Regulatory Experimentation: Moving ahead on the Agile Regulatory Governance Agenda

OECD Public Governance Policy Papers

April 2024

OECD

OECD Public Governance Policy Papers

Regulatory Experimentation: Moving ahead on the Agile Regulatory Governance Agenda

This paper was authorised for publication by Elsa Pilichowski, Director, Public Governance Directorate.

Abstract. This policy paper aims to help governments develop regulatory experimentation constructively and appropriately as part of their implementation of the 2021 OECD Recommendation for Agile Regulatory Governance to Harness Innovation. Regulatory experimentation can help promote adaptive learning and innovative and better-informed regulatory policies and practices. This policy paper examines key concepts, definitions and constitutive elements of regulatory experimentation. It outlines the rationale for using regulatory experimentation, discusses enabling factors and governance requirements, and presents a set of forward-looking conclusions.

Acknowledgements. This paper was prepared by the Regulatory Policy Division, headed by Anna Pietikaïnen, under the leadership of Elsa Pilichowski, Director of the Public Governance Directorate. This report was drafted by Miguel Amaral, Senior Policy Analyst, and Guillermo Hernandez, Policy Analyst, OECD Regulatory Policy Division. Thanks are extended to OECD Secretariat officials who provided comments to the paper and support during the process, in particular Elsa Pilichowski. The paper was prepared for publication by Jennifer Stein with editorial support from Andrea Uhrhammer. This document follows up on the regulatory experimentation roundtable organised in April 2022 during the 26th meeting of the OECD Regulatory Policy Committee (RPC). It was approved for publication on 21 December following the 29th meeting of the RPC on 29-30 November 2023.

Photo credits: Cover picture © Viktoria Kurpas / Shutterstock.com

ISSN: 24140996

Table of contents

Executive summary

By testing new products, services, or regulatory approaches and their implementation, regulatory experimentation (RE) generates knowledge and evidence that can improve regulatory quality and outcomes. As stated in the OECD Recommendation for Agile Regulatory Governance to Harness Innovation (OECD, 2021[1]), if used appropriately and in combination with other relevant approaches and regulatory co-operation, RE can improve adaptive learning, policy coherence, and the evidence base for regulatory design, delivery and adaptation, resulting in more effective and efficient public policies. RE can be particularly useful in addressing innovation-induced disruptions and the resulting uncertainty.

RE adoption has been expanding in areas such as financial services, mobility, and energy for several years, often in the form of regulatory sandboxes. Despite growing recognition of its potential and increasing uptake across countries, effective adoption of experimentation by the regulatory community is still relatively limited. Moreover, it varies considerably across sectors and jurisdictions in terms of focus, scope, and level of ambition. There is thus significant potential for increasing the uptake of RE from a whole-of-government perspective and in ways that maximise benefits from a public policy standpoint.

To help broaden the use of RE and maximise its positive impact, it is important to develop a shared understanding and characterisation of the various forms that RE can take and how suitable they are depending on the objectives, context, and available resources. For instance, while regulatory sandboxes are an important instrument for RE, the latter can be effective in the absence of regulatory sandboxing, and other tools and approaches may be more suitable.

While systematically considering the potential use of RE for regulating better is likely to prove beneficial in and of itself, experimentation involves trade-offs (e.g., regarding legality, feasibility, resources, and equity) and opportunity costs. The potential use of RE should thus be appraised against available alternatives, regulatory or otherwise, and their relative merits. Moreover, if RE is to help modernise and strengthen regulatory systems, it must be applied to the contexts and areas where it effectively informs public policy choices. This requires careful planning, resourcing and preparation, and awareness of the potential effects of political economy factors.

In addition to careful prior appraisal, successful RE implementation involves adapting organisational and regulatory culture and working methods and creating the necessary institutional and governance frameworks – particularly appropriate oversight and systematic monitoring, evaluation and stakeholder engagement. The OECD can help support the constructive and effective development of RE by working with governments and regulators to identify key implementation avenues. It is also well placed to facilitate the exchange of relevant information and experience that can help countries target RE efforts appropriately and develop relevant insights.

Introduction

To fulfil their mission, governments need to adapt their regulatory practices to ensure relevance and effectiveness. Governments are indeed confronted with complex and interrelated regulatory challenges that they must anticipate and address in a context of ever shortening policy cycles (OECD, 2019[2]). Many citizens around the world are experiencing regulations that either fall short of their intended effects or outright fail to offer the protections they promise. A key concern is that inappropriate rules may lead to a loss of trust in institutions and even in government itself. Sound governance and regulatory approach is a key factor determining the effectiveness of government action to deliver better economic and social outcomes. As such, it plays a crucial role in terms of building and preserving public trust in democratic values, processes, and institutions.

In this context, several tools and approaches can help governments address the regulatory governance challenges they face. Regulatory experimentation (hereinafter “RE”), which aims at promoting regulatory learning and informing regulatory design, delivery, and adaptation, offers great potential. By testing new products, services, or regulatory approaches and implementation modalities, RE generates knowledge and evidence for decision-making purposes. The OECD Recommendation for Agile Regulatory Governance to Harness Innovation (OECD, 2021[1]) clearly acknowledges the RE’s relevance, and there is growing interest and awareness among OECD member and partner countries. RE is also gaining traction beyond the Better Regulation community, notably in the field of science, technology, and innovation. The OECD has indeed contributed key insights in specific technology areas that lay groundwork for this study.

RE must be limited in terms of scope and time span. If this is not the case, it may amount to circumventing the regulatory process - a practice known as "regulation by exemption" that risks compromising public trust in governance. In addition, RE needs to be well integrated into the regulatory cycle. If used in combination with more established regulatory management tools (regulatory impact assessment, stakeholder engagement and ex-post evaluation) and enhanced regulatory co-operation within as well as across borders, RE can help bring about more effective and efficient public policy action through adaptive learning, increased coherence, an enhanced evidence base and, ultimately, increased regulatory quality.

Creating spaces for experimentation is particularly important considering innovation-induced disruptions and the resulting uncertainties surrounding decision making. If regulatory frameworks are not agile enough to accommodate the fast pace of innovation, rules can become outdated and stop being relevant. In other words, “the baseline for effective regulation has changed” and there is an increasing need to “rely on shorter and more inclusive policy cycles, agile regulatory responses and continuous experimentation, to match the pace of innovation and the ambition of the global development agenda” (International Telecommunication Union, 2023[3]). In addition, governments and regulators may lack knowledge and capacity to assess how new technologies will affect markets and society more broadly. They are therefore struggling to realise the benefits of innovation while upholding public protection. RE can be highly valuable in this regard, as it can enable better and more timely policy learning and adaptation grounded in a better understanding of risks and opportunities brought by innovation.

Admittedly, RE is not new but, in recent years, the value of RE and of experimentation more broadly has been increasingly acknowledged. For example, in 2019, Esther Duflo together with Abhijit Banerjee and Michael Kremer received the Nobel economics prize for their experimental approach to alleviating global

poverty. Similarly, the 2021 Nobel economics prize rewarded pioneering "natural experiments" for helping to shed light on important issues such as the impact of minimum wage increases on unemployment levels or of immigration on wages and employment (The Nobel Prize, 2021[4]).

Against this background, RE adoption has been expanding in areas such as financial services, mobility, and energy[1] for several years, often in the form of regulatory sandboxes. It is also at the core of emerging regulatory initiatives at EU level, such as the European Commission proposal for a regulation on artificial intelligence (AI), which notably aims to enable the development and testing of innovative AI systems through regulatory sandboxing. The same applies to the field of renewable energy and decarbonisation technologies. However, despite growing recognition of its potential and increasing uptake across countries, effective adoption of experimentation by the regulatory community is still at a relatively early stage. It arguably has much broader potential applicability and utility to regulators than is currently being exploited (Centre for Regulatory Innovation, 2021[5]).

In this context, the present working paper aims to support governments develop RE constructively and appropriately with a double-pronged objective: 1) enhance RE as policy tool to improve public policy, promote adaptive learning and enhance the body of relevant evidence in the face of uncertainty and knowledge gaps and 2) foster innovation by businesses (i.e. introduction of new ideas, products and business models) and governments (e.g. trialling new approaches to regulating). As such, it aims to contribute to the implementation of the OECD Recommendation for Agile Regulatory Governance to Harness Innovation (OECD, 2021[1]),

The working paper follows up on the main forward-looking conclusions of the regulatory experimentation roundtable that was organised in April 2022, during the 26th meeting of the OECD Regulatory Policy Committee (see Box 1).

Box 1. Conclusions from the Regulatory experimentation roundtable organised during the 26th meeting of the OECD Regulatory Policy Committee (April 2022)

- It would be beneficial to define and characterise the notion of regulatory sandboxes more precisely, to account for the variety of existing initiatives and enable comparability.
- In addition to the promotion of innovation through the lifting or easing of regulatory constraints, attention should be paid to the role of RE in generating evidence in complex and fast-changing policy environments, thus helping to identify relevant approaches to achieve public policy goals.
- RE comes in a range of various forms going well beyond regulatory sandboxes, each of them suited to specific contexts and objectives (e.g. accommodate innovation, set up new regulatory processes, improve regulatory frameworks…). Enhancing the evidence base regarding the typology of available approaches as well as their outcomes should be considered a priority.
- Given the transboundary nature of innovation, strong international regulatory co-operation is necessary to capitalise on the most relevant knowledge and expertise as well as to facilitate the design and implementation of cross-border RE initiatives.

With the above-mentioned objectives in mind, this working paper is structured as follows. Chapter 1 briefly discusses key concepts and definitions pertaining to RE as well as the main constitutive elements of RE initiatives and their implementation. Chapter 2 articulates the rationale for resorting to RE to improve the design and implementation of regulation and public policy action. Chapter 3 discusses enabling factors and governance requirements, including associated safeguards and cross-border implications. Chapter 4 concludes.

Key messages

- Creating spaces for experimentation is particularly important considering innovation-induced disruptions and the resulting uncertainties surrounding decision making. If used appropriately and in combination with other relevant approaches and regulatory co-operation, regulatory experimentation can improve adaptive learning, policy coherence, and the evidence base for regulatory design, delivery and adaptation, resulting in more effective and efficient public policies.
- Effective adoption of experimentation by the regulatory community is still relatively limited and regulatory experimentation initiatives vary considerably across sectors and jurisdictions in terms of focus, scope, and level of ambition. This report aims to help governments develop a shared understanding and characterisation of the various forms that regulatory experimentation can take and how suitable they are depending on the objectives, context, and available resources.
- Regulatory experimentation must be limited in terms of scope and time span. It also has to be fully integrated into the regulatory cycle, in combination with other regulatory management tools (such as regulatory impact assessment) to help bring about more effective and efficient public policy action through adaptive learning, increased coherence, an enhanced evidence base.
- The use of regulatory experimentation involves trade-offs and opportunity costs that should be properly assessed. This requires careful planning, resourcing and preparation, and awareness of the potential effects of political economy factors.
- Successful RE implementation involves adapting organisational and regulatory culture and working methods and creating the necessary institutional and governance frameworks – particularly appropriate oversight and systematic monitoring, evaluation and stakeholder engagement.

1 Regulatory experimentation: Definitions and main forms

Characterising regulatory experimentation

There is no widely accepted definition of regulatory experimentation or closely related terms such as "experimental legislation", "experimental regulation", "regulatory experiment" or "regulatory pilot". These concepts depend to a significant extent on national legal frameworks and scholarly interpretations (Ranchordas, 2021[6]). The term "regulatory sandbox" is also being increasingly used to describe a relatively large variety of settings and practices.

According to Canada's Centre for Regulatory Innovation (CRI) (Centre for Regulatory Innovation, 2021[5]), regulatory experiments enable "a test or trial of a new product, service, approach or process designed to generate evidence or information that can inform the design or administration of a regulatory regime". Alternative definitions emphasise in turn the "temporary nature with limited geographic and/or subject application" of regulatory experiments[2] as well as the prospect of an evaluation at the end of the experimental period (Ranchordas, 2021[6]). Rigorous evaluation of RE's effects regarding a given set of objectives is indeed imperative if it is to enlighten decision making given the uncertainties with which decisionmakers must contend (which can be reduced by testing related hypotheses (Conseil d'État, 2019[7]). The World Economic Forum, in turn, characterises RE as regulators' engagement with businesses on proposed ideas, products, and business models to learn how both parties need to adapt (World Economic Forum, 2020[8]).

The notion of test is central to RE. Sweden's Committee for Technological Innovation and Ethics (Komet) defines tests as work involving both experimentation and verification of new solutions in a real-world environment under controlled conditions and with clear delimitations. One test can include testing and verification of multiple new solutions at the same time (Komet, 2021[9]). Testing can be conducted for regulatory exploration purposes if it is unclear whether a new product or innovation is covered in an existing regulatory regime, how existing regulations would apply, or whether new regulations are required (Business at OECD, 2020[10]) (NESTA, 2019[11]).

