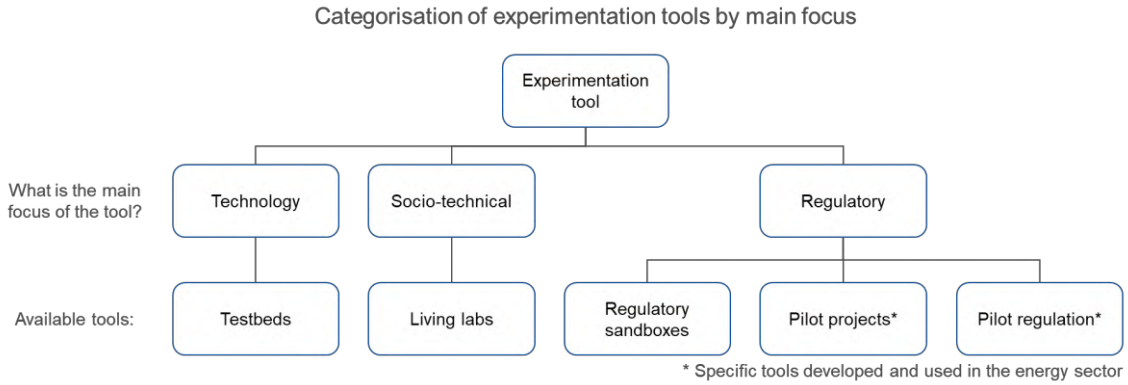
The term 'experimentation spaces' is relatively new. Most notably, it is mentioned in the European Commission's New European Innovation Agenda. Experimentation spaces allow innovators and regulators to explore the link between innovation and regulation by using a combination of experimentation tools. Three **types of experimentation tools** (regulatory sandboxes, testbeds and living labs) are commonly in use and will be the main focus of this Staff Working Document. **Regulatory sandboxes** are structured frameworks for cooperation with competent authorities that allow innovators to develop and test new ideas, products, business models and services in a controlled real-world environment under the supervision of a competent authority. Existing rules or their enforcement may be relaxed or suspended during the test under certain conditions. Competent authorities may also provide participants in the sandbox with bespoke guidance to address legal uncertainty on how legal rules and requirements apply to specific products or services developed in the sandbox. Regulatory sandboxes are always limited in terms of time and scope. **Testbeds** are used for the development, testing and scaling up of innovations in a dedicated environment. Unlike regulatory sandboxes there is no direct link to regulation because the testing focuses on technologies with some

[3] Kert, K., Vebrova, M. and Schade, S., Regulatory learning in experimentation spaces, European Commission, 2022, see here.

consultancy and advisory services on regulatory aspects. **Living labs** combine the experimentation feature with citizen engagement throughout the process. The main goals of living labs are to explore the effect of innovations on users and society and to better calibrate the relevant requirements.

These tools are the main ones in use during the inception and development phases of the innovation process and help to narrow the gap between regulation and innovation. Moreover, testbeds and living labs can also be operated as technology infrastructures and serve as facilitators during the commercialisation phase, assisting with the scaling-up and market entry of new technology [4]. Figure 1 below further illustrates the differences between regulatory sandboxes and other experimentation tools, and provides a 'decision tree' for innovators and public authorities interested in organising experimentation.

Figure 1: experimentation tool decision tree



All three experimentation tools can offer significant **benefits**. Regulatory sandboxes facilitate dialogue between regulators and innovators, increase innovators' knowledge of and compliance with regulatory frameworks, can accelerate the introduction of new products and services into the market and foster regulatory learning. Living labs help innovators and regulators by revealing hidden user needs and possible social impacts. Living labs also provide strategic foresight about future socio-technical systems. The benefits of testbeds are similar to those of sandboxes and living labs but there is more emphasis on technical aspects. While these remain distinct tools for regulatory experimentation, synergies between them are also beneficial as they can mutually reinforce and complement each other to support innovation.

1.1 How can experimentation support regulatory learning and legal certainty?

Innovation is supported by **R&I funding** (e.g. the EU's Horizon Europe programme, the Innovation Fund and national funding schemes) but also through **favourable policies** and an **enabling regulatory framework**, including regulatory experimentation. Once innovations are close enough to the marketing stage, the question of how they link with regulation automatically arises. This often creates legal uncertainty for all actors involved. It is also at this stage that regulators need to strike the right balance between

[4] For further details on technology infrastructures (including concrete examples), see the Commission's staff working document 'Technology Infrastructures', SWD(2019) 158.

(i) regulatory flexibility and learning (where needed) and (ii) preserving regulatory certainty, predictability and appropriate safeguards for public interest policy objectives.

Frameworks for regulatory experimentation can **increase legal certainty** for the different actors:

a) for **regulators** and other competent authorities, by empowering them to support innovation and to use regulatory experimentation tools because this might otherwise not be among their competences;

b) for **innovators**, they provide reassurance that an innovative activity can fit within the existing regulatory framework or that it would be appropriate to provide temporary derogations for testing;

c) for all **market participants**, by levelling the playing field and avoiding or minimising any competition distortion effect and by sharing the learning outcomes;

d) for **consumers** and the public through appropriate safeguards and protection measures put in place.

Prior to moving to the definitions of regulatory sandboxes, testbeds and living labs, it is worth concluding with a general observation on the context in which experimentation plays a role. Innovations – whatever their nature – may either occur in a new and therefore unregulated field or in a regulated sector (e.g. financial services and energy). All the actors' legal certainty needs will vary accordingly, particularly for innovators and regulators. When innovation occurs in a new and unregulated field, the main objectives of all actors are (i) to understand the nature of the innovation, its potential and associated risks; (ii) to learn and test different approaches to harnessing innovation; and (iii) to ensure consistency with core policy objectives and values. In such cases, experimentation spaces make it possible to explore and fine-tune solutions (including through trial and error) on a small scale and in a dedicated environment – which would not be possible in the real world without generating unintended consequences. This can also happen in a field where new regulation on complex technology is just emerging (e.g. artificial intelligence) to enable regulatory learning with practical experience, good practices and lessons learnt to inform further guidance, standards and benchmarks on how to interpret and implement new legal requirements.[5]

Conversely, when innovation occurs in an already regulated field, the exact needs of the actors involved should be carefully assessed in order to determine and select a suitable approach to increasing legal certainty. Innovators often require clarity on which rules apply to their specific case and under which circumstances. They may also need advice on interpreting these rules or confirmation that their compliance strategy is correct. Advisory services and guidance may be sufficient to bridge the gap between innovation and regulation, and can already indicate to what extent the innovation fits within the existing framework. Box 1 shows that various possibilities exist at EU level to provide

[5] See for example a pilot project of an AI sandbox launched in Spain with similar objectives to facilitate the future implementation of the draft AI Act (currently under negotiations). Launch event for the Spanish Regulatory Sandbox on Artificial Intelligence | Shaping Europe's digital future (europa.eu).

such clarification. Similar guidance and support services are also available at the national and local levels, for example through innovation hubs [6] or through regulatory sandboxes[7]. In some instances, however, an innovation will stretch the boundaries of the applicable regulatory framework, raising the question of whether it is still fit for purpose or would need some adaptation to continue serving its intended policy objectives (e.g. consumer protection), while accommodating new developments in the sector. Experimentation spaces can in those cases help all actors involved to identify a way forward.

Box 2: advisory services available at EU level

Innovators seeking guidance or clarification on applicable EU policies and legislation can rely on various services and sources of information. These sources also raise awareness about existing regulatory frameworks, so that innovators can adjust accordingly. Examples of services that provide such guidance at EU level include:

- the **Enterprise Europe Network**, which provides a global support network for SMEs with international ambitions. Members include local chambers of commerce, universities and innovation agencies. Businesses cannot become members, but they can benefit from the services provided;

- the **Horizon Results Booster**, which helps Horizon Europe beneficiaries bring their products to the market. The goal is to help new businesses to identify and address potential obstacles to commercialisation;

- the **European Cluster Collaboration Platform**, where innovators can share their experiences, needs and solutions with one another. The platform includes SMEs, large companies, research centres and public authorities. The goal of the platform is to improve cluster competitiveness and help with market expansion.

As the next section explains, different approaches to experimentation are possible. To use them, however, and particularly in already regulated fields, the competent authority needs to be able to do so, either through a legal basis in the legislation applicable to the innovation at stake, or if its mandate features the possibility to support innovation, including through experiments or a degree of flexibility in applying existing rules.[8] As

[6] For an illustration in the financial sector, see Parenti, R., *Regulatory Sandboxes and Innovation Hubs for FinTech: Impact on innovation, financial stability and supervisory convergence*, 2020. This was produced by the European Parliament's Policy Department for Economic, Scientific and Quality of Life Policies.

[7] See for example the data protection sandbox launched by the French Data Protection Authority (CNIL).

[8] Not all frameworks or national mandates of competent authorities provide such flexibility. Legislative changes may be necessary to empower regulators to employ regulatory experimentation. For instance, in the energy sector, France changed the mandate of the energy regulator, while in Italy the energy regulator's existing competences have been broad enough to apply regulatory experimentation tools (mainly pilot projects and pilot regulations) without the need for further enabling provisions in energy sector legislation (Sources: Council of European Energy Regulators - CEER Paper on Regulatory Sandboxes in Incentive Regulation Distribution Systems Working Group Ref: C21-DS-74-04 25 May 2022, [CEER, 2022] and Gangale, F., Mengolini, A.M., Covrig, L., Chondrogiannis, S. and Shortall, R., *Making energy regulation fit for purpose. State of play of regulatory experimentation in the EU*, EUR 31438 EN, Publications Office of the European Union, Luxembourg, 2023, ISBN 978-92-68-00415-9, doi:10.2760/32253, JRC132259 [JRC, 2023]). A similar issue may also arise at the level of EU agencies. See for instance the example of aircraft product certification in the Commission's 2019 staff working document 'Better regulations for

the concrete examples included in Sections 3 to 5 show, different sectors tend to have different arrangements for competent authorities to experiment.

Section 2 defines three types of experimentation tools and provides details on their main elements. Sections 3 to 5 showcase examples of experimentation at EU, non-EU and national levels. This is followed by a comparative analysis of the examples and final conclusions.

2. DEFINITIONS

Experimentation tools such as testbeds, living labs and regulatory sandboxes enable experimenting with innovative solutions in a controlled or uncontrolled space that is or resembles a (near) real-world environment. They typically involve multiple stakeholders, including users, and this allows the co-development of innovative solutions and associated regulations. New technologies, products services and business models can be developed in tandem with gathering evidence and information relevant for regulatory policies. Experimentation spaces thus provide a setting in which different stakeholders can build constructive relationships of knowledge exchange and trust, which help improve the regulatory governance of innovation and ultimately facilitate and accelerate the deployment of innovative solutions.

While the difference between regulatory sandboxes, testbeds and living labs may not be perfectly clear-cut in specific applications, the experience accumulated so far with designing and setting up such schemes across the EU has identified distinctive elements in each case. These are presented below in order to define and describe these different approaches to experimentation.

2.1 Regulatory sandboxes and pilots

Following the Conclusions of the Council of the European Union of 16 November 2020 [9], which listed key regulatory sandbox elements, the Commission developed Tool #69 of its Better Regulation Toolbox. According to the Tool, regulatory sandboxes are **schemes that enable the testing of innovations in a controlled real-world environment, under a specific plan developed and monitored by a competent authority**. They are usually organised on a case-by-case basis, may involve a temporary loosening of applicable rules and feature safeguards to preserve overarching regulatory objectives, such as safety and consumer protection.

There are two approaches for setting up a sandbox: one where the request (and identification of a regulatory barrier) is initiated by innovators (the bottom-up approach);

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innovation-driven investments at EU level' (pages 23-26). Another approach is to rely on experimentation clauses in legislation, as illustrated in Section 3.

[9] The Council further noted (recital 8) that experimentation clauses are often the legal basis for regulatory sandboxes and are already used in EU legislation and in Member States' legal frameworks. It also described experimentation clauses as 'legal provisions which enable the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in relation to testing innovative technologies, products, services or approaches' (recital 9).

and another where the regulator identifies legislative provisions for testing and calls for applications by interested organisations (the top-down approach). Additional approaches or a combination of the above may emerge with time.

It should be noted that in some cases sandboxes may be used to test innovations in a yet unregulated field. This may or may not affect existing and applicable rules, depending on each case.

Considering the toolbox definition and available evidence from concrete examples to date, it can be said that regulatory sandboxes should:

- involve a **structured approach to development and testing of** innovative technologies, products, services or business models (a genuine innovative element is needed)[10] in view of possible further deployment and market release;
- be used in a **controlled environment, which is often in real world**;
- fall under a specific **plan developed** with, **and monitored** by, a **competent authority** or agreed among several competent authorities;
- have **safeguards** to preserve overarching regulatory objectives (safety and consumer protection); and
- be aimed at **regulatory learning**.

Competent authorities may also provide participants in the sandbox with bespoke guidance to address legal uncertainty on how the legal framework and requirements apply to the specific innovation developed or tested in the sandbox. Competent authorities may also dispose of a certain degree of flexibility within the limits of the law and margin of appreciation on how to apply the legal requirements in a proportionate and context specific manner. When derogation from existing legislation is foreseen by a regulatory sandbox, a specific **experimentation clause in legislation** is required and serves as the legal basis for the sandbox. This binding legal basis must exist for the competent authority to be able to exercise the necessary degree of flexibility to derogate from applicable legislation. In some sectors such as energy (see Annex 1 for further details), a regulatory sandbox can also be based on a derogation from ordinances of regulatory authorities if the **competences of the regulator** so allow (especially if those competences include 'support for innovation').

It is important to note that the **presence of a derogation is not a necessary element of regulatory sandboxes**[11] but that the involvement of a competent authority is necessary. The presence of the competent authority makes it possible to make a link with existing or future legislation and thus to follow up (if appropriate) the regulatory learning generated by the sandbox. In this respect, and particularly for cross-sectoral innovations, sandboxes can enhance communication and coordination between different public authorities (regulators) and innovators.

[10] As explained in the Better Regulation Tool #69, genuine innovation "is not currently available in the market. A new use of an existing technology can also qualify".
[11] This is without prejudice to other approaches to testing established in specific legislative acts.

The following two forms of innovation are sector-specific and cannot be applied to all industries. For the most part, these innovation forms can be found in the **energy sector**.

Regulatory pilot projects (pilot projects) represent a specific area of regulatory experimentation, where the regulator defines the exact scope of the trial instead of leaving it up to the participants to choose or request (possibly from a predefined set of regulatory areas) the area of experimentation (policy-driven vs innovator-driven). Regulatory pilot projects might share several characteristics with regulatory sandboxes (selection procedure and decision on a case-by-case basis; supervision of a competent authority; derogations). There are also some differences, however, as examples [12] show that the application of regulatory pilot projects is also possible when no general framework for regulatory sandboxes has been created by the legislator. The use of pilot projects generally goes hand in hand with a proactive regulator that is keen on regulatory learning with clear ideas of where regulatory adaptation might be necessary.

Pilot regulation consists of a temporary regulatory framework applicable on a voluntary basis. This may be applicable to all market actors or a group of them (e.g. distribution system operators). There is no selection procedure, but it is open to all or a specific group of market actors for voluntary participation and the pilot is therefore non-discriminatory. It might be useful for the competent authority to try out regulatory options before deciding and making the final change [13].

2.2 Testbeds and living labs

Policymakers and innovators can also rely on other experimentation tools to foster learning, including regulatory learning. Two rather widespread and established tools are testbeds and living labs. Recently, additional approaches – often with a narrower scope of application – have been emerging, including lighthouses [14] and innovation deals. Finally, EU legislation from the past two decades includes examples of additional flexibility. For instance, experimentation clauses to support innovation were identified in various legal acts and contributed to keeping the EU's regulatory framework future-proof and adaptable. These different forms of experimentation are briefly described below. Section 3 contains concrete EU-level examples of each. An extended description of key examples is provided in Annex 2.

Testbeds can be described as experiments to develop, test and upscale a product or service in a dedicated environment. The focus of the experiment is mostly technical. The type of evidence generated by testbeds concerns technology requirements and

[12] An example of extensive use of pilot projects is Italy, where ARERA (the energy regulator) has wide competences to use regulatory experimentation tools but where there is no general legislative framework for a sandbox scheme in the energy legislation.

[13] Based on the experience of the Italian energy regulator, ARERA, CEER distinguishes between pilot regulation (applicable to all market players) and regulatory experiments (applicable only to network operators), always on a voluntary basis.

[14] Lighthouses are single sites, like farms or parks, where scientifically proven good practices and solutions are demonstrated. Lighthouses can also be single sites that are part of the Living Labs. They are emerging as an additional tool to experiment on and support innovative solutions, particularly in the context of Horizon Europe missions.

performance, including user needs and consumer protection features. It is common for testbeds to feature access to dedicated research and technology infrastructures, and to support and advise. Funding is also often provided in order to support experimentation. Testbeds usually do not have a link with regulation and do not require as a necessary component the presence of a competent authority.

Living labs are another widespread experimentation tool to co-create, prototype, test and upscale innovative solutions to (local) needs in real-life settings. One of their distinguishing features is the involvement of citizens as well as several other stakeholders and the end-users as co-creators during the entire experimentation process. The type of evidence generated by living labs is socio-technical and makes it possible to explore the effect of an innovation on users and society, thus leading to better calibration of requirements. Living labs also make it possible to assess user uptake and acceptance. The link with regulation is not a systematic or required characteristic of living labs, but these can be used by policymakers to anticipate future regulatory needs.

2.3 Other forms of experimentation

Policy experimentation is a mechanism for assessing innovative interventions or evaluating the effectiveness of existing policies to enhance their design and implementation through modelling. Policy experimentation complements the other tools and can be used to test their results more systematically and on a larger scale. It can take the form of randomised controlled trials (behavioural economics), and policy scenarios tested through system dynamics simulation and other methods [15]. Consequently, policy experiments can be employed, for instance, to assess the efficacy of a programme, refine an existing programme or investigate the root causes of a problem [16]. Horizon Europe [17] encourages the development of innovative policies, institutional frameworks and governance structures by leveraging robust empirical evidence and experimentation practices, thus making it possible to adapt policy designs to emerging challenges and the formulation of future strategies.

Innovation deals are another way to address existing or perceived regulatory barriers to innovation in EU legislation. They are voluntary agreements with stakeholders: innovators, civil society, national, regional or local authorities and the Commission. Innovation deals feed in the evaluation and the Regulatory Fitness and Performance Programme (REFIT) process of the Commission and may result in a revision of EU rules, following established decision-making procedures. An innovation deal consists of 1) the definition of the perceived regulatory problem encountered by innovators; and 2) the identification of a solution to this problem in cooperation with the innovation deal team.

2.4 Comparative overview of the three main experimentation tools

Testbeds, living labs and regulatory sandboxes form a toolset of complementary approaches to experimentation. None of these approaches is 'better' than the others –

[15] Commission staff working document, 'A new ERA for research and innovation', SWD/2020/214 final.
[16] Increasing the impact of public investments in innovation
[17] Horizon Europe Strategic Plan (2021-2024).

each tool can enable regulatory learning and provide evidence and insights on and into innovation and regulatory governance. They can all increase the legitimacy of, and trust in, innovative solutions and regulatory governance by incorporating in the process all those affected by regulation.

Paying attention not only to the distinguishing features but also the commonalities can help policymakers and innovators decide which approach (or combination of approaches) can best support their needs and goals. This is because testbeds, living labs and regulatory sandboxes:

- respond to **different motivations** for testing because they provide different types of evidence and learning, ranging from technical to societal to legal aspects (see Figure 1 in the introduction);

- support innovation and regulatory governance at **different stages** of the R&I process, from conceptualisation to proof-of-concept to demonstration;

- engage and bring value to **different constellations** of stakeholders, including innovators (from research institutes to start-ups and from SMEs to industry players), policymakers and regulators (at local, regional, national and EU level) and the public (individual users or communities of citizens); and

- allow **different forms** of involvement of regulators. Depending on the available resources and policy objectives, the role of the other stakeholders also varies according to the type of experimentation.

Table 1 summarises and compares the main characteristics of these three tools. It is important to note that the classification criteria (in the left-hand column) need to be used in a complementary manner to identify each type of experiment. Basing the classification on a single criterion (e.g. technology readiness levels (TRLs)) could lead to an inaccurate representation of existing experiments or become a straitjacket to experimentation in what is still an evolving landscape.

As noted above, the presence of a competent authority and regulatory learning as the main objective are distinguishing features of sandboxes. Likewise, the involvement of end users and a focus on co-creation is a typical feature of living labs.

Table 1: experimentation spaces and their features (continued on the next page)

*Note: technology readiness level (TRL) is an estimate of the maturity of a technology, based on a scale from 1 to 9.

	TESTBEDS	LIVING LABS	REGULATORY SANDBOXES
Primary motivation	Develop, test and upscale a product or service	Co-create, prototype, test, and upscale innovative solutions	Develop and test innovations in the market achieve legal security and foster innovation and regulatory learning
Context	Controlled, resembling real-world; physical or virtual facilities	Uncontrolled (near) real-world; physical or virtual environment	Controlled and often real-world; no common physical location
Timeframe	Limited	Varied	Strictly limited
TRL*	4 and above	It depends on the test case	7-9
Access rules	Competitive with funding	Project-dependent	Competitive, based on eligibility criteria
Value proposition for innovators	Access to research or technology infrastructure Access to services and support (including technical and legal expertise) Access to funding	Access to collective knowledge in innovation ecosystem Access to users/the public Enables multi-method approach to R&I process	Access to real customers Enhanced legal certainty and access to regulatory and compliance support, comfort from enforcement, possible derogations Potential increase in investor and consumer confidence
Users' role	Test users	Co-creators	Real customers
Regulators' role & scope of regulatory flexibility	Varied: May be involved in governance and may grant regulatory flexibility (e.g. experimentation clauses and special permits)	Ad hoc: Rarely systematically involved in living labs and rarely offer regulatory flexibility but may join certain activities as project stakeholders	Leading role: Set up and supervise schemes where innovations can be developed and tested, may apply rules in a flexible manner within the limits of law, may grant temporary exceptions in the legal framework (e.g. via experimentation clauses)
Mechanisms of regulatory learning	Top-down: Regulators may collaborate with innovators to gain input for specific regulation. Bottom-up: Evidence relevant to current or future regulation may emerge in the testing process.	Top-down: Regulators may approach a Living Lab for input for existing or future regulation. Bottom-up: Insights relevant to current or future regulation may emerge in the R&I process.	Top-down: Regulatory authority invites companies to validate innovative propositions that may inform the development of future regulation or adaptation of existing one. Bottom-up: Additional lessons may emerge, possibly prompting adaptation in regulation.
Type of evidence each framework is best suited to produce	Technical Test technology requirements/performance (e.g. technical regulations and standards) Assess user needs and consumer protection	Socio-technical Explore requirements and effects of innovation on users/society Assess uptake and acceptance Anticipate future regulatory needs	Techno-legal Test the modification of a regulation Interpret/apply a regulation Assess risks for the market and consumers

Source: adapted from Kert, K., Vebrova, M. and Schade, S. (2022) Regulatory learning in experimentation spaces, European Commission, 2022.

3. EXAMPLES AT EU LEVEL

This section discusses EU initiatives to support innovation and regulatory learning. There are two subsections: the first focuses solely on regulatory sandboxes and the second subsection covers other forms of experimentation. Annex 2 contains additional examples of all three experimentation tools.

3.1 Regulatory sandboxes

This section provides an overview of the existing and planned frameworks for the setting up and implementation of regulatory sandboxes in EU legislation. The situation is evolving rather rapidly and the use of sandboxes may be considered in other sectors in the future, but existing examples relate to digitalisation in the broader sense, financial services, energy including net-zero technologies to meet the EU's climate objectives, health and food safety, law enforcement and transport.

Digital

The **Commission proposal for a regulation on artificial intelligence (AI)** [18] would provide a a legal basis and a common framework for the establishment and implementation of AI regulatory sandboxes by one or more Member States' competent authorities or the European Data Protection Supervisor. It would also provide for the coordination of those schemes within the European Artificial Intelligence Board (Article 53 of the proposal). The goal is to foster innovation by enabling the development and testing of innovative AI systems in a controlled environment based on a plan agreed with the competent authorities responsible for the AI Act implementation. Where appropriate, other authorities should be also associated to the sandbox if other Union or Member States legislation is supervised, depending on the needs and the types of AI systems developed and tested in the sandbox. Synergies are also encouraged with other relevant initiatives in the AI ecosystem of excellence such as data spaces[19] and testing and experimentation facilities that can provide participants with added value services, for example access to physical and testing infrastructure and high-quality datasets. Regulatory learning is also an important goal of the AI regulatory sandboxes. To that end, competent authorities should prepare annual reports on the results from the implementation of the sandboxes to be shared with the Commission and the AI Board and considered, as appropriate, in their tasks. Article 54 would provide the legal basis for the further processing of personal data for the development in the sandbox of certain innovative AI systems in the public interest but subject to certain conditions.

[18] Proposal of 21 April 2021 for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts, COM(2021) 206 final.

[19] For a concrete application in a specific field, the European Health Data Space (EHDS) currently under development could provide data that are GDPR-compliant, of high quality and quickly accessible, with a clear legal framework, trusted governance, and secure infrastructure. Such data from the EHDS could be of particular use to the training, testing and validation of high-risk AI systems in healthcare.

The **Commission Communication** '**An SME Strategy for a sustainable and digital Europe**' [20] provides a basis for launching a pilot for the live testing of innovative solutions with supervisors and regulators to 'encourage Member States to develop proposals for regulatory sandboxes'.

The Commission proposal for an **Interoperable Europe Act** [21] would create a legal basis for launching sandboxes to test innovative solutions for digital public services in cross-border contexts. Public administrations at all administrative levels (from EU to local) and from all sectors can participate in the experimentation in the sandbox that is established based on a specific plan, in coordination with the relevant supervisory authorities. This allows testing a scenario also across several legislations and to provide input to the involved regulators (e.g. EU and several authorities from different Member States).

Energy

The **Commission Recommendation on speeding up permit-granting procedures for renewable energy projects and facilitating Power Purchase Agreements** [22], published on 18 May 2022 in the framework of **REPowerEU**, notes that sandboxes could support innovative decarbonisation technologies needed for climate neutrality. It encourages Member States 'to put in place regulatory sandboxes to grant targeted exemptions from the national, regional or local legislative or regulatory framework for innovative technologies, products, services or approaches, to facilitate permit-granting in support of the deployment and system integration of renewable energy, storage, and other decarbonisation technologies, in line with Union legislation'. Moreover, the **legislative proposal to amend the Renewable Energy Directive 2018/2001** [23], which is also part of the 18 May 2022 package, includes an obligation for Member States to promote the testing of new renewable energy technologies in pilot projects in a real-world environment. It also provides, with appropriate safeguards, for the possibility to test innovative mitigation measures to eliminate or reduce environmental impacts linked with renewable projects. Annex I presents more specific examples in this field.

[20] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 10 March 2020, 'An SME strategy for a sustainable and digital Europe', COM(2020) 103 final.

[21] Proposal of 18 November 2022 for a regulation of the European Parliament and of the Council laying down measures for a high level of public-sector interoperability across the Union (Interoperable Europe Act), COM(2022) 720 final.

[22] Commission Recommendation on speeding up permit-granting procedures for renewable energy projects and facilitating Power Purchase Agreements of 18 May 2022, C(2022) 3219 final; and the accompanying Commission staff working document 'Guidance to Member States on good practices to speed up permit-granting procedures for renewable energy projects and on facilitating Power Purchase Agreements', SWD(2022) 149 final.

[23] Proposal for a directive of the European Parliament and of the Council amending Directive (EU) 2018/2001 on the promotion of the use of energy from renewable sources, Directive 2010/31/EU on the energy performance of buildings and Directive 2012/27/EU on energy efficiency, COM(2022) 222 final.

Financial services

The pilot regime for market infrastructures based on the Distributed Ledger Technology Pilot Regulation (the DLTPR) [24] entered into application on 23 March 2023 and will allow time-limited exemptions from EU rules under certain conditions and safeguards to enable testing DLT for trading and settlement of financial instruments in tokenised form. The DLTPR aims to provide a flexible regulatory framework for market participants to set up trading venues and settlement systems relying on DLT, which is the base layer used for asset tokenisation.

The DLTPR will allow not only issuance and transfer of tokenised assets using DLT, but also settlement of the so-called 'cash' leg of a securities transaction in tokenised money (be it electronic money tokens or tokenised central bank money) where it is available or tokenised commercial bank money as an alternative. Programmable money is another innovation with great potential.

The experience gained from this experiment will inform the consideration of future legislation to enable the wider use of this technology for capital markets.

Participation in the pilot will be undertaken in close cooperation with the financial services regulators. The aim is to take stock after 3 years of application and consider whether further changes to the regulations are necessary.

Health and food safety

Existing legislation allows for experiments following Article 13a in Directive 66/402/EEC on marketing cereal seed [25].

Currently, there is also a proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency.[26] This proposal would make it possible to establish **regulatory sandboxes in the pharmaceutical area**. It would introduce 'sandboxes' to make it possible to test new regulatory approaches for novel therapies in real-world conditions. Regulatory sandboxes can provide the opportunity to advance regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially when a medicinal product is at a very early stage of development. This can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies. This is currently relevant in the context of digitalisation or

[24] Regulation (EU) 2022/858 of the European Parliament and of the Council of 30 May 2022 on a pilot regime for market infrastructures based on distributed ledger technology.
[25] Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed. Article 13a states that 'for the purpose of seeking improved alternatives to certain provisions set out in this directive, it may be decided to organise temporary experiments under specified conditions at Community level in accordance with the provisions laid down in Article 21'.
[26] Proposal of 26 April for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, COM(2023) 193 final.

the use of artificial intelligence and machine learning in the life cycle of medicinal products, from drug discovery and development to the administration of medicinal products.