It is important to note that the concepts "regulation" and "regulatory experiments" in this context are not limited to prescriptive laws in terms of "command-and-control" approaches or the narrowly defined regulation of networks and monopolies, as they also include the whole range of institutional arrangements of public policy instruments, procedures and organisational structures (Bauknecht, D. et al, 2021[12]) for developing, implementing, evaluating and adapting laws and regulations.

The current relative lack of conceptual clarity might undermine the development of well-coordinated and effective regulatory experimentation initiatives, along with their subsequent evaluation. To help address this shortcoming, this chapter discusses RE's main constitutive elements as well as the objectives that it can help pursue. It does so on the understanding that RE can exist in a variety of forms as well as in different contexts.

Main forms of RE and their use

Discussions during the 26th meeting of the OECD Regulatory Policy Committee evidenced that RE comes in a range of various forms, each of them suited to specific contexts and objectives. This section provides an overview of selected relevant features that can help apprehend RE in its diversity.[3] It also attempts to clarify how different forms of RE can be used. As will be discussed, regulatory sandboxes are an important instrument for RE. However, RE can be effective in the absence of regulatory sandboxing, and other approaches may be more suitable depending on the purported objectives, context, and available resources.

The section first considers RE forms from the standpoint of their focus, scope and objectives. It then discusses implementation modalities and associated tools for RE initiatives, as well as their legal underpinning.

RE forms according to their focus

Several "levels" of application can be distinguished when considering RE. A fundamental difference relates to whether experiments focus on the implications of *innovations that may be brought onto the market* or, alternatively, *on regulation itself* as main object of experimentation and learning. While not identical, the latter also relates to the notion of *experimentalist governance*, which "reflects an approach to rule-making and policy implementation based on the recursive review or monitoring of the experience of different jurisdictions with policy implementation at the local and regional levels" (Wolfe, 2018[13]).

RE focusing on new products, service or business models

Regulatory experiments focusing on a new product, service or business model will seek to understand the implications of these innovations, notably their potential impact in real-world settings and how easy they would be to regulate by means of existing instruments. Examples notably include legal provisions allowing for the testing autonomous driving and delivery vehicles as well as innovations in the energy and fintech sectors (Bauknecht, D. et al, 2021[12]). The focus, objectives and modalities of RE will notably depend on whether the innovation at hand occurs in a field that is already regulated or, on the contrary, in one that is still unregulated or where the regulatory framework is under development.

Regulatory experiments focusing on the implications of innovations that may be brought onto the market will often, although not always, consist of waving certain legal obligations applicable to a specific group of citizens, sector or geographical region for a predetermined period (see "Experimentation by derogation" for more details on the latter). These experiments may also consist of creating custom legal obligations. Advisory services including regulatory guidance may enable a certain degree of exploratory experimentation without resorting to exemptions.

Regulation as the main object of experimentation

In experiments focusing on regulation per se, the main aim is to test new regulatory options and learn about their implementation and impact before introducing them on a permanent basis and possibly on a larger scale. Sometimes referred to in the literature as regulatory innovation trials (Bauknecht, D. et al, 2021[12]), experiments within this category may follow different modalities (Centre for Regulatory Innovation, 2021[5]):

- Trial a *new approach to regulating* (e.g. punitive versus cooperative; prescriptive input- or rule-based versus outcome- or performance-based) or a *new (version of) a regulation* under controlled conditions in order to monitor its effects.[4] For example, regulators may test proposed regulations with a small group of regulated entities to assess their effectiveness before being formally implemented (e.g. Open Banking), or test new rules in a geographically limited area.

- *A policy or regulatory process* to test, for example, different ways of interacting with stakeholders on the design of new regulations. An interesting example stems from the Global Financial Innovation Network (GFIN), which aims to create a new framework for co-operation between financial services regulators on innovation-related topics, sharing different experiences and approachest. It also includes a pilot for firms wishing to test innovative products, services or business models across more than one jurisdiction.[5]
- *Delivery modalities* such as testing a new licensing system, decide between alternative potential disclosure requirements for a new product class by systematically comparing their performance.

A relevant example relates to France's Center of expertise for digital platform regulation (PEReN). PEReN has been enabled, through a regulatory exemption, to test regulatory tools and approaches directly on digital platforms, which are, under certain conditions (including the obligation to delete data once the test is over), legally mandated to co-operate. Relevant areas of PEReN's contribution notably include the exploration of technical modalities for online age control, contribution to the future regulation aimed at combating child sexual abuse, inputs to work on AI regulation, and the development of regulatory and assessment tools (Center of expertise for digital platform regulation, 2022[14]).

RE can also be useful for testing regulatory measures in less technology-dominated environments. For example, a permanent "green arrow" traffic sign for cyclists at city crossroads (allowing cyclists to always turn right) has been tested in cities including Paris, Berlin and Basel. These initiatives required a temporary adjustment of the existing regulatory framework to be implemented. In Germany, the Federal Transport Ministry has piloted this concept in nine cities. Based on these pilots' results, it adapted road traffic regulations so they generally allow green arrows for cyclists across the country (Bauknecht, D. et al, 2021[12]).

To promote regulatory learning, the European Commission has created an Interoperability Test Bed[6] that can notably be used to experiment with new solutions simulating their effect on the digital systems of public administrations (European Commission, 2023[15]).

As illustrated by the initiatives undertaken by Portugal's energy regulator (ERSE) (see Box 1.1), it is worth noting that regulators are increasingly combining RE initiatives in a variety of forms.

Box 1.1. Regulatory experimentation by ERSE

Against the background of the energy transition and the European Green Deal, European regulators are increasingly making use of regulatory experimentation to further support their policy objectives. Portugal's energy regulator, ERSE, has developed or overseen a number of regulatory experimentation initiatives in the Portuguese energy sector, which include:

- Approving rules for time-limited pilot projects with dynamic tariffs (i.e. differentiation in time and location) to improve pricing structures and promote a more efficient use of electricity networks. These projects were made possible by the regulatory discretion granted to ERSE and allowing for the amendment of regulations that apply to the energy sector
- Establishing a regulation on time-limited projects of no more than three years in electric mobility
- Using regulatory sandboxes in the gas sector to facilitate the use of hydrogen.

RE initiatives according to their scope and objectives

RE can also be apprehended in terms of its scope, objectives and level of ambition. Nesta, a UK-based innovation foundation, have identified three main approaches to adaptive regulation that cut across the categories presented in the previous sub-section (NESTA, 2019[11]) and can also be relevant for characterising RE. These approaches, which may be applied sequentially, are briefly presented below.

- *Advisory approaches*, which help businesses make sure that new products and services adhere to existing regulations. Strictly speaking, these approaches do not constitute regulatory experiments as such. They enable, however, regulatory exploration, and can help target RE efforts further down the line, e.g. by helping to identify situations where a regulation creates unnecessary barriers to the development of an innovation, thus potentially warranting considering a regulatory experiment. Such advisory work is currently at play in several OECD countries including *Sperimentazione Italia*'s welcome office, *France Experimentation*, and Croatia's Innovation Hub for financial services. In 2018, Denmark's Danish Business Authority set up a one-stop-shop for new technologies and business models that provides government-wide co-ordination as well as guidance for innovative businesses. Advisory services also exist at EU level (e.g. Enterprise Europe Network, Horizon Results Booster). Officials working in dedicated advisory services set up in countries including Italy, France and the UK concurred with the fact that new products, services and business models envisioned by firms are often found to be compatible with existing regulatory frameworks. As highlighted, for example, by (Attrey, Lesher and Lomax, 2020[16]) in the case of the "Innovation Link" service[7] developed by the UK's energy regulator OFGEM, data from 2018 showed that in most cases the programme was used to deliver rapid regulatory advice about how a proposed innovation could be conducted within the constraints of existing energy regulation.
- *Adaptive approaches*, which support innovations by adapting existing regulatory frameworks. Adaptive licensing may be considered a relevant example here. A new pharmaceutical drug may for example be initially approved only for a limited subpopulation (e.g. those for whom it may offer the greatest net benefits), which is then studied to observe efficacy and side effects in practice (going beyond smaller clinical trials) with careful analysis of genetic and other factors that may help predict health effects in the broader population (Bennear, L.S and Wiener, J.B., 2019[17]). Autonomous and connected mobility is, according to Wiener, another area that could require an adaptive approach taking into account learning over time: automated vehicles may be licensed first for the drivers who would benefit most from them (e.g. the least experienced drivers, those unable to drive, or those who have the worst accident records). Automated vehicle use can then be progressively expanded as technology improves and emerging evidence is used to improve vehicles and networks. (Duke Law, 2019[18])
- *Anticipatory approaches*, which involve iterative development of regulation and standards in an emerging field. The goal is to better understand the impact of one or several drivers (e.g. technological, socioeconomic…) on the economy and on society, and the associated regulatory needs over time. Anticipatory approaches to RE need to be used in combination with a broader set of measures to develop and implement resilient and forward-looking governance frameworks for emerging and disruptive technologies. They should, for instance, be able to adapt and improve based on the knowledge and intelligence gained through anticipatory approaches such as (regulatory) foresight. The Regulators' Pioneer Fund launched in 2017 by the UK's Better Regulation Executive (part of the former Department for Business, Energy and Industrial Strategy) is an example of such approach. This initiative aims to fund regulators to promote the testing of new ideas, products, services, processes or business models, for example through new licensing or sandbox regimes.

Certain experiments encompass elements from various approaches. For instance, Japan's Regulatory Sandbox Scheme aims to enable demonstration tests and pilot projects for new technologies and business models that are not accounted for by existing regulations and ascertain how innovations fit into existing regulation and which changes, if any, may be necessary (winnovation consulting, 2020[19]). Information and documentations as outcomes of such demonstrations are made available to promote and facilitate regulatory reform (METI, 2020[20]). *France Expérimentation*, in turn, combines an advisory with an adaptive component. This inter-ministerial programme aims at enabling the removal of legal obstacles that hinder the implementation of innovative projects through the establishment of temporary exemptions. It also offers a legal support solution when projects are found to be feasible within the existing legal framework. In the absence of any legal obstacles identified by the relevant regulatory authorities, businesses can benefit from a guarantee that the project is feasible within the current legal framework.

In addition to the typology presented above, it can be useful to distinguish between RE approaches that seek to *facilitate* experimentation (e.g. advisory services, regulatory sandboxes or pilots) and those whose main aim consists of *stimulating* it (e.g. regulatory challenges or prizes). Regulatory challenges or prizes, aim at stimulating the development of new ideas, products and business models that help achieve policy goals or missions, and they "can be a powerful mechanism to help encourage innovation in highly-regulated markets where there are perceived barriers to entry" (World Economic Forum, 2020[8]). The WEF notes that the notion of organising competitions is a long-standing component of public innovation-funding schemes but has only recently been introduced to regulatory practice combining grants or loans to innovators with a degree of regulatory support to test innovations as part of the prize. Due consideration should however be given to potential inappropriate market distortion risks.

A relevant example relates to joint work between the Solicitors Regulation Authority in England and Wales and innovation foundation Nesta to set up the *Legal Access Challenge*. This challenge's main aim is "to accelerate the development of products, services and platforms that will help individuals and small and medium-sized enterprises understand and resolve their legal problems with greater ease" (World Economic Forum, 2020[8]). It is also expected to help the regulator identify potential regulatory barriers to mass market legal technology solutions and possible measures to address them.

Implementation modalities for RE

RE, with the various forms and objectives discussed in the previous sub-sections, may be implemented in several ways. The main available options are:

- By using available legal flexibility;
- By testing, under certain conditions, new regulations, regulatory processes or enforcement approaches;
- By means of devolution, i.e. state, national or local levels of government are allowed to establish new regulations in their own jurisdictions on a particular policy area or objective;
- By allowing temporary regulatory exemptions/derogating from existing legislation.

These implementation modalities, which may overlap to a certain degree, are discussed next.

Using available legal flexibility

Flexibility within existing legislation may allow for various forms of experimentation without recourse to legal changes. According to the European Commission, competent authorities may "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". This kind of approach generally requires certain competences on the side of regulators (e.g. to promote innovation) (European Commission, 2023[15]). The same as for the other RE implementation modalities, the objective is to enable regulatory

learning though practical experience that informs the potential adaptation of existing regulatory frameworks. In addition, to be considered as regulatory experiments, such initiatives must be time-limited.

Experimentation using existing flexibility may notably include the following cases:

- Leniency for testing and piloting and/or regulatory exploration, i.e. testing conducted when it is unclear whether a new product or innovation is covered in an existing regulatory regime, how existing regulations would apply, and whether new regulations are required.
- The temporary development and application of alternatives to traditional means-based regulation such as outcome-based regulation, which focuses on the intended results from a regulation, as opposed to prescribing a specific process or action that must be followed.
- Allowing regulatory experiments at local/sub-national level, whereby these decentralised government units experiment *within their own powers* and adapt national policies to their specific needs (see also "Experimentation by devolution").

Moreover, a large-scale basic income experiment conducted in Finland in 2017–2018 showed, according to a spokesperson for the Strategic Research Council[8], that conducting extensive social experiments in the country was possible from a legislative viewpoint. It should however be noted that this experiment ended up being narrower in scope than anticipated due to concerns that certain components would run counter the "equal treatment" principle (e.g. different amounts of basic income could not be tested; instead, the amounts were downscaled to equal the net level of unemployment benefits) (OECD, 2017[21]). Ensuring equal treatment and a level playing field is indeed a fundamental parameter that needs to be considered regarding RE development (see the next chapter for further details).

Piloting new regulations or processes

When it comes to the trialling of new regulatory approaches or processes, pilot regulations (pilots) are often used to that end. Pilots, which require a legal basis to be implemented, involve testing a novel approach in a limited geographical region, or for a limited group of users. According to a 2003 UK Government document (Cabinet Office, 2003[22]), a pilot is a *test run* the results of which will help to influence the shape and delivery of the final policy. The same document distinguishes between impact and process pilots.

- *Impact pilots* are tests of the likely effects of new policies, measuring or assessing their early outcomes.
- *Process pilots* are designed to explore the practicalities of implementing a policy in a particular way or by a particular route, assessing what methods of delivery work best or are most cost-effective.

In practice, many pilots seek to achieve both aims simultaneously. In addition, impact *and* process pilots can be used to "help improve an existing policy or its methods of implementation, or to develop a new policy from a preliminary idea" (Cabinet Office, 2003[22]). The European Commission defines pilot regulations as "temporary regulatory frameworks applicable on a voluntary basis" that can help competent authorities try out possible options before deciding and making final changes. It distinguishes them from regulatory pilot projects, in which the regulator defines the exact scope of the trial. Pilot projects tend to be championed by "proactive regulators keen on regulatory learning". They share certain features with regulatory sandboxes (see Experimentation by derogation, including regulatory sandboxes) but are possible also in the absence of a general framework for those (European Commission, 2023[15]).

In an interesting example of testing initiative in co-operation with innovators, Spain is currently conducting an experiment aimed at connecting innovators and regulators, and facilitating the development, testing and validation of innovative AI systems to ensure compliance with the requirements of the upcoming AI Act, an EU Regulation. This experiment seeks to help establish a common EU framework and harmonised standards for AI regulatory sandboxes by providing practical experience through the application of the various features of the AI Act proposal to specific AI projects (e.g. requirements, conformity assessments

and certain post-market activities) and making guidelines, toolkits and good-practice materials available (Gobierno de España, 2022[23]) (European Commission, 2022[24])[9].

Experimentation by devolution

Devolution involves "assigning responsibility to players to conduct activities that they are normally not allowed to engage in" (Schittekatte et al., 2021[25]). In experimentation by devolution, a federal, supranational or national government decides to empower lower levels of government to establish in parallel new regulations in their own jurisdictions on a particular policy area or objective, e.g. waive federal requirements and implement their own legislative and policy solutions adapted to specific challenges. Devolution creates opportunities to enact new laws, adapt national policies to local circumstances and budgets, and initiate policy experiments. It may also enable different local or regional governments to enact different experiments, in which case not all the units in the sample group will apply the same legal conditions to their citizens. Each local unit may experiment with its own solution as long as this fits the federal or supranational experimental framework" (Ranchordas, S. and van Klink, B., 2022[26]). As for other modalities, the objective is draw on the lessons learned from the experiment to help determine the extent to which as well as how existing regulatory frameworks need to be adapted.

Experimental legislation in the United States has traditionally allowed states to experiment, within their powers, with the implementation of multiple laws and innovate beyond existing federal initiatives. Experimentation in this context is often referred to as "states-as-laboratories" (in a 1932 Decision, U.S. Supreme Court Justice Louis Brandeis had referred to states as "laboratories of democracy"). France's Constitution allows since 2003 the adoption of experimental laws and regulations at both national and sub-national levels (Articles 37 and 72). These constitutional dispositions are further developed in sector-specific legislation and organic law (2021) to facilitate enactment at local level (Ranchordas and van 't Schip, 2019[27]) (Ranchordas, 2021[6]).

Experimentation by derogation, including regulatory sandboxes

In the case of experimentation by derogation, certain rules will not be applied to a certain group of regulated entities, geographical region or sector for a predetermined period. Derogation may involve waiving certain legal obligations and/or creating custom ones (e.g. to ensure that the experiment is carried out safely and appropriately).

Within derogation-based approaches to RE, regulatory sandboxes, which were pioneered by the UK's prudential financial regulator (FCA) in 2015 to test the market introduction of Fintech products, have since started developing also in sectors such as health, transport, legal services, aviation and energy. A regulatory sandbox typically involves a limited form of regulatory waiver or flexibility so that new products, services or business models can be tested under reduced regulatory constraints. The purpose of regulatory sandboxes is to learn about the opportunities and risks that a particular innovation carries and to develop the right regulatory environment to accommodate it (Federal Ministry for Economic Affairs and Climate Action, 2023[28]).

Regulatory sandboxes are typically organised and administered on a case-by-case basis by the relevant regulatory authority, which, as will be discussed in Chapter 4 on Enabling factors for effective RE, entails strong co-ordination needs given that many innovation cut across departmental mandates (e.g. data or digitally enabled services have emerged in virtually every sector) (Attrey, Lesher and Lomax, 2020[16]) (Centre for Regulatory Innovation, 2021[5]). To improve co-ordination and consistency in implementation, several countries including Germany, Japan and Denmark are developing regulatory sandboxes (as well as other RE initiatives) that are not sector-specific but rather cross-cutting in nature. Co-ordination can also be strengthened by integrating sandboxes into broader innovation policies and programmes such as innovation hubs.

Box 1.2. UK Civil Aviation Authority's Innovation Hub and Innovation Sandbox

In April 2019, the UK Civil Aviation Authority (CAA) launched its Innovation Hub with the following objectives in mind:

- Making it easier for innovators to access CAA expertise, guidance, and viewpoints on regulations and providing a focal point of contact and information;
- Helping innovators maximise regulatory readiness for the demonstration of their aviation systems by testing them in safe environments and learning how they address regulatory challenges; and
- Accelerating the development of new policies and regulations by anticipating regulatory challenges in areas of innovation, then defining the requirements for new policies and regulations.

The cornerstone of this scheme is the Innovation Sandbox, which notably focuses on future innovation in aviation, including air mobility, and relies on an iterative, co-operative approach (through workshops, live trials and simulations). In this context, the CAA's website states that, "whilst existing aviation regulations can enable the exploration and trialling of innovative future air mobility solutions, they do not yet enable commercial operations or fully provide a scalable, proven certification approach", and recognises that the CAA needs to play a role "in identifying and supporting answers to regulatory challenges and working alongside Government, industry and public stakeholders".

The Sandbox is conceived as a learning platform for policy and regulation as well as a means of accelerating the development of a robust evidence base that will support regulatory approvals for demonstration flights.

There are no restrictions to apply to the so-called Sandbox challenges. Some of the sandbox participants – including smaller firms with limited resources – receive UK Government funding, which allows them to access CAA support in this way (but the CAA does not provide funding for innovation related projects). Moreover, although it seeks to improve the regulatory readiness of participating companies, the CAA does not help them with the approval procedure itself as this could confer them an unfair advantage. In addition, it shares openly all relevant information generated by the Sandbox. The CAA has published two case studies based on its experience with this instrument: respectively, on the experience of Volocopter, one of the first companies to join the Innovation Sandbox, and on unmanned aircraft operating Beyond Visual Line of Sight.

Source: (Hernández and Amaral, 2022[29]).

Regulatory sandboxes often have a derogation component of some kind. It should be noted, however, that the term "regulatory sandboxes" has also been used to refer to other forms of RE as well as to designate RE more generally.[10] For instance, a 2020 study for by winnovation consulting for Business Europe (winnovation consulting, 2020[19]) distinguishes between sandboxes based on "an explicit, timewise limited experimentation clause" and those that do not involve any exemptions but instead rely on supervision and collaboration, e.g. to provide innovators with certainty on the legal classification of the innovation at hand. The innovation study gives as an example of the first type the regulatory sandbox conducted by the UK Solicitors Regulation Authority,[11] which focuses on innovative technology-driven legal solutions that will help individuals and small and medium-sized enterprises (SMEs) to better understand, prevent or resolve their legal problems. The sandbox provides guidance on existing legal requirements as well as waivers for special cases. The second type is somehow comparable to the advisory and adaptive approaches identified by Nesta (NESTA, 2019[11]) and discussed earlier in this chapter.

Other derogation-based approaches to RE

Based on their analysis of regulatory approaches to foster innovation in the financial sector, (Zetzsche et al., 2017[30]) classify these approaches in several categories ranging from doing nothing, to cautious permissiveness (either on a case-by-case basis or through special charters), structured experimentalism and developing specific new regulatory frameworks.[12] The authors consider regulatory sandboxes to fall within the structured experimentalism category and point to other derogation-based alternatives within that category, including:

- Class waivers for eligible products, which typically provide more certainty but less space for experimentation
- Leniency for testing and piloting (also discussed above). (Zetzsche et al., 2017[30]) note that regulators in the US, Germany, Luxembourg and France had at the time of writing preferred this approach to developing sandboxes, and that other regulators had used extensive piloting programs to substitute for a regulatory sandbox (e.g. the Taiwanese Financial Supervisory Commission's FinTech Pilot Program).
- Sandbox umbrellas: instead of focusing on the regulated entity, regulators may provide a specific testing environment in the form of a public sector body supported by stakeholder groups that helps set up a fully licensed development platform run in the public interest. The authors point out, however, the absence of examples of publicly sponsored sandbox umbrellas having worked efficiently in the long-term so far.

Designing regulatory experiments

RE practices may involve various types of experimental design and levels of predictive power[13]. From a methodological perspective, regulatory experiments may therefore be grouped according to their approach to experimental design as well as the tools involved.

A 2023 OECD publication (Varazzani et al., 2023[31]) provides a comprehensive account of experimental and observational methods that can be used for investigating the outcomes of a policy solution before scaling it up. While focused primarily on behavioural insights, this report discusses several key methodological choices that are relevant in the context of RE.

Experimental design should aim, to the extent possible, to create a counterfactual, i.e. "an estimation of what would have happened if the experiment hadn't taken place". Their ability to do this is crucial because it directly impacts the level of causal effect that can be attributed to the intervention concerning the observed changes (Centre for Regulatory Innovation, 2021[5]). While not all regulatory experiments may establish a counterfactual, sound experimental design is necessary for thorough and effective evidence and insight collection to inform regulatory decision-making.

Regulatory experiments can be considered along a continuum between randomised experiments (highest causal power) and pre-post experiments (lowest causal power), with implementation feasibility generally being inversely correlated with causal power levels. Box 1.3 outlines the main features of each of these experiment types. Further guidance on the choice of experimental design is provided in Part C (pp. 28-35) of CRI's Experimentation Toolkit (Centre for Regulatory Innovation, 2021[5]).

Box 1.3. Selected categories of regulatory experiments

Randomised experiments, which are often described as the 'gold standard' of experiments, separate participants into two groups to understand the effect of a given intervention: a treatment group (which receives an intervention) and a control group (which does not receive it). Groups need to be randomly assigned to avoid any biases. It should be noted that randomisation may be difficult in a regulatory context: in most situations, it is impossible to randomise who must comply with a set of regulations. Randomised experiments can however be used to test, among others: compliance mechanisms (e.g. new digital systems); inspection approaches (e.g. effect of timing or use of new technologies from predictive analytics to drones), methods for post-market surveillance of critical products and services, and approaches to interactions with stakeholders (e.g. advice centres, general guidance, workshops, online support…). As mentionned (Varazzani et al., 2023[31]), randomised experiments usually require more extensive resources (e.g. research funds, time, skills) to set up the design in the most efficient way.

In **non-randomized and quasi-experimental designs**, to identify a counterfactual, a comparison group is created using statistical models to ensure it is as similar to the treatment group as possible. According to (Centre for Regulatory Innovation, 2021[5]), most types of regulatory intervention can be tested through this method, which can help assess the impact of innovative regulatory methods or new forms of public engagement.