The sandbox provisions cover the development phase prior to the authorisation, the authorisation of the medicinal product itself and the subsequent placing on the market. The establishment of a regulatory sandbox will be based on a Commission decision following a recommendation of the European Medicines Agency. This decision will be based on a detailed plan outlining the particular features of the sandbox as well as describing the products to be covered. A regulatory sandbox may be terminated at any time for public health reasons. Medicinal products developed under a regulatory sandbox may be authorised subject to specific conditions and subsequently placed on the market. The learning stemming from a regulatory sandbox should inform future changes to the legal framework to fully integrate the innovative aspects into the medicinal product regulation.

Industry

Net Zero Industry Act[27]

The proposal introduces Net-Zero regulatory sandboxes to test innovative net-zero technologies in a controlled environment for a limited amount of time. The Act provides for Member States to introduce such exceptional and temporary regulatory regimes allowing for the development, testing and validation of innovative, net-zero technologies before their placement on the market or putting into service. Such sandboxes can be established by the Member States at the request of any company developing innovative net-zero technologies, complying with a set of eligibility and selection criteria. When eligible, small- and medium-sized enterprises should have priority access to the sandboxes.

The net-zero regulatory sandboxes shall be designed and implemented in a way to facilitate cross-border cooperation between the national competent authorities, when relevant. Member States that have established net-zero regulatory sandboxes shall coordinate their activities and cooperate within the framework of the Net-Zero Europe Platform with the objectives of sharing relevant information. They shall also report annually to the Commission on the results of the implementation of regulatory sandboxes, including good practices, lessons learnt and recommendations on their setup.

The modalities and the conditions for the establishment and operation of the net-zero regulatory sandboxes will be clarified in secondary legislation, namely implementing acts, stemming from the proposed Regulation.

[27] Proposal for a regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act), COM(2023) 161 final.

Law Enforcement

Since 2022, Europol's strengthened mandate under its revised regulation[28] (Art. 18(2)(e) of the Europol Regulation) allows Europol and the Member States to process and to experiment with operational datasets including personal data, in a regulatory safe haven. This would mean an isolated technical infrastructure, hosted at Europol where algorithms can be developed, trained and validated on operational data including personal data (Art. 33(a), "Processing of personal data for research and innovation"). The European Commission supports the creation of the Europol sandbox environment, to explore the benefits it can bring to innovation for law enforcement and identify constraints faced. The future Europol sandbox would be of benefit for the EU research and innovation with the EU security research programme (Horizon Europe) as part of it. Such a sandbox would also lead to increasing the uptake of EU security research outcomes and could be relevant for the purpose of implementing the AI Act.

Transport

Chapter 12.8 of the Annex to the Implementing Regulation on civil aviation security on 'methods of screening using new technologies' provides for cases where Member States wish to experiment with new screening methods.

European statistics

The **Commission proposal for a regulation on European statistics**[29] introduces a new Chapter IIIa on '*Development of European statistics*' with an experimentation clause loosening the requirement to fulfil all the quality criteria for European 'statistics under development'. The experimental clause puts in place a framework under which European statistics can be:

- developed in specific statistical domains as part of a collective effort by the European Statistical System, with a use of novel data sources and integrating new technologies and
- disseminated with explicit indication for potential users that these statistics are under development

and it retains the requirement that the process remains in full compliance with the general statistical principles set out in Article 2(1) of the Regulation.

With this regulatory sandbox for the experimentation and testing with users' new statistics in a coordinated manner across the European Statistical System, Eurostat in collaboration with EU National Statistical Institutes can continuously innovate, develop new statistical outputs and insights based on all available data sources, and use state-of-

[28] Regulation (EU) 2022/991 of the European Parliament and of the Council of 8 June 2022 amending Regulation (EU) 2016/794, as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role in research and innovation.

[29] Proposal of 10 July 2023 for a regulation of the European Parliament and of the Council amending Regulation (EC) No 223/2009 on European statistics, COM/2023/402 final.

the-art technologies, with the aim of eventually integrating them in the regular production of European statistics. The need to fully comply with the statistical principles of professional independence, impartiality, objectivity, reliability, statistical confidentiality and costs effectiveness provides safeguards to preserve overarching objectives of Regulation 223/2009 on European Statistics to ensure trust in the data on the EU produced by the European Statistical System.

Finally, EU-level legislation in various sectors had already included experimentation clauses that enabled competent authorities to follow a new interpretation of the existing rules or exercise their margin of appreciation to implement the rules in a proportionate manner in specific cases. Box 1 provides some examples.

3.2 Testbeds and living labs in the EU

This section provides examples of other forms of experimentation, starting with testbeds and living labs. As already mentioned, additional approaches keep emerging and the differences between each form are not always clear-cut. It is, however, broadly agreed that in terms of the evidence generated for (regulatory) learning purposes and for the type of aspects to be tested, testbeds tend to be more focused on technology, while living labs have a stronger socio-technical element and an emphasis on co-creation to gather behavioural insights.

3.2.1 Examples of testbeds

Interoperability Test Bed [30]

With the Interoperability Test Bed, the Commission's Directorate-General for Informatics (DG DIGIT) provides a service that can be used for free by all public administrations in the EU for the design, development and experimentation of and with digital solutions.

The flow of information between IT systems lies at the core of the digital services used today by citizens, businesses and public administrations. Such exchanges are made possible by ensuring that IT systems are **interoperable** (i.e. they communicate in a common way and share an understanding over exchanged messages and the processing which they entail).

Policymakers setting requirements for IT systems are not always aware of the effect of legal provisions on the digital environment of public administrations. The Interoperability Test Bed can be used to experiment with new solutions simulating their effect on related digital systems.

[30] See Interoperability Test Bed and ITB in support of the Once-Only Technical System

SHOW Project - automated vehicles for sustainable urban transport [31]

The EU-funded SHOW project is a consortium of 70 partners from 13 European countries. The goal of the project is to estimate and evaluate the role of autonomous vehicles in making urban transport more effective, sustainable and user-friendly.

The project involves 74 autonomous vehicles suitable for all transport users being used in both mixed-traffic and dedicated lanes. The project aims to test technical solutions in order to make urban transport more sustainable. It also tries to identify new business roles and models for sustainable automated fleet operations; and to develop an open-system architecture that enables cross-site, vehicle and operator data collection and analysis. The project is also intended to improve the necessary functionalities of all vehicle types and to support the deployment of urban traffic automation through guidelines, road-mapping, certification and standardisation.

ENSEMBLE – Enabling Safe Multi-Brand Platooning for Europe [32]

The main goal of the ENSEMBLE project is to pave the way for the adoption of multi-brand truck platooning in Europe in order to improve fuel economy, traffic safety and throughput. Six differently branded trucks are driven in one (or more) platoon(s) in real-world traffic conditions across national borders.

Truck platooning comprises several trucks equipped with driving support systems – one following the other. They together form a platoon in which the trucks are driven by smart technology and communicate with each other. ENSEMBLE's aim is to define pre-standards for interoperability (standardisation of manoeuvres for forming and dissolving of platoons, operational conditions, communication protocols, message sets and safety mechanisms) between truck platoons and logistics solution providers. The purpose is to speed up actual market pick-up of (sub)system development and implementation, and to enable the harmonisation of legal frameworks in the Member States.

Baden-Württemberg Autonomous Driving Test Bed

This testbed is run by a consortium of scientific and municipal partners. It allows companies and research organisations to assess solutions involving connected and automated driving in real-world conditions. The testbed permits the regulatory and legal framework conditions to be evaluated and updated, and can provide insights for the development of legislation and policy. The project also runs citizen engagement activities to raise awareness of mobility concepts and address fears of autonomous driving.

[31] SHared automation Operating models for Worldwide adoption | SHOW | Project | Fact sheet | H2020 | CORDIS | European Commission (europa.eu). For additional details, see show-project.eu.
[32] ENabling SafE Multi-Brand pLatooning for Europe | ENSEMBLE | Project | Fact sheet | H2020 | CORDIS | European Commission (europa.eu). For further details, see: Homepage | Platooning Ensemble.

End-to-End digitalised production testbeds [33]

The cross-Knowledge and Innovation Community (KIC) activity is run together by EIT Manufacturing, EIT Digital, EIT Food and EIT Raw Materials. Its main goal is to encourage EU industry to remain competitive by adopting digital solutions, such as artificial intelligence and 5G. It supports the establishment of innovative end-to-end, customer-centric testbeds covering the whole product life cycle.

- **SAIFE - Safety testbeds through AI for Food production Environment** focuses on reducing the number of forklift accidents on EU shopfloors. The goal is to provide forklift drivers with real-time information about moving persons on the shopfloor in order to prevent accidents. This intelligent system works via visual sensors complemented by AI software and tablets on the forklifts. In a preliminary implementation, six testbeds have been installed in the food industry in real production environments across the EU. This also includes one mobile testbed that is to be rented out.
- **eMOTOR Virtual Testbed** is an EU innovation project that aims to evaluate electric motors made with recycled magnets from their technical performance. It takes into consideration the LCA (Life Cycle Assessment) of the final product and circular manufacturing processes. It also embeds a digital twin to support AI-driven analytics. The testbed will incorporate motor fast-redesign tools which will make it possible to consider recycled parts' characteristics, their production processes and how the long-time performances can be affected due to the use of recycled motor parts. The testbed will evaluate the key performance indicators (KPIs) of the recycled motor from a holistic point of view with LCA techniques.

Open innovation test beds (OITBs)

- In the field of **renewable hydrogen**, Horizon Europe [34] supports the establishment of **open innovation test beds (OITBs)** to offer access to physical facilities, capabilities and services required for the development, testing and upscaling of technology in industrial environments. They can cover all activities from the prototyping to industrial production, and especially testing in an industrial environment, regulatory compliance assessment and circularity assessment.
- The Horizon Europe project **Convert2Green** [35] establishes an OITB that focuses on the integration of innovative, circular and carbon-neutral materials solutions for the key value chains: clean autonomous vehicles, smart health, industrial IoT, low-carbon industry and clean energy. It completes eco-impact analysis from raw material to product-as-a-service and establishes procedures and contract models for licensing the joint ownership of intellectual property rights.

[33] EIT Community Testbeds
[34] Horizon Europe Work Programme 2023-2024, *8. Climate, Energy and Mobility*. See here
[35] Convert2Green

- Another Horizon Europe project related to **net-zero energy buildings (nZEBs)**, **Exploit4InnoMat OITB** [36], makes available a high-end OITB network for building envelopes including roofs and facades, and enabling the replication of prototypes in different buildings. The fields covered include (i) nano-enabled cement, non-cement premixes and ceramics, advanced coatings and glazing solutions loaded with aerogel, fibres, phase change material (PCMs) and other nanomaterials providing multifunctional properties; (ii) pilot lines for nano-dispersion, 3D printing and robotic spraying; and (iii) a network of four real-scale living laboratories for nZEB technologies evaluation. Additionally, a semi-automated tool combining business information modelling (BIM) analysis, fast-track modelling and simulation makes possible a digital tool for utilising building blocks (structural, solar thermal and building-integrated photovoltaics (BIPV)) to create a harmonised and aesthetically pleasing urban environment.

Eurostat's Experimental Statistics Test Bed

For development and testing of European statistics in various statistical fields, Eurostat has introduced a definition and label of 'Experimental statistics'. It also established a procedure for assigning and modifying such a status to/for indicators produced in pilot projects, after an evaluation of the methodology followed in the data compilation process and quality of the outputs. Moreover, Eurostat set up a dedicated website[37] for dissemination of its experimental statistics and for collecting feedback on the indicators from users. The users' feedback on (some elements of) the data's quality is one of the critical factors considered once deciding on (dis)continuation of the work on the indicators and/or their potential upgrading to the status of 'regular' European statistics.

3.2.2 Examples of living labs

MOVE 21 - testing an integrated method towards greener transport systems [38]

MOVE 21 tackles the integration of passenger and freight transport, thereby increasing the resilience of European transport systems. The project operates three living laboratories (in Oslo, Gothenburg and Hamburg), in which different types of mobility hubs and associated innovations are tested and means to overcome barriers for clean and smart mobility are deployed. The co-creation processes are supported by consistent policy measures and by increasing innovation capacity in city governments and local ecosystems. The proposed solutions will deliver new, close-to-market-ready solutions that have been proven to work in different regulatory and governance settings. The project's societal aspect is focused on increasing social cohesion in cities. MOVE 21 comprises 24 partners (6 public authorities, 2 public transport companies owned by

[36] Its scope includes end-user market needs for low-cost, flexible, on-demand material-based solutions, which are assessed through materials characterisation and modelling, monitoring and process control, environmental and assessment, regulatory and standardisation, social acceptance and innovation management.

[37] Experimental statistics – Overview

[38] Multimodal and interconnected hubs for freight and passenger transport contributing to a zero emission 21st century | MOVE21 | Project | Fact sheet | H2020 | CORDIS | European Commission (europa.eu). For further details, see: Main Home - Move21

municipalities, 6 industry partners (including 2 SMEs), 6 research organisations and 4 network organisations) from 7 different European countries.

UP 2030 - urban planning with a focus on climate change [39]

UP 2030 aims to guide cities through the socio-technical transitions required to meet their climate neutrality ambitions. The approach uses urban planning and design to create better connected, more compact, net-zero neighbourhoods in the city pilots. The project is developing a methodological framework that supports cities in (i) updating policies, codes and regulations; (ii) upskilling by building the capacities of the entire city stakeholder ecosystem that will deliver actions; (iii) upgrading through the development of solution prototypes (digital and physical) in selected neighbourhoods; (iv) upscaling to achieve city-wide impact by shaping the governance arrangements and matching project portfolios to financial resources; and (v) sharing best practices between cities. Inclusive participation is key throughout the project's full cycle of activities so that communities' real needs are reflected in the city-specific visions and co-designed interventions maximise the delivery of co-benefits. UP2030 will therefore (a) improve social cohesion; and (b) enable citizens to participate in the transition by becoming agents of change themselves through their own sustainable changes in behaviour.

Limerick's Citizen Innovation Lab

Limerick's Citizen Innovation Lab is a living lab that engages citizens via digital tools in creating a citizen-sourced open-data portal to enable local policy and regulatory change (funded under the Positive City Exchange project, Horizon 2020). It was used to develop smart sensors to gather evidence with a view to enabling change in the building and fire regulations in Limerick (a project that was supported by the Small Business Innovation Research challenge in Ireland).

Kraków Living Lab

The Kraków living lab organises policy learning labs (PLL) with innovators and citizens, where policymakers can learn about concrete applications of emerging technologies, the barriers that innovators have encountered and the ways in which citizens feel affected. In a PLL focused on AI, companies identified challenges requiring regulatory standardisation. Interactions in PLLs have also helped shape the Regional Innovation Strategy and an air pollution regulation.

User validation labs (ULabs) [40]

User validation labs are a programme run by EIT Health. It helps organise and execute a validation study for start-ups' innovation. The ULabs include living labs, accelerators, hospitals and innovation centres that can help innovators gain access to, and collect feedback from, future-end users. It makes it possible to test products or services with patients, clinicians and medical staff in Europe.

[39] Urban Planning and design ready for 2030 | UP2030 | Project | Fact sheet | HORIZON | CORDIS | European Commission (europa.eu)
[40] User Validation Labs (ULabs)

Box 3: The JRC Living Labs

The JRC Living Labs are an experimental regulatory-support tool for the Commission. They provide an environment for regulatory learning and discovery, where the regulatory implications of innovative technologies can be observed and shaped, especially over longer timeframes. The aspiration is that the JRC Living Labs can anticipate and respond to regulatory-support needs.

The JRC has living labs at two of its research sites in Ispra (Italy) and Petten (Netherlands) in order to co-create innovative smart city solutions. The projects focus on digital energy and future mobility solutions. They simulate urban environments with a large number of staff, buildings, roads and utilities using dedicated experimental facilities. These facilities provide an environment for SMEs and start-ups to test and demonstrate in almost-real-life settings a variety of innovative technologies (e.g. connected and automated vehicles, delivery droids and smart e-charging platforms) and research methodologies (e.g. user-centric research design, co-creation, and citizen engagement methods).

An additional living lab is being created at the third JRC site in Geel (Belgium), with a Counter-Unmanned Aerial System (C-UAS) solution implemented.[41] The facility will be open to stakeholders to test C- UAS solutions and how these can be applied in real life. The living lab implementation is designed to comply with the legally mandated protection requirements for the Geel site (Class 1 Nuclear installation).

A Digital Connectivity Lab is currently under development, paving the way for experimentation and demonstration of next-generation connectivity systems (e.g., 5G, 6G, satellite communications, future evolutions of Wi-Fi networks, etc.) to support EU policies through a real-life experimental setup.

Furthermore, with a structured involvement of non-traditional policy actors at its core (i.e. researchers, innovators and citizens), the living labs approach supports the Commission's better regulation agenda, which aims to involve citizens, businesses and stakeholders in the decision-making process. As an example, in the field of connected, cooperative and automated mobility (CCAM) JRC's Living Labs played an important role in shaping many aspects of the Commission Implementing Regulation (EU) 2022/1426. This is due to the possibility to conduct real-life experiments and engage citizens directly with a technology that was only available in a limited number of prototypes.

[41] The living lab was announced in the staff working document accompanying the Communication from the Commission, "A Drone Strategy 2.0 for a Smart and Sustainable Unmanned Aircraft Eco-System in Europe", COM(2022) 652 final.

3.3 Additional initiatives supporting innovation and regulatory learning

Technical Support Instrument

Under the Technical Support Instrument (TSI), the European Commission can support the Member States to launch and implement regulatory sandboxes and other forms of regulatory experimentation at national level. In recent years, the Commission supported the implementation of several regulatory sandboxes for the financial sector, upon the request of as many as four Member States. Besides, the Commission currently supports Croatia, in partnership with the OECD, through a TSI project on, among others, a regulatory sandbox methodology to facilitate innovative business models, the implementation of regulatory experimentation initiatives, as well as agile regulatory governance. For 2024, the TSI includes a Flagship project on Support to the Green Deal Industrial Plan, which, among others, offers support for setting-up regulatory sandboxes to test innovative net-zero technologies and stimulate innovation. The TSI 2024 will also include a flagship on AI that can be also used to establish regulatory sandboxes under the AI Act.

Horizon Europe Missions [42] and European partnerships

EU Missions are a new way to apply concrete solutions to some of our greatest challenges. They have ambitious goals and will deliver results by 2030. They will do so by putting research and innovation into a new role, combined with new forms of governance and collaboration, and by engaging citizens. EU Missions are a new feature of the Horizon Europe research and innovation programme for 2021-2027. They are a coordinated effort by the Commission to pool the necessary resources in terms of funding programmes, policies and regulations, as well as other activities. They also aim to mobilise and activate public and private actors, such as EU Member States, regional and local authorities, research institutes, farmers and land managers, entrepreneurs and investors to create a real and lasting impact. EU Missions are engaging with citizens with the ultimate goal of boosting societal uptake of new solutions and approaches. **EU Missions are at the intersection between policy and research, so offer a suitable ground for experimentation**. They can help identify innovative solutions that require exemptions from applicable rules and actively contribute to testing such solutions in real-life environments. For instance, the **EU Mission 'a soil deal for Europe'** [43] aims to establish 100 Living Labs and Lighthouses to lead the transition towards healthy soils by 2030. Good practices are tested in real-life conditions involving a wide variety of stakeholders in a co-creation manner and responding to local needs to encourage other practitioners to move towards sustainable soil and land management.

In the field of health, the **Cancer Mission** [44] and European partnerships such as the Innovative Health Initiative [45] joint undertaking are especially well placed to identify

[42] The legal basis for EU Missions is in the Horizon Europe Regulation: EUR-Lex - 32021R0695 - EN - EUR-Lex (europa.eu)
[43] Living labs & lighthouses (soilmissionsupport.eu)
[44] EU Mission : Cancer
[45] Innovative Health Initiative

specific needs for, and experiment with, regulatory sandboxes that are proposed in the draft proposal for the pharmaceutical regulation [46].

The **Climate-neutral and Smart Cities Mission** also provides a valuable setting for experimenting further using regulatory sandboxes [47]. One of the recurrent issues raised by cities (in addition to the need for additional funding) is existing regulatory barriers, mostly at national level. To implement innovative projects and to pioneer or upscale new or innovative solutions (at both technical and governance levels), cities need in some instances to be granted exemptions from existing regulatory frameworks. Testbeds and living labs have been explored using EU funding, but the use of sandboxes for cities in the context of the green and digital transition is still somewhat limited. Local energy communities and use of public space are one area where this could be further explored.

Financial services

In its Digital Finance Strategy for the EU [48], adopted in September 2020, the Commission made a commitment to build an EU Digital Finance Platform to better connect innovative financial firms and national supervisors. The Platform became operational in mid-2022. The two main objectives of the initiative are to bring innovative financial firms and national supervisors closer together and to offer practical tools supporting firms seeking to scale up their activities and offer their products and services to more than one Member State. A key part of the Platform is dedicated to enabling firms to launch sandbox-testing processes with national supervisors, with the possibility of involving multiple authorities in one step. This feature will build on the Procedural Framework for Cross-Border Testing [49] developed by the European Forum for Innovation Facilitators, which brings together representatives of national supervisors working on innovation and digital issues. While continuing to rely on national sandboxes and national requirements, the cross-border testing section of the EU Digital Finance Platform is designed to make it easier for fintech firms to contact supervisors and scale up their activities across the Internal Market.

The Commission is currently developing phase 2 of the Platform [50]. The main initiative is the Data Hub. This new element will complement national sandboxes and innovation hubs, as well as cross-border testing, by making specific datasets of non-public, non-personal data available to participating firms so that they can test their innovative solutions. Data sources could also come from the private sector. The aim is to foster data-driven innovation – a key priority of the Digital Finance Strategy – and to further strengthen dialogue between supervisory authorities and innovative financial firms. Legal

[46] Reform of the EU pharmaceutical legislation
[47] The Cities Mission involves local authorities, citizens, businesses, investors, and regional and national authorities to: (i) deliver 100 climate-neutral and smart cities by 2030; and (ii) ensure that these cities act as experimentation and innovation hubs to enable all EU cities to follow suit by 2050.
[48] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a Digital Finance Strategy for the EU, COM(2020) 591 final.
[49] Procedural Framework for Innovation Facilitator Cross-Border Testing
[50] IT development and procurement strategy choices will be subject to pre-approval by the European Commission Information Technology and Cybersecurity Board.

constraints currently make it very difficult for national authorities in particular to give the Commission or market participants access to their data, so the Commission intends to start building the Data Hub with synthetic data.

The solution envisaged by the Commission will enable authorities to use software provided by a private provider, along with training and support, to create synthetic data themselves, modelling it on the original data they hold. This would make it possible to generate synthetic data that provides the necessary level of anonymisation while preserving, as far as possible, the characteristics of the original data that make it relevant for testing purposes. This approach of creating synthetic data was successfully tested in summer 2022 in a pilot involving the Bank of Spain. A contractor is currently working on the objectives of the Data Hub together with the participating authorities to synthesise data.

Digital

The **European Blockchain Services Infrastructure (EBSI)** aims to build a pan-European blockchain infrastructure for the delivery of public services in line with EU values and standards. The EBSI provides an informal testing and pilot environment for different use-cases. In addition, a **European Blockchain Regulatory Sandbox** was launched under the **Digital Europe Programme**. The sandbox is governed by the European Blockchain Partnership (EBP). Distributed ledger technology (DLT) pilots have shown significant potential in different industry sectors, but there is legal uncertainty because governance is shared between many actors. To increase legal certainty in support of the EU's ambition for digital leadership in this Digital Decade, there is a need for enhanced dialogue between regulators and innovators. The European Blockchain Regulatory Sandbox addresses this need by providing a trusted environment in which regulators and providers of DLT technologies can engage with one another. The aim of the sandbox is to clarify the applicable legal framework and increase legal certainty to European start-ups and market players that innovate with blockchain-based solutions. This will enable harmonised interpretation of regulations and the flexibility needed for innovation. This sandbox is running from 2023 to 2026 and will support 20 projects annually, including public-sector use-cases on the EBSI. Projects will be chosen through calls for expression of interest. It will support companies and start-ups in the sandbox in the assessment of legal and business obstacles that may arise when they deploy their solutions. Regulatory questions may concern any area of law. The sandbox will allow supervisors to enhance their knowledge of cutting-edge technologies involving DLT. Lessons learnt will be shared between participating regulators, thus helping the Commission to identify best practices.

Mobility

Research and regulation are very clearly intertwined in the road transport area of Connected, Cooperative and Automated Mobility (CCAM). Any vehicle used on EU roads must comply with the EU's vehicle type-approval regulation and with national rules (particularly road traffic and safety regulations).

As previously illustrated in the JRC living labs box, the development of EU regulation on automated driving systems has therefore been strongly based not only on the JRC's

experiments but also on the outcomes of several EU-funded research projects such as the SHOW project [51].

Moreover, in addition to having to research how to adapt national road safety and traffic rules to enable the deployment of automated vehicles, national authorities have to regularly issue exemptions from current regulations so that research tests can be conducted in real traffic situations (e.g. where there is no driver/operator in the vehicle). This exemption process is extremely cumbersome because it is often delegated to the regional or even local levels (municipalities). The EU CCAM partnership's State Representative Group is therefore looking for the most effective ways of simplifying the exemption process while also attempting to harmonise this process throughout the EU. This would ultimately avoid cross-border EU research projects having to launch completely different procedures in different testing locations.

Box 4: real-life testing of CCAM solutions at national level – the L3Pilot and HiDrive experiences

As part of the preparation for large-scale pilot programmes on public roads, L3Pilot [52] conducted a detailed survey of legislation and regulation in each country where the experiments took place (Belgium, Germany, France, Italy, the Netherlands, Sweden and the United Kingdom). This work on legal aspects was needed in order to obtain permission to drive on public roads and to clarify the conditions for possible cross-border operations. It turned out that exemption procedures are time-consuming and differ strongly from country to country.

In preparation for L3Pilot's final event in Hamburg, Germany, the first steps towards the centralisation of the exemption process have been taken. TÜV Süd Rail (the entity responsible for the exemption process in Germany) worked closely with L3Pilot to obtain permission to drive on public roads in Hamburg. The exemptions obtained in the Member States (e.g. Italy and France) were considered in the process and this significantly simplified and shortened the exemption process.

The cumbersome process motivated the consortium to pursue this important topic further, to involve TÜV SÜD Rail in the follow-up project Hi-Drive [53] and to work on harmonised admission procedures for testing CADs on public roads across Europe.

Horizontal application

Two **innovation deals** [54] have been piloted so far in the area of the circular economy.

- The first innovation deal investigated the (perceived) regulatory barriers that may prevent a broader application of anaerobic membrane bioreactor (AnMBR) technology to allow reuse of reclaimed water and nutrients in agriculture. The innovation deal identified as a regulatory barrier the fact that the technology could

[51] The SHOW Project
[52] L3 Pilot
[53] Hi-Drive
[54] Signed Innovation Deals

not receive a permit to operate in sensitive areas. The deal produced recommendations to change the existing rules in order to permit fertigation in sensitive areas while also respecting environmental objectives; to develop guidance for Member States on how to take account of environmental risks relating to nutrients; and to reflect on methods for water pricing and recovering costs from polluters when water is reused in agriculture.

- The second innovation deal [55] analysed whether existing EU law hinders the recycling or reuse of propulsion batteries for electric vehicles. The analysis found that there is: (i) a risk of prematurely classifying EV batteries as waste; (ii) a double-energy tax payment and grid fees for bidirectional smart-charging; and (iii) a lack of incentives to roll out smart-charging infrastructure. A revised version of innovation deals is under preparation, based on the lessons learnt from the pilots. These lessons indicate that some of the perceived barriers encountered by innovators can be resolved by clarifying existing rules. Other barriers may require intervention at national level or a revision of EU rules to benefit all innovators facing similar obstacles.

4. OVERVIEW OF PRACTICE AT THE NATIONAL LEVEL

In the second half of 2021, the Slovenian Presidency of the Council facilitated the exchange of experiences regarding the legal basis, implementation and evaluation of regulatory sandboxes in the Member States. The Slovenian Presidency invited national delegates to the Working Party on Better Regulation to help with data collection from relevant institutions at the national level, using an adapted version of the questionnaire developed for data collection in the Commission [56].

There were 40 cases of existing regulatory sandboxes by the end of 2021, 7 cases of sandboxes being established or set up, and 15 cases falling into the category of other forms of experimentation provisions and tests. Annex 3 provides a full overview and details of the cases analysed.

[55] Innovation Deal: The Virtuous Loop of Electric Vehicle

[56] To mirror data collection at EU level, the questionnaire prepared by the Slovenian Presidency had two parts. Part one collected information on regulatory sandboxes and their possible accompanying experimentation clauses. Part two collected information on other forms of experimentation provisions and tests that exist in the Member States but which are not necessarily called regulatory sandboxes.