Pre-post experiments do not involve a comparison group. Instead, they measure the state of the same group before and after receiving an intervention, i.e. the 'before' state, or baseline, becomes the de-facto counterfactual. Pre-post experiments can take different forms: A/B testing studies, differences-In-differences (Diff-In-Diff) analysis and before-after studies (see (Varazzani et al., 2023[31]) for a detailed description of the different methods). While easier and less costly to conduct, pre-post experiments' main shortcoming is that other factors that may have produced changes cannot be easily controlled for, unless a sound econometric analysis is developped. They can however be suitable in cases where implementation cannot be randomised (Varazzani et al., 2023[31]), or as a feasibility test (Centre for Regulatory Innovation, 2021[5]). Conducting pre-post experiments is often faster and cheaper that running randomised and non randomised experiments and might therefore be more suitable when resources are limited (Varazzani et al., 2023[31]), According to (Centre for Regulatory Innovation, 2021[5]), many initial regulatory experiments might fall into this category, and over time, further experiments may move up to the more rigorous levels.

Source: Adapted from (Centre for Regulatory Innovation, 2021[5]) and (Varazzani et al., 2023[31]).

The legal basis for RE

The legal basis for regulatory experimentation depends on the specific context and, as mentioned earlier in this paper, involves in practice the use of a variety of legal terms. It has already been stated that flexibility within existing legislation may allow for various forms of experimentation without recourse to legal changes. Although exemptions are in most cases explicitly granted through a regulatory decision, regulators can also allow these exemptions "implicitly" by adopting a wait-and-see approach for new activities or actors (Schittekatte et al., 2021[25]).

It can be useful to distinguish between experimentation-enabling clauses integrated into legislation to enable RE under a given law or in a specific sector on the one hand, and general laws or provisions enabling regulatory experiments. In some cases, such as France, the possibility of resorting to

experimentation is enshrined in the Constitution. Some countries are also opting for general legal provisions enabling regulatory experimentation. Canada is for example considering setting up a whole-of-government framework for experimentation as a complement to existing mandates and responsibilities held by individual regulators (Government of Canada, 2023[32]), and the German federal government has been exploring whether a general experimentation clause and a federal experimentation act should be established. This will however not be a viable option in all cases. Estonia's framework for public sector experimentation, for instance, acknowledges the need for a legislative process to help experiment quickly, legitimately and ethically, while ruling out the creation of a general law for organising experiments (Riigikantselei, 2022[33]).

If the existing legal framework does not allow the desired regulatory experiment to be carried out, experimentation clauses may be necessary. The main aim of these clauses is to introduce legal flexibility enabling the conduct of innovative projects, which may subsequently become a permanent part of the governance framework (Winkler-Portmann et al, 2020[34]) (Maaß, 2003[35]).[14]

As far as regulatory pilots are concerned, there will often be a choice between structuring the experiment as a sunset or permanent rule. A permanent rule refers to a regulatory provision that requires modification or removal through regulatory procedures to reverse to the status quo rather than undergoing automatic termination according to a sunset clause (Gubler, 2017[36]). This choice needs to be consistent with the probability that the experiment will be a success: if it is sufficiently likely that the experimental results will justify adopting, on a permanent basis, the rule that is the subject of the experiment, the regulatory authority should probably structure it as a permanent rule when it adopts the experiment (should the rule be maintained after the experiment, the regulatory experimentation comes to an end). Otherwise, it should be structured as a sunset rule, which expires automatically once the experiment is completed (Gubler, 2017[36]).

Examples of legal bases for RE

Evidence from regulatory sandbox used in the energy, health, mobility and financial services sectors illustrate the diversity of approaches for accommodating RE into national legal frameworks (see Box 1.4).

Box 1.4. Legal basis for regulatory sandboxes: selected examples from energy, health, mobility and financial services

Energy

- In Denmark and the United Kingdom regulatory sandboxes in the energy sector were established within the framework of existing energy sector regulation and use exemptions provided under current national legislation.
- In both France and Lithuania, regulatory sandboxes were established in the energy sector by amending relevant national energy sector regulation. In France, amendments to the Energy-Climate Law now make it possible to grant exemptions regarding the conditions of access to and use of energy networks and facilities.
- In Lithuania, amendments to the Law on Energy establish the main principles and criteria for the regulatory sandbox and the rights and obligations of participants in this regulatory approach along with other specific legislative amendments related to the sandbox issue in heat, electricity and gas supply activities.

Health

- In the United Kingdom, the regulatory sandbox in the health sector was established within the framework of existing Health sector regulation and use exemptions provided under current national legislation.
- In Canada, the regulatory sandbox in the health sector will also be established within a new framework under the existing Canadian Food and Drugs Act. This legal framework was introduced in 2019 to allow for authorizing innovative, unique medical products that are not compatible with existing rules.

Mobility

Drones

- In Canada and Germany the sandboxes for drones were established within the framework of existing regulation.
- In Denmark new legal provisions were introduced through an executive order on supplementary provisions to EU Regulation on rules and procedures for operation of unmanned aircraft.

Self-driving vehicles and units

- In Estonia, the sandbox for self-driving vehicles was established within the framework of existing regulation.
- In Austria, Denmark and Germany new legal provisions to allow testing of self-driving vehicles and units were introduced. In Austria the National Type approval law defines legal requirements for different use cases of automated mobility. In Denmark permission can be granted for tests with self-driving motor vehicles pursuant to the Traffic Act. In Germany, exemptions can be given based on the experimentation clause pursuant to the Carriage of Passengers Act and the Road Vehicles Registration and Licensing Regulations.

Autonomous shipping and related maritime technologies

- In Denmark, the sandbox for autonomous shipping was established within the framework of existing Danish regulation.

Financial services

- In Greece, Japan, Latvia, Malta, The United Kingdom and the United Arab Emirates regulatory sandboxes in the Financial Services sector were established within the framework of existing Financial Services sector regulation.
- In Austria, Bahrain, Denmark, Italy and one of the United Arab Emirates sandboxes in the Financial Services sector were established within the framework of existing regulation and use exemptions provided under current national legislation.
- In Spain, Lithuania and one of The United Arab Emirates sandboxes the regulatory sandboxes were established in the financial sector by amending relevant national financial sector regulation.

Source: Agile Nations Network (forthcoming).

According to the Council Conclusions on Regulatory sandboxes and experimentation clauses, experimentation clauses are often the legal basis for regulatory sandboxes and are already used in EU legislation and in many Member States' legal frameworks (Council of the EU, 2020[37]). Experimentation

clauses can be applied at various levels of legislation and rely on various regulatory techniques. They also vary widely in terms of design and implementation modalities. They may, for instance take the form of:

- An exemption from a prohibition
- An exception from an approval requirement
- An exemption from requirements to provide documentation or deploy certain equipment
- A catch-all clause (Federal Ministry for Economic Affairs and Energy (BMWi), 2019[38])

Building blocks for experimentation clauses: Germany's example

The German government's Guide for formulating experimentation clauses (Federal Ministry for Economic Affairs and Energy (BMWi), 2020[39]) presents the main building blocks that these clauses may encompass (see Table 1.1 below).

Table 1.1. Main components of experimentation clauses (Model experimentation clause, Germany's Federal Ministry for Economic Affairs and Energy)

SECTION 1: [Purpose of the testing]
SECTION 2: Constituent elements and legal consequences General part: [Competence] [authorisation of authority] [operative part of decision], if [object of testing] and [material limitation]. Special part: [Procedural requirements for application]. [Scope (material and spatial) of the testing]. [Accompanying obligations]. [Time limit of permission/approval]. [Other ancillary provisions]. [Possibility of revocation].
SECTION 3: [Evaluation including transfer]. [Time limit for the clause].
SECTION 4: [Authorisation to issue ordinances or naming of the legal basis].

Note: The rationale and various components (both "essential", in black font, and "optional", in blue) of each section are discussed in pages 11 to 23 of the abovementioned Guide. The latter also notes that, certain essential elements may not need to be included in the experimentation clause, e.g. if already covered by general regulations in place.
Source: (Federal Ministry for Economic Affairs and Energy (BMWi), 2020[39]).

The experimentation clause contained in Section 7(2) of the Carriage of Passengers Act is often presented as a good practice example in the above-mentioned guide.[15]

> *"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 maximum period of four years, insofar as they do not conflict with public transport interests".*

Additional examples from Germany of legal bases for RE are also provided in the country's 2019 Handbook for regulatory sandboxes.

Section 13 Trade Regulation Act:

> *"The governments of the Länder shall be authorised to issue ordinances to test out simplifications, particularly to facilitate start-ups and take-overs of companies, for a period of up to five years, permitting exemptions from rules on the exercise of occupations pursuant to this Act and the related ordinances, to the extent that the rules on the exercise of occupations are not based on binding rules of European Community law and the impact of the exemptions is restricted to the area of the respective Land."*

Section 20 of the eGovernment Act of Saxony:

> *(1) The relevant supreme state authority shall be authorised to permit materially or spatially limited exemptions from the application of various rules of Saxony on administrative procedures and costs for a period of up to five years in order to introduce and develop eGovernment, in agreement with the Information Technology Commissioner of the Free State of Saxony and following approval from the State Ministry of the Interior and in the case of number 3 in agreement with State Ministry of Finance [...].*
>
> *(2) The same applies to other provisions on competence and procedure.*

This section has presented, for illustrative purposes, some of the fundamental features of the legal architecture underpinning selected RE initiatives. Further evidence and analysis will be required in this respect in order to gain a deeper understanding of the most effective approaches and promote coherence and comparability. A related, crucial topic relates to the need for appropriate monitoring and oversight to ensure that regulatory experiments respect constitutional rights. This question falling however outside the scope of this report, further work would need to be undertaken to help governments ensure that RE does not contravene constitutional requirements in their respective countries.

2 The case for considering regulatory experimentation

Resorting to RE can improve regulatory quality and outcomes in various ad interrelated ways. First, it can render regulatory frameworks more adaptive through ongoing learning and adjustment, as well make them more innovation-friendly and technology-neutral. Second, it can help reduce uncertainty levels surrounding regulatory decision-making, particularly in innovation-dominated environments where sufficient reliable information on potential impacts or effectiveness of policy/regulatory options at hand cannot be obtained through traditional approaches such as information gathering and consultations. Third, it enhances the evidence base that can help inform the revision of existing regulation or inspire new regulation, thus complementing those very traditional regulatory tools and approaches. Each of these categories of potential benefits[16] is discussed briefly in this section.

The content of this chapter should be considered by bearing in mind several caveats:

- There is relatively little quantifiable evidence to date on the benefits of RE;
- Given the context-specific nature of regulatory experiments, relevant counterfactual scenarios are seldom available;
- As for most regulatory decisions, RE entails costs as well as benefits that need to be weighed against each other to the extent possible (see also “RE is no “silver bullet" and it involves trade-offs” later in this chapter). In the same vein, the “RE” option should be appraised in light of available alternatives, regulatory or otherwise, and their relative merits.

As a result, careful monitoring and evaluation of RE initiatives will be paramount to help develop relevant insights that inform decisions about whether to resort to RE, and in which form. As the present chapter attempts to show, however, considering systematically the potential use of RE for regulating better is likely to prove beneficial in and of itself.

RE can contribute to more agile, adaptive, and innovation-friendly regulation

RE can help modernise and strengthen regulatory governance frameworks

As stated in the OECD Recommendation for Agile Regulatory Governance to Harness Innovation, enabling further experimentation, testing, and trialling under regulatory supervision is part of the set of adaptations that can help governments foster agile and adaptive regulation if applied in a coherent and complementary fashion (OECD, 2021[1]). RE can help develop regulatory frameworks that achieve regulatory goals without hindering the introduction of new ideas, products and business models. Such frameworks are particularly needed in the current context of rapid transformation, which makes market developments and future public policy concerns difficult to predict.

The WEF concurs with this view by noting that "experimentation should form part of a more agile approach to regulation in general" and that it can support the adoption of other agile regulatory practices (World Economic Forum, 2020[8]). Providing regulatory advice services and piloting initiatives can encourage innovators to collaborate with regulatory authorities, simplifying monitoring of technological development and horizon scanning activities. Conversely, RE will need to be developed alongside other "agile" regulatory approaches if is to be successfully. For example, outcome-focused regulation can provide the necessary flexibility for RE initiatives, and well-coordinated approaches to regulation will help provide clarity and coherent incentives to those involved in, or considering, RE. The procedural framework for cross-border testing developed by the European forum for innovation facilitators (EFIF), for example, aims at facilitating bilateral and multilateral cooperation between national competent authorities on financial innovation including regulatory sandboxes (notably by simplifying cross-border communication, transparency, and access to information)[17]. Similarly, the European Commission's proposal for an Interoperable Europe Act would create a legal basis for launching sandboxes to test innovative solutions for digital public services in cross-border contexts (European Commission, 2023[15]).

An OECD working paper focusing on regulatory sandboxes highlights several examples of RE's contribution to improving and modernising regulatory frameworks in fintech (see Box 2.1).

Box 2.1. Examples of RE's contribution to improving and modernising regulatory frameworks in fintech

The evidence-based, dynamic approaches to regulation offered by RE including regulatory sandboxes can inform rulemaking and regulatory adaptation.

As an example, one of the projects in the fifth UK FCA fintech sandbox cohort led to regulatory amendments that allow the use of portable, electronic identity (eID) in the financial services industry. This resulted in updates to anti-money laundering regulations that allow financial institutions to use customers' eID (Almeida Shimizu, 2020[40]).

A common result consists of guidance being issued by regulators on how to interpret existing legal frameworks rather than amending laws, absent substantial need (Business at OECD, 2020[10]); (Almeida Shimizu, 2020[40]). Relevant examples include:

- The UK FCA PS19/22 guidance on crypto assets
- The Hong Kong Monetary Authority 2020 feedback from thematic reviews of anti-money laundering and countering terrorism financing control measures for customer onboarding initiatives
- The Canadian securities administrators and investment industry regulatory organisation joint 2019 consultation paper 21-402: Proposed framework for crypto-asset trading platforms.

Source: Adapted from (OECD, 2023[41])

Bennear and Wiener (Bennear, L.S and Wiener, J.B., 2019[17]), in turn, identify experimentation among several adaptive instrument options. They note that with rapid changes in science, technology, and social conditions, there is interest in moving from static to adaptive regulation. They define the latter as "a structured regulatory process that enables learning and modification of policy over time via adjustments informed by data collection and analysis" or "laws built to learn", i.e. adaptation over time is part of a systematic review that draws on evidence and analysis. Bennear and Wiener refer to a "spectrum of adaptivity", its most developed or "most adaptive" form consisting of "a planned series of ongoing monitoring, data collection, and analysis", with periodic evaluation of the consequences (e.g. recurring

RIA) and iterative updating and revision. They note that “such ongoing evaluation with periodic iterative updating puts a focus on questions such as: how frequent the intervals for evaluation and revision should be (periodicity), which impacts or consequences should be monitored (scope), and which institutions should have the authority to undertake each task and adopt which types of revisions (power)” (Bennear, L.S and Wiener, J.B., 2019[17]) (Schittekatte et al., 2021[25]). Substantial skills and resources are required to undertake this type of work meaningfully and reliably. A key challenge here will thus consist of ensuring that regulatory authorities are adequately endowed in that context.

RE can foster innovation-friendly and technology-neutral regulation

Digitally enabled and innovative products and business models often differ significantly to those in traditional markets, and in some cases, they do not fit well with existing regulatory frameworks (OECD, 2019[2]). RE has been presented, particularly in innovation-dominated environments, as a potential solution to the dilemma whereby regulators “believe they must opt for either reckless action (regulation without sufficient facts) or paralysis (doing nothing)” (Fenwick, M.D.; Kaal, W.A., and Vermeulen, E.P.M., 2017[42]). Proponents of this view argue that, in the absence of adaptive approaches to regulation such as RE, “because technological transition is going to be a permanent state in the age of disruptive innovation, rule makers’ inability to address regulatory issues associated with disruptive innovation will likely generate high levels of legal uncertainty and inconsistency that inhibit innovation during technological transition periods” (Fenwick, M.D.; Kaal, W.A., and Vermeulen, E.P.M., 2017[42]).

In a similar vein, (Ranchordas and van ’t Schip, 2019[27]) note that experimentation promotes the implementation of iterative and trial-and-error approaches that can support the advancement of innovation policies. They also highlight the resilience-enhancing power of RE: by distinguishing between permanent and temporary elements, experimental dispositions guarantee that the main pillars of a policy remain standing despite potential future changes – experimentation’s main aim being to test different ways to achieve specific goals and gather information over time.

The idea that RE can be harnessed to promote innovation is also laid down is the OECD Recommendation on Artificial Intelligence, which recommends that governments "consider using experimentation to provide a controlled environment in which AI systems can be tested and scaled up as appropriate” (OECD, 2019[43]). This principle aims at improving the adaptability, reactivity, versatility, and enforcement of policy instruments to accelerate the transition from development to deployment and, where relevant, commercialization (OECD, 2023[41]).

Unlike traditional regulatory tools, controlled experiments with different set-ups can be tested out in parallel, e.g., ownership models for electric vehicle charging infrastructure or storage. If well designed and governed, they can provide regulated entities with incentives to demonstrate their capabilities and “claim” the right to conduct a new activity (Schittekatte et al., 2021[25]).

RE can help address the “knowledge problem” in decision making

RE can be harnessed to enhance the evidence base

When significant informational deficits are at play, regulatory management tools such as regulatory impact assessment may be inadequately informed and thus lead to suboptimal decisions. To counter this risk, regulators should explore the use of RE together with other tools and approaches, including stakeholder engagement and technology-enabled retrospective analysis, that help them address this “knowledge problem”, learn and adapt (Sunstein, 2022[44]). By relying on deliberate and methodologically valid testing, RE can help to ground policy and regulatory decisions and their implementation in empirical evidence. Moreover, by enhancing the evidence base underpinning decision making, RE can contribute to building trust in government.

A relevant example relates to the regulatory sandbox put in place by the French Energy Regulatory Commission (*Commission de Régulation de l'Énergie*, CRE). This sandbox, which encompasses a strong evaluation component, was introduced as part of the November 2019 Energy and Climate law. It seeks to allow relevant authorities (CRE or Ministry of Energy) to grant, under certain conditions, temporary regulatory exemptions (for a 4 years' time frame and renewable once) for the experimental deployment of innovative technologies or services in support of the energy transition and smart networks and infrastructures. It is not clear at the time of writing whether these objectives are being fulfilled, notably as a result of feasibility constraints. However, this initiative has also created avenues for communication and information exchange with market players. In some cases, the prospect of benefiting from sandbox participation seems to have allowed and incentivised the regular provision of relevant information on potential regulatory flaws, e.g. provisions that may unnecessarily curb. Regulatory authorities can then use this information, which would be very challenging to obtain otherwise, for decision-making purposes.

The benefits mentioned so far in this sub-section hold true even in cases where a solid basis for a given policy's merits exists, as RE "enables the necessary comparison of the cost-effectiveness of different implementation options, which allows for the optimal use of scarce resources" (Centre for Public Impact, 2018[45]). Moreover, RE (and experimentation more generally) can help address methodological challenges relating to limited availability of evidence for causal inference: for a causal hypothesis to have any practical relevance, it needs to undergo a meaningful test (Moss, David, and John Cisternino, eds., 2009[46]).

RE can also complement traditional regulatory tools. The experience gained via the experiments reduces indeed the asymmetry of information between the regulator and innovators and enable improved dialogue and understanding between the regulator and innovator (who may help identify regulatory barriers of which the regulator was not aware). As such, it can be a useful tool to inform the revision of existing regulation or inspire new regulation (Schittekatte et al., 2021[25]).

RE can help reduce uncertainty and limits implementation-related risks

When it comes to reducing uncertainty, RE is "particularly relevant in relation to innovation where alternative courses of action, such as research and speaking with stakeholders, may be unavailable or unable to sufficiently satisfy a regulator's information needs" (Centre for Regulatory Innovation, 2021[5]). In some cases, uncertainty may come from the fact that information about the impact of innovations can be "sparse, fragmented and contested or missing entirely relative to that available for more established technologies or practices" (Centre for Regulatory Innovation, 2021[5]). It may also relate to unknowns regarding the effects of changes to regulatory frameworks, policies, or mechanisms on innovation. Such uncertainty may stem from the fact that none of the most promising regulatory or policy options have been tried in a similar context before, or that existing precedents offer little guidance.

RE can contribute to reducing uncertainty by generating valuable insights on the potential impacts of innovation as well as on the likely effectiveness and implementation requirements of different regulatory approaches at hand. It can also help limit, in time as well as in space, the implementation risks of new regulations (Ranchordas and van 't Schip, 2019[27])[18], as mistakes tend to be less costly when new approaches to regulation that helps limit risks are first tested out via RE (Schittekatte et al., 2021[25]).

RE is no "silver bullet" and it involves trade-offs

While potentially useful in many situations where adaptive learning is critical for regulatory relevance and effectiveness, its benefits are neither automatic nor uncontested. Moreover, there are potential constraints regarding legality, feasibility, resources, and equity. Importantly, beyond the resource and capacity requirements, as noted in the previous chapter, regulatory experiments should be in line with constitutional norms, including regarding equal treatment.

There are several types of costs and potential drawbacks associated with RE that need to be considered and weighted against the potential benefits discussed earlier in this chapter. They can be grouped around two broad categories, direct and indirect.

Direct costs associated with RE

RE-related direct costs relate to the time and resources required to prepare, coordinate, and carry out RE activities, such as:

- Intra-government co-ordination costs;
- Set-up, data collection and analysis, monitoring;
- Communication and stakeholder engagement;
- Reviewing and revising policies and regulation (if applicable).

Indirect costs and potential trade-offs of RE

When considering indirect as well as opportunity costs (e.g. of any other policies not being addressed) relating to the use of RE, as well as the trade-offs that they imply, several issues deserve particular attention. These issues are outlined below and the following chapter discusses possible actions to address them.

Potential competition and equity distortions

Regulatory experiments may create a risk of competition distortion by advantaging certain market players who may obtain regulatory approval or otherwise benefit from information generated through a given regulatory experiment. Competition distortions can be particularly acute in embryonic markets, as they will likely affect the level playing field between firms (Parenti, 2020[47]). For instance, in derogation-based regulatory experiments such as sandboxes, there is the risk of de facto conferring exclusivity on a selected technology that may then become an essential technology due to the sandboxing process and the artificial exclusion of potential competitors (OECD, 2023[41]). Since company selection, legal waivers or other testing methods applied, and *ex post* market actions can impact markets and competition considerably, they warrant further research (OECD, 2023[41]) (Knight and Mitchell, 2020[48]); (UK FCA, 2014[49]); (Chen, 2019[50]). The same goes for the applicability of liability regimes in regulatory experiments, as these have implications for innovation and competition (Business at OECD, 2020[10]).

Related equity issues may arise in cases where certain sectors or population groups (but not others) have access to special legal conditions. It has been pointed out that, if adaptive regulation (e.g. in the form of RE) is perceived as favouring interest groups rather than promoting social well-being, “it may call into question the credibility of the government’s commitment to stick to the initial rules, thereby undermining compliance” (Bennear, L.S and Wiener, J.B., 2019[17]). Moreover, as noted earlier in this report, regulatory experiments may raise concerns regarding constitutional rights in terms of unequal treatment.

As (Schittekatte et al., 2021[25]) put it, there is a trade-off between, on the one hand, allowing a derogation for one sort of actor or activity and risking the distortion of competition and, on the other hand, not allowing a derogation for that actor but risking that a potential welfare-enhancing innovation does not materialise. Referring to the energy sector, they note that discrimination risks also exist in the case of regulated parties, e.g. if a distribution system operator (DSO) is allowed to implement an innovative network tariff, then the grid users in that area are positively or negatively discriminated compared to the grid users under a default network tariff. The same authors point out that, while allowing each experiment to have tailored derogations can create more room for creativity and innovation, it also increases discrimination risk as well as the effort and resources needed to run a given experiment.

To prevent competition and equity distortions, ensuring an equitable access to RE initiatives and related intelligence is therefore essential (see also the next Chapter for further elements regarding regulatory capture risks). Here again, trade-offs apply. It has been debated whether all information concerning regulatory experiments should be made public. For instance, a guidance document on regulatory sandboxes issued by the Finnish government states that sandbox operating model and results must be communicated openly to allay suspicion or fears of favouritism (Ministry of Economic Affairs and Employment, 2021[51]). Doing so may allow actors not having taken part in the experiment to benefit from its results. However, there is also the risk that innovators oppose full disclosure of the experiment to protect their business ideas, thus refraining from engaging in experiments (Schittekatte et al., 2021[25]).

Legal certainty

RE can arguably impose costs if it reduces the predictability of legal rules, especially if this reduction has not been anticipated. A very predictable regulatory framework may be warranted in some cases to avoid undue influence by powerful interest groups. Moreover, perceived instability may undermine public trust in regulation - although so can rules that are no longer fit for purpose.

Conversely, it has been argued that a forward-looking, experimentation-enabled approach to legislation can favour legal certainty by helping to avoid scenarios of “deeply ineffective and obsolete laws” and ensuring that innovative technologies and discoveries fit more effortlessly into the existing system. This view is predicated on the assumption that the principle of legal certainty cannot be reduced to its continuity dimension and that, on the contrary, it contains other equally important dimensions such as predictability and clarity, which encompass a dynamic interpretation (Ranchordas and van ’t Schip, 2019[27]).

Regulatory burdens and complexity

RE may generate its own share of new rules, thus potentially increasing regulatory burdens. According to the Council of State’s analysis of RE practices in France, experimental legislation, while trying to reduce the individual burdens for individuals, has also increased the overall number of regulatory burdens as experimental regulations also establish new compliance rules (Conseil d'État, 2019[7]). Allowing each individual experiment to have tailored derogations also has implications in terms of resource requirements and regulatory effort.