Figure 2: number of cases per Member State

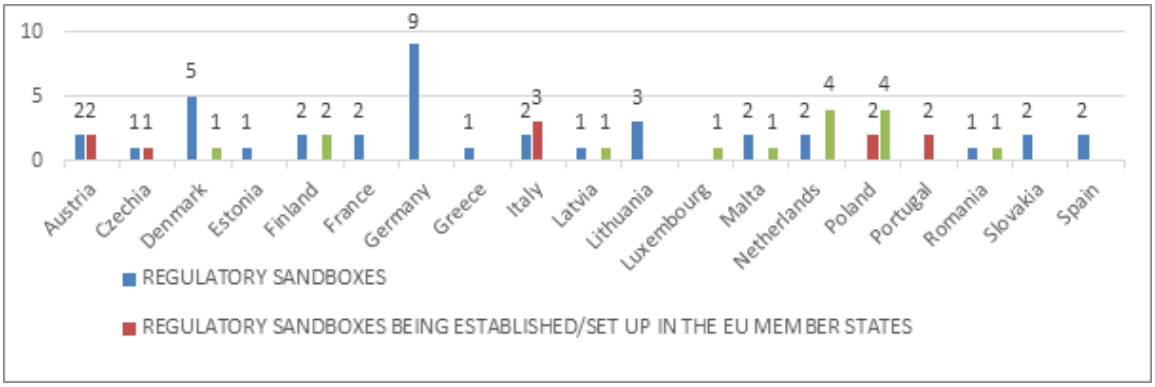
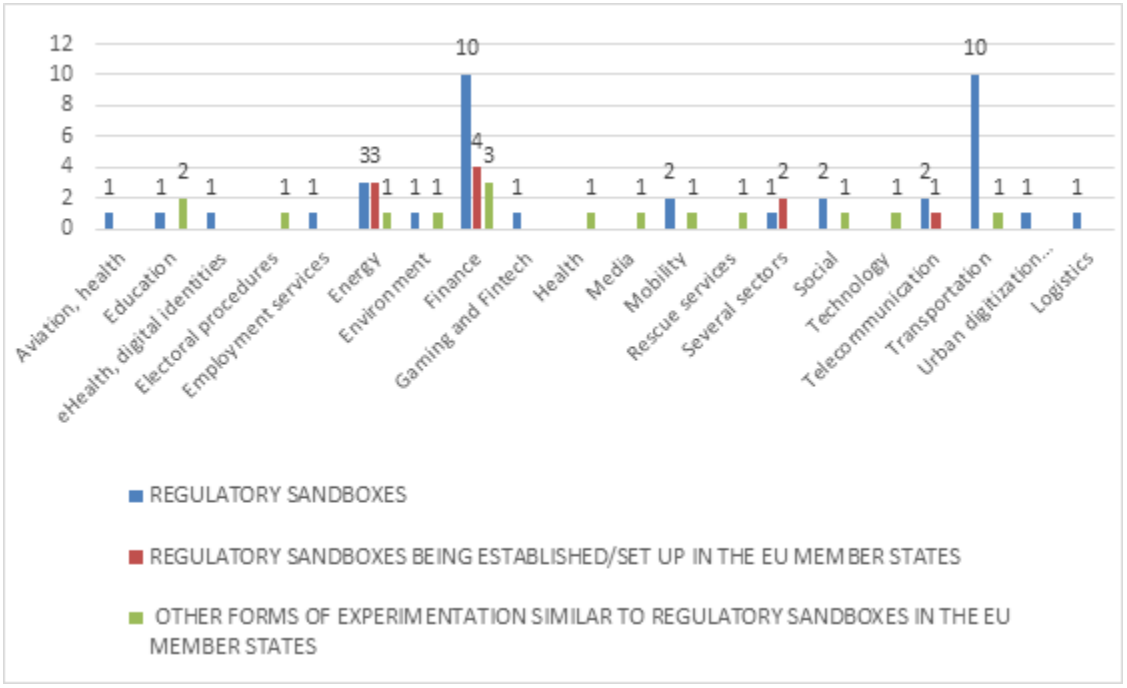


Figure 3: number of cases per sector



Most of the reported sandboxes were set up in 2019-2020, so it is still too early to draw complete lessons on implementation and results. The information collected nevertheless points to a number of factors.

- There were 6 cases where existing legislation already enabled experimentation. Sandboxes were very often made possible by adapting a single article of primary or secondary legislation. Various terminology was used, such as 'exceptions', 'derogations', 'special rules', 'legal instructions' or 'special agreements'.
- The data showed that regulatory sandboxes are evolving in various sectors, but that the majority were in the finance (10 cases), transport (10 cases) and energy (4 cases) sectors. Similar testing was being done in the different Member States (e.g. testing of self-driving vehicles).
- Most of the examples lasted longer than 5 years (10 cases) or only 1 year (8 cases).

- 1 case had several hundred participants, 6 cases had between 20 and 50 participants and 7 cases had only 1participant.
- It was usually too early to tell whether the sandbox exercise would prompt a change in regulation. Nevertheless, the regulatory sandbox had already led to a change in regulation in 9 cases while there had been no changes in 5 cases.

5. EXAMPLES OUTSIDE THE EUROPEAN UNION

The concept of regulatory sandboxes is explored not only in the EU but also internationally. Most sandboxes at global level (just like sandboxes in many EU Member States) support the digital, energy and mobility sectors.

In the digital sector, **Canada** [57] has completed a sandbox on electronic shipping documents. **Saudi Arabia** [58] has created a sandbox welcoming digital innovators by allowing them to test their products (e.g. open banking services [59]) in a 'live' environment. After its initial clampdown on the local fintech (e.g. peer-to-peer lending) industry, **China** [60] launched projects that enable innovators to experiment with new technology initiatives, with the goal of further digitising capital markets. In May 2023**, Namibia** [61] signed an agreement with a Nigerian biometrics provider to promote the development of the country's digital economy by developing a digital identity framework and thereby supporting the local fintech scene.

In the transport sector, **Australia** [62] is currently conducting a regulatory sandbox with autonomous maritime vessels without the need to apply for a permit. In 2021, **Korea** [63] ran a sandbox allowing non-licensed taxi operators to continue providing their services after the exit of one of the largest ride-hailing operators from the market. **Singapore** [64] launched the testing of autonomous vehicles in one part of the island in 2019.

Additional examples can also be found of testing innovations in other sectors. For instance, **Korea** [65] launched a regulatory sandbox in 2019 to better understand the barriers SMEs face in the development of new technologies and to entry into the market for innovative industries. In May 2023, **Indonesia** [66] announced its regulatory sandbox programme for telehealth providers as a way to provide more equitable and accessible health services in the community. In the defence sector, **Canada** [67] finalised two

[57] Electronic shipping documents (canada.ca)
[58] G20 Survey on Agile Approaches to the Regulatory Governance of Innovation (oecd-ilibrary.org)
[59] Permitted fintechs (sama.gov.sa)
[60] Guangzhou to host fintech projects in government sandbox in race with Beijing, Shanghai | South China Morning Post (scmp.com)
[61] Namibia's financial regulator partners with Prembly on digital ID regulatory sandbox | Biometric Update
[62] ReefWorks granted Australia's first permit-free marine tech testing status | AIMS
[63] Korean mobility platforms rush to fill void after Tada's departure - 매일경제 영문뉴스 펄스 (Pulse) (pulsenews.co.kr)
[64] Singapore expands test site for autonomous vehicles | ZDNET
[65] G20 Survey on Agile Approaches to the Regulatory Governance of Innovation (oecd-ilibrary.org)
[66] Minister announces 15 health innovators chosen for regulatory sandbox - ANTARA News
[67] Sandboxes - Canada.ca

sandboxes on anti-uncrewed-aerial systems in 2019 and 2022, with another follow-up sandbox in 2024. The goal of these sandboxes was to test the technology's capabilities and limitations and for the innovators to understand the requirements of the armed forces. There are also examples of other forms of experimentation. For instance, in **Israel**, the Tel Aviv Yafo municipality, Tel Aviv University and Atidim Park Tel Aviv established CityZone [68], an urban-tech living lab and open innovation hub that operates a year-long smart city and smart mobility start-up acceleration programme.

An example of systematic international cooperation is the **Agile Nations** [69,70] network which has the goal of bringing together governments and industry from different countries and sectors to collaborate on creating an innovation-friendly environment globally. While there are many regulatory sandboxes in operation, only a small number of them have been completed, so it is still too early to draw firm conclusions on regulatory sandboxes or other experimentation spaces. The EU is also preparing the ground to cooperate internationally on regulatory sandboxes. For instance, in the energy-clean tech chains and raw materials sector, the free-trade agreements or the future net-zero partnerships could include provisions on cooperation on research and innovation with (selected) third countries[71].

Frameworks for regulatory sandboxes have different governance structures depending on the country in which they are run. Either one single authority is responsible for the deployment of sandboxes or they are run by different authorities depending on the scope and focus of the sandbox. For instance, the **Canadian** [72] legal base for establishing sandboxes follows on from the creation of the Centre for Regulatory Innovation in 2018. This institution helps regulators across different sectors to keep pace with technological innovations and oversees the running of regulatory sandboxes and other projects related to innovation. The **Korean** [73] government announced its regulatory innovation programme in 2017 when it designed the Korean Regulatory Sandbox programme. This programme covers four sectors (ICT, industrial convergence, innovative finance and regional innovation). The responsible regulatory authority varies by sector, but the Office of Government Policy Coordination oversees the overall mechanism.

[68] CityZone is supported by EIT Urban Mobility. The selected projects have the Tel Aviv municipality as a design partner, can test their technologies at the municipality's testing ground and have access to the city's data. In addition, CityZone has collaborations with cities and corporations around the world. Further details are available at: https://www.city-zone.co/.
[69] Agile Nations - GOV.UK (www.gov.uk)
[70] Canada, Denmark, Italy, Japan, Singapore, the UAE and the UK are members of the group.
[71] An example of relevant provision included in an already concluded Free Trade Agreement states that: "The Parties recognise that research, development and innovation are key elements to further develop efficiency, sustainability and competitiveness in the energy and raw materials sectors. The Parties shall cooperate, as appropriate, inter alia, in: (a) promoting the research, development, innovation and dissemination of environmentally sound and cost-effective technologies, processes and practices in the areas of energy and raw materials; (b) promoting value addition to the mutual benefit of the Parties and enhancement of productive capacity in energy and raw materials; and (c) strengthening capacity building in the context of research, development and innovation initiatives".
[72] Centre for Regulatory Innovation: who we are - Canada.ca
[73] Regulatory quality and competition policy in Korea (oecd.org)

A comparable situation to Korea is found in **Australia** [74], where individual government authorities are responsible for their regulatory sandboxes. The Australian Securities and Investment Commission is responsible for the Enhanced Regulatory Sandbox, which is targeting fintech innovations, while the Australian National Transport Commission is responsible for the regulatory sandbox focused on autonomous vehicles.

Saudi Arabia [75] has so far experimented with regulatory sandboxes in the financial sector through the Regulatory Sandbox Framework developed by the Saudi Central Bank and with the Emerging Technologies Sandbox, which is administered by the Communications, Space and Technology Commission.

Experimental activity using regulatory sandboxes is also present in the **United States**. Due to current legislation, regulatory sandboxes only exist at the state level. Arizona is a frontrunner in the use of regulatory sandboxes in the US, and launched sandboxes focused on property technology and fintech. Sandboxes also run in North Carolina, Utah, Hawaii, Kentucky, Vermont, and Nevada. Out of the selection, Utah is the only state with a universal sandbox so far[76].

6. OVERALL CONCLUSIONS AND THE WAY FORWARD

Experience with the tools covered in this Staff Working Document remains limited, notably because such policies are new and hardly evaluated yet. However, some preliminary conclusions can be drawn from the evidence already available. In particular, the examples presented in the previous sections and in Annexes 1 and 2 show that there is no one-size-fits-all instrument that can be used in each and every case. Rather, one must carefully consider the goal of experimentation and the stakeholders involved in order to design a tool that is fit for purpose in each particular situation. The underlying motivation for using experimentation tools should be to enable innovation and regulatory learning. Available experience also indicates that regulatory experimentation works better as part of a broader strategy, serving long-term objectives to be achieved through concrete projects and within specific policy frameworks.

National regulatory authorities need to ensure that they have the mandate and the resources to engage in experimentation and regulatory learning. When it comes to using more legally structured methods (e.g. regulatory sandboxes), it is crucial to implement well-designed reporting and monitoring schemes to make the projects successful and to extract lessons from the experiment, thus enabling regulatory learning.

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[74] For further details see: The role of sandboxes in promoting flexibility and innovation in the digital age (oecd.org); Enhanced regulatory sandbox | ASIC

[75] For further details, see: Sandbox (sama.gov.sa); Emerging Technologies Sandbox (cst.gov.sa)

[76] For further details, see: EU and U.S. Regulatory Sandboxes: Groundbreaking Tools for Fostering Innovation and Shaping Applicable Regulations | Jones Day - JDSupra; Regulatory Sandboxes Give States An Edge Attracting Innovation And Investment (forbes.com), and Regulatory Sandboxes Speed Innovation - Stand Together Trust.

An important role of competent authorities is to consult and advise innovators on the boundaries set by existing regulatory frameworks to their activities. The availability at national level of one-stop shops, where innovators can find guidance on regulatory matters specific to the respective country or territory remains in high demand. In this context, the EU could position itself as the link between national authorities by assuming two distinct roles.

The first role would be a knowledge-management role to facilitate exchanges on national practices. Coordinated knowledge-sharing could help national regulators when they develop national regulatory sandboxes, implement them consistently across the EU Member States and ensure consistency with EU law. This is particularly important for a well-functioning EU Internal Market, preventing fragmentation and ensuring that its potential is fully exploited. The EU can support consistent experimentation within the Internal Market by providing clarity on operational elements through delegated and implementing acts, or in non-legislative instruments when provided for in the basic act. For instance, the Net-Zero Industry Act and the AI Act encourage national authorities to establish regulatory sandboxes in these two sectors. However, the modalities and conditions for the operation of these sandboxes (i.e. eligibility criteria, procedure for application, selection, participation in and exiting from the sandbox, as well as the rights and obligations of sandbox participants) will be set through implementing acts at EU level. Additionally, both acts envisage platforms for cross-border cooperation and knowledge-sharing (e.g. the Net Zero Platform) and coordination at EU level within relevant governance frameworks. This is also particularly important to ensure that the results from the sandboxes become widely available to everyone and that they are effectively used for EU policy and regulatory purposes.

Second, the EU could update regularly relevant information on existing experimentation schemes (e.g. legislative frameworks, regulatory sandbox examples (including application procedures), concrete trials, impacts and regulatory learning, lessons learnt, and use of other forms of regulatory experimentation). This would over time facilitate a comparative analysis of existing barriers to innovation and identify where additional room for experimentation is needed (either through experimentation clauses to be included in existing or future legislation or by expanding the mandate of competent authorities), and by supporting experimentation under relevant EU programmes, such as Horizon Europe and the Digital Europe Programme, to create an overall enabling environment.

6.1 General findings on regulatory sandboxes

Considering the relative novelty of regulatory sandboxes in the EU and globally, there is still no established *legal* definition of this practice. However, this has not constrained the development of this tool at EU and national level, and the key characteristics that distinguish regulatory sandboxes from other forms of experimentation are gradually stabilising. These include a clear focus on regulatory learning; a structured approach to testing innovation, in a controlled real-world environment under supervision by one or more competent authorities; an explicit link with legislation through a legal base; possible flexibility within the law in applying legal requirements in a proportionate and context specific manner and temporary derogations and exemptions from those parts of the legislation that are relevant for a specific sandbox; and the use of appropriate

safeguards. There are usually two approaches to design sandboxes: top-down schemes (also called policy-oriented) launched by competent authorities to address specific goals, and bottom-up schemes (also called innovator-oriented) where innovators propose the field of experimentation. A combination of these two approaches is also possible. In terms of duration, existing examples last from less than one year to over 5 years, usually when physical infrastructure is concerned (see Annex 2).

Sandboxes can serve different purposes, as the examples included in this document have shown. For instance, when a regulatory sandbox is established in an already regulated field, the purpose of the sandbox is to provide legal certainty on how existing rules apply, experiment, test and understand whether an adaptation of the legislative framework would make sense, under what conditions and with which requirements. A sandbox could also help the regulator understand new risks and impacts. This could ultimately lead to a change in the legislation or to a different interpretation, and ensure it remains fit for purpose and future-proof based on operational evidence. A sandbox could also be used to develop the implementing rules and guidelines for a recently adopted piece of legislation and prepare for its implementation by testing various approaches and drawing lessons on good practices and possible shortcomings. When a regulatory sandbox is set up in an unregulated field, the likely purpose of the sandbox is to learn and establish whether regulation is even possible and desirable.

The literature suggests that effective and fruitful regulatory learning results from a combination of a sound sandbox methodology and productive interactions between regulators and innovators. Both academic and government publications emphasise the need to start each regulatory sandbox project with a hypothesis to test, a rigorous plan for collecting and analysing key data (possibly with the help of an independent third party), and wide dissemination of the results (including to policymakers responsible for policy preparation, the public and the wider innovation ecosystem).

Avoiding or minimising any competition distortion effect and sharing the learning outcomes of the sandbox is important and should be incorporated already at the design phase.

In addition to these general remarks on the nature of regulatory sandboxes, it is important when referring to the EU context to keep in mind that EU law is different from Member States' laws. Member States have greater freedom to legislate in their territory as they see fit. The EU, however, can only act within the competences granted by the Treaties. Another consideration is whether the identified regulatory barriers exist in EU law or rather in the national context. The implementation of the regulatory sandboxes under the proposed Interoperable Europe Act could in the future help for joint learnings for cross-border use cases feeding into several jurisdictions.

The co-existence of sandboxes and other types of experimentation at EU and national level raises the question of the link (if any) between these national experiences and EU legislation in the same sector or on the same topic. These national experiences may also have implications from an Internal Market perspective and in terms of implementation and enforcement of existing EU legislation in the same sector.

6.2 General findings on testbeds and living labs

The objective of testbeds is to test technological solutions in (near) real-life scenarios. Examples in Section 3 have shown that, as part of the testing, testbeds may serve additional functions. These additional functions include i) identifying new business models; ii) improving the functionality of innovations; iii) establishing standards and protocols; and iv) integrating new solutions, products and services into a real-life environment.

In addition to checking the validity of innovations from the technological perspective, living labs put a stronger focus on the societal aspect of innovations and their acceptance by potential users. In fact, the societal aspect and a focus on inclusive participation through citizen engagement is the key feature that distinguishes living labs from other tools. The examples included in Section 3 show that living labs can i) increase social cohesion and involve a diverse set of stakeholders; ii) catalyse citizen engagement; iii) measure social impact; and iv) assess the validity of technical solutions for user needs.

Since neither testbeds nor living labs are designed with regulatory learning as their primary objective, additional evidence and experience is needed to clarify how these projects can best inform and contribute to policymaking.

ANNEX 1: REGULATORY SANDBOXES AND EXPERIMENTATION IN THE FIELD OF ENERGY

1. WHY DO WE NEED REGULATORY EXPERIMENTATION IN THE ENERGY SECTOR?

1.1 Transformation in the energy sector

The EU's energy system is engaged in a **profound transformation in the context of the digital and green transition** that has been further accelerated by the geopolitical changes which occurred in 2022. The EU's objectives for 2050 are ambitious. As part of the objectives of the European Green Deal [77], the EU aims to bring its net emissions of greenhouse gases down to zero by 2050. To get there, the EU agreed to the binding objective of reducing Greenhouse Gas (GHG) emissions by at least 55% by 2030 compared with 1990. The Fit for 55 package[78] outlines the path to this 2030 objective by revising energy and climate legislation and creating the appropriate framework. The Russian war of aggression against Ukraine has forced the EU to further increase and accelerate these ambitions in the short term. The REPowerEU Plan [79] therefore seeks to end the EU's dependence on Russian fossil fuels through energy savings, diversification of energy supplies, and accelerated roll-out of renewable energy. The EU's digital strategy[80] aims to contribute to the achievement of the 2050 climate-neutral and 2030 GHG-reduction targets, and the EU action plan on digitalising the energy system[81] sets out the concrete pathways for digitalisation in the energy sector. The climate and security supply objectives together with the consideration of competitiveness and a sense of urgency make **energy efficiency, renewable energy** (with a considerable share of variable renewable energy sources, **smart energy systems** key to this transformation. They also require **accelerated deployment** of several technologies and energy carriers (onshore and offshore wind, solar, renewable hydrogen, biomethane, heat pumps, etc.), deep renovations of buildings, demand-side management, and continuous innovation in terms of the **governance** and **funding** of this transformation.

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[77] Communication from the Commission to the European Parliament, the European Council, the Council, the Economic and Social Committee and the Committee of the Regions on the European Green Deal, COM(2019) 640 final. Apart from the aims of no net emissions of greenhouse gases in 2050 and decoupling economic growth from resource use, the European Green Deal also aims to protect, conserve and enhance the EU's natural capital, and to protect the health and well-being of citizens from environment-related risks and impacts.

[78] Communication from the Commission to the European Parliament, the European Council, the Council, the Economic and Social Committee and the Committee of the Regions on 'Fit for 55': delivering the EU's 2030 Climate Target on the way to climate neutrality of 14 July 2021, COM(2021) 550 final.

[79] Communication from the Commission to the European Parliament, the European Council, the Council, the Economic and Social Committee and the Committee of the Regions on the REPowerEU Plan, COM(2022) 230 final.

[80] Communication from the Commission to the European Parliament, the European Council, the Council, the Economic and Social Committee and the Committee of the Regions on Shaping Europe's digital future, COM(2020) 67 final.

[81] Communication from the Commission to the European Parliament, the European Council, the Council, the Economic and Social Committee and the Committee of the Regions on Digitalising the energy system - EU action plan, COM(2022) 552 final.

Motivated by the depths and pace of this change, **innovation**, which is one of the most important levers, is key to enabling the complex transformation of the energy sector required to reaching our objectives. Many components of this change, (namely **digitalisation, decentralisation, decarbonisation, sustainability, electrification, empowerment of consumers, aggregation of energy demand, innovative funding, roll-out of renewables, intermittent resources, energy efficiency, the energy-efficiency-first principle, renewable hydrogen, low-carbon gases, storage**, **circularity**, **sustainable supply of raw materials** and **carbon removal**) require much more research to develop innovative solutions. Moreover, as almost half of the CO_2 reductions by 2050 are expected to come from technologies that are not yet available in the market, major innovation efforts must already take place in this decade [82]. However, innovative solutions often entail higher risks[83] that create challenges in a sector that is typically committed to attaining the highest possible standards in terms of reliability of supply and is traditionally risk averse.

1.2 Regulatory barriers for innovative energy projects

Innovative energy projects might face different types of **barriers**[84]. For instance, there can be technical challenges in integrating innovative solutions with existing ones (especially related to digitalisation: interoperability, data security and privacy); limited resources to fund research and innovation; higher financial risks related to uncertain outcomes; and resistance to change among stakeholders.

Being a strategic sector makes security of supply of paramount importance. In addition, the heavily regulated feature of the market also sets high standards of consumer protection. Moreover, the activities of the grid operators are closely regulated and supervised by the national regulatory authority (NRA). The sector's risk aversion is also reflected in its **regulatory framework**, which does not always authorise the introduction of innovative but more investment-intensive solutions. However, even if a significant number of energy legislative proposals have been adopted in the EU in past years in order to adapt to the new circumstances and challenges, many of them need more time for transposition and implementation.

Delays in transposition [85] affect areas like collective self-consumption (CSC), renewable energy communities (REC), the role of aggregators, and electrification of transport together with the deployment of charging points for electric vehicles in parking

[82] IEA: Net Zero by 2050: a Roadmap for the Global Energy Sector; Flagship Report 2021
[83] These risks can be not only technical, but also financial or of the supply chain.
[84] Barriers to innovation as perceived by the market actors have been looked at by ETIP SNET through a survey to its members and network, representing the industry, manufacturers, academia, researchers and market participants (including end users) in the ETIP SNET Regulatory Sandboxes Questionnaire - Answers Compilation WG5 Regulatory Sandboxes Task Force, May 2023. Other sources that identify regulatory barriers have been the EnTEC Final Report Study on Regulatory Sandboxes in the Energy Sector, May 2023; other stakeholder associations in the renewable energy field (SolarPower Europe; WindEurope, EUREC, etc.); and R&I projects financed under H2020 and Horizon Europe.
[85] Transposition by Member States takes time even if the legislative framework has been set at EU level on these topics.

spaces [86]; or storage located between generation assets and transmission/distribution grids [87]. There have been measures, like pilot regulations (e.g. related to energy communities) in different Member States over the last years to test and enable the regulatory framework to accommodate new elements of the energy market with transitional instruments.

Lack of sufficiently streamlined regulation might cause uncertainties and delays in specific new fields too. Last year's need to reduce the EU's gas consumption by accelerating deployment of renewable energy in response to Russia's weaponisation of energy showed that, even if an effective regulatory framework for renewable energy was in place, targeted and urgent new measures as well as a streamlining of the existing measures were needed to respond effectively to this challenge. The Commission proposed and the Council adopted last year the regulation laying down a temporary framework to accelerate the permit-granting process and the deployment of renewable energy projects, with measures to simplify and streamline their permitting requirements. The revised Renewable Energy Directive also takes a significant step to address the permitting bottleneck, by addressing the issue in a comprehensive manner through spatial planning, simplification and shortening of procedures. These legislative changes in the area of permitting for renewables are an example of how the Commission removes obstacles by streamlining the existing regulatory framework. Moreover, the Net-Zero Industry Act provides a regulatory framework that simplifies and speeds up permitting net-zero technology manufacturing plants.[88]

Lack of regulation might cause uncertainties and delays in specific new fields. This is less common in the energy sector, but an example is the application of distributed ledger technologies (DLT) blockchain in the energy context [89].

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[86] Regulation is in place at EU level: AFIR (Alternative Fuels Infrastructure Regulation) regulates public recharging infrastructure, and the EPBD (Energy Performance of Buildings Directive) and RED (Renewable Energy Directive) regulate a private one. In terms of barriers to bidirectional recharging, there are key principles at EU level in EMD (Electricity Market Design), but application still faces local-level barriers due to safety issues, depending on several competent authorities without applicable clear rules put in place.

[87] An example of a barrier, as stated in the H2020-funded project TILOS (Technology Innovation for the Local Scale, Optimum Integration of Battery Energy Storage), was the lack of clarity on how energy storage can participate or provide services to the grid and the functional classification of energy storage (e.g. whether it is classified as generation, transmission or distribution asset).

[88] The Act will ensure a faster roll-out of manufacturing capacities through simplifying and fast-tracking the permitting procedures with strict deadlines and a single point of contact at national level (one-stop shop), therefore it will accelerate permits for all projects in the value chain. Strategic projects would benefit from even shorter permitting timelines.

[89] For instance, according to the H2020-funded DRIMPAC project (unified DR (distributed resources) interoperability framework enabling market participation of active energy consumers), no regulatory framework has been defined in Italy and there is no legislative initiative under discussion that regulates the application of blockchain or DLT technologies in the energy context. There is a defined regulation for blockchain technologies but only for the purposes of limiting money laundering through the use of cryptocurrencies. Gaps in the regulation of the use of blockchain technology in smart contracts have also been identified by the H2020 projects BEYOND (a reference big-data platform implementation and AI-analytics toolkit to promote innovative data-sharing-driven energy service ecosystems for the building sector and beyond) and BRIGHT (boosting DR through increased community-level consumer engagement

However, a more frequent issue in the energy sector [90] is the fact that the regulatory framework was initially **designed for a different system**: centralised production, predictable loads, one-way flows and clearly distinguished roles for the different actors. It had only recently foreseen some of the new solutions (either technical or societal) which may now be facing **'unintended' regulatory barriers**. Some of the many examples include: (i) grid tariff design which has not catered for prosumers and collective self-consumers in the market or innovative smart grid solutions in the network [91]; (ii) flexibility and balancing services where the framework has been focusing on centralised production; (iii) gas network access standards defined for natural gas but not taking into account the characteristics of biomethane or hydrogen; and (iv) new impacts on, and relations with, other sectors (agriculture, transport infrastructure, environment, construction, maritime spatial planning, etc.).

Finally, **split incentives** (in cases where two or more stakeholders need to share the burden and the benefits of a project or technological solution) can hinder the implementation of regulation or targets that are in place but cannot be effectively materialised. Examples of split incentives include those between owners and tenants (when it comes to renovating dwellings); or those between different departments of public or private entities (when it comes to funding and then reporting the benefits of a green energy project).

However, not all barriers perceived by enterprises willing to innovate can be considered regulatory barriers that should be removed. The limitations built into the regulatory framework are there to serve well-justified societal purposes, such as consumer and citizen protection, fair competition, environmental protection and the correct functioning of the Internal Market, etc. Those rules, which a competent authority considers necessary and for which it is excluding any possible changes, do not provide an opportunity for any regulatory learning and are therefore not within the scope of regulatory experimentation.

In accordance with the range of regulatory analyses and recommendations delivered by H2020-funded projects during their deployment, many barriers hinder the scalability and/or replicability of innovative solutions. For instance, challenges in the regulatory framework to create flexibility markets range from clarifying the role and responsibility of the DSO in procuring flexibility services and improving coordination between network operators for the provision of ancillary services by DER to regulate aggregated demand-side flexibility [92].

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by combining data-driven and blockchain technology tools with social science approaches and multi-value service design).

[90] The energy sector has a strong regulatory framework due to its strategic importance for the whole economy. This includes regulated and competitive market players, as well as infrastructure with natural monopolies.

[91] An example of a barrier, as stated in CEER's May 2022 paper on regulatory sandboxes and incentive regulation can be 'the methodologies NRAs use for setting allowed revenues that treat OPEX (operational expenditure) and CAPEX (capital expenditure) differently; typically applying a price cap or revenue cap on OPEX and recognising CAPEX through a cost-plus methodology. This regulatory approach tends to favour CAPEX, thereby discouraging innovative operational solutions'.