The French Council of State’s analysis also shed light on the potential difficulties associated with the planning and execution of RE. Considering the French experience, it identified multiple shortcomings, such as unclear or contradictory objectives, undue interruption and subsequent generalisation of experiments without prior evaluation of results, and incorrect sample size selection (Conseil d'État, 2019[7]). Some of these methodological problems have also been identified in The Netherlands and Israel, and at EU level in the context of the experimental regime for a reduced VAT rate on labour-intensive services.

Deciding whether RE is the right approach

The above-mentioned trade-offs inherent to RE warrant assessing carefully when and where to use it, and in which form, to privilege instances in which it can yield the highest net benefits – regulating being understood as “a productive activity converting information, norms, and decisional and enforcement capacity into outputs of social value” (Super, 2011[52]).

Deciding to resort to RE will by definition be context-specific. This sub-section discusses some of the parameters that can help inform those decisions. While precise calculations are not straightforward and may not be warranted in all cases, an attempt should be made to weigh, to the extent possible, the expected benefits of the information that will result from the regulatory experiment against the costs of undertaking the experiment (see Box 2.2 for further details).

Box 2.2. Break-even analysis of potential regulatory experiments

When considering whether to engage in a regulatory experiment testing new rules or regulatory approaches, it can be useful to carry out a break-even analysis, especially it is harder to estimate the net benefits of the rule in question than the costs of experimentation. This kind of analysis allows to estimate, given the costs of the experiment, the magnitude of the net benefits the rule must generate to justify the experiment.

Conducting a break-even analysis for RE requires estimating the costs of the experiment, the probability that the rule "fails" under the experiment (the net benefits of the rule do not end up justifying adoption of the rule on a permanent basis), and the net benefits of the rule if the experiment fails. The regulatory authority can then calculate the net benefits the rule would need to generate in the best-case scenario to justify the experiment. In doing so, it is worth noting that adopting a rule on a temporary basis generate information relevant to the decision about whether to adopt it on a more permanent basis always leaves the option of reverting back to the status quo. This will help minimise the downside risk of the rule that is the subject of the experiment (thus reducing welfare losses to the few years that the experiment is in force). Given inherent uncertainty, this calculation will generally require resorting to probabilities and discounting net benefits by the likelihood of different scenarios.

Experimental benefits are the informational benefits generated by the experiment even if the rule at hand does not end up being adopted on a permanent basis. They are also relevant to decide whether it makes sense to engage in RE and should be considered to the extent possible. However, they are generally harder and costlier to quantify given their more speculative nature ("what one ends up learning from a failure depends on the precise nature of the failure"). If this category of benefits is not factored in (e.g. on cost-efficiency grounds), it should be borne in mind that net benefits of RE are likely to be underestimated.

Source: (Gubler, 2017[36]).

Situations in which RE may be appropriate

According to work by the CRI, regulatory experiments are particularly well suited to answer questions around impact and a need for evidence: "Did something work (i.e. have the desired impact)? And why?" (Centre for Regulatory Innovation, 2021[5]). As such, resorting to RE is predicated on a realistic expectation that its results can impact decision-making.

The CRI's Experimentation Toolkit[19] states that the case for RE is "strong" when there is:

- A high-stakes decision to be taken where the strength of evidence informing the decision is important (e.g. large budgetary needs, big downside risks);
- Insufficient relevant evidence or experience available to inform a decision;
- No strong theoretical basis for taking the decision;
- Time available, i.e. RE is not suitable for crisis situations, and sufficient resources to conduct the experiment;
- A context in which it is ethically appropriate to experiment.

As noted in the introduction, RE efforts should arguably focus on rules or regulatory areas with significant potential net benefits relative to the status quo. Based on academic work on adaptive regulation (Bennear, L.S and Wiener, J.B., 2019[17]), it can be argued that the potential benefits of RE depend on two critical factors. The first one is how much governments and regulators can expect to learn out of a given

experiment. The second one relates to how quickly the regulated activity's risk profile (i.e. how much risk it presents and to whom) is bound to evolve. For example, disruptive technologies such as autonomous vehicles, genetic engineering and editing, personalised medicine, and nanotechnology can potentially improve quality of life while but present risks that are uncertain and changing over time. In this situation, it is essential to adapt regulatory approaches as knowledge regarding the technology evolves. RE may be highly instrumental in that regard.

Gaining the necessary understanding of the risks at hand is likely to require polling experts in the field, such as economists and engineers, so as to gather relevant perspectives that can complement those from legal professionals. Moreover, in regulation as in every other field, not every question may need an experiment to get at the right answer. Experimentation will probably be justified to understand whether a treatment drug that has only been tested on animals will work well in humans, yet it is likely to be a wasteful course of action to run an experiment to determine the effects of a generic drug with the same active ingredients as a currently manufactured patented drug (Gubler, 2017[36]). The next subsection discusses several alternatives to regulatory experiments.

Comparing RE with available alternatives

To target regulatory efforts appropriately, the "RE option" should be compared at the outset to other available approaches. Relevant comparison parameters include feasibility, cost, timing, expected quality of evidence, and ethical as well as legal implications (Centre for Regulatory Innovation, 2021[5]). For example, as discussed, it may be possible to test certain socio-technical innovations within existing regulation before setting up an experiment. Moreover, it may be preferable in some cases to opt for full-fledged implementation of a regulatory approach and then extract relevant knowledge by evaluating results (Bauknecht, D. et al, 2021[12]). The CRI has identified several alternatives to experimentation when it comes to gathering evidence and support complex decision-making processes (see Table 2.1), while noting that available options need not be mutually exclusive and can be envisioned as a sequence, e.g. since research tends to be less resource-intensive than carrying out experiments, it may be worth conducting research before deciding to experiment.

Table 2.1. *Pros* and *cons* of potential alternatives to regulatory experiments (CRI)

Option	Description	*Pros*	*Cons*
Rely on existing individual, team, or institutional experience	Involves drawing on experiential data already available	Speed Low cost	Potential bias and difficulties to gain wider support
Desk research	Examine experimental evidence and case study insights in the same area or sector, or examples of similar questions addressed in other sectors/areas	Speed Low cost	Relevant research may not exist yet
Consult experts	Interviews, referrals to additional resources, commissioning analyses	Low cost	Relevant expertise may not be available Potential bias
Consult the public and other stakeholders	Investigate their priorities, perceptions, and preferences	May shed light on likely outcomes, provide relevant experience that diminishes or eliminates the need to experiment	Potentially high-cost and time-consuming May need complementing through desk research and/or expert views
Implement, then evaluate	Implement at scale, without prior testing, but evaluate results *ex post*	May be appropriate if a political situation requires decisive and timely action, or when a highly likely course of action or best decision already exists Provides opportunities to adapt and learn by doing	Implementation risks and potential delays High-cost and high-risk if untested solutions implemented end up revealing a bad decision

Option	Description	*Pros*	*Cons*
Monitor, assess, and revisit	'Wait and see' by monitoring the relevant regulatory space, assessing it, and revisiting it to consider intervening at a later date	Enables observation and knowledge building May be appropriate if the cost and potential risks of delayed action or inaction are low	High-cost and high-risk and ethical issues if a decision is urgent and important

Source: Based on (Centre for Regulatory Innovation, 2021[5]).

The so-called sunrise clauses, which combine some of the elements presented in Table 2.1, have also been presented in the literature as a potential alternative to RE for governments to address emerging regulatory challenges. Several states in the USA have used these clauses in the form of "sunrise reviews" to determine whether the legislature should enact legislation to regulate an "as of yet unregulated profession or occupation in order to protect the health, safety or welfare of the public" (Ranchordas, 2015[53]). According to Ranchordas, these clauses are comparable to condition-subject clauses in contracts: a disposition is included in the law, but it lies dormant until a certain condition is verified; e.g. driverless cars may be allowed to circulate if they are able to pass certain road safety tests. The author acknowledges that little attention has been devoted to sunrise clauses or contingent legislation more generally, but notes that "by making the coming into effect of a law dependent on a future condition, regulators can avoid unnecessary regulation, allow the industry to mature and invest in the technicalities which might be necessary to comply with certain standards" (Ranchordas, 2015[53]).

3 Enabling factors for effective RE

Several enabling factors must be at play if RE is to help strengthen regulatory frameworks, processes and institutions. These factors notably relate to appropriate governance and oversight, including a strong focus on evaluation and effective mechanisms for broad-based and systematic stakeholder engagement and institutional co-operation. Substantial changes in organisational and regulatory culture and working methods are also likely to be necessary in most cases. This section summarises some of the main aspects to consider in this respect.

A shift in regulatory culture is needed

Anticipatory regulation and RE may call into question the traditional understanding of regulation as a typically reactive mechanism to market failures or risks (Ranchordas, 2021[6]). If RE is to take hold and deliver its benefits, regulatory culture needs to evolve regarding several key aspects. This sub-section delves deeper into some of the most important ones.

As underlined by the French Council of State, experimentation requires a culture favouring innovation and the scientific evaluation of public policies' results. Evaluation is necessary to identify the need for a given reform, decide whether it should be pursued or generalised, and, further down the line, understand whether it should be maintained, modified or terminated (Conseil d'État, 2019[7]). A whole-of-government commitment to evidence-based decision-making is, in other words, a pre-condition for RE to work out.

Putting experimentation into practice requires an organisational culture acknowledging that experiments revealing a policy to be flawed or ineffective is essentially a success, insofar as it helps avoid potentially greater political or economic costs (Centre for Public Impact, 2018[45]). While the notion of successful outcome has traditionally been associated with laws, regulations or processes "that work", effective RE involves recognising failure as an ally: "When taking an experimental approach, good failure is an unavoidable part of the learning process, and bad failure is a preventable failure that doesn't result in new learning" (Centre for Regulatory Innovation, 2021[5]). These changes need to take place at all levels, from the individual to organisations' functioning and the environment within which they operate.

As an example, Canada encourages government departments to test new approaches to learn what works and what does not work using different experimentation methods, including (Centre for Regulatory Innovation, 2021[5]):

- Deliberate, thoughtful, and ethical experimental design;
- Comparisons between interventions and base cases to gather evidence (e.g. randomised controlled trials, A/B testing, counterfactual experiments, baseline performance data, pre- and post-tests);
- Randomized assignment to test and control groups, whenever possible;
- Rigorous impact measurement and causality assessment;
- Transparent publication of positive, negative and neutral results.

It is not uncommon, particularly among those with an initial aversion to RE, to conflate the latter with compromising fundamental regulatory protections or objectives. It is indeed crucial to ensure this is not the case and build the necessary ownership and buy-in. Bringing about the necessary adaptations in regulatory culture will thus crucially involve ensuring appropriate oversight and communicating on the relevant safeguards having been put in place (see "Oversight of RE initiatives") later in this chapter.

An additional shift required in regulatory culture has been referred to as *principle–based contingency,* which involves "a re–thinking — or re–framing — of what decision–making involves in a regulatory context". (Fenwick, M.D.; Kaal, W.A., and Vermeulen, E.P.M., 2017[42]). French sociologist Michel Callon (Callon et al, 2009[54]) claims that regulatory decisions should not be thought of as final events. They should instead be understood as "measured decision–making" i.e., open–ended and highly contingent choices that form one stage in a longer process. The corollary is that "regulators need to abandon a fixation on finality and legal certainty and embrace contingency, flexibility and an openness to new ideas". Regarding innovation and disruptive technologies, this shift notably involves a shift from rules to principles: "re–framing regulation in this way and adopting a principle–based approach facilitates action and allows future revisions in the regulatory regime to be based on the incorporation of new knowledge or subsequent discoveries".

While not discussed at length here, another important component of a culture favourable to regulatory experimentation consists of ensuring that regulatory experiments are ethical and proportionate. This will often involve creating a code of research ethics as well as the appointment of a well-endowed oversight body.

Effective RE requires a clear legal anchoring, and enabling administrative and scientific ecosystem

Generally, the specific institutional and legislative context determines regulators' room for discretion and thus the extent to which legislative action (such as amendments) is needed prior to undertaking RE activities (see also Chapter 2 for more details on modalities of legal framing of RE and experimentation clauses). A clear legal anchoring and enabling administrative and scientific ecosystem are thus particularly important when it comes to developing RE (Conseil d'État, 2019[7]). As an example, the European Commission's proposed Artificial Intelligence (AI) Act aims to create a legal framework that is innovation-friendly, future-proof and resilient to disruption by encouraging national competent authorities to set up regulatory sandboxes. AI regulatory sandboxes will be expected to establish a controlled environment to test innovative technologies for a limited time based on a testing plan agreed with the competent authorities. Conversely, there may be cases in which EU rules hinder experimentation, as may have been the case for energy according to the EU Agency for the Cooperation of Energy Regulators (ACER) and the Council of European Energy Regulators (CEER). Referring to a context of growing use of EU Regulations, which are directly applicable, instead of Directives, which give Member States more leeway for implementation, it was noted that "the only way to deviate from EU Regulations is when an exemption procedure is included in a regulation" (Schittekatte et al., 2021[25]).