[92] Integrid, Interflex, Flexigrid, Coordinet TwinENERGY, MAGNITUDE, MERLON, Flexitranstore and SmarterEMC2.

Concerning waste-heat recovery: lack of pricing regulation, tariff schemes, thermal energy sales to third parties in district heating networks, as well as environmental barriers have been identified [93] as crucial obstacles to be overcome in order to facilitate waste thermal energy supply to the DH/C networks.

A more efficient management of energy (in the system, at the edge of the system and on the demand-side) is the prerequisite for a successful energy transition. The effective integration of demand-side assets in the system will require changes in the regulatory framework to allow these assets to operate effectively in the system and to compete on the markets with supply-side assets. The **regulatory sandboxes on the integration of demand-side assets in energy markets and in a real-time energy system management** might help to put into practice the general aims of the energy decentralisation.

Stakeholders [94] have also suggested other areas to explore due to perceived regulatory barriers. According to ETIP SNET, there should be more opportunities in citizen prosumer use-cases to test different options and regulatory needs for smart-charging, dynamic tariffs and demand-side response. They also suggest exploring community energy-storage options and allow for a revision of TSO procurement strategies and their better alignment with public acceptance.

For the wind industry, the first floating offshore wind farms may face particular permit-related challenges in a multiannual planning cycle. This may be considered too long for some areas to be granted the required designation, which is a precondition for the first projects to emerge. The recycling of blades is a further area because cross-border transportation of used blades (waste) is not possible at the moment due to the lack of an appropriate waste code under the waste management legislative framework.

For the PV industry, a similar difficulty is that regulatory barriers are not always restricted to energy legislation but extend to other sectors (e.g. agricultural, environmental, personal data protection or even waste legislation, as seen above). The energy regulator or ministry therefore has no competences. Agri-PV projects might face the problem that agricultural land's status is degraded if a PV plant is built on it. Floating PV in the maritime environment might also raise regulatory issues partly because they are not always considered in maritime spatial plans. Integrated PV systems do not always fit into building code requirements.

1.3 Regulatory experimentation tools used in the energy sector

In the energy sector, many of the perceived barriers are related to project promoters not being certain that the proposed solution will be compliant with the applicable regulatory framework. **Advisory-consultation services** provided by the regulator or another

[93] According to H2020 ReUseHeat and SOWHAT projects.
[94] ETIP SNET.

authority where market participants can clarify the compliance of their project with existing regulation are therefore needed and are often also sufficient to support innovation without requiring any regulatory exemptions or the setting up of a regulatory sandbox project. The Danish example shows that this service can be very useful for stakeholders and help them to find solutions within the boundaries of the existing regulatory frameworks. However, it can be very **resource-intensive** for the public body providing this service.

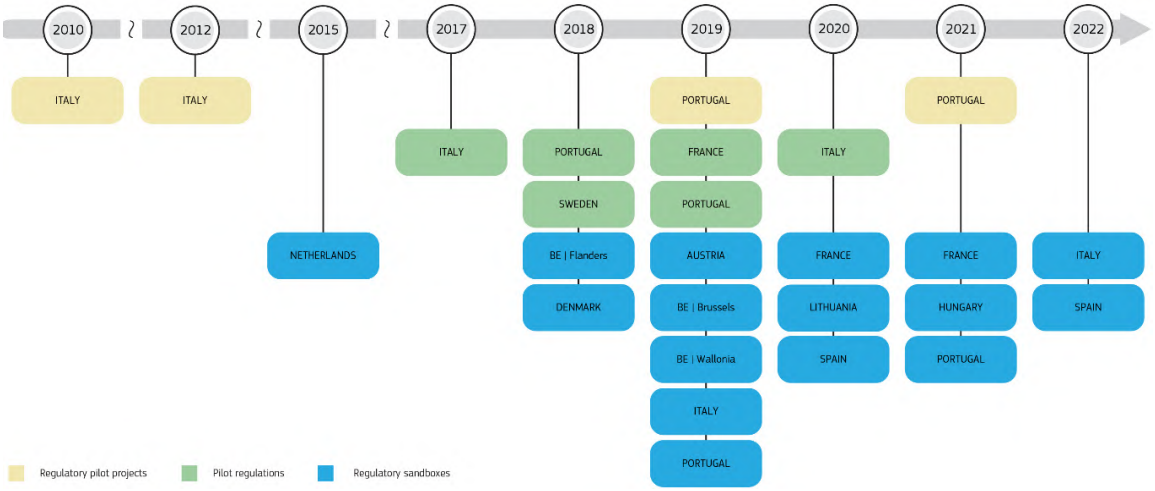
When a concrete regulatory barrier is identified as hindering the entrance of the innovative solution into the market, **regulatory flexibility or derogation** might be needed in order to test that solution. In these cases, there are **different instruments** that national competent authorities have been developing and using in practice for the energy market.

Even if there is some inconsistency in how the different tools are named in different languages and national environments [95], an effort has to be made to clarify concepts. A classification published by the Council of European Energy Regulators (CEER) [96] and subsequently used by many other studies establishes a first distinction between tools that are only relevant to regulated actors in the energy market (grid-distribution and transmission-system operators) and those that are addressed to all (regulated and competitive) market players. Another distinction can be drawn based on the scale on which the tool is used (large vs small scale), which is a consequence of the procedure: direct application open to actors (albeit on a voluntary basis) without a selection procedure vs a case-by-case approach based on a selection procedure. These distinctions and modalities are likely to be a particular feature of the energy sector where there is a differentiated role for regulators in each part (regulated vs competitive) of the market.

A representation of the history of the different tools used at national level in the energy sector has been provided by the Commission's Joint Research Centre (JRC)[97] in Figure 4.

[95] Similar tools may have different names (regulatory sandbox, regulation-free zone, technology-free zone, etc.) or the same name (regulatory sandbox) may be used for tools with different characteristics.
[96] CEER Paper on Regulatory Sandboxes in Incentive Regulation Distribution Systems Working Group Ref: C21-DS-74-04 25 May 2022; see here.
[97] JRC, 2023

Figure 4: different regulatory experimentation tools used at national level in the energy sector



Source: JRC (2023)

Regulatory sandbox is the term typically used when the competent authority (the energy regulator or the ministry) provides a wider scheme that is theoretically open to all market actors. In line with the definition provided in Section 2.1 of this document and based on the national experiences in the energy sector, the following typical characteristics can be observed:

- a transparent framework that is potentially open to all market actors;
- an application and selection procedure
  - providing time-limited derogations;
  - on a case-by case basis;
- a requirement for an innovative element from the project;
- a requirement to serve the (EU and national) energy policy objectives providing directly societal/ consumer benefits;
- safeguards for general regulatory objectives (safety, consumer protection, Internal Market, competition);
- reporting obligations for the participants;
- monitoring and evaluation responsibilities for the competent authority;
- publication of results to the wider public; and
- a regulatory learning element [98].

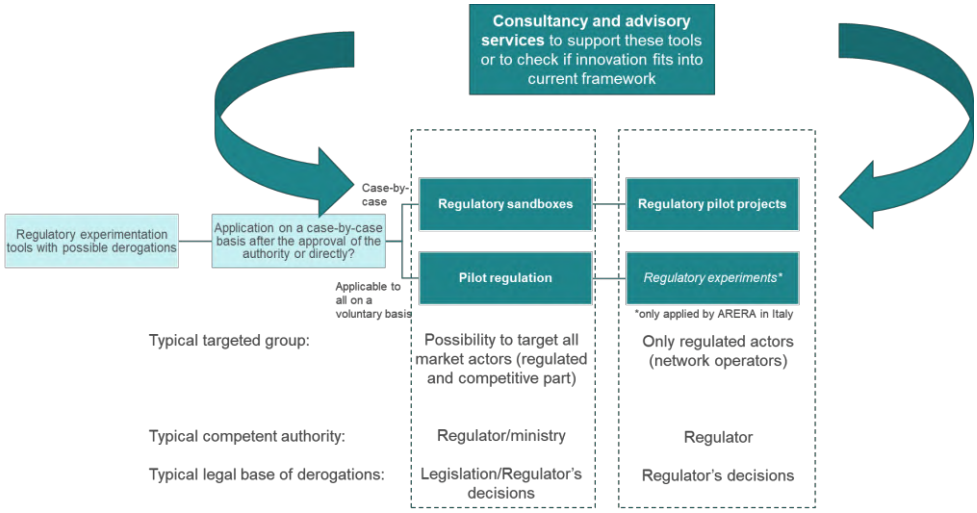
The regulatory sandbox has a legal base in national sectoral (energy) or wider legislation in order to provide powers for derogations. There is a degree of variability as to:

- who manages the programme (ministry, energy regulator or other governmental body);
- the target group (any market participants or a predefined group);
- the scope of possible derogations (only certain predefined aspects, or any provision of the specific law, or even going beyond the sectoral legislation);
- how regulatory learning is ensured.

[98] According to CEER (2022), the three main pillars of the definition are: 1) time limits; 2) learning orientation; and 3) derogations from regulation.

Regulatory pilot projects (pilot projects) and **pilot regulations** are defined in Section 2.1 of the main part of this document. Moreover, another tool (regulatory experiments) is used only in Italy to test new regulation among grid operators. One possible classification of these different types of regulatory experimentation instruments is presented in Figure 5.

Figure 5: a possible classification of the regulatory experimentation tools used in the energy sector



2. CURRENT EU AND NATIONAL REGULATORY FRAMEWORKS TO SUPPORT INNOVATION IN THE ENERGY SECTOR

The following sub-sections on the energy sector will focus on regulatory sandboxes and will mention other regulatory instruments, such as pilot regulations and regulatory pilot projects.

2.1 EU level

At EU level there are a few cases of regulatory sandboxes being promoted in the energy sector legislative framework.

In the framework of the REPowerEU Plan, the Commission Recommendation on speeding up permit-granting procedures for renewable energy projects and facilitating Power Purchase Agreements [99] has **encouraged Member States to set up regulatory sandboxes** to facilitate permit-granting for the deployment and system-integration of renewable energy, storage and other decarbonisation technologies, in line with EU legislation [100]. In addition, the provisional agreement to amend the Renewable Energy

[99] Commission Recommendation of 18 May 2022 on speeding up permit-granting procedures for renewable energy projects and facilitating Power Purchase Agreements C(2022) 3219 final.
[100] Targeted exemptions could be granted from the national, regional or local legislative or regulatory framework.

Directive [101] requires Member States to **promote the testing of new renewable energy technologies** in pilot projects in a real-world environment, for a limited period of time and under the supervision of a competent authority. The proposal also allows for pilot projects [102] to use innovative mitigation measures to prevent as much as possible the killing and disturbance of species protected under the Habitats Directive [103] and the Birds Directive [104].

More recently, the proposal for a Net-Zero Industry Act (NZIA) [105] would set up a common framework for **net-zero regulatory sandboxes** [106] in order to promote and create a level playing field for innovation in net-zero technologies with a longer-term objective of ensuring the competitiveness of EU industry. Net-zero regulatory sandboxes are limited to the testing of innovative net-zero technologies [107]. The proposal would require net-zero regulatory sandboxes to be introduced in Member States, in particular at the request of companies active in innovative net-zero technologies. There would be additional support measures for SMEs, and evaluation of experiment and exchanges through the Net-Zero Platform.

The Net-Zero Industry Act will support a level playing field for innovation on net-zero technologies in the Union without undermining other regulatory and policy objectives. Moreover, by providing a legal basis for regulatory sandboxes at European level, the proposal ensures the possibility of their implementation in those Member States where there is currently no such scheme. Alternatively, their introduction at national level must start at the request of a company whose application could trigger the implementation of a regulatory sandbox if their application is accepted by the competent authorities.

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[101] Proposal for a Directive of the European Parliament and of the Council amending Directive (EU) 2018/2001 on the promotion of the use of energy from renewable sources, Directive 2010/31/EU on the energy performance of buildings and Directive 2012/27/EU on energy efficiency, COM(2022) 222 final.
[102] This term is not used in the same sense as (regulatory) pilot projects defined above.
[103] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora.
[104] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds.
[105] Proposal for a regulation on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act), COM(2023) 161 final.
[106] The Commission has proposed that the NZIA would include the following definition in line with the Commission's Better Regulation Toolbox: 'net-zero regulatory sandbox' means a scheme that enables undertakings to test innovative net-zero technologies in a controlled real-world environment, under a specific plan, developed and monitored by a competent authority.
[107] In the Commission's proposal, 'innovative net-zero technologies' means technologies which satisfy the definition of 'net-zero technologies', except that they have not reached a technology readiness level of at least 8 and except that they involve genuine innovation which is not currently available on the market and advanced enough to be tested in a controlled environment. 'Net-zero technologies' are renewable energy technologies; electricity and heat storage technologies; heat pumps; grid technologies; renewable fuels of non-biological origin technologies; sustainable alternative fuels technologies; electrolysers and fuel cells; advanced technologies to produce energy from nuclear processes with minimal waste from the fuel cycle, small modular reactors and related best-in-class fuels; carbon capture, utilisation and storage technologies; and energy-system-related energy-efficiency technologies. They refer to the final products, specific components and specific machinery primarily used for the production of those products. They must have reached a technology readiness level of at least 8.

The concrete modalities and conditions for the establishment and operation of net-zero regulatory sandboxes are to be defined through implementing acts to create uniform conditions for the implementation, while considering that these aspects have administrative and technical nature which might take various forms. National competent authorities that are to be assigned to supervise the net-zero regulatory sandbox will maintain their supervisory and corrective powers. These competent authorities in the energy sector are most often ministries, national regulatory bodies, or other bodies appointed by the former ones. They will set up the concrete scheme, run the call for application, provide advice, evaluate and select proposals and monitor and evaluate the outcome of the concrete projects in the net-zero regulatory sandbox scheme. Competent authorities are also requested to exercise their supervisory powers in a flexible manner promoting innovative net-zero technologies within the limits of the relevant legislation. National experience of many regulatory bodies and other competent authorities in the use of regulatory sandboxes show that providing derogations and exemptions from the existing legislative framework is not always necessary. With appropriate guidance to applicants in many cases solutions can be found to test new technologies in the existing legislative framework.

Regulatory exemptions and derogations are important when the current legislative framework has not foreseen new technological solutions and might constitute an unintended barrier to innovative solutions to enter the market. For regulatory sandboxes there must be a regulatory learning element from the competent authorities' side. Currently in the EU regulatory framework there are some enabling provisions for allowing for derogations from European Union law[108] for testing innovative solutions which might be relevant for net-zero innovative technologies.

The creation of regulatory sandboxes is subject to appropriate safeguards to ensure that any exemption from Union and national law (to the extend those exemptions or derogations are already allowed) is accompanied by appropriate mitigation measures to ensure that the regulatory objectives are fulfilled while supporting innovation. The proposal also provides a level of protection to the companies testing the innovative technologies, provided they respect the plan and terms agreed with the competent authorities, to which they must receive no fines or penalties when acting in good faith. Nonetheless third-party liability under other applicable legislation remains in place. The conditions for the sandboxes will be adopted via an implementing act at a later stage.

In line with the Council Conclusions on regulatory sandboxes[109] which call on the Commission to organise an exchange of information and good practices regarding regulatory sandboxes, the NZIA Regulation assigns the Net-Zero Europe Platform to be the framework also for coordination and cooperation activities between Member States and the Commission on net-zero regulatory sandboxes. This will ensure a future-proof legislation that considers the ever-evolving sector of net-zero technologies, national regulators and eventually the European Commission via the Platform, will be able to monitor the evolution of certain technologies that might eventually need to enter the scope of the NZIA (that would scale up their manufacturing capacities to meet a growing demand caused by the EU's climate ambitions), as well as inform regulatory decisions at national and European level on those technologies. The annual reporting and the continuous exchange of information and best practices ensure the monitoring and evaluation of the tool, encourages flexible use with the aim of continuous improvement.

A particular consideration is included for SMEs to ensure they will have priority access to the sandboxes, should they wish to enter them, as well as tailored SME support. In general, larger companies have an easier time participating in regulatory sandboxes, while SMEs often face more problems due to lack of information, confusion regarding the objectives of the sandboxes, lack of resources and others. To address this problem, the proposal asks Member States to consider these particularities when addressing SME requests. More concretely, national authorities are encouraged to raise awareness between the SME community, provide guidance and administrative support to SMEs the context of regulatory sandboxes, as well as granting them priority access.

Many provisions of internal electricity and gas market legislation leave flexibility to national regulators, allowing them to take into account the specificities of individual cases, including the need to promote innovation [108].

In addition, the energy storage staff working document [109] foresees a role for regulatory sandboxes in small-scale testing of innovative solutions. Lastly, the proposal for the amendment of Directive 2010/75/EC on industrial emissions [110] would cater for the testing of emerging techniques and might be applicable to parts of the energy sector.

2.2 National level

In the energy sector, there is a growing interest in **regulatory experimentation** in general and in the use of regulatory sandboxes in national legislation in particular. 12 Member States [111] (Belgium, Denmark, Spain, France, Croatia, Italy, Lithuania, Hungary, the Netherlands, Austria, Portugal and Sweden) currently have regulatory experimentation tools or an enabling framework in place with a focus on energy. Another 7 Member States (Czechia, Germany, Latvia, Luxembourg, Poland, Slovenia and Finland) are considering or already developing their own scheme (Table 2).

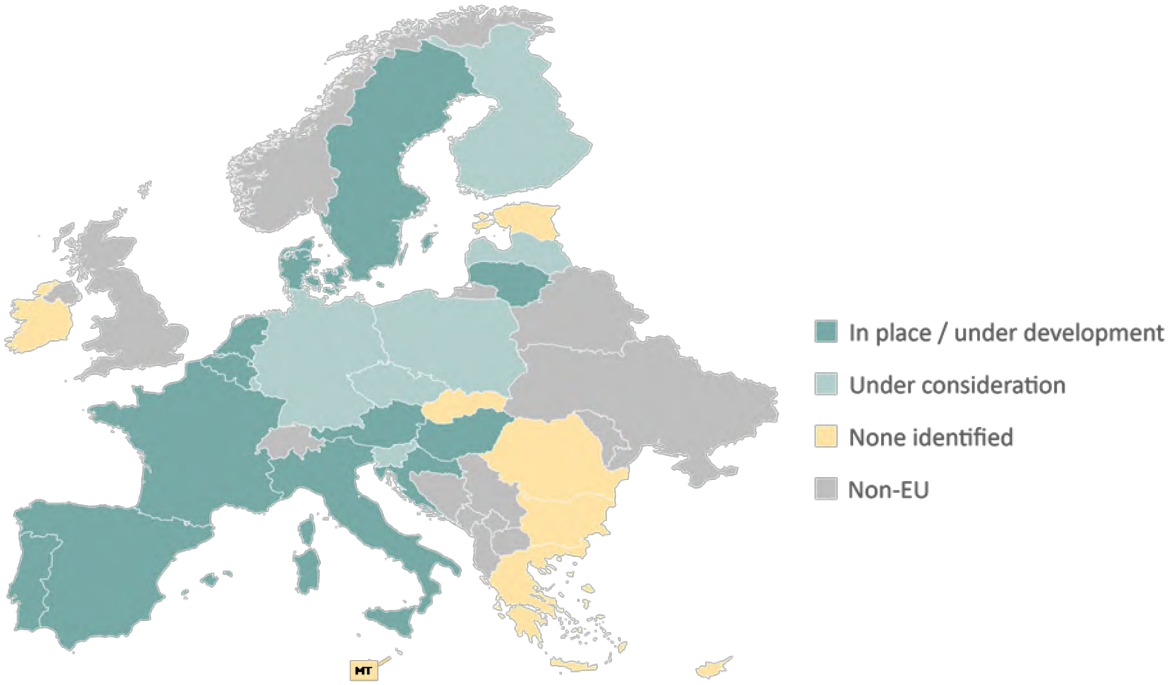
108 See, for example, the Commission regulation on so-called 'grid connection' rules, which leave national regulators ample possibilities for derogations (Regulations 2016/1388, 2016/631 and 2016/1447).
109 Commission staff working document on 'Energy Storage - Underpinning a decarbonised and secure EU energy system', SWD(2023) 57 final.
110 Proposal for a directive amending Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control), COM(2022) 156 final/3.
111 This is according to the recent studies (JRC, 2023; EnTEC, 2023) and direct contacts with national administrations. In Germany there are instruments for experimentation in the energy sector but no possibility of derogations. The SINTEG and 'Reallabore' mechanisms do not allow exemptions. The regulatory sandbox scheme for energy is under development and a draft law is expected to be presented and discussed in the German national parliament in late 2023.

Table 2: overview of regulatory experimentation for the energy sector in the EU Member States

Regulatory experimentation in place	Regulatory experimentation under development or consideration	No regulatory experimentation under consideration
Belgium	Czechia	Bulgaria
Denmark	Germany	Estonia
Spain	Latvia	Ireland
France	Luxembourg	Greece
Croatia	Poland	Cyprus
Italy	Slovenia	Malta
Lithuania	Finland	Romania
Hungary		Slovakia
Netherlands		
Austria		
Portugal		
Sweden		

The same information is presented in Figure 6.

Figure 6: Member States with regulatory experimentation frameworks (in place, under development or under consideration)



Source: EnTEC: Final Report – Study on Regulatory Sandboxes in the Energy Sector; based on desk research and JRC (2023)

➢ Type of regulatory experimentation

There is a **wide variety of experiences** among those Member States which already have some kind of tool in place. In Italy, for instance, the broad competences of the energy regulator have led to the use of **several tools**, mainly **pilot projects** and **pilot**

regulations without a legally pre-established regulatory sandbox scheme. In some other Member States, there is an **overall scheme for regulatory sandboxes** [112] in the energy sector, which in principle creates a more stable and transparent environment for experimentation. However, the existence of an overall scheme does not necessarily mean that it will be used for concrete projects and conversely, as seen in the example of Italy, regulatory experimentation tools can be used intensively in many projects, even in the absence of an overall scheme (albeit with the energy regulator having wide-ranging competences).

The different types of regulatory experimentation tools [113] used by various Member States in the energy sector are:

- regulatory sandboxes
- pilot projects
- pilot regulations

Regulatory sandboxes and their schemes are further analysed in detail in Section 2. Based on the definition provided in the general part of this document, regulatory sandboxes are schemes which enable a wide range of participants to request derogations from some elements of the existing regulatory framework (from a closed list of provisions for which exemptions can be made; identifying only one particular field; or more widely related to any provision of a certain piece of legislation).

Pilot projects (a much more narrowly defined experimentation field than sandboxes and mainly applied only to grid operators) set a specific area of experimentation, where companies/entities submit their application and can participate in the pilot upon receipt of the competent authority's approval. Pilot projects usually involve a strong steer from the energy regulator, which initiates the programme due to a pre-identified regulatory issue when it considers that regulatory learning through this experimentation is necessary.

Pilot regulation is another instrument which has been used in the energy sector. It reflects a clear predefined focus field for experimentation by the regulator, with an identified need to change some aspects of the existing regulation. Even if the direction is clear, the concept has to be tested before any permanent change is introduced. Pilot regulation consists of a temporary regulatory framework which is open to all but applies on a voluntary basis to all actors or to a group of market actors without any application or selection procedure. The authority setting up the instrument therefore has no discretionary powers.

In most of the concrete examples, the experimentation tool is not linked to any **financial support** to innovators. There are some exceptions, however. The Austrian scheme applies only to R&I projects under the 'Energie.Frei.Raum' programme (or other equivalent programmes), which is an R&I funding scheme. In Lithuania, there is also a funding possibility. Some of the experimentation (mainly pilot projects) explicitly targets network investment cost recognition and network tariff design (Italy, Croatia and

[112] Belgium, Denmark, Spain, France, Croatia, Lithuania, Hungary, the Netherlands, Austria and Portugal.
[113] Definitions are provided above in Section 2.

Portugal), which already provides better financial conditions for innovative solutions. The need for financial support for innovative projects (in addition to regulatory experimentation aspects) has been reported by several stakeholders [114]. A combination of different instruments for concrete projects is possible: for instance, entrance into a sandbox project and financing it from R&I programmes (e.g. Horizon Europe, the Innovation Fund and national funding programmes).

- **Possible derogations**

France has a framework with the **broadest approach**; the 'France Expérimentation' ('FE') scheme [115] is a general framework for experimentation overcoming sectoral limitations and extending beyond the energy sector. This scheme also provides an example of a one-stop-shop procedure for applicants through one contact point, the FE Secretariat, which handles communication with other governmental bodies from different ministries. In France, this scheme distinguishes between the regulatory barriers that lie in national regulation (for which it is easier to provide exemptions upon request) and those that are in national legislation (for which exemptions are possible only if the legislation provides derogations in enabling clauses).

In the Netherlands, the experimentation clause is in the Crisis and Recovery Law (2023), so the list of legislative acts from which exemptions might be granted extends **beyond the energy sector** [116].

In most of the examples, the sandbox scheme has its legal basis in energy legislation (electricity and/or gas acts) and involves derogations from (all or some of) the provisions of the same act. In several Member States there is a **regulatory sandbox scheme** that allows a **broad range of exemptions related to national energy law** [117]. Examples of this wider approach can be found in the Danish, Spanish, French [118], Lithuanian, Dutch and Portuguese schemes.

However, some Member States have a **general framework** in place but on which has **a very narrow focus** when providing derogations. They may, for example, only focus on network charges (Austria); network investment costs (Croatia) or issues related to energy communities (Belgium).

In those Member States where there is no general framework in place, the energy regulator may (depending on its competences) decide for which regulatory aspect(s)

[114] ETIP SNET Regulatory Sandboxes Questionnaire-Answers Compilation WG5 Regulatory Sandboxes Task Force, 5 May 2023; ISGAN (Smart Grid Case Studies Innovative Regulatory Approaches with Focus on Experimental Sandboxes 2.0 Casebook Austria, Belgium, Canada, Denmark, France, Israel, Italy, Norway, Sweden and the United Kingdom ISGAN Annex 2 October 2021).
[115] For further details, see France Expérimentation Administrations.
[116] In the Netherlands, derogations are possible for the following acts: Electricity Act, Heritage Act, Gas Act, Housing Act, Vacant Property Act, Heat Act, Water Act, Environmental Law, Ammonia and Animal Husbandry Act, Soil Protection Act, Noise Abatement Act, Odour Abatement Act, Air Pollution Act, Environmental Management Act, Spatial Planning Act and Housing Act.
[117] Denmark, Spain, France, Lithuania, Hungary, the Netherlands and Portugal.
[118] Apart from the France Expérimentation scheme, French energy legislation also contains a sector-specific sandbox scheme.

under its own powers it will allow exemptions (Italy has a broader approach and Sweden has a narrower approach).

Experimentation competences are mostly given to the energy regulator and/or ministry competent for energy. This already sets the framework and focus for the energy regulatory framework. However, **some regulatory barriers might fall outside the scope of energy legislation** [119] and derogation cannot therefore be granted by the energy regulator or the competent ministry for energy (there is another competent authority for the specific legislation, which does not, however, have a role in the specific energy regulatory sandbox scheme). Some examples (e.g. France and the Netherlands) show that these issues can be resolved if the scheme covers legislation and involves competent authorities beyond the energy sector.

In addition, as these concrete schemes are national ones, any derogation has to be **in line with EU legislation**. The study carried out by the JRC based on questionnaires and interviews to energy regulators has revealed that **EU law was not perceived as an obstacle to setting up regulatory experimentation initiatives** [120] because the concrete barriers are in national legislation or regulation. However, some NRAs are reluctant to grant derogations due to concerns about a possible misinterpretation of EU law.

Table 3 shows examples of possible derogations in different Member States related to regulatory sandboxes.

[119] These areas are typically the environment (water, habitat, species protection), spatial planning, agriculture (soil use), transport (infrastructure and vehicle as a product), maritime and similar legislation, and building codes.

[120] The Dutch Council of State recommended an exemption in 2020 for cases where EU law is considered to be blocking the establishment of a scheme (at least temporarily) and advised that a draft decree on experimentation to support the energy transition should be abandoned.