Careful planning, robust oversight and coordination hold the key to effective implementation of RE

Successful RE requires careful planning and preparation

Implementation should be a key focus of RE activities

In addition to regulatory design, implementation is of critical importance if RE is to bring the expected benefits. Available evidence suggests that inefficient implementation of RE initiatives such as regulatory sandboxes can lead to unanticipated negative impacts on competition, consumers, and regulation (OECD,

2023[41]). A 2019 report (UNSGSA, 2019[55]) found that a quarter of regulators launched sandbox initiatives without first evaluating feasibility, demand, potential outcomes, or collateral effects. Regulators reported being unprepared for the level of effort and resources required to process sandbox applications and develop testing plans.

(Greenstone, 2009[56]) recommends implementing regulations so that they lend themselves to experimental or quasi experimental *evaluation*. As discussed in chapter 2 of this paper, this can notably be achieved by launching regulatory measures on a small scale before applying them on a wider scale. In federal regimes such as the USA, sub-national instances may also be allowed to implement different regulations, which in case of success may be scaled up (e.g. to the federal level) (Moss, David, and John Cisternino, eds., 2009[46]).[20]

The importance of data and information management strategies

Appropriate data and information management strategies should be devised. It is crucial for governments to carefully consider the source and nature of the data they will need to collect, who will be responsible for collecting it, and how it will be analysed. Failing to do so could compromise the very aim of experimentation, which, as mentioned above, is to build evidence on a phenomenon for which, by definition, there is little information available regarding risks and opportunities. By planning data and information management from the outset, governments can ensure that the experimentation is conducted transparently and effectively, ultimately leading to reliable findings that will inform future policy development.

An article focusing on the context of articulation between US federal and states and other sub-federal actors (but whose reasoning remains valid, e.g. across ministries, across borders...) stresses the importance of good baseline information, as understanding the laws and regulations enacted by other jurisdictions is key to learn from the latter's successes and failures. There tends to be, however, an information deficit, particularly in technical policy areas ("those that do not follow uniform codes and require expertise to understand, like hydraulic fracturing and health care"). This situation may limit the experimental upside of laboratories—informed, efficient, and innovative regulatory approaches while increasing the costs to private entities of complying with different standards. Increasing the availability of regulatory information will enable more informed experimentation and allow monitoring of policy gaps (Wiseman, H.J., 2014[57]).

Oversight of RE initiatives

Appropriate regulatory oversight and co-ordination are essential to implement effective governance frameworks for RE. Core regulatory oversight functions, as discussed in relevant OECD work, are: quality control of regulatory management tools (i.e. reviewing the quality of individual regulatory impact assessments, stakeholder engagement processes, and *ex post* evaluations); issuance or provision of relevant guidance on the use of regulatory management tools; co-ordination on regulatory policy; and systematic evaluation of regulatory policy (OECD, 2021[58]) (Renda, Castro and Hernández, 2022[59]). In this context, for RE specifically, the role of regulatory oversight bodies (ROBs) can be particularly instrumental regarding the provision of clear and actionable guidance as well as advice on the case for resorting (or not) to RE and the relative merits of available approaches and implementation modalities. In addition, ROBs will need to coordinate, oversee and evaluate the use of RE (including on a cross-border basis). In doing so, and provided they have sufficient power and resources, they can help ensure adherence to good regulatory practice, prevent regulatory capture,[21] and, crucially, facilitate linkages with regulatory management tools (see also "Appropriate data and information management strategies and integration into the regulatory policy cycle" below). Moreover, robust oversight is necessary regarding safeguard mechanisms (see Box 3.1 for a short overview of these mechanisms in the context or regulatory sandboxes).

Box 3.1. Safeguard mechanisms for regulatory sandboxes

Most regulatory sandboxes include safeguards or mechanisms to achieve overarching regulatory objectives, including with respect to consumer protection, safety and data governance. Some more prescriptive sandboxes outline the specific forms of products or services that can be tested through the sandbox to limit any potential negative consequences.

Analysis by the International Monetary Fund on the characteristics of eight FinTech sandboxes in Australia, Canada, Hong Kong China, Malaysia, Singapore, Switzerland, the United Arab Emirates and the United Kingdom found that all had some safeguards on the potential risks introduced by hitherto untested financial products and services on the open market. These safeguards included limits on the number of customers or value of services offered; additional reporting obligations or closer monitoring; additional consumer protection or risk mitigation; or the specification of regulations that could or would not be waived in the regulatory sandbox.

Other forms of regulatory sandboxes may determine that other safeguards are necessary. In the case of the regulatory sandbox operated by the Singapore Ministry of Health, relevant firms are obliged to bear the regulatory sandbox logo and adhere to strict minimum standards with respect to health and data governance.

Source: (Attrey, Lesher and Lomax, 2020[16]).

Another important task that ROBs can fulfil in the context of RE consists of increasing the availability of regulatory information, e.g. by co-ordinating information collection and provision, in collaboration with other relevant actors such as universities and sub-national levels of government (Wiseman, H.J., 2014[57]). Helping to prevent ethical violations in regulatory experiments also requires appropriate oversight (Moss, David, and John Cisternino, eds., 2009[46]).

Strong coordination, including across borders, is essential

As innovation often transcends traditional sectors and administrative boundaries, regulatory experimentation initiatives might raise a strong need for co-operation across policy areas and between the national and subnational levels of government. A regulatory sandbox may for instance require exemptions from regulations that are administered by different agencies or at different levels of government. Regulatory sandboxes relating to artificial intelligence applications are a case in point. Several countries facilitate such cooperation. Spain's Network of Excellence in AI exchanges interdisciplinary knowledge generated by universities and administrations. Its EU AI Act sandbox involves various government institutions such as the Data Protection Agency and the Agency of Medicines and Medical Devices. The UK's Digital Regulation Cooperation Forum and Regulators Pioneer Fund advisory service pilot bring together competition, communication/media, financial, and data protection authorities, all of which are actors in AI policy (OECD, 2023[41]).

Standardisation bodies are also relevant actors in this context, as illustrated by the European Parliament's call for the AI regulatory sandbox to "allow and facilitate the involvement of notified bodies, standardisation bodies, and other relevant stakeholders when relevant" as part of its assessment of the AI Act amendments (proposal for amendment of art 53(1)(a) (OECD, 2023[41]). Authorities in charge of regulatory experimentation are also engaging with bodies such as trade institutions and innovation accelerators (UK FCA, 2014[49]).

It is therefore essential to ensure a whole of government approach identifying all necessary exemptions and involving all relevant instances in the experimentation process. While this coordination and knowledge-brokering role oversight bodies could be played by regulatory oversight bodies, it raises the broader question of whether a dedicated central authority for regulatory experimentation would be appropriate. Such an authority could help ensure consistent implementation (e.g. eligibility and testing criteria of regulatory experiments as well as their governance), the respect of the prerogatives of involved entities, comparability of results and, if relevant, scalability of RE initiatives (including cross-border). Additionally, it could help alleviate the burden on individual agencies by providing centralised coordination and support.

Beyond their cross-cutting effects within jurisdictions, innovations also have a transboundary reach in many cases. This characteristic underscores the need for international regulatory cooperation around shared principles and standards (Parenti, 2020[60]). Harmonising to the extent possible the definition, interpretation, and analysis of core, common eligibility criteria for regulatory experiments including sandboxes, such as innovativeness, public interest, and readiness for testing, could prove beneficial. In addition, the use of compatibility tools such as the recognition of equivalence and the “arrangements for conformity assessment” under the World Trade Organisation’s Agreement on Technical Barriers to Trade could be explored as a means of enabling cross-border interoperability of regulatory sandboxes in certain areas (OECD, 2023[41]).

Such co-operation could be further facilitated by dedicated institutional arrangements. For instance, in the EU, the European AI Board is expected to act as an overarching institution to coordinate national level implementation of tools such as regulatory sandboxes and help address concerns about legal uncertainty regarding coordination (OECD, 2023[41]) (Ranchordás, 2021[61]).

Engaging proactively with stakeholders regarding the design, implementation and evaluation of RE is crucial for effectiveness and appropriate risk management

The development of regulatory experimentation initiatives also involves developing an appropriate risk management strategy. Testing innovations can indeed entail risks, whether perceived or real. Therefore, it is necessary to define what the acceptable risks are and how they will be mitigated in practice. This requires strong strategic foresight skills and systems analysis capabilities. In addition, engaging with stakeholders appears crucial to help manage concerns around the additional risks the experimentation can entail and secure the necessary support for the experimentation outcomes.

More generally, appropriate stakeholder engagement is key condition for the success of experimentation initiatives. Engaging with relevant stakeholders (representatives from the business community, other governments agencies, civil society organisations, etc.), both within and across jurisdictions, can help ensure an inclusive and effective process. Such engagement offers an opportunity to "soundboard" or seek feedback on early-stage sandbox concepts before committing to a specific approach. By involving relevant parties early in the development of a sandbox or regulatory experimentation initiative, governments can receive valuable input to understand the likely benefits of the regulatory experimentation initiative and help address potential challenges. This early-stage collaboration can lead to more effective regulatory experiments, improving the likelihood of achieving desired outcomes while minimising unintended consequences. As mentioned above, involving stakeholders should also ensure that concerns stemming from regulatory experimentation and the risk strategy adopted by governments receive the necessary support.

The engagement should however not be a one-off exercise at the design stage. It should be established throughout the various stages of the initiative, i.e. during the design, the implementation, but also at the evaluation phase. It is especially important that governments can clearly communicate the results of the

initiative (particularly in relation to the new risks it may have entailed) and allow everyone to provide feedback on how the results could be used to inform policy making.

Useful avenues for stakeholder engagement include mechanisms such as innovation hubs, which also help regulators access relevant information, keep abreast of changes in innovative marketplaces and adjust their approaches and policies on a case-by-case basis accordingly (Zetzsche et al., 2017[30]).

RE outcomes should be used to inform policy making to the extent possible

RE's primary aim consists of helping governments to develop knowledge and capacity and gather evidence in complex and fast-changing ecosystems to identify relevant approaches for achieving policy objectives. To do so, it is essential to make the best possible use of RE results and ensure that the information produced thanks is effectively and timely used by decision-makers. Moreover, appropriate data strategies and knowledge management need to be in place.

Ensuring that correct lessons are drawn from regulatory experiments constitutes, therefore, a priority. It is however not an easy task, and there is still limited evidence on how learnings from experiments have been translated into regulatory or policy change. Depending on specific needs, available resources and in-house expertise, it may be useful to commission studies, set up expert panels, or launch public calls for papers to that end.

Integrating experimentation into the regulatory policy cycle is essential to extract the maximum value from the initiative and avoid an undesirable misalignment between the experimentation period and the design of a regulatory change. This relates to one of the key tenets of the OECD Recommendation for Agile Regulatory Governance, i.e. developing more adaptive, iterative, and flexible regulatory assessment cycles. Similarly, (Ribeiro, 2018[62])argues that the foresight/hindsight divide between *ex ante* and *ex post* RIA exposes the system to the risk of missing the correct timing for policy adjustments, therefore failing to avoid unwanted welfare losses, and proposes the idea of Adaptive Regulatory Impact Assessment. On a related note, Estonia's framework for public sector experimentation discusses the option of embedding testing as a tool for impact assessment. Doing so could help to improve the evidence base for decision-making and the quality of the assessment (Riigikantselei, 2022[33]). Moreover, "agile" regulatory assessment and adjustment can also confer to the regulatory experimentation system the kind of confidence that lawmakers need to try a wider range of potential regulations. With the assurance that ineffective regulations will be repealed, lawmakers are likely to feel more confident about experimenting (Moss, David, and John Cisternino, eds., 2009[46]).

In addition, governments should establish a clear and transparent strategy regarding the potential legal changes arising from experimentation outcomes (e.g. *France Expérimentation* applies legal exemptions in a non-discriminatory fashion).

4 Conclusions

Regulatory experimentation can contribute significantly to enhance the effectiveness of policies and regulations. In line with the OECD Recommendation for Agile Regulatory Governance to Harness Innovation, it can help enable the transition towards regulatory governance frameworks and practices that will live up to emerging and interconnected regulatory challenges in fast-paced, innovation-dominated environments. If well governed and appropriately integrated into regulatory policy processes, RE also has the potential to enhance the evidence base underpinning decision-making. Moreover, it can act as a powerful vector for institutional co-operation both within and across national borders.

Although its potential is increasingly recognised, RE development varies considerably across sectors and jurisdictions in terms of focus, scope and level of ambition. While promising initiatives exist and continue to develop, especially in certain sectors, overall, there seems to be significant potential for increasing the uptake of RE, in its different forms, from a whole-of-government perspective.