Table 3: overview of regulatory experimentation type and possible derogations in Member States [121]

Country	Regulatory experimentation type	Field of derogations - exemptions	Competent authority	Public funding related to the sandbox scheme	Concrete projects ongoing
Belgium					
Brussels	regulatory sandbox scheme	for limited geographic areas or electricity zones for a limited time on distribution tariffs, supply condition, demand optimisation measures	BRUGEL (electricity, gas and water regulator)	No	Yes
Flanders	regulation-free zone for energy communities (due to lack of legislation on energy communities - currently the only way to establish an energy	creation of energy community through regulation-free zone: organization of electricity and gas market, the organization and exploitation of thermal grids, some provisions concerning energy efficiency, RES and the energy performance of	Flemish government (responsible; procedure, eligibility, derrogations; projects reporting to the governement)	No	Yes
Wallonia	special conditions for renewable energy communities	only for RES communities: renewable energy community (REC) is exempt from having to obtain a license to supply electricity for collectively self-consumed electricity within the REC; in addition can apply for: further derogations on metering rules; the obligation related to the supply electricity; from the invoicing terms of the network's operator tariffs	CWaPE (energy regulator)	No	Yes
Denmark	regulatory sandbox scheme	from provisions of the Electricity and Gas Acts (related to sector integration across the electricity, heating and gas sectors, etc.; increased flexibility in the energy system; better balancing of the electricity grid; optimizing the market for system services; integration of fluctuating renewable energy production, including energy conversion and storage (PtX); digitization solutions; more efficient use of energy and energy	Ministry for Climate, Energy and Utilities (Danish Energy Agency for guidance service and handling applications)	No	Yes
Spain	regulatory sandbox scheme	Participants will be granted, following the opening of a specific application call, temporary derogations from any provision of the electricity sector legislation compatible with the European internal market, including the possibility of operating in the absence of a specific enabling provision	administration of the sandbox to the Secretary of State for energy: preliminary evaluation: secretary of State and CNMC (regulator); Coordination Commission	No	No
France	regulatory sandbox scheme	from the conditions of access and use of networks and installations to test innovative technologies or services for the energy transition and smart grids and infrastructures; (in the field of electricity transmission, distribution and access to network; storage, transmission, distribution and network	Ministry for Energy Transition and CRE (energy regulator)	No	Yes
	also pilot regulation for CSC initiative as an experimental framework	law introduced a temporary experimental framework that enlarged the maximum CSC perimeter for CSC operations below 3 MW of total power, to a circle with a 1-Km radius, this has been made later permanent and actually the radius for exemptions is 20 km (the normal limit is 2 km). Reasons for derrogation: isolation of site, dispersed nature of habitat and low population density.		No	Yes
Croatia	recognition of network costs for innovative projects of network operators	in the methodology set by the energy regulator on tariff items of the electricity transmission and distribution network (possibility of derogations is under examination)	HERA (energy regulator)	Yes (network investments)	No
Italy	NRA-driven initiatives: pilot regulations, pilot projects	broad set of areas under the competences of the regulator	ARERA (wide regulatory powers to carry out regulatory experiments aiming at energy system innovation	No/(Yes - network tariff design)	Yes
Lithuania	regulatory sandbox scheme	grant derogations from the rules setting licensing and permitting requirements, as well as from any other provision set by VERT, on a case-by case basis; changing and applying the technical parameters set out in the legislation to other indicators that have the same impact on the operation of the energy system; reduce requirements and/-or exemptions without compromising security of supply, reliability and	VERT (regulatory authority)	Yes	No
Hungary	regulatory sandbox scheme	general framework set up - but implementation is not in place	MEKH (energy regulator)	No	No
The Netherlands	regulatory sandbox scheme	legal clause on experimentation covering several sectoral regulations, comprising energy but also environmental protection and spatial planning legislation: derogations are possible from several Acts listed	Ministry of Interior Affairs together with other Ministries	No	No
Austria	regulatory sandbox scheme	to enable R&I projects to experiment with network charges	E-control (for the derogations)	Yes (main characteristic of the Energie.Frei.Raum)	Under evaluation
Portugal	experimental initiatives: regulatory sandboxes (technological free zones) by DGEG and pilot projects and pilot regulations by ERSE	promote innovation in the fields of electricity production, self-consumption and storage, as well as in the electric mobility field; e.g. exemption from payment of network access fees, as well as other charges related to the participation in the networks, and a reserve of injection capacity in the public service electrical network	ERSE (energy regulator) and ministry DGEG (TFZ)	No/(Yes - network tariff design)	Yes
Sweden	pilot regulation	pilot regulation: a derogation from the general requirement of uniform network tariffs	Ei (regulator) for the extension	No	Yes

121 Some of the experimentation types are atypical and do not really fit into the categories.

- **Competent authorities**

The competent authority for regulatory experimentation in the energy sector in most Member States is the **national regulatory authority** (the NRA) for energy. Alternatively, the **Ministry responsible for energy policy** might have strong exclusive [122] or shared [123] powers. In a few cases, **other ministries** [124] or **governmental bodies or agencies** [125] might be involved.

As concrete examples show, there are **considerable differences between NRAs in terms of competences** in the innovation field [126]. In Italy and Portugal the energy regulator has been driving the process for regulatory experimentation and this is reflected in the rich experience of regulatory pilot projects and pilot regulations that they have initiated. In several Member States [127] the NRA has a key role in running the regulatory sandbox scheme, sometimes sharing competences with the ministry. They might have extensive competences related to the setting up of the application and selection procedure, the granting of derogations, the follow-up and monitoring of projects, and the drawing of conclusions from the experiment for regulatory learning. It is exceptional for an NRA to have no role [128] when a dedicated sandbox scheme exists.

However, many Member States have no regulatory sandbox scheme and the NRA does not have any competence related to innovation and regulatory experimentation. According to the survey carried out by the JRC, NRAs see the absence of a legal basis as the main obstacle to adopting a regulatory experimentation initiative. In several Member States it was necessary to empower regulators which had not yet been given such powers and competences, especially when (i) they lacked the necessary competences to initiate a regulatory experimentation and (ii) there was no enabling legal provision to derogate from the general regulatory framework. As some examples show [129], changing the legislative framework can be a prerequisite for providing the regulator with the necessary competences. In other cases, these competences were assigned to the competent ministry. In only a few cases could regulators exercise their role of supporting innovation without any changes.

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[122] In Belgium-Flanders and Denmark.

[123] In Spain, France and Portugal. In France for instance, some areas of energy law are under the responsibility and supervision of the regulator, while others are directly under the responsibility of the ministry. In the French sandbox schemes, both the regulator and the ministry are involved (for their respective legislative areas).

[124] Ministry for Interior Affairs in the Netherlands and the Direction interministerielle de la transformation publique in France.

[125] In Belgium-Flanders: VEKA (the Flemish Energy and Climate Agency) and VLAIO (the Flanders innovation and entrepreneurship agency); in Denmark: the Danish Energy Agency; in the Netherlands (for the former scheme): the Netherlands Enterprise Agency (Rijksdienst voor ondernemend Nederland, RVO); and in Austria: the Research Promotion Agency (FFG) for Energie.Frei.Raum.

[126] The CEER report on Dynamic NRAs to Boost Innovation (Ref: C22-RBM-37-04, 31 May 2022) distinguishes between NRAs driving the dynamic regulation process and others facilitating it, while a third category only has limited involvement.

[127] Spain, France, Lithuania and Hungary.

[128] Only in Denmark.

[129] For example, in France, the Energy and Climate Law of November 2019 enables the regulator to grant derogations.

Table 4 lists NRAs for energy in each Member State with their current role related to regulatory sandboxes.

Table 4: overview of energy NRAs and their competences related to regulatory experimentation in the EU Member States

Country	Energy regulator	Competence related to regulatory sandbox
Belgium	Commission de Régulation de l'Electricité et du Gaz (CREG)	
Brussels	BRUGEL ('autorité bruxelloise de régulation dans les domaines de l'électricité, du gaz et du contrôle du prix de l'eau)	can adopt specific rules for limited geographic areas or electricity zones for a limited time
Flanders	CWaPE (Commission wallonne pour l'Energie, le régulateur wallon des marchés de l'électricité et du gaz)	advisory role, no decision role in sandboxes (Flemish government responsible for the scheme)
Wallonia	VREG	selection procedure for certain exemptions to renewable energy communities (RECs)
Bulgaria	Energy and Water Regulatory Commission / Комисия за енергийно и водно регулиране (EWRC - KEBP)	none
Czechia	Energetický Regulační Úřad (ERÚ) / Energy Regulatory Office (ERO)	none
Denmark	Forsyningstilsynet - Danish Utility Regulator (DUR)	none (the Danish Energy Agency provides guidance service and handling applications, while ministry is responsible for regualtory sandboxes)
Germany	Federal Network Agency for Electricity, Gas, Telecommunications, Posts and Railway (Bundesnetzagentur - BNetzA)	none
Estonia	Konkurentsiamet - Estonian Competition Authority (ECA)	none
Ireland	An Coimisiún um Rialáil Fóntais / Commission for Regulation of Utilities (CRU)	none
Greece	Ρυθμιστική Αρχή Ενέργειας / Regulatory Authority for Energy (PAE / RAE)	none
Spain	Comisión Nacional de los Mercados y la Competencia / National Commission for Markets and Competition (CNMC)	participation in the Coordination Commission with the Secretary of State for Energy and in the preliminary evaluation (administration of the sandbox with the Secretary of State)
France	Commission de régulation de l'énergie (CRE)	reception of appications, decision on derrogations in those, where competent (otherwise decision is with the ministry)
Croatia	HERA - Croatian Energy Regulatory Agency Hrvatska energetska regulatorna agencija (HERA)	launching initiative on inclusion of innovative projects for tariff items of the electricity transmission and distribution network
Italy	ARERA (L'Autorità di Regolazione per Energia Reti e Ambiente) Italian Regulatory Authority for Energy, Networks and the Environment	wide regulatory powers enabling to carry out regulatory experiments aiming at energy system innovation (no general sandbox scheme)
Cyprus	Cyprus Energy Regulatory Authority (CERA)	none
Latvia	Sabiedrisko pakalpojumu regulēšanas komisija / Public Utilities Commission (PUC)	none
Lithuania	Lithuanian national regulatory authority (Valstybinė Energetikos Reguliavimo Taryba - VERT	active counseling for participants; providing derogations that the energy legislation allows for; promoting energy innovation through incentive mechanisms for entities in the regulated part of
Luxembourg	Institut Luxembourgeois de Régulation (ILR)	none
Hungary	Magyar Energetikai és Közmű-szabályozási Hivatal (MEKH) - Hungarian Energy and Public Utility Regulatory Authority (MEKH)	establishment of concrete framework for regulatory sandboxes (objectives, participants, eligibility and selection criteria and procedure, rights and obligations, and duration)
Malta	Regulator for energy and water services (REWS)	none
The Netherlands	Autoriteit Consument & Markt (ACM)	limited to checking the calculation method for the energy and transport tariffs (a decision on derogation under the new scheme is with the Ministry of Interior Affairs)
Austria	Energie Control Austria (E-Control)	providing derogations according to the electricity and gas acts to R&D projects to experiment with network charges
Poland	Urząd Regulacji Energetyki / Energy Regulatory Office (URE / ERO)	none
Portugal	Entidade Reguladora dos Serviços Energéticos / Energy Services Regulatory Authority (ERSE)	experimental initiatives to promote innovation in the energy sector (regulatory sandboxes, pilot projects, pilot regulations) and inform about possible regulatory change (the Ministry (DGEG) can also carry out regulatory experimentation in its area of competences).
Romania	Antoritatea Națională de Reglementare în domeniul Energiei / Romanian Energy Regulatory Authority (ANRE)	none
Slovenia	Agencija za energijo / Energy Agency	none
Slovakia	Úrad pre reguláciu sieťových odvetví (URSO) / Regulatory Office for Network Industries (RONI)	none
Finland	Energiavirasto (EV) - Energy Authority	none
Sweden	Energimarknadsinspektionen / Swedish Energy Markets Inspectorate (Ei)	none (pilot regulation on network tariffs)

➢ Experimentation clauses and framework for sandboxes

According to the **Council Conclusions on Regulatory Sandboxes and Experimentation Clauses**[130] of 16 November 2020, **experimentation clauses** are 'legal provisions which enable the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in relation to testing innovative technologies, products, services or approaches'. It also notes 'that experimentation clauses are often the legal basis for regulatory sandboxes and are already used in EU legislation and in many Member States' legal frameworks'. Table 5 shows that there is always a **legal basis** for the use of regulatory experimentation and especially for regulatory sandboxes, which often require secondary legislation to establish the

[130] Council Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age. 13026/20

concrete application procedure and eligibility conditions to participate in the regulatory sandbox scheme, as well as their measures related to execution, reporting, monitoring and evaluation.

Table 5: overview of experimentation clauses and rules setting down a detailed framework for regulatory sandboxes

Country	Regulatory experimentation type	Experimentation clause	Sandbox scheme
Belgium			
Brussels	regulatory sandbox scheme	Art. 90 of **Ordinance of 23 July 2018**	**Brugel Decision 20190605-97** of 05 June 2019
Flanders	regulation free zone for energy communities	in the **Energy Decree** of 8 May 2009 amendment of 24 December 2018 - the experimentation clause: Art. 14.1.1.1 and Art. 14.1.1.2 experimental regulations and low-regulation zones	
Wallonia	renewable energy communities	the **Decree 2 May 2019** modifying decrees of 12 April 2001 on the organisation of the regional electricity market and of the Decree of 19 December 2002 of organisation of the regional gas market to promote renewable energy	concerns only RECs
Denmark	regulatory sandbox scheme	not identified, only in political agreement; **Electricity and Gas Act** provides for exeptions, but not based on innovativeness	
Spain	regulatory sandbox scheme	**Spanish Royal Decree-law 23/2020**, of 23 June changed the Electricity Sector Law in order to enable the government to establish a regulatory sandbox programme for the implementation of research and innovative projects in the electricity	**Royal Decree 568/2022**, of 11 July established the general framework of the regulatory sandbox in the electricity sector; in 2019, the Spanish National Markets and Competition Commission (CNMC) adopted in a Decision the methodology to regulate
France	regulatory sandbox scheme	Article 61 of Law of 8 November **2019 on Energy and Climate**.	**Decision** of 4 June 2020 on the CRE framework for the implementation of the regulatory experimentation system
Croatia	recognition of network costs for innovative projects of network operators	methodology for determining the amount of tariff items for electricity transmission - **HERA 1284** Methodology for determining the amount of tariff items for electricity distribution - **HERA 1283**	
Italy	NRA-driven initiatives: pilot regulations, pilot projects	competences of the energy regulator: Law no 481 of 14 November 1995	e.g. Integrated text of the Output-based Distribution Service Regulation and measure of the electricity system for 2016-2023 Art. 27bis regulatory experimentations; Deliberation of 2 August 2022 404/2022/R on gas pilot projects for the optimisation of management and innovative use of
Lithuania	regulatory sandbox scheme	**Energy Law No. IX-884** Amendment of Articles 2, 3, 8,13, 1, 19, 27 and **Supplementing the Act** with Article 181 Law **of 2020** April 28 **No XIII-2867** supporting innovation and providing a legal basis for the enactment of regulatory	**VERT resolution** 03E-699/2020
Hungary	regulatory sandbox scheme	**Law CXXXVI of 2007** (modification of 2021) Section 114/I on regulatory sandboxes	
The Netherlands	regulatory sandbox scheme	**2023 Crisis and Recovery Law** ('Crisis- en herstelwet') includes a legal clause on experimentation covering several sectoral regulations, comprising not only energy but also environmental protection and spatial planning	
Austria	regulatory sandbox scheme	experimentation clause in both the **Electricity and Gas Acts** (Art. 58a Electricity Act 2010 (EIWOG 2010) and Art. 78a of Gas Act 2011 (GWG 2011)) to enable R&I projects to experiment with network charges	on the basis of the legal provisions, the regulatory authority can allow exceptions to the system usage charges (set by the ordinance) by means of an administrative decision
Portugal	regulatory sandboxes (technological free zones) by DGEG	**Resolution of the Council of Ministers no 29/2020** establishes the general principles for the creation and regulation of the TFZs, while **Decree-Law No. 67/2021** establishes the regime and defines the governance model for the promotion of technology-based innovation through the creation of TFZs	**Decree-Law 15/2022** establishes the specific framework for the creation of TFZs in the electricity sector
Sweden	pilot regulation	**1997 Electricity Act** (**2018 amendment** on pilot regulation): possibility for electricity network companies to test new tariffs on a limited group of electricity users within a customer category	

- **Focus areas – fields of experimentation**

The policy objectives set in the energy sector (**sustainability, competitiveness and security of supply** which imply **decentralisation, digitalisation and electrification**) orient the new development and innovation needs, and also have a direct impact on the concrete areas where regulatory experimentation is carried out in this sector. These main objectives can translate into objectives to obtain higher shares of (variable) renewable energy sources and more decentralised generation; the management of a more complex network supported by digitalisation; the empowerment of consumers; changing roles for participants and a more active demand-response; as well as sector-coupling and electrification of the transport sector. These tendencies are interrelated and mutually supporting. Based on the recent study[131] of the JRC that has identified the main fields of experimentation in the energy sector, based on concrete examples of regulatory experimentation from Member States, the following (sometimes overlapping) categories can be highlighted:

- **Related to the higher share of (variable) RES** and **decentralised production**
  - **Integration of RES into the electricity network** – the aim is to accommodate a higher amount of renewable energy generation capacity in the electricity system by supporting permit-granting or optimising the use of the grid capacity by the system operators [132]. Examples [133] are:
    - projects from the French sandbox scheme on pooling the connection of wind and PV – building on their complementarity, allowing higher capacity connections beyond the nominal permitted capacity limit and making it possible to connect to the distribution network instead of the transmission network (the BayWa r.e. project);
    - wind farm capacity increase without adaptation of the Regional Renewable Energies Master Plans (the Boralex project);
    - optimising investments experimenting with two different methods for the size of primary substations (the ReFlex project);
    - a wind farm project with an alternative connection solution that involves additional costs and losses but accelerates connection (the Magnac-Laval wind farm project).
  - **Integration of renewable and low carbon gases (including hydrogen) in gas networks** (related to the increasing need to revise the quality parameters of gas consumed and transported) - integration of sustainable biogas, biomethane, biofuels, renewable and low-carbon hydrogen, and synthetic fuels. Examples [134] can be found in the French

[131] JRC, 2023
[132] The need for these kinds of experiments has also been highlighted by WindEurope.
[133] More details on the concrete projects can be found in JRC, 2023.
[134] More details on the concrete projects can be found in JRC, 2023.

sandbox scheme and the Italian and Portuguese regulatory pilot projects on injection of synthetic methane into distribution networks; a compressed natural gas station for flexibility for biomethane; methane injection to the natural gas network; gas from biomass and solid recovered fuels; and innovative uses of existing natural gas infrastructure to accommodate RES gases and hydrogen [135].

- **Integration of RES with sector-coupling: production of renewable hydrogen with an electrolyser** – to accommodate surplus wind energy by operating in an island mode, an example from the Danish sandbox experiment [136].

- **Related to the empowerment of consumers and demand-response**
  - **Collective self-consumption and energy communities** – there is a need to experiment with new regulatory frameworks that can support the formation, operation and integration into the grid of citizen energy communities (CECs) and renewable energy communities (RECs). This involves engaging and empowering consumers and increasing the acceptance of RES through new business models. Technical issues might include self-consumption, peer-to-peer trading for energy-sharing or supporting energy storage. Concrete examples [137] of regulatory experimentation are often in the form of pilot regulation (applicable for all) or pilot projects (awarded by the NRA on a case-by-case basis). There are transitional enabling frameworks for tariff setting, supplier obligations, and the right to operate and own the grid (in the Netherlands; in the 3 regions of Belgium; in Italy in the form of a pilot regulation; and in Portugal in the form of pilot projects that make it possible to grant derogations to use dynamic energy-sharing coefficients or to the energy-sharing rules of electricity self-consumption).
  - **Demand Response to Residential customers –** Regulatory frameworks are also needed for facilitating participation of residential customers to demand response programs. So far, several pilot projects have taken place including such consumers into demand response programs (through aggregation). The regulatory framework needs to be enforced in this direction, so as to have clear roles for aggregators, energy providers and consumers. In addition, the conditions under which customers can participate in such programs need to be cleared. Different Member States have different programs and rules for demand response programs. One of the studies carried out by the

[135] Stakeholders (ETIP SNET) have identified possible additional regulatory barriers because reverse flow is not regulated and no definition of the tariff remuneration is consequently envisaged for the network operators, while reverse flow can be an important option when optimising the connection of biomethane plants to the gas network.
[136] More details on the concrete projects can be found in JRC, 2023.
[137] More details on the concrete projects can be found in JRC, 2023.

European Commission in 2019, addressed the gaps and barriers in the sector and paved the way for further steps[138]

- **Investment and management of a more complex network (digitalisation, changing roles and decentralisation)**
  - **Electricity network tariff design** – ETIP SNET underlines the fact that transmission-network-use-of-system (TUoS) and distribution-network-use-of-system (DUoS) tariffs determine what types of expenditures are prioritised (OPEX vs CAPEX) or what payback periods are reflected in regulatory schemes and what then impacts innovative solutions. They call on NRAs to develop incentive-based targets and rewards. Croatia's NRA is empowered to approve the costs of innovative elements incurred by network operators if they have been included in 10-year-development plans.
    Other very important areas to explore in relation to network tariffs include the framing of adequate support for the proper integration of distributed renewables (DER) into the power system; and stimulating demand-side flexibility, as well as the uptake of innovative technologies. Examples are:
    - a Swedish pilot regulation on testing new tariffs;
    - a French experiment with a mobile peak-tariff option to reflect network costs more accurately and smoothen consumption peaks;
    - a Portuguese pilot regulation testing new dynamic network access tariffs; and
    - an Austrian scheme enabling R&I projects to experiment with network charges (whereby the NRA might allow exceptions to the system usage charges).
  - **Smart grids –** there is a need to support the adoption of digital technologies (smart meters, sensors, internet of things (IoT) technologies, the large amount of data made available for use by artificial intelligence (AI) technologies, etc.). In Portuguese pilot projects, DSOs are experimenting with the possible use of smart-meter data on technical quality of service (development and testing of new network management solutions and new services to consumers). In Italy there has been a 2% increase in the rate of return on invested capital for smart grid pilots and a smart grid pilot on alternative paths for improving the reliability of indicators.
  - **Flexibility and balancing services** – distributed generation, demand-response and storage offer new solutions for system management, especially to promote the flexibility of the system, with an important aim of reducing RES curtailment. Concrete experiments are being

[138] European Smart Grids Task Force Expert Group 3 for the Deployment of Demand Response, Final Report: Demand Side Flexibility – Perceived Barriers and Proposed Recommendations, Apr 2019, available here.

conducted [139], such as the Italian pilot regulation on aggregation, which aims at opening up ancillary services and balancing market to all participants (non-programmable RES, storage providers, demand-response players and DER). Other examples include the French regulatory sandbox on the participation of battery storage in system services; the Spanish regulatory sandbox to trial an ancillary service for voltage control at the request of the Spanish TSO; and the Portuguese pilot regulation for the participation of demand-response in the balancing market.

- **Storage participation in balancing** – the aim is to support the integration of renewable energy into the grid, thus improving grid resilience and reducing costs. Regulatory frameworks for energy storage are still evolving and experiments are being conducted with new business models and pricing structures that can support the deployment of these technologies. In France, sandbox projects are addressing the participation of storage in system services, hybridisation with other means of production and facilitating connection of storage assets (creating conditions for connection associated with dynamic management of storage, similarly to RES production). In Italy, a pilot project on storage in the transmission gird makes it possible to increase the rate of return by 2% [140].

- **Sector-coupling and electrification of other sectors**
  - **Electromobility** – the electrification of transportation is expected to have a significant impact on the electric sector because its integration into the power system is creating new challenges and opportunities. Regulatory experimentation can help develop new approaches to managing the charging infrastructure and addressing the challenges of grid integration (managing local demand peaks by using the flexibility potential of smart-charging, V2G and G2V). Concrete examples [141] can be found in Italy, which has a pilot regulation on recharging EV during off-peak hours without requesting contracted power increase (demand management and tariff design) and a pilot project for EV-charging infrastructure in public places. In Portugal, a regulatory sandbox aims at testing V2G technologies and evaluating benefits for users and system operators, as well as taking part in balancing services.

There might be further areas to explore. For example, ETIP SNET has identified a need for experimentation in relation to the management of peak electricity demand, reducing costs and increasing grid reliability. In their view, current regulatory frameworks often limit the participation of residential customers and there is a need to experiment with new approaches to incentivise their participation. For example, in the area of energy management, there could be experiments with the integration of, and interaction between,

[139] More details on the concrete projects can be found in JRC, 2023.
[140] More details on the concrete projects can be found in JRC, 2023.
[141] More details on the concrete projects can be found in JRC, 2023.

different devices (e.g. different loads within the same house) with the DSO ensuring the observability/flexibility of the demand.

Table 6 gives examples of regulatory experimentation tools in Member States by area of experimentation.

Table 6: examples of regulatory experimentation tools applied in Member States in the energy sector

	Integration of RES to the network	Flexibility and balancing services	Storage – participation in balancing	Smart grids / digitalisation	Electricity network tariff design	Integration of renewable and low carbon gases (including H2) in the gas networks	Collective self-consumption and energy communities	Electromobility
Belgium								
Brussels							**allows only for this:** (6) related to network charges, supply conditions and supply-demand optimisation	
Flanders							**allows only for this:** (1) low regulation zone - energy community only throught this	
Wallonia							**allows only for this:** (3) only renewable energy community (REC)	
Denmark (theoretically possible in all areas)	**(2) concrete projects approved related to green hydrogen**							
Spain (theoretically possible in all areas)								
France (theoretically possible in all areas)	(4) sandbox projects	(3) sandbox projects	(2) regulatory sandbox projects			(17) regulatory sandbox projects	pilot regulation	
Croatia					**allows only for this:** (0) approval of costs incurred by network operators (included in 10-year-development plans)			
Italy (theoretically possible in all areas on the initiative of the Regulator)		pilot regulation	regulatory sandbox / pilot projects (5)	regulatory sandbox? / pilot projects (7)		regulatory sandbox? / pilot projects	pilot regulation	pilot regulation + ((4) regulatory pilot projects)
Lithuania (theoretically possible in all areas)								
Hungary (theoretically possible in all areas)								
The Netherlands (theoretically possible in all areas)								
Austria					**allows only for this:** (0) regulatory sandbox - no derogated project yet			
Portugal (theoretically possible in all areas)		pilot regulation		regulatory sandbox / pilot projects	pilot regulation	regulatory sandbox / pilot projects	regulatory sandbox / pilot projects (4)	regulatory sandbox / pilot projects
Sweden					**allows only for this:** pilot regulation			

3. COMPONENTS OF REGULATORY SANDBOXES

This section focuses on the policy tools commonly known as regulatory sandboxes [142] and reviews the typical elements of the sandbox scheme, based on real-life examples from such schemes established in some Member States. It is important to note that projects are admitted to participation in regulatory sandboxes and are provided with derogation **on a case-by-case basis**, thereby avoiding distortions in the energy market. Transparent rules are needed with clear eligibility and selection criteria. In addition, concrete projects and experiences have to be monitored and evaluated at the end of the experiment to assess their scalability and for regulatory learning purposes. Regulatory pilot projects are usually not considered regulatory sandboxes but might share some of their elements and characteristics because they are also awarded on a case-by-case basis.

[142] In practice, there may be instruments that are not called sandboxes that nevertheless have all or several of the main characteristics of a sandbox scheme. By contrast, some instruments that are called sandboxes do not have the main characteristics of regulatory sandbox – as described in Section 2.

As reported in recent studies [143], regulatory sandboxes are a promising tool for supporting innovation and a growing number of EU Member States and non-EU countries around the world are using them. However, they are not always the most appropriate tool and there are situations and objectives when the use of other tools (such as one of the tools described above) might be more appropriate.

3.1 Phases

- **Design of the scheme**

The design phase is of crucial importance because it determines the project's functioning and successful implementation. In addition, errors made in this phase might have long-lasting consequences and even prevent the project being implemented. In this phase, all the elements and following phases have to be carefully fixed.

Setting up a regulatory sandbox scheme has its costs. As stated in the EnTEC report, badly designed frameworks can even block innovation: even though participation in the sandbox is voluntary, they may increase overall uncertainty for innovators and represent a missed opportunity if expectations are raised but not met.

The design phase therefore merits strategic thinking (involving a review of, and decision on, the desired long-term consequences) in addition to the consideration of all country-specific jurisdictional, institutional and market characteristics that should be taken into account [144] (instead of simply copying schemes from other sectors or countries). Concrete experience [145] shows that the early involvement of a wide range of stakeholders always improves the design of regulatory sandboxes. Moreover, there have to be in-built monitoring and revision mechanisms for the scheme itself, as well as enough flexibility to adapt it to future circumstances [146].

An **adequate design of the concrete scheme** is crucial for providing an effective tool to promote innovation. The various national examples include schemes that fulfil this requirement and have proven to stimulate the testing and proving of new solutions and regulatory adaptation. There have also been examples of an inadequate design failing to promote innovative projects and perhaps even becoming a barrier – representing a missed opportunity and failing to meet the expectations that have been raised.

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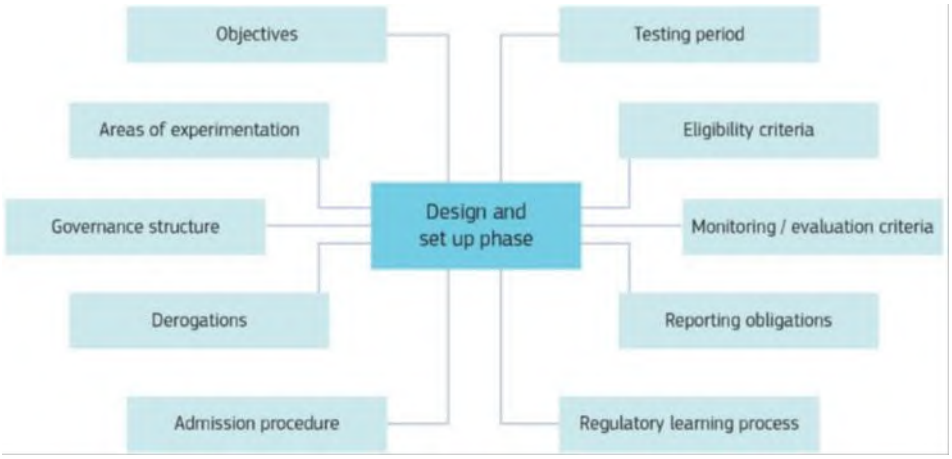
[143] JRC, 2023, ISGAN, 2021 and CEER, 2022

[144] According to ISGAN's Innovative Regulatory Approaches with Focus on Experimental Sandboxes 2.0 Casebook, October 2021, there is no one-size-fits all model for experimentation and the type of experiment that best suits a particular concrete needs to be deployed. The report is based on extensive exchange of experience with concrete sandbox projects in Austria, Belgium, Canada, Denmark, France, Israel, Italy, Norway, Sweden and the UK through their Community of Practice.

[145] For example, the concrete experience shared by NRAs and ministries in the Regulatory Sandbox Community of Practice of ISGAN (IEA).

[146] Many national schemes are adapted after their use. In France, the setting of an application window period has resulted in a large number of applications. In order to better distribute the evaluation workload, applications can be presented at any time (there are no longer any deadlines). This also results in more mature proposals because innovators do not have to rush to present project ideas to meet a deadline before they are ready.

Figure 7: main regulatory sandbox elements



Source: JRC, 2023

- **Application – selection - granting**

Regulatory sandbox participation is decided on a case-by-case basis, so the rules governing the application procedure, the eligibility and selection criteria, the possible derogations to be granted and the question of who grants these derogations (and how) all need to be clear. The detailed procedure can be enshrined in legislation or, if the NRA is the competent authority, can sometimes be based on the NRA's own decision. Concrete examples of the description of sandbox procedure can be found in Table 5 (under 'Overview of experimentation clauses and rules setting down a detailed framework for regulatory sandboxes').

The application procedure can be open continuously within the boundaries of a large time window or operate with narrower windows or deadlines for the presentation of proposals. Participation might be open to all market participants or to a predefined group of market players. The scope of derogation can be narrowly set by the legislator or by the competent authority applying the scheme (identifying precise provisions or articles of law from which derogation is possible) or left open (for instance, derogation might be possible from a wide range of legislation and it is often for the applicant to decide from which precise provisions he will request derogation). Additional services (such as pre-consultation, advice and funding) may or may not be provided as part of the scheme. Table 7 reflects the variety of choices made at national level in relation to these elements of the application and granting procedure.

Table 7: choices made by EU Member States for the application, selection and granting phases of regulatory sandboxes (based on JRC, 2023)

		BE-BRU	BE-FL	BE-WA	DK	ES	FR	HR	IT	LT	HU	NL	AT	PT	SE
Competent authority		R	M	R	M	M/R	R/M	R	R	R	R	M	R	R/M	R
Area of experimentation	**targeted to specific topics**	x	x	x				x	x				x		x
	open to all topics				x	x	x				x	x		x	
Admission procedure	**application window**					x	x		x					x	x
	on demand	x	x	x	x		x	x		x	x	x	x		
Length of derogation (years)		2 (+2)	10 (+5)	5	2	not pre-defined	4 (+4)		3 to 4	1 or 3 (+1 or +2)	2 (+2)	not pre-defined	3	1 or 3	
Scope of derogation	**narrowly predefined**	x	x	x				x	x				x		x
	open (typically to broader set of articles or all articles of a specific piece of	x			x	x	x			x	x	x		x	
Consultancy services					x					x					
Funding provided									(x)	x			x	(x)	

The eligibility criteria are a key component of the sandbox scheme. Their design should minimise market distortion effects and allow the objective application of the rules. The most common criteria (see also in Table 8) are:

- the innovative character of the project;
- identification by the applicant of a regulatory barrier;
- contribution to energy policy objectives and consumer/ societal benefits;
- safeguards for consumers / the wider environment;
- proof of maturity of the project;
- time limit;
- publication requirements;
- scalability; and further development potential.

The competent authority, when authorising participation in the regulatory sandbox scheme, indicates the concrete derogations granted, their time limit and the reporting obligations of the participant. Table 8 indicates which eligibility criteria are used in the different national schemes.

Table 8: eligibility criteria applied in EU Member States for regulatory sandboxes in the energy sector (based on JRC, 2023)

Elegibility criteria	BE-BRU	BE-FL	BE-WA	DK	ES	FR	HR	IT	LT	HU	NL	AT	PT	SE
Innovative dimension	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Contribution to energy policy objectives			x	x		x				x	x	x		
Identification of regulatory barrier by applicant				x	x	x		x			x		x	
Scalability - potential for further development	x	x	x			x		x			x			
Benerfits for consumers/ businesses/society	x	x		x	x	x			x					
Third-party/consumer safeguards		x		x	x			x	x		x		x	
Sufficiently mature		x		x	x				x					
Time limit / exit strategy			x	x	x				x		x			
Publication of results set			x	x									x	

- **Execution of project with reporting and monitoring and final evaluation**

During the execution phase, the participant has reporting obligations, while the competent authority has monitoring and supervising powers. The aim of reporting and monitoring is to ensure that the testing is carried out in compliance with the framework and conditions of the experiment. Moreover, the competent authority systematically collects evidence on the success of the experiment. Monitoring also helps ensure that safeguard measures are respected and that there is no consumer harm or other type of harm that would require the project to be terminated or suspended (there might also be shortcomings in the trial that have to be adjusted and adapted over its course once detected).

In the final evaluation, the project is usually assessed against the predefined indicators. Moreover, and as a key objective of the whole scheme from the regulatory learning perspective, competent authorities assess whether it is necessary and appropriate to introduce new or updated elements into the regulatory framework based on the lessons learnt. Wider societal benefits can be ensured by the publication of the reports and the lessons learnt, and by the communication of the results to different stakeholders.

3.2 Regulatory sandbox ‘toolbox’ based on previous experiences (lessons learnt and best practices)

Based on the **empirical knowledge gathered through the national examples** and analysed in various papers, the main elements of a sandbox scheme can be listed, revisiting the **different options for their design** and **what they are good for**, or what are the most **probable consequences** of different choices. The ‘toolbox’ below can therefore be useful for the design of any new scheme. Moreover, some typical **success factors** and **common errors** can be identified related to their application.

The following aspects merit consideration when designing a regulatory experiment:

- definition of objectives and potential impact
- choice of tool

- sectoral vs general approach
- broad definition of areas vs focused approach
- top-down vs bottom-up initiatives
- the competent authority
- the participants and their involvement
- the innovative element – and how it is defined and evaluated
- derogations
- duration of the trials
- safeguards
- transparency and flexibility of the scheme
- the application process: call windows vs continuous (on-demand) evaluation
- indicators – reporting and monitoring
- impact and replicability
- exchange of knowledge
- regulatory learning mechanism
- advisory service

➢ **Definition of objectives and potential impact**

The definition of the objectives of the sandbox scheme is fundamental. The most usual objectives are those related to achieving **energy policy** goals (decarbonisation, decentralisation, digitalisation, electrification, etc.) or wider **societal targets** (competitiveness of the economy through secure and affordable energy supply, enabling market entry or raising consumer benefits). The overarching goal is to contribute to achieving those objectives by supporting innovation and addressing regulatory barriers. **Identification of possible benefits**, the **innovative character** of the trial and the **regulatory learning** goals therefore have to be minimum components of any scheme.

Two further objectives of the scheme can be the **identification** of (i) **the most impactful innovations** needed; and (ii) the range of **regulatory barriers** to be addressed. A sandbox scheme might also aim **at enhanced cooperation and communication** between public authorities or competent authorities (e.g. regulators) and innovators.

The definition of objectives and targets has consequences for the **approach to be chosen**, the **scope of the experiment**, the assignation of **competent authorities** and the definition of **involved stakeholders.**

Key elements for success

A **well-orchestrated strategy** is key, with **clarity and agreement on objectives**: why is a sandbox needed in this situation, what will it be used for and what are its potential limitations? This requires the **involvement of different stakeholders** (through a consultation process) in order to support the creation of an effective tool. The ISGAN casebook [147] also concludes that regulatory experiments are stronger if aligned with a

[147] ISGAN: Smart Grid Case Studies. Innovative Regulatory Approaches with Focus on Experimental Sandboxes 2.0 Casebook, October 2021.

broader transition strategy, a clear vision of the future energy system, a well-defined roadmap and supportive innovation programmes. As these experiments are about regulatory learning, alternative regulatory options should be tested (instead of simply granting exemptions upon request) or at least envisaged and/or explored to some extent. **Predefined objectives** help to identify the trials' expected contribution to the improvement of the general system and might therefore ensure their **scalability**.

Common difficulties

The tool will most probably fail without clear, well-defined and broadly shared objectives. If the objectives are not clear, the design of the scheme cannot be optimised and aligned with those objectives, and there is no way to evaluate the effectiveness of the scheme. Uncommunicated or unshared goals among the different stakeholders might lead to high expectations which may not be met. Approving an experiment without linking it to the wider policy objectives might lead to difficulties in scaling it up later or in ensuring regulatory learning. The regulatory exemption itself should never be a self-standing objective. Moreover, the regulatory learning objective should be clear and confirmed by the regulator because the experiment would make no sense unless subsequent regulatory learning is possible (i.e. providing derogations to rules, which the regulator plans to revise if necessary afterwards).

- **Choice of the tool**

Problem definition is key to selecting the best suitable instrument. Before deciding on a regulatory experimentation scheme, the question of whether the barriers are technological, behavioural, related to financing or regulatory needs to be clarified. In the first three cases, the setting up of **testbeds, living labs or financial support** to innovation (respectively) might be more appropriate. All these other support instruments can also bring elements which can be useful from a regulatory learning perspective. Regulation is not their main focus, however, especially if derogations are not necessary to run the tests.

If the identified barrier is regulatory in nature or the scheme aims at identifying and addressing regulatory barriers, there are still several options for selecting the most suitable tool in the energy sector: regulatory sandbox, pilot project or pilot regulation.

In the case of **regulatory sandboxes**, energy regulators can have different roles and competences (from running the whole scheme to participating with shared competences together with ministries to no role at all if the competent authority is the ministry). However, for **pilot projects**, it is usually the regulator who leads the process. Pilot projects might be possible without an explicit experimentation clause in the legislation, and energy regulators, which have competences to support energy transition and innovation, might have direct powers to implement them (as is the case for ARERA, the Italian NRA).

If there is a clearer view on the regulatory barrier and the desired change, and large-scale testing of the possible new rule provides additional benefits, one option might be to test it through a **pilot regulation**, which applies directly but on a voluntary basis for all market players or for a defined group of them. No discretional element is therefore involved and

there is no need for any application and selection process. However, in some cases, where the necessary regulatory changes are already clear, direct revision of the regulatory framework might be more appropriate [148].

Key elements for success

Regulatory sandbox schemes are more expensive to set up than other tools because they need a legal basis and it is necessary to set up a transparent and well-defined application and selection procedure. Sandboxes are potentially broader in application as regards the areas of legislation open to derogation, the fields of experiments or the type of participants (potentially all market actors). They might also be the most appropriate instrument to address cross-sectoral considerations.

From the market participants' perspective [149], broad regulatory sandbox schemes are the preferred option because they offer parallel experimentation with different options and might provide a broader scope for areas of innovation (including bottom-up proposals). For regulated entities (TSOs and DSOs), close cooperation between them and the energy regulator might lead to well-focused and effective pilot projects or pilot regulations. Moreover, an institutional framework for experimentation might ensure better management and more widespread communication of the knowledge gathered in the trials.

Based on the analyses of the concrete regulatory experimentation frameworks [150], it is commonly understood that there is **no one-size-fit-all model** in the energy sector: policy makers and regulatory bodies have been developing different types of instruments to suit their specific needs. As regards the design of the scheme, what works well in one Member State might be less effective in another national environment due to different objectives, barriers, priorities, regulator competences or stakeholder attitudes.

Common difficulties

Free choice between all possible tools might not be an option if there is no legal basis for setting up a regulatory sandbox scheme. The absence of competences in innovation and other objectives (such as the energy transition) of certain NRAs beyond their core competences in the functioning of the internal energy market and consumer protection can also strongly limit their possible role and openness to regulatory experimentation. In addition, the lack of communication and consultation between public authorities designing the scheme and a wide range of stakeholders who could be possible participants in that scheme might create a mismatch between the type and scope of the scheme and real regulatory problems that innovators face in practice. It could also lead to non-use [151] or low effectiveness of the whole experimentation scheme. Setting up the

[148] If so, some transitional measures might be needed in case the change is urgently needed and the adaptation of the regulatory framework would take longer.
[149] ETIP SNET (2023)
[150] ISGAN Innovative Regulatory Approaches with Focus on Experimental Sandboxes 2.0, October 2021, CEER (2022) JRC (2023), EnTEC (2023).
[151] A relatively complex and comprehensive scheme set-up means that there are currently no applications or concrete experimentation projects in Lithuania or Hungary.

experimentation tool should never be an objective in itself but should clearly be an effective means that is carefully chosen and crafted to achieve specific energy policy targets.

- **Sectoral vs general approach**

The focus of the scheme is usually **limited to energy legislation** or even more narrowly defined elements of it. However, there can be a more general approach beyond the energy sector: looking at possible regulatory barriers that energy-market innovators face in other sectors (e.g. the environment, spatial planning, agriculture, electromobility and personal data protection). The decision to adopt a sectoral or **cross-sectoral approach** has an impact on the competent authorities in charge of the scheme because energy regulators or ministries responsible for energy policies usually have no competences outside that sector and will not have the authority to act upon requests for derogations from other sectoral legislation.

Key elements for success

If the chosen approach is to focus on the energy regulatory framework, the competent authority might be the ministry or the energy regulator. Even in that case, the authority needs to be given the necessary competence along with the relevant legal basis for it. In the case of a cross-sectoral approach, interministerial coordination [152] as well as the involvement of, and communication between, different regulatory authorities should be planned. One-stop-shop entities have proven useful in easing the application process for applicants.

Common difficulties

An overly narrow approach might systematically ignore barriers that lie outside the energy regulatory framework, but an overly broad approach entails higher costs for the authority setting up the scheme. Such costs need to be compared with the expected additional benefits of the scheme.

- **Broad** definition of areas vs **focused** approach

Certain Member States have a wide range of possible areas of experimentation [153] within the energy legislative framework, while others only allow derogations from a very restricted set of provisions in their legislation [154]. A broader scope might make it possible to identify new and previously unknown regulatory barriers, while a narrower scope might result from a previous consultation exercise or from in-depth analysis of the most

[152] Examples include the French scheme and the main coordinating role of the Ministry of Interior in the new Dutch scheme.
[153] Denmark, Spain, France, Hungary, Lithuania, the Netherlands and Portugal.
[154] In Austria, where the regulatory sandbox complements the Energie.Frei.Raum R&I support scheme, derogation is possible only for one specific aspect (experimenting with network charges) and only those projects that participate in the funding scheme and with the regulator's explicit approval granted after an application has been submitted. This scope has been defined following extensive consultation and exploration of needs and targeting the most promising field for changes. In Belgium, the experimentation tool focuses on energy communities.

urgent issues for regulatory revision. This latter approach might also reflect a stronger steer from the competent authorities, with clearer views on where regulatory learning is necessary and possibly resulting in easier measurement of results.

Key elements for success

If a focused approach is chosen, in order to ensure a higher probability of success of the scheme, it is important to address areas where there is an issue to be resolved. To identify such areas, it is important to involve stakeholders more broadly and to study the different options. This consultation and exchange can be performed at the design stage of the scheme or built into the scheme itself (as a provision allowing innovators to propose new areas for experimentation).

It can also be relevant to envisage a combination of the two approaches, whereby competent authorities make use of different tools; for instance, a combination of sandboxes with a broad regulatory scope with more targeted calls with concrete problem-setting (e.g. pilot projects proposed by NRAs) [155].

Common difficulties

Narrowly designed schemes might become too rigid and not identify regulatory barriers beyond their scope. In order to avoid this rigidity, those schemes that predefine a narrow set of provisions from which derogations should be granted should incorporate a flexible element in order to make it possible to periodically review the relevance of possible extensions of the sandbox scheme to other areas of legislation (or to open new areas for pilot projects). This may need to be assessed with enhanced communication, and cooperation on regulatory barriers might be necessary between public authorities and energy-market stakeholders.

Broadly designed schemes might not be able to address challenges in the most effective way and the granted experimentations might not cover the most urgent policy needs of the regulators. Therefore, and in order to complement the scheme, competent authorities might wish to steer regulatory experimentation and indicate priority areas for experimentation more proactively.

- **Top-down – bottom-up initiatives**

The main question related to this aspect is: **who proposes the fields of experimentation?** Top-down (also called policy-oriented) schemes are launched by **competent authorities** to address specific goals. Bottom-up (also called innovator-oriented) initiatives are demand-led: **innovators** propose the field of experimentation and tend to respond to the near-term needs of innovators seeking to bring new products or services to the market.

[155] An example of the application of different tools and approaches is in Portugal, where both the ministry and the energy regulator use different tools.

Key elements for success

The 'bottom-up' logic allows new ideas to emerge and to be tested, so it is most appropriate when the fields of experimentation are rather open and not all the new regulatory barriers have been clearly identified. Innovators might prefer this because it gives them more opportunities to test innovations that are facing regulatory barriers.

The top-down approach usually results from clear priority-setting by the competent authorities. It might favour increasing the targeting of regulatory learning as an outcome of the experiment.

Common difficulties

Bottom-up schemes might make a less straightforward contribution in terms of regulatory learning because the fields of experimentation proposed by innovators might not match strategic regulatory learning objectives identified by the regulator and their scalability might be more complicated. This problem could be addressed by requiring a clear link between the fields of experimentation proposed by innovators and the energy policy priorities set by the regulators.

There is also a risk that top-down schemes might become too rigid and not correspond to the needs of market actors. It might therefore be useful if periodic consultation processes identify the scope of the trials.

- **Competent authority**

In the energy sector, the competent authority [156] for regulatory experimentation is typically the **ministry** responsible for energy policy [157] or the **national regulatory authority** (NRA) responsible for energy regulation [158] or both [159]. It is less common for another ministry to be responsible for a broader scheme [160]. Other governmental bodies [161] sometimes have a prominent or supporting role.

Key elements for success

Resourcing is key: regulatory experimentation tools (especially if consultation services are included) are quite resource-intensive instruments from the relevant authority's perspective (in terms of both time and expertise), so the competent authority should be adequately staffed in terms of both the number of people assigned and their relevant skills and competencies. It is also key to have **a clear mandate** to run the scheme, which usually requires a legal basis.

[156] See Table 3 (Overview of regulatory experimentation type and possible derogations in Member States) and Table 4 (Overview of NRAs and their competences related to regulatory experimentation in the EU Member States) in Section 2.2 of this Annex for concrete examples of choices of competent authority and the role of the NRA in each MS.
[157] Denmark.
[158] Hungary, Italy, Lithuania and Austria.
[159] Spain, France and Portugal.
[160] In the Netherlands, the Ministry for Interior Affairs.
[161] In Denmark, the Danish Energy Agency related to advisory services and the handling of applications.

Irrespective of whether they play a prominent role in regulatory experiments, **NRAs can support innovation and energy transition within their mandate**, at least in the regulated activities [162]. For effective **regulatory learning**, **both NRAs and ministries** should be involved in the evaluation of the impact of the projects.

Common difficulties

Having two competent authorities with shared responsibilities can increase complexity and create lack of clarity for applicants, as shown in the French example [163]. One possible solution could be to have only one authority in charge of the whole application process (a 'one-stop shop') with a mechanism allowing or mandating it to consult other competent authorities who have to grant the derogation.

When several authorities are involved, lack of coordination between them can stop the scheme functioning properly. Coordination mechanisms that assign clear roles and responsibilities to all relevant actors should therefore be planned at the design stage.

The NRAs' ranges of competences vary significantly from one Member State to another. Some still do not have a more active role related to the needs of innovation and the energy transition because they lack explicit competences [164]. Some of them have therefore suggested [165] that provisions at EU level to empower them with the competence of setting up regulatory experiments and granting derogations from national regulation could promote an equal level playing field.

Regulators often identify [166] insufficient resources as a major issue when developing and managing a sandbox scheme.

- **Participants and their involvement**

The possible participants in a sandbox scheme include, but are not limited to, energy-market participants, who are an ever-growing circle of stakeholders: regulated entities (transmission and distribution network operators), and energy producers and suppliers. They also include new players: energy service providers, ICT and software providers, public institutions, prosumers, citizen energy communities (CECs) and renewable energy communities (RECs).

[162] CEER has proposed that the NRA's institutional remit should provide a legal basis for **specific incentive regulation** related to large-scale innovation and for small-scale pilot projects. Additionally, projects that benefit from regulatory sandboxes should inform NRAs when designing incentive regulation (CEER, 2022). ETIP SNET has similar views: 'regulators should have competences to operate with incentivised regulation: taking into account strategic goals such as energy transition and decarbonisation, and therefore recognise R&D costs, incentivise and mark up on regulatory returns for DSOs implementing concrete measures that drive the energy transition, and might have no real incentives for these measures' (ETIP SNET, 2023).

[163] JRC, 2023.

[164] In the JRC, 2023 survey of NRAs on regulatory experimentation, 11 out of 15 respondents mentioned this as the main obstacle.

[165] JRC, 2023.

[166] In the JRC, 2023 survey of NRAs on regulatory experimentation, 8 out of 15 respondents mentioned this as one of the major difficulties.

Depending on the selected experimentation tool, the scope of the testing and any derogations, participation in the scheme can be open to all or restricted to certain groups.

Table 9: overview of main participants in the surveyed projects according to the main theme of the experimentation

	NETWORK OPERATOR	MARKET PARTICIPANT	TYPE OF MARKET PARTICIPANT
CSC and energy communities	Yes	Yes	Energy market players | Public institutions | Research and technology orgs. | Technology and service providers | Others
Electromobility	Yes	Yes	Energy market players | Technology and service providers
Flexibility and balancing services	No	Yes	Energy market players | Technology and service providers | Others
Gas networks	No	Yes	Energy market players | Public institutions | Technology and service providers | Others
Integration of RES	Yes	Yes	Energy market players | Research and technology orgs. | Technology and service providers | Others
Smart Grids	Yes	No	-
Storage	Yes	Yes	Energy market players
Tariff design	Yes	No	-

Source: JRC, 2023.

Key elements for success

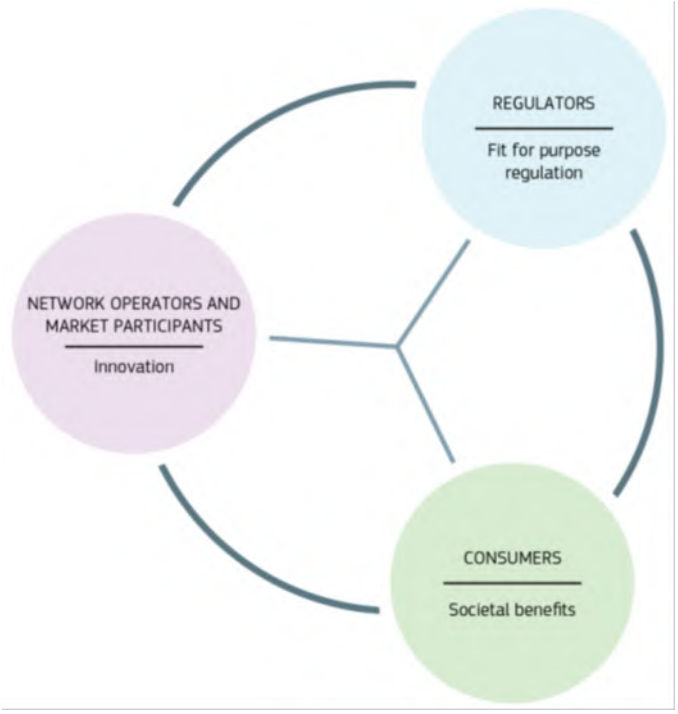
Broad involvement and dialogue with stakeholders have proven to be major success factors. A wide range of stakeholders can be involved in the design and setting-up of a scheme and should also receive information about the results and evaluation of the concrete projects [167]. According to the policy recommendations of ISGAN, which are based on concrete international case studies, stakeholder involvement needs to be **explicitly organised and coordinated.**

Involvement of all players in the supply chain and an active involvement of the **end user and the public** might also be important (especially when they are affected) when identifying the real needs of the market and shaping the experiment.

A clear definition and **common understanding of the roles and responsibilities** of the different actors of the scheme provides the basis for good cooperation. The set-up of an experimentation scheme usually contributes to much **closer cooperation** between market actors, and regulators and agencies throughout the entire development process.

[167] ETIP SNET identified wide stakeholder involvement as a key factor of success for REC trials in Italy, resulting in legally established and technically operational RECs. ISGAN underlines the point that research institutes can play an important role in helping energy regulators evaluate trials.

Figure 8: main participants in a sandbox scheme and their motivations (JRC, 2023)



Source: JRC, 2023

Common difficulties

A lack of consultation with stakeholders results in a scheme not being able to respond to the real needs of the market, especially if the scheme is narrow in scope. Lack of communication and information may result in low participation.

In addition, key players' particular roles and relationship with innovation should be well assessed and addressed [168].

- **Innovative element** – and how it is defined and evaluated

The innovative character of a project is a basic requirement for all regulatory sandbox schemes. This innovative element means that the regulation should be revised and that temporary derogation can be applied with the objectives of testing, regulatory learning and finally adaptation if needed. According to the Better Regulation Toolbox, 'genuine innovation is **not currently available in the market**. A **new use of an existing** technology can also qualify'. This broad definition usually means that an innovation can be a new technology, product, service, business model or methodology. However, there is often another requirement – to be **ready for testing in a real-world environment** –

[168] According to CEER (2022), grid operators are neutral market facilitators and should become enablers of innovation, but they often need to be incentivised. There is therefore a need for adaptive regulation that recognises the DSO's role as an enabler of innovation. Project results can therefore inform NRAs when they design incentive regulation and set parameters.

and this complements the definition, filtering out less mature innovations in favour of innovations 'closer to market readiness'.

Key elements for success

Broad consultation and transparent processes might help to achieve a common understanding and acceptance of what should be considered innovative for the purposes of the experiment.

The existence of a regulatory barrier might also help to characterise the innovative character of a new technology, product, service, business model or methodology because something that is not available in the market due to regulatory barriers could still be 'a new use of an existing technology' (as defined above) and its trial through a derogation would offer the possibility of regulatory learning.

Common difficulties

Some NRAs find that the most difficult aspect to implement in practice is to verify and confirm the innovative character of a proposed project and to subsequently assess its impacts and risks. There might still be a degree of discretion in the assessment [169].

There might also be similar projects with the same innovative character. One possible solution for this difficulty that was applied in the French scheme has been to require an additional innovative element: any derogation that is granted should result in new information for regulatory change and a project that fails to do so can be considered ineligible.

Another problem might arise with an overly narrow definition of innovativeness or with the introduction of (low) TRL-level requirements in the calls for regulatory sandbox projects. This is because it might be challenging to find suitable projects which are both innovative in this strict sense and ready for testing.

- **Derogations**

Derogation is the other basic element of a sandbox scheme. It is possible in all the analysed national schemes (the tool would otherwise be considered to be something else: for example, a test bed or a living lab – even if it is called a 'sandbox' in a national language).

Derogations need a legal basis. The French scheme involves an interesting distinction, which may be applicable in other Member States as well. France distinguishes between legislative and regulatory experimentation, depending on which provisions need to be updated or derogated from: legislative experimentation requires an appropriate legislative

[169] JRC, 2023: according to the French experience it is difficult to define the innovative character of a project (this has become the most controversial point). In that practice only the firstly filed proposal with that scientific innovative character is considered innovative.

vehicle (usually requiring parliamentary approval), while regulatory experimentation may be conducted by regulators [170].

The option to derogate can be defined in the concrete provisions of a legislative act, the whole act or, even more broadly, (a group of) sectoral frameworks. Concrete examples from Member States are listed in Table 3 (Overview of regulatory experimentation type and possible derogations in Member States in Section 2.2 of this annex).

Key elements for success

The selection of provisions where derogation is possible indicates which public authority should be the competent one. When there are several authorities with different or overlapping competences, coordination between them is crucial, especially towards applicants (an example of the proposed one-stop-shop procedures).

Moreover, the obligation to clearly identify the regulatory obstacle might be a considerable burden for applicants, who do not always clearly know the regulatory framework in force (e.g. newcomers, SMEs and foreign players). Consultancy services, which can be very demanding in time and expertise for authorities, have therefore proven to be a very useful support for innovators in Denmark and France. Such a consultancy service or a preselection procedure can filter out applications that can proceed in compliance with the existing regulatory framework and without the need to participate in the sandbox.

Common difficulties

Derogations or exceptions can create market distortions, so regulators need to carefully assess the impact of the derogation on the Internal Market and the benefit the derogation may bring on a case-by-case basis. Respecting the principle of proportionality, transparency with the application scheme, and dissemination of project results and possible impacts might help to minimise risks for market functioning.

Several Member States have also indicated concerns regarding possible non-compliance with EU legislation. Indeed, if derogation is not explicitly provided for, EU legislation would be (one of the) limits to possible exceptions.

- **Duration of the trials**

Regulatory experimentation tools and sandboxes have a predefined duration of 1 to 10 years in most of the national examples [171] which shows a considerable variation. This interval usually constitutes the upper limit and can be extended. OBJ The duration of a concrete trial is usually defined on a case-by-case basis. In Section 3.1, Table 7 (Choices of sandbox elements in EU Member States) sets out the different possible durations of trials in the national schemes.

[170] Article 37(1) of the French constitution provides the legislative clause for regulatory experimentation provisions in laws and regulations (EnTEC, 2023).
[171] The Spanish and Dutch schemes do not predefine the maximum duration, but they do specify that it has to be limited in time.

Key elements for success

The experimentation needs to last long enough for potential benefits to be realised. This might vary significantly, depending on the nature or the complexity of the project. Projects with heavy investment needs usually require longer trial periods [172].

Common difficulties

Stakeholders in the ETIP SNET (ETIP SNET, 2023) paper indicated that the **long-term perspective** is always key for investments [173]: the trial is important but even more important is whether the activity can be expected to continue in the longer term [174].

- **Safeguards**

Consumer safeguard measures are also typical elements of regulatory sandboxes in the energy sector. They might be among the evaluation criteria because the testing might entail certain risks [175] (security of supply, financial, etc.) to consumers.

Key elements for success

Safety standards should always be respected. In relation to risk for consumers, innovators should provide evidence in the application that they have identified the risks and will put mitigation measures in place [176]. Conversely, NRAs need to analyse expected costs and benefits, taking consumer protection aspects into account as well.

Common difficulties

A common difficulty is the assessment of all possible risks, so it is important that competent authorities maintain their powers during the monitoring of the project execution and stand ready to intervene in case of need to prevent consumer harm.

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[172] According to CRE (the French NRA), the 4-year-period applied in their scheme 'seems to be enough to provide evidence of what is working and what is not, to inform regulators on the change that is needed and to overcome identified barriers. However, the suitability of a longer period could be assessed for projects requiring substantial investments' (JRC, 2023).

[173] For example, to avoid stranded assets.

[174] In the UK, Ofgem has also indicated that the long-term perspective for businesses is key: 'Innovators want to launch enduring businesses rather than trials. They require some certainty that they can continue to operate after the trial' (JRC, 2023). Similar views were expressed by energy-market operators during the interviews for the 2023 EnTEC study. Also, a similar problem was detected during the Italian Fast Reserve pilot project, put in place by Terna in 2020. The sole remuneration provided by the TSO for the service provision was unable to entirely support investments (e.g. installation of bulk storage). For this reason, the interested companies had to consider a revenue-stacking business case that remained profitable also in the worst-case scenario, i.e. if the service provision (and associated remuneration) was interrupted after the pilot projects.

[175] According to CEER, 2022: these risks could include higher-than-expected costs, technological and/or contractual lock-in that limits consumer choice, deterioration in the reliability of supply, less safe energy services, etc.

[176] JRC, 2023: 'Mitigation measures may include disclosure about being involved in a sandbox test, limits on the number and types of consumers involved, compensation arrangements, dispute resolution and redress mechanisms.'

- **Transparency and flexibility of the scheme**

Transparency of the scheme and the application procedure are both key when derogations are granted on a case-by-case basis.

Key elements for success

The supporting tool has to provide predictability and legal certainty with clear requirements that include transparency. Even if there might be aspects that require certain discretional choices from the competent authority when selecting the projects, objectivity and equal opportunities principles should be ensured for participants. This principle should also extend to the enhanced information and advisory need of certain actors (SMEs, newcomers, citizens and their communities, etc.).

Apart from predictability and transparency, the scheme itself should allow for revisions and improvement: it should be flexible by design and should benefit from learning during its application.

Common difficulties

Informing all market actors adequately about application and selection procedures might require additional efforts from the competent authority.

According to ETIP SNET, the absence of proper transparency on applications or delays might have a significant impact on innovation progress and participating organisations.

- **Application process: call windows vs continuous (on-demand) evaluation**

As decisions on regulatory sandboxes are taken on a case-by-case basis, there needs to be an application filed by the innovator. There are two main ways to gather applications: defining tender-call windows with clear deadlines or leaving open the possibility on a continuous basis within the boundaries of a large time window to present proposals.

Key elements for success

Application windows might help to better streamline the regulatory processes, especially if there is a concrete field of experimentation predefined by the competent authority.

Conversely, a continuously open call might result in better spreading of the competent authority's proposal-assessment workload. It can also improve the quality of proposals: if there is no deadline, proposals can be better prepared and presented when they are mature enough for a sandbox scheme. As the JRC report notes [177], most sandboxes are currently on-demand (i.e. open on a continuous basis).

[177] Mention is also made of the French example, where there was a switch from application windows to continuous evaluation: 'After two CRE application windows, it seems preferable to process requests as they are received.' (JRC, 2023)

Common difficulties

Application windows might place a very large administrative burden on competent authorities if a large number of applications are received by the end date. The burden can be even greater if there is no preselection element built into the system (either a formal preselection process or advisory services that applicants can use).

In the past, application window deadlines have forced immature projects to be presented (therefore also unnecessarily inflating the number of applications), leading to higher failure rates.

- **Indicators – Reporting and Monitoring**

Regulatory sandboxes focus on testing innovative solutions with the aim of enabling their wider application as well as regulatory learning. Setting clear objectives at the beginning of the trial is therefore fundamental. Consequently, indicators are usually defined in such a way as to measure impact against those objectives. Participants are required to report on the project itself as well as on the indicators on a regular basis (in multiannual trials, usually on a yearly basis), while the competent authority managing admission to the scheme monitors the correct development of the project in the sandbox framework (this includes paying a particular attention to the safeguard measures) during its execution.

Key elements for success

A decisive success factor is to have a clear plan for reporting and monitoring from the outset. The participants' obligations regarding reporting are often described in the definition of the sandbox scheme (as a good transparency practice). The fact that some impacts (benefits) may take longer to be adequately assessed should be adequately factored into the reporting and monitoring provisions [178].

Adequate reporting, monitoring and consequent evaluation is key to providing evidence for regulatory learning and the assessment of further regulatory changes.

Publication of the different reports and evaluation makes the scheme transparent and might contribute to ensuring public support.

The annual progress report together with the final report might be important for detecting and pursuing a permanent development of the regulatory sandbox scheme itself.

Common difficulties

It is a complex and possibly challenging task to define suitable indicators and a rigorous methodology to measure experimentation results [179]. Resourcing the competent authority

[178] ETIP SNET (2023) points out that it is important to select an appropriate period for properly reporting and evaluating benefits because there might be long-term effects or because larger-scale impacts might be different. Estimations should therefore also be made (possibly with follow-up action) after the end of the trial.

[179] Several NRAs have echoed this during the consultation carried out by the JRC (JRC, 2023).

can be decisive in this regard. To address this issue, ARERA in Italy has involved universities and research centres in order to get support for this work [180].

- **Impact and replicability**

Reporting, monitoring and final evaluation should be about impact and replicability. Projects that have no replication or scalability potential would most probably fail to show connection with, or value to, energy policy objectives, and consumer and societal benefits. Scalability and potential for further development are therefore usually part of the criteria for selection to enter a sandbox (see Table 8: eligibility criteria applied in EU Member States for regulatory sandboxes in the energy sector in Section 3.1 of this annex).

Key elements for success

For assessing the potential impact and ensuring replicability and scalability, the involvement of a wide range of stakeholders (public authorities, industry experts, technology providers, consumers, citizens, etc.) can be beneficial during the execution of the project and the final evaluation.

Common difficulties

It is not always easy to assess a project's potential impact because projects might focus on tailored needs or the conditions of a specific context. However, that difficulty could be an indication of the ability of the proposal to justify the need for the trial in relation to the overall objectives (e.g. energy policy, societal benefit and regulatory learning).

- **Exchange of knowledge**

Regulatory sandboxes, as a learning tool, have a significant knowledge-management aspect. Knowledge-sharing might have various dimensions related to regulatory experimentation: competent authorities – participants – a wider group of market players – consumers.

Key elements for success

Continuous exchange between competent authorities (regulator, ministry, etc.) and market players (possible participants in the scheme) has proven to be beneficial not only in order to identify and reach a common understanding on regulatory barriers and needs for experimentation, but also during the evaluation phase of the concrete projects and afterwards to help to formulate conclusions.

Coordination between different public administration bodies might be needed. This is especially the case for schemes where competences are shared between different bodies

[180] ARERA also indicates that 'designing indicators implies defining the experiment's boundaries, distinguishing between main and side effects'. Apart from ARERA, ERSE (the Portuguese NRA) has also mentioned collaboration with research institutes and universities as a way to address the problem of resources (JRC, 2023).

(NRA and ministry). Even if the management of the scheme and the granting of derogations fall within the competence of only one authority, others should still be kept informed of the trials and their (possible) impacts. Enhanced cooperation is also required for cross-sectoral approaches, where other regulators may have some of the necessary competences.

Communication and involvement of end users might be necessary, especially if the trial and the possible scaling has a direct impact on them.

Most NRAs and ministries have confirmed [181] that exchanging best practices between the EU Member State authorities and with the EU is desirable so that they can learn from others' experiences to build on the previous efforts and avoid unnecessary duplication and repetition of errors.

The international dimension in the Sandbox Practice Community of ISGAN in the framework of the International Energy Agency is an important ongoing knowledge-sharing platform for energy regulators, ministries and other governmental bodies.

Common difficulties

Different stakeholders (e.g. energy regulators and innovators) do not always 'speak the same language', so creating new communication channels supports mutual learning.

The participation of SMEs, start-ups and non-professional stakeholders (such as citizen and renewable energy communities) in these exchanges might be more difficult and should therefore receive additional support.

- **Regulatory learning – mechanism**

Regulatory learning is one of the main objectives of a sandbox scheme and of the concrete trials. It is the main driver of any regulatory experimentation from the NRA's perspective. Their usefulness and effectiveness therefore depend on there being some opportunity for regulatory learning (i.e. consideration of whether to adapt current rules).

Key elements for success

It is easier to develop an effective sandbox scheme if the competent authorities can clearly see the possible opportunities for regulatory learning. A strong link is needed with the derogations that are provided, and regulatory learning opportunities should be the main justification for those derogations.

Feedback loops therefore have to be built into the projects to ensure systematic regulatory learning and replicability checks. For the regulated part of the market, the results of projects can be important for NRAs when designing incentive regulation and setting parameters for it.

[181] The need for exchanges between Member States (and for the Commission to coordinate these exchanges) was echoed by most NRAs participating in the JRC survey. Several national authorities participating in the Concerted Action on RES (RES-CA) have also underlined this need.

The regulatory learning step can be built into the design of the sandbox scheme, not only through the reporting obligations of the projects but also by tasking the regulator to assess and present for consideration the regulatory development potential with a clear timeframe after the termination of each project admitted to the scheme [182].

Common difficulties

Without a clear vision, just introducing regulatory exemptions makes it difficult to learn from the experiment for future regulation, and calls into question the justification for admitting the project to the sandbox scheme.

- **Advisory service**

As Ofgem stated [183], 'innovators commonly need advice, not a sandbox, as it is not always clear to them what they can and cannot do'. New entrants (especially start-ups) might seek to signal low investment risk to investors by having the NRA confirm that their business idea raises no regulatory issues.

Key elements for success

The different national examples of regulatory sandboxes show that dialogue is key for running an effective scheme. Advisory services that provide confirmation that projects already fit into the current framework provide a strong preselection and filtering tool to exclude proposals that should not be admitted to the scheme (thus also reducing the workload for competent authorities that have to evaluate proposals). This service can also help innovators to define their proposal and identify the regulatory barriers. It might also provide individual guidance on specific rules, confirming that an activity is compliant with existing rules and that activity is permissible.

This support for innovators can be especially relevant in the case of SMEs, new entrants, start-ups and non-professional stakeholders (e.g. energy communities) so that they can better understand the rules of the energy sector, gain knowledge of the scheme and clarify the need for a possible regulatory derogation.

Common difficulties

Advisory and consultancy services might be very resource-consuming (time and expertise) and regulators might lack the necessary resources to provide them. They might be seen by the regulator (or another body running them) as an unnecessary burden that outweighs the possible gains (regulatory learning) [184]. An interesting initiative to address this issue has been the Australian regulator's online tool to filter typical consultations before confirming the need for further direct consultation [185]. The lack of such a service

[182] The Lithuanian regulatory sandbox in the energy sector foresees this assessment as a necessary step.
[183] JRC, 2023.
[184] In Denmark, besides the heavy consultation service run by the Danish Energy Agency, only two projects have been granted.
[185] The Australian energy regulator's online tool and the Energy Innovation Toolkit

can jeopardise the whole scheme, especially if participation is expected from non-incumbent or non-professional entities [186].

4. FINAL REMARKS ON LESSONS LEARNT ON REGULATORY SANDBOXES AND SIMILAR EXPERIMENTATION IN THE ENERGY SECTOR

Some of the lessons learnt from regulatory experimentation in the energy sector in various Member States suggest that a number of issues might be relevant to be considered.

The evidence gathered so far suggests that there is **no single instrument** that is suitable in all circumstances. **Selection of the right tool** and **designing** it with the **involvement of stakeholders** has proven to be beneficial.

- **Energy regulators** (NRAs) need to have **competences to support innovation** in the energy market and to use regulatory experimentation tools. If granted, these competences should be reflected in their mandate.
- Several analyses suggest that NRAs should **always be able to support innovation in regulated activities** by applying incentive regulation in large-scale and smaller-scale pilot projects.
- A fundamental design element was identified: regulatory experiments should be **part of a broader strategy serving the long-term objectives** of the energy transition and mutually supporting other roadmap instruments. Projects should therefore prove that they make a concrete contribution to that policy framework.
- **Regulatory learning** is always a clear objective when granting derogations.
- **Well-designed reporting and monitoring with appropriate indicators** to capture the trial's contribution to energy policy and societal objectives, and to provide input for regulatory learning and scaling-up is key for a successful scheme.
- The stakeholders need competent authorities (particularly for energy regulators) to provide **consulting/advisory services** that help market participants understand the boundaries set by the regulatory framework for their activities.
- **A one-stop-shop approach** is highly appreciated when different authorities are competent to provide derogations in the same field.
- It is fundamental that **communication** takes place **effectively** to spread the lessons learnt from regulatory sandboxes for their future use also in other projects

[186] The Dutch scheme might have had lower participation and significant delays in project implementation, possibly because it was focusing on energy communities. Non-professional stakeholders might have had difficulties with the complexity of the energy system.

Support at EU level

At **EU level** there has been a **strong support** since last year for the establishment and use of regulatory sandboxes at national level in the energy sector. This support was expressed in the **REPowerEU Plan**, which revised the proposal on the review of the Renewable Energy Directive and lay the ground for recommendations on speeding up permit granting procedures. In order to ensure a common level playing field, the **Net-Zero Industry Act** goes a step further by establishing net-zero regulatory sandboxes and ensuring common principles across the EU.

Moreover, it is a common view of national competent authorities [187] in the energy sector that the EU should play an even more important role in **knowledge management** related to regulatory experimentation experiences: it could **facilitate the exchange** of best practices and lessons learnt between national competent authorities by setting up a **communication platform** [188]. It could inspire regulators to set up regulatory innovation initiatives tailored to their own national context. The net-zero platform proposed in the Net-Zero Industry Act responds to this request.

There also seems to be high demand for a permanently updated **repository** for relevant information related to existing schemes on:

- legislative frameworks
- regulatory sandbox schemes (including application procedures)
- concrete trials
- impacts and regulatory learning
- lessons learnt and other forms of regulatory experimentation in the energy sector.

Some national authorities indicate that **EU support and advice** would be appreciated in clarifying whether proposed derogations would be **consistent with EU law**. Some suggest that enabling clauses could also be introduced into EU legislation.

[187] Based on answers provided to surveys and interviews (JRC, 2023).
[188] ACER and the Concerted Action on the Renewable Energy Directive could contribute to this exchange.

ANNEX 2: DETAILED DESCRIPTION OF REGULATORY SANDBOXES AND OTHER FORMS OF EXPERIMENTATION

This annex describes the examples presented in Section 3 in greater detail, in order to further clarify key elements of the approach followed in each case (e.g. for the applicable legal base, the type of experiment authorised and its features, and the proposed governance structure of the sandbox). It also describes the approach taken in cases that include cross-border cooperation between authorities across the EU.

Artificial intelligence (AI) regulatory sandboxes

The **Commission proposal for an Artificial Intelligence Act (AI Act)**[189] proposes to set-up AI regulatory sandboxes with a view to fostering AI innovation and keeping the legal framework for AI future-proof and resilient to technological disruptions. The objectives are to provide legal certainty to prospective providers of AI systems, enhance competent authorities' oversight and understanding of the opportunities, emerging risks and impacts of AI and to accelerate access to the market of innovative AI solutions, in particular for Small and Medium Sized Enterprises, which are given priority access to the sandboxes.

Article 53 of the proposal provides the legal basis and the general framework for the establishment and operation of the AI regulatory sandboxes that may be set up by one or more Member States' competent authorities responsible for the implementation of the AI Act. The European Data Protection Supervisor may also establish an AI sandbox for the EU institutions, bodies and agencies that develop innovative AI systems in-house or procure such systems from the market. The sandboxes should provide a controlled environment for the development, testing and validation of innovative AI systems for a limited time pursuant to a specific plan agreed with the competent authority. Where appropriate, other authorities should also be associated, if other Union or Member States' legislation is supervised in the sandbox, depending on the needs and the types of AI systems developed and tested in the sandbox. Synergies are also encouraged with other relevant initiatives in the AI ecosystem of excellence such as data spaces[190] and testing and experimentation facilities that can provide participants with added value services, for example access to physical and testing infrastructure and high-quality datasets.

Regulatory learning is an important goal of the AI regulatory sandboxes. To that end, competent authorities should prepare annual reports on the results from the implementation of the sandboxes to be shared with the Commission and the European Artificial Intelligence Board that should take them into account, as appropriate, in their tasks under the AI Act. Competent authorities should also coordinate their activities and

[189] Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts. COM(2021) 206 final.

[190] For a concrete application in a specific field, the European Health Data Space (EHDS) currently under development could provide data that are GDPR-compliant, of high quality and quickly accessible, with a clear legal framework, trusted governance, and secure infrastructure. Such data from the EHDS could be of particular use to the training, testing and validation of high-risk AI systems in healthcare.

cooperate within the framework of the AI Board to ensure consistent implementation of the sandboxes across the Union and effective cross-border cooperation.

To avoid market fragmentation, it is proposed to define the concrete modalities and common conditions for the operation of the AI regulatory sandboxes in implementing acts (e.g. the eligibility and selection criteria, the terms and conditions for participation, procedures for selection, monitoring and exiting from the sandbox). Article 54 also provides a special legal basis for the processing of lawfully collected personal data that may be re-used in the sandbox for the training and testing of certain AI systems in the public interest, subject to common safeguards and conditions.

The proposed AI Act is currently under negotiations and the EU co-legislators have proposed a number of amendments that further specify the objectives and the operation of the AI sandboxes and make them more useful for regulatory learning purposes and attractive to innovators. Some of the main changes proposed (not yet agreed) include the following:

- Evidence-based regulatory learning is added as an explicit objective of the AI sandboxes. In this relation, exit reports are required for all AI sandbox projects specifying the learning outcomes that should be taken into account, as appropriate, by the Commission and the AI Board when issuing guidance or in future revisions of the AI Act. The sandboxes should also facilitate the development of tools and infrastructure for testing, benchmarking, assessing and clarifying different dimensions of AI systems and risk mitigating measures relevant for regulatory learning purposes.
- Competent authorities should provide bespoke guidance to participants in the sandbox on how the AI Act requirements would apply to specific high-risk AI use case developed and tested in the sandbox.
- Competent authorities may apply their supervisory powers in a flexible manner within their margin of appreciation and limits of the relevant legislation supervised in the sandbox with the objective of supporting innovation in AI.
- The testing of the AI systems can be done in real world conditions subject to safeguards to be agreed with the competent authority in the testing plan.
- Participants that respect the sandbox plan and the terms and conditions and follow in good faith the guidance given by the authorities should not be subject to administrative fines.
- Participants may obtain a documented proof of the activities conducted in the sandbox and may use the outcomes for the purpose of the conformity assessment required under the AI Act. The exit reports and the activities in the sandbox should also be considered by market surveillance authorities and notified bodies in their checks.
- Participation in the sandbox should be mutually and uniformly recognised and carry the same legal effects across the Union. The sandboxes should also be designed in a way that support cross-border cooperation, where relevant.
- The Commission is given a complementary role to support with advice and supporting tools competent authorities who have established or wish to establish sandboxes. It should also proactively coordinate with competent authorities,

where relevant, and develop a single and dedicated interface containing all relevant information related to the AI sandboxes.

- Competent authorities should allocate sufficient resources for the establishment and operation of the sandboxes. The European Parliament has also proposed to make the sandboxes compulsory with at least one sandbox established in each Member State with national coverage (an obligation that can be also fulfilled jointly with other Member States or through participation in a sandbox established by the Commission).
- The interplay with sandboxes established under sectoral legislation is clarified and competent authorities are required to cooperate when AI systems are supervised in the AI sandboxes or those other sectoral sandboxes.

Pilot regime for distributed ledger technology (DLT) market infrastructure

The pilot regime for market infrastructures based on the Distributed Ledger Technology Pilot Regulation (the DLTPR) [191] entered into application on 23 March 2023. It is part of a package of measures to further enable and support the potential of digital finance in terms of innovation and competition while mitigating the risks. The digital finance package included a new strategy on digital finance for the EU financial sector (the Strategy), as well as a proposal for a regulation on markets in crypto assets (the MiCA Regulation) [192], a proposal for digital operational resilience and a proposal to clarify or amend certain related EU financial services rules.

One of the Strategy's identified priority areas is ensuring that the EU's financial services regulatory framework is innovation-friendly and does not pose obstacles to the application of new technologies. Indeed, digital transformation begs the question of how the EU's financial rules handle new technologies such as DLT and crypto assets.

This proposal and the MiCA Regulation are the first concrete actions in this area. They seek to provide appropriate levels of consumer and investor protection, provide legal certainty for crypto-assets, enable innovative firms to make use of blockchain, DLT and crypto-assets, and ensure financial stability. It remains to be seen whether financial products and services provided using such decentralised means will be widely used and whether they would require specific rules. The Commission and the European Supervisory Authorities are continuously monitoring the regulatory situation.

The pilot regime for market infrastructures based on the Distributed Ledger Technology Pilot Regulation (the DLTPR) entered into application on 23 March 2023 and will allow time-limited exemptions from EU rules under certain conditions and safeguards to make it possible to test DLT for trading and settlement of financial instruments in tokenised form. The DLTPR aims to provide a flexible regulatory framework for market participants so that they can set up trading venues and settlement systems relying on DLT, which is the base layer used for asset tokenisation.

[191] Regulation (EU) 2022/858 of the European Parliament and of the Council of 30 May 2022 on a pilot regime for market infrastructures based on distributed ledger technology.
[192] Regulation (EU) 2023/1114 of the European Parliament and of the Council of 31 May 2023 on markets in crypto-assets, and amending Regulations (EU) No 1093/2010 and (EU) No 1095/2010 and Directives 2013/36/EU and (EU) 2019/1937.

The DLTPR will allow not only the issuance and transfer of tokenised assets using DLT but also settlement of the so-called 'cash' leg of a securities transaction in tokenised money (either electronic money tokens or tokenised central bank money) where it is available – or tokenised commercial bank money as an alternative. Programmable money is another innovation which holds great potential. The experience gained from this experiment will inform the consideration of future legislative developments to enable the wider use of this technology in the capital markets.

Participation in the pilot will be undertaken in close cooperation with the financial services regulators.

The long-term objective of gaining experience with the application and limits of the existing financial services legislation to DLT market infrastructures requires this to be done at EU level. ESMA will therefore evaluate the outcomes annually and prepare an overall assessment in 3 years. On this basis, the Commission will report to the European Parliament and Council and might propose an extension, modification or termination of the pilot regime or amendments to other pieces of EU legislation to enable wider use of this technology in the capital markets.

Main features and implementation of the pilot regime for DLT market infrastructures

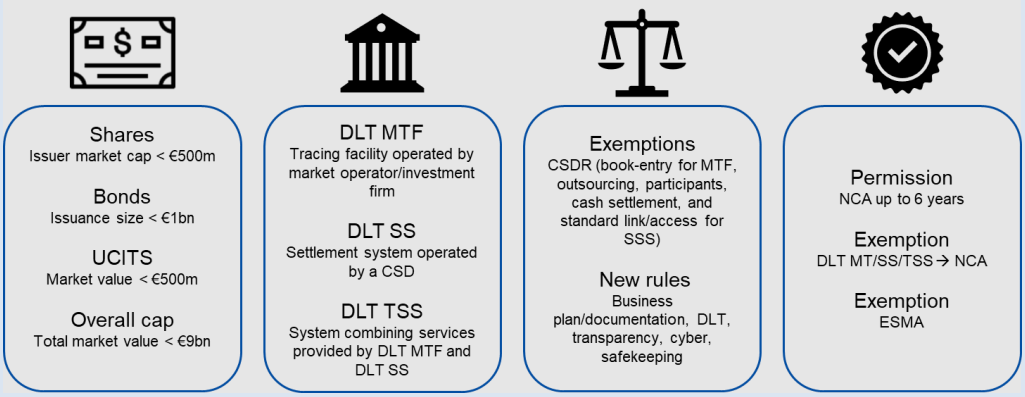
The pilot regime aims to enable market participants to operate a DLT market infrastructure (a DLT multilateral trading facility, a DLT settlement system or a DLT system that combines trading and settlement). It does so by establishing clear and uniform operating requirements and by making it possible for certain firms to seek permission from national competent authorities to operate DLT market infrastructures, and to seek exemptions from specific requirements set out in EU legislation so that they can test issuing, trading and settling of securities using DLT.

- The overall objective is for stakeholders to gain experience with the application of DLT in market infrastructures and for policymakers to learn more about regulatory hurdles to the issuance, trading and post-trading of financial instruments in crypto-asset form.
- The pilot regime is based on Article 114 Treaty on the Functioning of the European Union, which confers on the European institutions the competence to lay down appropriate provisions for the approximation of the Member States' laws that have as their objective the establishment and functioning of the Internal Market. The proposal aims to allow experimentation through derogations for the use of DLT in the trading and post-trading of crypto assets that qualify as financial instruments, where existing legislation may preclude or limit their use.
- The pilot regime establishes conditions for acquiring a permit to operate a DLT market infrastructure, sets limitations on financial instruments that can be admitted to trading and frames the cooperation between the DLT market infrastructure, competent authorities and ESMA. The DLTPR mandates ESMA to review the application of the pilot regime 3 years after its entry into force.
- The proposed pilot regime will enable DLT market infrastructures to ask national competent authorities for exemptions from certain provisions of the Markets in Financial Instruments Directive/Regulation (MiFID/MiFIR) and the Central

Securities Depositories Regulation (CSDR) that have proven to be difficult to apply for DLT-based infrastructures.

- The pilot regime proposes safeguards to ensure consumer protection, market integrity and financial stability. It proposes a controlled environment for a limited set of assets and transactions. It will not be a large-scale operation that replaces current markets and their infrastructures. All participants will also have to provide a clear exit strategy, to ensure smooth transitions once the pilot period is over.

Pilot regime attributes (Articles 3-9)



The **proposal for a regulation on markets in crypto-assets**[193] can help innovative crypto-finance projects. It can provide common schemes for experimentation and for the regulation of specific activities, thereby overcoming the impediments currently faced by firms when seeking to upscale their cross-border activities, while ensuring risks to consumers and to operational resilience are effectively mitigated.

Council Directive 66/402/EEC on marketing cereal seeds

For the purpose of seeking improved alternatives to certain provisions in Council Directive 66/402/EEC, it may be decided to organise temporary experiments under specified conditions at EU level in accordance with the provisions laid down in Article 21. In the framework of such experiments, Member States may be released from certain obligations laid down in the Directive. The extent of that release is to be defined with reference to the provisions to which it applies. No experiment is to last more than 7 years.

Examples include:

- Implementing Decision (EU) 2020/1106 on the organisation of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC and 2002/57/EC as regards the official checking rate for field inspection under official

[193] Proposal for a regulation of the European Parliament and of the Council on markets in crypto-assets, and amending Directive (EU) 2019/1937, COM(2020) 593 final.

supervision for basic seed, bred seed of generations prior to basic seed and certified seed;

- Decision 2017/547 on the organisation of a temporary experiment under Council Directive 2002/56/EC as regards seed potato tubers derived from true potato seed;
- Implementing Decision 2014/150/EU on the organisation of a temporary experiment providing for certain derogations for the marketing of populations of the plant species wheat, barley, oats and maize pursuant to Council Directive 66/402/EEC;
- Implementing Decision 2012/340/EU on the organisation of a temporary experiment as regards field inspection under official supervision.

Regulatory sandboxes in the Pharmaceutical Regulation

Chapter IX of the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (the Agency) would introduce the possibility of establishing regulatory sandboxes in the pharmaceutical area.

Regulatory sandboxes can provide an opportunity to advance regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best way to regulate innovations based on real-world evidence. This is especially the case when a medicinal product is at a very early stage of development, which can involve high uncertainty and disruptive challenges, as well as when preparing new policies. Regulatory sandboxes provide a structured context for experimentation. They also make possible, where appropriate, testing in a real-world environment of innovative technologies, products, services and approaches (especially, at the present time, in the context of digitalisation or use of artificial intelligence and machine learning in the life cycle of medicinal products from drug discovery and development to the administration of medicinal products) for a limited time and in a limited part of a sector or area under regulatory supervision, ensuring that appropriate safeguards are in place.

The establishment of a regulatory sandbox should be based on a Commission decision following a recommendation from the Agency. Such a decision should be based on a detailed plan that outlines the particular features of the sandbox and describes the products to be covered. A regulatory sandbox should be limited in duration and may be terminated at any time for public health reasons. Lessons learnt from a regulatory sandbox should inform future changes to the legal framework in order to fully integrate particularly innovative aspects into the medicinal product regulation. Where appropriate, adapted frameworks may be developed by the Commission based on the results of a regulatory sandbox.

Interoperable Europe regulatory sandboxes

In its recent **proposal for an Interoperable Europe Act**[194], the Commission put forward provisions for regulatory sandboxes (Articles 11 and 12):

- to facilitate the development and roll-out of innovative digital interoperability solutions for public services;
- facilitate cross-border cooperation;
- enhance authorities' understanding of the opportunities for, and barriers to, cross-border interoperability of innovative interoperability solutions, including legal barriers.

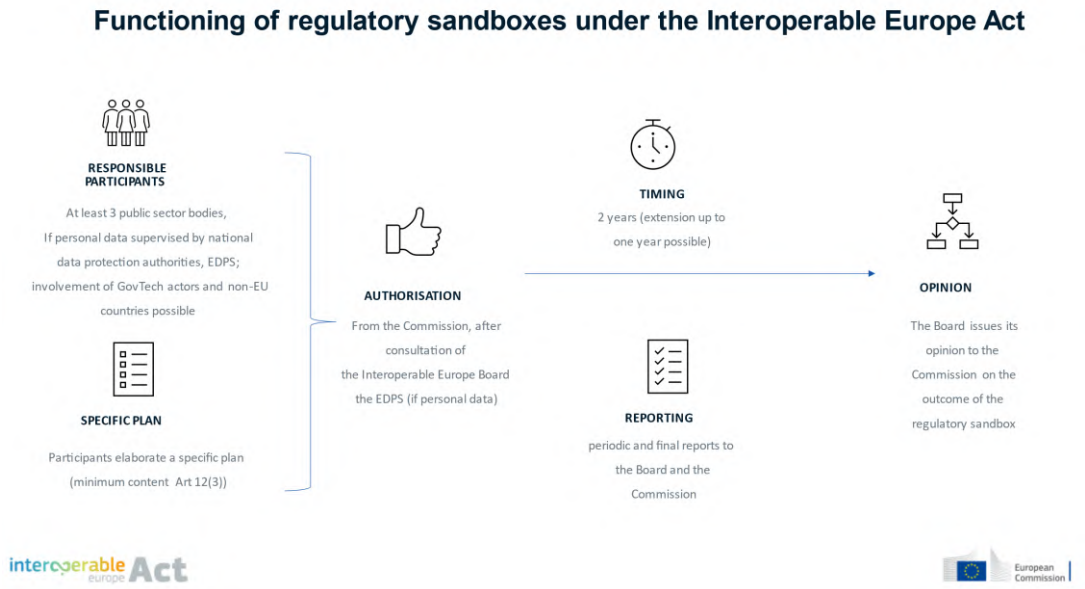
When designing policy, the discussions with the experts from the Member States showed that having regulatory sandboxes at Member State level was not enough to promote innovative and interoperable digital public services in the EU.

The Interoperable Europe Act would establish regulatory sandboxes upon the joint request of three administrations at any administrative level from EU to local and based on a specific plan setting out the details of the planned experimentation. If personal data will be processed in the sandbox, the European Data Protection Supervisor (EDPS) and the respective national supervisory authorities are involved.

The results of the experiment will be presented to the Interoperable Europe Board (the Board), which is the main governance body of the future structured collaboration on public-sector interoperability. The Board will address an opinion to the Commission on the outcome of the sandbox with a view to promoting clear follow-up. Figure 9 below illustrates the functioning of regulatory sandboxes under the Interoperable Europe Act, as envisaged in the Commission's proposal. The co-legislators are currently negotiating the text, so some of these features could change (e.g. the timing of the experiment).

[194] Proposal for a regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act), COM(2022) 720 final.

Figure 9: functioning of regulatory sandboxes under the Interoperable Europe Act



Examples of other forms of experimentation

The European Blockchain Services Infrastructure (EBSI)

The EBSI aims to build a pan-European infrastructure for the delivery of public services while meeting the highest standards of security, privacy, sustainability and compliance with EU laws. The Commission is working with technical experts from the 27 EU Member States, Norway and Liechtenstein under the auspices of the European Blockchain Partnership (EBP) to develop the EBSI. The EBSI is not a formal sandbox, but it is now in the pilot phase and provides an informal testing environment for use-cases that are at an advanced stage. EBSI is preparing for additional use through the EBSI early adopter programme. There will also be a formal regulatory sandbox at EU level under the Digital Europe Programme (in collaboration with the European Blockchain Partnership), that will aim to remove legal uncertainties by facilitating regulatory dialogue for use-cases deploying decentralised blockchain solutions (possibly in combination with other technologies, such as AI and the internet of things) within the EBSI and beyond (see Section II, EU level examples).

As part of the EBSI use-cases, the Commission works with national experts who develop the diploma use-case in relation to the implementation of **European Digital Credentials** (launched under the 2018 Digital Education Action Plan). European Digital Credentials have been piloted by 18 countries and are currently in the launch phase. The EBSI provides a pilot environment for new technologies that can support European Digital Credentials, and in the longer term provide (parts of) the infrastructure needed for digital credentialing.

In the area of employment, the Commission – as announced in the European Pillar of Social Rights Action Plan in March 2021 – started the **European Social Security Pass** pilot to explore by 2023 a digital solution to facilitate interaction between mobile citizens and national authorities, and to improve the portability of social security rights across borders. In a first phase, the Commission is supporting national experts who are developing the **European Social Security Pass pilot** use-case, which will be deployed within the framework of the EBSI to pilot the cross-border verification of the authenticity and validity of the A1 portable document (PD), which attests the social security legislation applicable to the holder. Based on the findings of this first phase, which became available in 2022, the Commission has launched further pilots for other PDs in the fields of sickness and unemployment benefits, accidents at work, occupational diseases, and pensions, and to the European Health Insurance Card.

There are also plans to experiment, where appropriate, in various projects under the **Digital Europe Programme**[195], in particular:

- **Data space for media**: the data space will provide an experimentation space for environment and interface services to promote pilots for, and host innovative media services developed through, initiatives other than Digital Europe (e.g. Horizon 2020 and Horizon Europe);
- The **Testing and Experimentation Facility (TEF) for Manufacturing*:*** the AI-MATTERS project is building a network of physical and digital facilities across Europe where innovators can validate their solutions under real-life conditions. The EU-project contributes to increasing the resilience and the flexibility of the European manufacturing sector through the deployment of the latest developments in AI, robotics, smart and autonomous systems. AI-MATTERS will provide an extensive catalogue of services to innovators in the following key topics: factory-level optimization, human-robot interaction, circular economy and adoption of emerging AI enabling technologies. All consortium members bring their expertise in manufacturing for different sectors such as automotive, space and mobility, textile, recycling, etc. Co-funded by the Digital Europe Programme, the 5-year project present in eight countries started in January 2023 with an overall budget of €60 million and is expected to achieve long-term financial sustainability;
- The **Testing and Experimentation Facility for Health AI and Robotics**: the EU project TEF-Health is a network of real testing facilities, such as hospital platforms, both physical infrastructures and data and compute infrastructures, living labs, etc., and laboratory testing facilities that will offer to innovators to carry out tests and experiments of their AI and robotics solutions in large-scale and sustainable real or realistic environments. The consortium is implementing evaluation activities that facilitate market access for trustworthy intelligent technologies, particularly by considering new regulatory requirements (certification, standardization, code of conduct, etc.). TEF- Health will ensure easy access to these evaluation resources (link with digital innovation hubs, etc.). In doing so, TEF-Health contributes to increasing effectiveness, resilience, sustainability of EU health and care systems; reduce healthcare delivery

[195] The Digital Europe Programme | Shaping Europe's digital future (europa.eu)

inequalities in EU; and ensure compliance with legal, ethical, quality and interoperability standards. A key component of an agile certification process are regulatory sandboxes where all relevant stakeholders can work together to create innovative testing and validation tools for trustworthy AI in medical devices for specific use-cases. The use-cases are defined in four domains: 1) Neurotec, 2) Cancer, 3) CardioVascular and 4) Intensive Care. Co-funded by the Digital Europe Programme, the 5-year project present in nine countries started in January 2023 with an overall budget of €60 million and is expected to achieve long-term financial sustainability;

- The **Testing and Experimentation Facility for Agri-Food**: Built as a network of physical and digital facilities across Europe, the EU project agrifoodTEF provides services that help assess and validate third party AI and Robotics solutions in real-world conditions aiming to foster sustainable and efficient food production. AgrifoodTEF offers validation tools to innovators so they can develop their ideas into market products and services. There are five impact sectors: arable farming (performance enhancement of autonomous driving vehicles), tree corps (optimisation of natural resources and inputs for Mediterranean crops), horticulture (finding the right nutrient balance as well as crop and yield quality), livestock farming (improvement of sustainability in cow, pig and paltry farming) and food processing (traceability of production and supply chains). The use cases include quality crops, agro-machinery, AI conformity assessment, agro-ecology in controlled environments, co-creation in agrifood production, HPC for agrifood, AI for arable and farmland machinery, and new frontiers for sustainable farming in the North. Co-funded by the Digital Europe Programme, the 5-year project present in eight countries started in January 2023 with an overall budget of €60 million and is expected to achieve long-term financial sustainability;
- The **Testing and Experimentation Facilities for Smart Cities and Communities**: the new EU-wide network of permanent testing and experimentation facility (TEF) for smart cities and communities will help accelerate the development of trustworthy AI in Europe by giving companies access to test and try out AI-based products in real-world conditions. By further developing and strengthening existing infrastructures and expertise, CitCom.ai provides reality lab-oriented conditions in test and experimental facilities, relevant for AI and robotics solutions targeting sustainable development of cities and communities. In doing so, Citcom.ai helps European cities and communities in the transition towards a greener and more digital Europe and in maintaining and developing their resilience and competitiveness. Citcom.AI focuses on three overarching themes – 1. POWER targeting changing energy systems and reducing energy consumption; 2. MOVE targets more efficient and greener transportation linked to logistics and mobility; and 3. CONNECT serves citizens through local infrastructures and cross-sector services. Co-funded by the Digital Europe Programme, the 5-year project present in eleven countries started in January with an overall budget of €40 million and is expected to achieve long-term financial sustainability.

Interoperability Test Bed

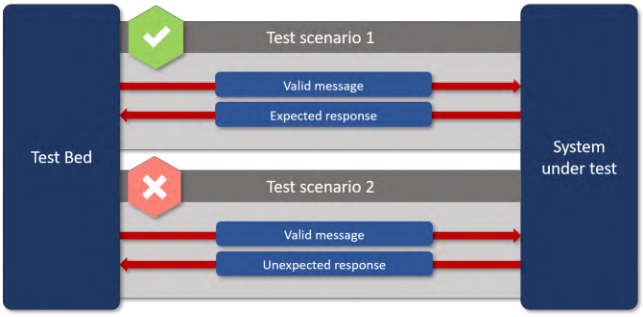
With the Interoperability Test Bed, the Commission's Directorate-General for Informatics (DG DIGIT) offers a service that can be used for free by all public administrations in the EU to design, develop and experiment with digital solutions.

The flow of information between IT systems lies at the core of the digital services used today by citizens, businesses and public administrations. Such exchanges are made possible by ensuring that IT systems are **interoperable**, meaning that they communicate in a common way and share an understanding over exchanged messages and the processing they entail.

Policymakers are setting requirements for IT systems but are not always aware of the consequences of legal provisions for the digital environment of public administrations. The Interoperability Test Bed can be used to experiment with new solutions that simulate their effect on related digital systems.

The Test Bed is itself a software system that can be downloaded and installed locally but also reused through a shared online installation operated by the Commission's department for informatics (DG DIGIT). It offers an intuitive **web-user interface** that allows administrators to define their project's overall testing set-up as well as allowing users to connect and run tests.

In terms of the testing approach that it follows, the Test Bed is typically used to **exchange messages** with the software systems being tested, supporting both the sending and receiving of messages and **validating** all steps against the target specification and according to the specific scenario's expectations. Such scenarios can focus on technical details but can also be defined at **business-level**, exposing details only when needed to troubleshoot failures.



The Test Bed can be **customised** for a specific project's testing and deployment needs and can be **extended** where necessary to support domain-specific capabilities. Throughout the process, project teams can also count on support from the **Test Bed team** in the design and realisation of their testing strategy. As a work in progress, the Test Bed can be continuously updated, allowing the content experts (e.g. policy officers) to test their design against their expectations.

Testing from the beginning of a design process is a powerful **quality assurance tool**. It ensures that the design is testable through clear assertions and highlights ambiguous points early on. It is also worth noting that any validation services set up as part of a solution design will also be **ready-to-use tools** for its target community once implementation begins.

Complementing such validator functions, the Interoperability Test Bed tool may also be used for experimentation offering test scenarios and simulators. This allows prospective implementers to preview the specifications' use and try out integrations in a safe and controlled environment. The development of solutions is facilitated through such experimentation, but feedback is also collected from the respective communities, thus contributing to regulatory learning (especially in the field of regulating digital solutions). In the past, the Test Bed has been used to support, for example, the implementation of eInvoicing solutions and the Business Registers Interconnection System (BRIS) [196]. The Interoperability Test Bed will also facilitate the development of state-of-the-art biometrics and digital identity wallets, including wallet onboarding, selective disclosure of data and verification of credentials [197]. In line with the commitments of the Commission's latest digital strategy [198] on digital-ready policymaking and the proposal for an Interoperable Europe Act, it is becoming a good practice to use the interoperability testbed not only to support policy implementation but also for experimentation already during the policy-design stage.

Examples of the European Institute of Innovation and Technology, Knowledge and Innovation Communities (EIT-KICs) innovation testing environments, testbeds and sandboxes

End-to-end digitalised production testbeds [199]

Cross-KIC activity is run jointly by EIT Manufacturing, EIT Digital, EIT Food and EIT Raw Materials. Its main goal is to promote the adoption of digital solutions, such as artificial intelligence (AI) and 5G, by EU industry to remain competitive. It supports the establishment of innovative end-to-end, customer-centric testbeds covering the whole product life cycle.

TFOOD – food-loss reduction and supply-chain efficiency are the focus of this digital testbed for the primary sector. A teaching factory bridges the gap between academia and industry, and creates a basis for new synergy models. The consortium, which consists of partners from the milk-processing industry, is working on a robotics-based demonstrator for food processing, applying autonomous pick-and-place operations to package small production batches. The testbed also consists of digitised milk-cooling tanks, which allow continuous monitoring. This results in better awareness of critical parameters for raw milk and less food loss.

The iFishCan testbed is a cognitive Industrial Internet of Things (IIoT) platform designed to improve the efficiency of the fish-canning industry. It addresses small and medium-sized enterprises that want to reduce their food waste and their environmental impact. iFishCan consists of a low-cost sensor network connected through an IIoT system, which collects data in real time. An advanced AI-engine coupled with a manufacturing execution system (MES) makes it possible to predict results for different

[196] User case studies | Joinup (europa.eu)
[197] The Test Bed in support of digital wallets for travel and mobility | Joinup (europa.eu)
[198] Communication to the Commission of 30 June 2022, 'European Commission digital strategy – next generation digital Commission', C(2022) 4388 final.
[199] EIT Community Testbeds

process indicators. The mobile testbed allows companies to make better-informed decisions, and to optimise water and energy consumption. iFishCan can be easily adapted and scaled to different types of fisheries and products with a high customisation grade.

EIT Health's **Digital Sandbox** helps start-ups tap into the massive amounts of medical data created through the digital revolution in health in order to create the test environments where healthcare innovations and the development of new products and services happen. Valuable data are obtained through EU biobanks, quality registers and sample holders.

ANNEX 3: EXAMPLES OF REGULATORY SANDBOXES AND OTHER FORMS OF EXPERIMENTATION FROM THE COUNCIL'S WORKING PAPER

The following examples were used for the analysis carried out by the Council of the European Union as part of its working paper on regulatory sandboxes and other forms of experimentation. Section 4 (Overview of practice at national level) discusses the results of this paper. The examples date from before 2021 and sandboxes launched after that date are not part of this overview.

Table 10: regulatory sandboxes in the EU Member States

MEMBER STATE	*SECTOR*	*NAME OF THE CASE*	*LEGAL BASE*	*YEAR OF ESTABLISHMENT*	*DURATION (YEARS)*
Austria	Finance	FMA Sandbox	The Financial Market Act, which is the organisational law of the FMA and contains some additional specific procedural law, was amended to establish the sandbox (BGBl. I Nr. 89/2020). The corresponding provision is Article 23a of the Financial Market Authority Act (FMABG), which contains the eligibility criteria, competences and procedural provisions.	2020	more than 5
Austria	Transportation	AutomatFahrVerordnung - Regulation on automated vehicle functionalities	The legal provision is established through a national regulation based on the national type-approval law. This 'Ordinance on Automated Driving' (Automatisiertes Fahren Verordnung – AutomatFahrV) defines the specific legal requirements for the different automated mobility use-cases. Further instructions and process descriptions for practical trials and test are defined in a code of practice. Further information: https://www.bmk.gv.at/en/topics/mobility/alternative_transport/automated/framework/roads.html	2016	more than 5
Austria	Energy	Ausnahmen von Systemnutzungsentgelten für Forschungs- und Demonstrationsprojekte	The legal basis is the Renewable Energy Package (Erneuerbaren-Ausbau-Gesetzespaket or 'EAG-Paket'), in particular Article 58a of the Electricity Sector Act (ElWOG 2010) and Article 78a of the Natural Gas Act (GWG 2011). The legal provisions, which entered into force in 2021, regulate eligibility criteria, competences and the procedures for exemptions from grid fees for research and demonstration projects.	2021	3
Czechia	Telecommunica	Use of radio	Article 19b (individual authorisation to use radio frequencies for experimental	2012	more than 5

	tions	frequencies for experimental purposes	purposes) introduced into the Electronic Communications Act (Law No 127/2005 Coll.) an amendment made by Act No 468/2011 Coll. amending Act No 127/2005 Coll. on Electronic Communications and amending certain related laws (the Electronic Communications Act).		
Denmark	Energy	Sandbox on energy technologies	'Energy Agreement 2018' The Danish Energy Agency's regulatory sandbox is one of several initiatives under the Agreement. However, there is no particular legislation or experimentation clause which provides the framework for this regulatory sandbox. The degree of regulatory flexibility is therefore also limited to the framework for exemptions provided under current legislation.	2019	5
Denmark	Finance	FinTech sandbox	Appropriation Request No 80 of 15 May 2017 from the Ministry of Industry, Business and Financial Affairs to the Parliamentary Finance Committee.	2017	more than 5
Denmark	Transportation	Sandbox for self-driving motor vehicles	Act amending the Danish Traffic Act: authorisation to lay down rules on, and grant permission for, experiments with self-driving motor vehicles (L120, parliamentary year 2016/2017).	2017	5
Denmark	Transportation	Regulatory sandbox for autonomous shipping and related technologies	All testing is conducted within the framework of existing Danish regulation. The Danish Maritime Authority allows testing of autonomous ships on the condition that there is someone aboard the ship, who can take over command if the autonomous system fails.	2018	5
Denmark	Transportation	Testing of drones, sensors, and other flight systems	The Danish Civil Aviation and Railway Authority can provide operational authorisation in the specific category specified in (EU) 2019/947 on the rules and procedures for the operation of unmanned aircraft.	2017	5
Estonia	Transportation	Self-driving vehicles	There is no specific Estonian regulation on experimentation clauses. However, the Estonian Road Traffic Act does not forbid the setting up of regulatory sandboxes for self-driving vehicles. Article 2(41) of the Road Act states that '[…] Any activity of a person while the person is not in the driver's seat but influences the driving direction or speed of the motor vehicle with the help of control devices (steering bars, steering wheel or other similar devices) is also deemed to be driving a motor vehicle'.	2017	5

			At the moment some amendments have already been made to the implementing acts, but not to the Road Act itself.		
Finland	Employment services	Testing effectiveness of a new subsidy for entrepreneurs or companies which are recruiting their first employee	The experiment is not yet in force and legislation has not yet been verified. The legal basis will be the law on the recruiting subsidy experiment. The goal is for the national parliament to verify legislation by the end of 2023. The experiment is currently just a proposal, so some changes are still possible.	2022	2
Finland	Social	The Basic Income Experiment	Law 1528/2016 on the Basic Income Experiment.	2017	2
France	Energy	Multiple sandboxes (established by the Energy Regulatory Commission - CRE)	Article 61 de la loi du 8 novembre 2019 relative à l'énergie et au climat.	n/a	4
France	Telecommunications	Multiple sandboxes (established by the Electronic Communications, Postal and Print Media Distribution Regulatory Authority -	Article L.42-1 (IV) et article L.44 (IV) du Code des postes et des communications électroniques (Loi pour une République numérique, 2016).	n/a	2

		ARCEP)			
France	All fields of economic activity	Multiple sandboxes (established by 'France Expérimentation', a one-stop interministerial agency led by the interministerial delegate for public transformation - DITP)	Article 37-1 de la Constitution française.	n/a	n/a
France	Personal Data	Multiple sandboxes (established by the Commission nationale de l'informatique et des libertés – CNIL)	n/a	n/a	n/a
Germany	Transportation	Line A01 – self-driving public	Registration of the vehicles for public road transport based on the exemption pursuant to Section 70 of the Road Vehicles Registration and Licensing Regulation	2020	more than 5

		bus in Monheim am Rhein	(StVZO) (https://www.gesetze-im-internet.de/stvzo_2012/70.html).		
Germany	Transportation	Hub Chain Osnabrück	Exemption on the basis of the experimentation clause pursuant to Section 2(7) of the Carriage of Passengers Act (PBefG) and Section 70 of the Road Vehicles Registration and Licensing Regulation (StVZO) (https://www.gesetze-im-internet.de/stvzo_2012/70.html). Section 2(7) PBefG: 'In order to allow for the practical testing of new modes or means of transport, the licensing authority may, upon request on a case-by-case basis, authorise exemptions from the provisions of this Act or from provisions adopted on the basis of this Act for a period of no longer than 5 years, insofar as they do not conflict with public transport interests.'	2019	2
Germany	Transportation	On-demand transportation – Hannover Region	Legal basis: Article 2(7) of the Personenbeförderungsgesetz (Passenger Transport Act).	2021	3
Germany	Transportation	'LÜMO' – LÜBECK	Experimentation clause §2 paragraph 7, PBefG.	2018	4
Germany	Logistics	DelivAIRy	Rules of the Air Traffic Regulation, Section 21b(3) (old law): 'In justified cases, the competent authority can permit exemptions from the prohibitions on operation pursuant to Subsection 1, sentence 1, numbers 1 to 9 if the preconditions of Section 21a(3) sentence 1 are met. Section 20(5) and Section 21a(5) and (6) shall apply accordingly.'	2019	1
Germany	Mobility	Dresden – the City of the Future: Empowering Citizens, Transforming Cities	Legal permission for the mobility experiment based on an experimentation clause in the federal road traffic regulations Article 45, paragraph 1, sentence 2, No 6; Straßenverkehrsordnung – StVO; Road Traffic Act).	2019	3

Germany	eHealth, digital identities	Nect Robo Ident	Testing authorised by the Federal Office for Social Security (BAS), which reviews the safeguards put in place for the protection of health data, etc. in accordance with Section 217f(4b) of the Social Code V (SGB V).	2019	1
Germany	Aviation, health	Medifly Hamburg	Rules of the Air Regulation Section 21b(3) (old law): 'In justified cases, the competent authority can permit exemptions from the prohibitions on operation pursuant to Subsection 1, sentence 1, numbers 1 to 9 if the preconditions of Section 21a(3) sentence 1 are met. Section 20(5) and Section 21a(5) and (6) shall apply accordingly.'	2019	1
Germany	Urban digitisation/development	Future City Ulm 2030 – Phase 3	The LoRaWAN demonstration garden was set up taking into consideration the following experimentation clauses / regulatory frameworks: •the data ethics concept established by the city administration and approved by the city council •regulations for data-processing relevant for cities •Creative Commons CC0 1.0 Public Domain Dedication and DataLicence Germany Zero 2.0 for use according to the Open Definition to mark data as being in the public domain and to ensure machine-readability •the applicable EU legal framework for innovative procurement that has been transposed into German law by Part 4 of the Act against Restraints of Competition (GWB) and the Ordinance on the Award of Public Contracts (VgV)	2018	4
Greece	Finance	Regulatory sandbox of the Bank of Greece	The Bank of Greece Executive Committee Act 189/1/14.05.2021 (available in English at https://www.bankofgreece.gr/RelatedDocuments/Executive_Committee_Act189_1_14052021.pdf),defines the terms and conditions for the establishment and operation of the Regulatory Sandbox.	2021	1
Italy	Several sectors	Sperimentazione Italia	Article 36 of Law-Decree No 76 of 16 July 2020 converted, with amendments, by Article 1 of Law No 120 of 11 September 2020.	2020	1

Latvia	Finance	Financial and Capital Market Authority sandbox	Law on the Financial and Capital Market Commission, Section 9, Articles 1 and 2 - Section 9.	2017	4
Lithuania	Finance	The regulatory sandbox of the Bank of Lithuania	The legal basis for the operation of the regulatory sandbox is usually the general principle of proportionality and certain legislative measures, which enable the financial markets supervisory authority (when issuing licences and adopting other supervisory decisions) to consider the circumstances of specific cases and not to apply certain legislative requirements in certain cases or impose sanctions for violation of such requirements. The Framework states that 'The Bank of Lithuania shall carry out the functions established in the Framework insofar as they are not vested in the European Central Bank in accordance with the provisions of Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions (OJ 2013 L 287, p. 63).' These principles were considered while creating the Regulatory Sandbox Framework of the Bank of Lithuania (https://www.lb.lt/uploads/documents/files/EN/our-functions/supervision-of-financial-institutions/sandbox/03-166_2018%2009%2019_EN.pdf).	2018	more than 5
Lithuania	Finance	Technological sandbox at the Bank of Lithuania LBChain	n/a	2019	more than 5
Lithuania	Energy	Regulatory sandbox for energy innovations	Article 18(1) of the Law on Energy of the Republic of Lithuania of 28 April 2020 establishes the main principles and criteria for this regulatory sandbox and the rights and obligations of participants in this regulatory approach. The amendment: https://www.e-	2020	more than 5

			tar.lt/portal/lt/legalAct/33f49d908f5611ea9515f752ff221ec9 The basic law: https://www.e-tar.lt/portal/lt/legalAct/TAR.44235B485568/asr		
Malta	Finance	MFSA FinTech Regulatory Sandbox	The sandbox was established under Rule 3 of the Malta Financial Services Act. Rule 3 was issued under Article 16(2)(a) of the Malta Financial Services Act (the MFSA Act) (Chapter 330 of the Laws of Malta), which provides the Malta Financial Services Authority (the MFSA) with the power to issue and publish rules regulating the procedures and duties of persons licensed or authorised by it or falling under its regulatory or supervisory functions. More information may be found here: https://www.mfsa.mt/fintech/regulatory-sandbox/.	2020	more than 5
Malta	Gaming and fintech	Gaming and fintech	The legal framework regulating virtual financial assets (VFAs) and innovative technology arrangements (ITAs) (Chapters 590, 591 and 592 of the Laws of Malta, and the relevant regulations issued thereunder). In accordance with Article 7 of the Gaming Act (Chapter 583 of the Laws of Malta), the Malta Gaming Authority is empowered to regulate, supervise and keep under review the practices, operations and activities related to the gaming sector and the matters regulated under the Gaming Act.	2018	3
Netherlands	Environment	Crisis and Recovery Act	Article 2(4) of the Crisis and Recovery Act, with more detailed provisions in the Order in Council on the implementation of the Crisis and Recovery Act.	2015	more than 5
Netherlands	Social	Participation Act	Article 83 of the Participation Act. If they comply with existing legislation, regulatory sandboxes and experiments are possible. The Temporary Order in Council on experiments in the Participation Act and the Temporary Regulation on Experiments in the Participation Act use this opportunity to make experiments possible. Other similar examples are Article 130 of the Unemployment Act and Article 82a of the Structure Implementation Organisation Act on Work and Income.	2019	2
Romania	Education	Experimental Schools	Art. 26/Law on Education no. 1/2011 - ”The Ministry of Education may establish, by Government decision, the operation of pilot, experimental and application units	2020	1

			in the pre-university education system."		
Slovakia	Finance	Sandbox of National Bank of Slovakia	n/a	2021	n/a
Slovakia	Transportation	Smart Parking in number of cities in Slovakia	n/a	2018	n/a
Spain	Finance	Digitalización servicios financieros	Ley 7/2020, de 13 de noviembre para la transformación de los servicios financieros.	2020	1
Spain	Finance	Financial Sector Regulatory Sandbox	Ley 7/2020, de 13 de noviembre, para la transformación digital del sistema financiero. https://www.boe.es/diario_boe/txt.php?id=BOEA-2020-14205	2020	1

Table 10: regulatory sandboxes being established / set up in the EU Member States

MEMBER STATE	*SECTOR*	*NAME OF THE CASE*	*LEGAL BASE*
Austria	Several sectors	Federal Regulatory Sandbox Law	The Federal Regulatory Sandbox Law is currently being drafted. It should contain all the generic regulations on sandboxes and thus create a uniform legal framework for specific laws on regulatory sandboxes.
Czechia	Energy	n/a	No regulatory sandbox currently exists, but there is an Energy Regulatory Office plan to establish some with current legislative tools. A stronger position on designing and managing regulatory sandboxes will be set out in the New Energy Act.
Italy	Banking, financial, insurance	n/a	Article 36, paragraphs 2bis-2novies of Law-Decree No 34/2019 (as converted by Law No 58/2019 and amended by Law-Decree No 125/2020 as converted by Law No 159/2020); Decree of the Minister of Economy and Finance No 100 of 30 April 2021 entered into force on 17 July 2021.
Poland	Energy	n/a	n/a
Poland	Finance	Tool for fintech solutions	n/a
Portugal	Several sectors	n/a	n/a
Portugal	Telecommunications	Technology-free zones	Decree-Law No 67/2021 of 30 July 2021.