RE does come, however, with its own share of potential trade-offs (e.g. regarding legality, feasibility, resources, and equity) as well as opportunity costs. Targeting its use to the contexts and areas where it can make a difference by effectively informing public policy choices is therefore essential. Doing so requires careful planning, resourcing and preparation, as well as an assessment of the potential effects of political economy factors – which may render RE redundant from a decision-making standpoint. Successful RE implementation also requires devising the necessary institutional and governance frameworks, including appropriate oversight and systematic evaluation and stakeholder engagement.

The OECD can play a key enabling role as far as the constructive and effective development of RE is concerned by working with governments and regulators to identify key implementation avenues. Building on existing work, it is also well placed for facilitating the sharing and exchange of relevant information and experience that can help target RE efforts appropriately. In that sense, it will be essential to develop a deeper understanding of the key factors determining RE's benefits, as well as to provide a common framework for characterising, designing, deploying, monitoring and evaluating RE initiatives in ways that maximise benefits to the Better Regulation community as a whole.

References

Almeida Shimizu, J. (2020), *Innovation Assessment in Regulatory Sandboxes*, Munich Intellectual Property Law Center. [40]

Attrey, A., M. Lesher and C. Lomax (2020), "The role of sandboxes in promoting flexibility and innovation in the digital age", *OECD Going Digital Toolkit Notes*, No. 2, OECD Publishing, Paris, https://doi.org/10.1787/cdf5ed45-en. [16]

Bauknecht, D. et al (2021), *How to design and evaluate a Regulatory Experiment? A Guide for Public Administrations*, https://www.researchgate.net/publication/350707383_How_to_design_and_evaluate_a_Regulatory_Experiment_A_Guide_for_Public_Administrations. [12]

Bennear, L.S and Wiener, J.B. (2019), *Adaptive Regulation: Instrument Choice for Policy Learning over Time. Draft working paper*, https://www.researchgate.net/publication/254201985_Adaptive_Regulation_Contours_of_a_Policy_Model_for_the_Internet. [17]

Business at OECD (2020), *Regulatory Sandboxes for Privacy Analytical Report*. [10]

Cabinet Office (2003), *Trying It Out. The Role of 'Pilots' in Policy-Making*, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/498256/Trying_it_out_the_role_of_pilots_in_policy.pdf. [22]

Callon et al (2009), *Acting in an Uncertain World: An Essay on Technical Democracy (Wiebe E. Bijkeyet al. eds., Graham Burchell trans., The MIT Press)*. [54]

Center of expertise for digital platform regulation (2022), *PEReN presents its Activity Report 2022*, https://www.peren.gouv.fr/en/actualites/2023-07-28_rapport_activite_2022/. [14]

Centre for Public Impact (2018), *A brief introduction to Policy Experimentation*, https://www.centreforpublicimpact.org/assets/documents/CPI-A-brief-intoduction-to-Policy-experimentation.pdf. [45]

Centre for Regulatory Innovation (2021), *Regulators' Experimentation Toolkit*. [5]

Chen, A. (2019), "Regulatory Sandbox and Competition of Financial Technologies in Taiwan", *Competition Policy International*. [50]

Conseil d'État (2019), *Les expérimentations: comment innover dans la conduite des politiques publiques?*. [7]

Council of the EU (2020), *Council Conclusions on Regulatory sandboxes and experimentation*, [37]

https://data.consilium.europa.eu/doc/document/ST-13026-2020-INIT/en/pdf.

Duke Law (2019), *Wiener: Applying adaptive regulation to the case of automated vehicles*, https://law.duke.edu/news/wiener-applying-adaptive-regulation-case-automated-vehicles/. [18]

European Commission (2023), *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*. [15]

European Commission (2022), *Launch event for the Spanish Regulatory Sandbox on Artificial Intelligence*, https://digital-strategy.ec.europa.eu/en/events/launch-event-spanish-regulatory-sandbox-artificial-intelligence. [24]

Federal Ministry for Economic Affairs and Climate Action (2023), *https://www.bmwk.de/Redaktion/EN/Dossier/regulatory-sandboxes.html*. [28]

Federal Ministry for Economic Affairs and Energy (BMWi) (2020), *New flexibility for innovation. Guide for formulating experimentation clauses*, https://www.bmwk.de/Redaktion/EN/Publikationen/Digitale-Welt/guide-new-flexibility-for-innovation-en-web-bf.pdf?__blob=publicationFile&v=1. [39]

Federal Ministry for Economic Affairs and Energy (BMWi) (2019), *Making space for innovation. The Handbook for regulatory sandboxes*, https://www.bmwk.de/Redaktion/EN/Publikationen/Digitale-Welt/handbook-regulatory-sandboxes.pdf?__blob=publicationFile&v=2. [38]

Fenwick, M.D.; Kaal, W.A., and Vermeulen, E.P.M. (2017), "Regulation Tomorrow: What Happens When Technology Is Faster", *American University Business Law Review, Vol. 6, No. 3*, http://digitalcommons.wcl.american.edu/aublr/vol6/iss3/1. [42]

Gangale, F. et al. (2023), "Making energy regulation fit for purpose. State of play of regulatory experimentation in the EU", https://doi.org/10.2760/32253. [63]

Gobierno de España (2022), *AI regulatory and ethical framework*, https://espanadigital.gob.es/en/measure/ai-regulatory-and-ethical-framework. [23]

Government of Canada (2023), *Minister Fortier invites Canadians to provide input on federal regulations*, https://www.canada.ca/en/treasury-board-secretariat/news/2023/03/minister-fortier-invites-canadians-to-provide-input-on-federal-regulations.html. [32]

Gubler, Z. (2017), *Administrative Conference of the United States. Regulatory experimentation. Final report: November 17, 2017*, https://www.acus.gov/sites/default/files/documents/ZGubler%20ACUS%20Final%20Report%2811-17%29.pdf. [36]

Hernández, G. and M. Amaral (2022), "Case studies on agile regulatory governance to harness innovation: Civilian drones and bio-solutions", *OECD Regulatory Policy Working Papers*, No. 18, OECD Publishing, Paris, https://doi.org/10.1787/0fa5e0e6-en. [29]

International Telecommunication Union (2023), *Global Digital Regulatory Outlook 2023*, https://www.itu.int/dms_pub/itu-d/opb/pref/D-PREF-BB.REG_OUT01-2023-PDF-E.pdf. [3]

Knight, B. and T. Mitchell (2020), *The Sandbox Paradox: Balancing the Need to Facilitate Innovation with the Risk of Regulatory Privilege*, Mercatus Center George Mason University, [48]

https://www.mercatus.org/publications/financial-markets/sandbox-paradox-balancing-need-facilitate-innovation-risk-regulatory.

Komet (2021), *Koment Information. Testing – a working method for quicker learning*. [9]

Maaß, V. (2003), *Experimentierklauseln für die Verwaltung und ihre verfassungsrechtlichen*. [35]

METI (2020), *Demonstration Plan under the Regulatory Sandbox Scheme Approved*, https://www.meti.go.jp/english/press/2020/0806_002.html. [20]

Ministry of Economic Affairs and Employment (2021), *Guidelines for planning and implementing regulatory experiments*, https://julkaisut.valtioneuvosto.fi/handle/10024/163768. [51]

Moss, David, and John Cisternino, eds. (2009), "New Perspectives on Regulation.", *The Tobin Project*, http://www.tobinproject.org. [46]

Moss, D. (ed.) (2009), *Toward a culture of persistent regulatory experimentation and evaluation*, Cambridge, MA. [56]

NESTA (2019), *Renewing Regulation: 'anticipatory regulation' in an age of disruption*. [11]

OECD (2023), "Regulatory sandboxes in artificial intelligence", *OECD Digital Economy Papers*, No. 356, OECD Publishing, Paris, https://doi.org/10.1787/8f80a0e6-en. [41]

OECD (2021), *OECD Regulatory Policy Outlook 2021*, OECD Publishing, Paris, https://doi.org/10.1787/38b0fdb1-en. [58]

OECD (2021), *Recommendation of the Council for Agile Regulatory Governance to Harness Innovation. OECD/LEGAL/0464*, https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0464. [1]

OECD (2019), *Recommendation of the Council on Artificial Intelligence. OECD/LEGAL/0449*, https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449. [43]

OECD (2019), *Regulatory effectiveness in the era of digitalisation*, OECD Publishing, https://www.oecd.org/gov/regulatory-policy/Regulatory-effectiveness-in-the-era-of-digitalisation.pdf. [2]

OECD (2017), *Systems Approaches to Public Sector Challenges: Working with Change*, OECD Publishing, Paris, https://doi.org/10.1787/9789264279865-en. [21]

Parenti, R. (2020), "Regulatory Sandboxes and Innovation Hubs for FinTech", *Study for the committee on Economic and Monetary Affairs*, https://www.europarl.europa.eu/RegData/etudes/STUD/2020/652752/IPOL_STU(2020)652752_EN.pdf. [47]

Parenti, R. (2020), *Regulatory Sandboxes and Innovation Hubs for FinTech. Study for the committee on Economic and Monetary Affairs,*, https://www.europarl.europa.eu/RegData/etudes/STUD/2020/652752/IPOL_STU(2020)652752_EN.pdf. [60]

Ranchordas, S. and van Klink, B. (2022), *Law and Method. Special Issue Experimental Legislation in Times of Crisis, Sofia Ranchordás & Bart van Klink (eds.)*, https://www.elevenjournals.com/tijdschrift/lawandmethod/2022/07/lawandmethod-D-22-00003. [26]

Ranchordas, S. (2021), "Experimental Regulations for AI: Sandboxes for Morals and Mores", *SSRN Electronic Journal*, https://doi.org/10.2139/ssrn.3839744. [6]

Ranchordas, S. (2015), *Innovation Experimentalism in the Age of the Sharing Economy*. [53]

Ranchordás, S. (2021), "Experimental Regulations for AI: Sandboxes for Morales and Mores", *Nomos Journal*, Vol. Morales and Machines/1, https://iris.luiss.it/bitstream/11385/210516/1/2747-5174-2021-1-86.pdf. [61]

Ranchordas, S. and M. van 't Schip (2019), "'Future-Proofing Legislation for the Digital Age'", *SSRN Electronic Journal*, https://doi.org/10.2139/ssrn.3466161. [27]

Renda, A., R. Castro and G. Hernández (2022), "Defining and contextualising regulatory oversight and co-ordination", *OECD Regulatory Policy Working Papers*, No. 17, OECD Publishing, Paris, https://doi.org/10.1787/a4225b62-en. [59]

Ribeiro, D. (2018), *Adaptive Regulatory Impact Assessment: Beyond the Foresight-Hindsight Divide*, PhD Thesis, Unpublished. [62]

Riigikantselei (2022), *Framework for public sector experimentation*, https://riigikantselei.ee/media/2007/download. [33]

Schittekatte, T. et al. (2021), "Regulatory experimentation in energy: Three pioneer countries and lessons for the green transition", *Energy Policy*, Vol. 156, p. 112382, https://doi.org/10.1016/j.enpol.2021.112382. [25]

Sunstein, C. (2022), "'We Test': An Imagined Regulatory Future", *SSRN Electronic Journal*, https://doi.org/10.2139/ssrn.4112291. [44]

Super, D. (2011), "Against Flexibility", *96 Cornell L. Rev. 1375*, https://scholarship.law.cornell.edu/clr/vol96/iss6/13. [52]

The Nobel Prize (2021), *The Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 2021. Press release.*, https://www.nobelprize.org/prizes/economic-sciences/2021/press-release/. [4]

UK FCA (2014), *Project Innovation: Call for Input, FS14/2*, https://www.fca.org.uk/publication/feedback/fs-14-2.pdf. [49]

UNSGSA (2019), *Early Lessons on Regulatory Innovations to Enable Inclusive Fintech: Innovation Offices, Regulatory Sandboxes, and RegTech*, Cambridge Centre for Alternative Finance, https://www.unsgsa.org/publications/early-lessons-regulatory-innovations-enable-inclusive-fintech-innovation-offices-regulatory-sandboxes-and-regtech. [55]

Varazzani, C. et al. (2023), "Seven routes to experimentation in policymaking: A guide to applied behavioural science methods", *OECD Working Papers on Public Governance*, No. 64, OECD Publishing, Paris, https://doi.org/10.1787/918b6a04-en. [31]

Winkler-Portmann et al (2020), *Regulatory experimentation as a tool to generate learning processes and govern innovation – An analysis of 26 international cases*, https://www.researchgate.net/publication/345950608_Regulatory_experimentation_as_a_tool_to_generate_learning_processes_and_govern_innovation_-_An_analysis_of_26_international_cases. [34]

winnovation consulting (2020), *Regulatory Sandboxes. Analytical paper for BusinessEurope*, [19]

https://www.businesseurope.eu/sites/buseur/files/media/other_docs/regulatory_sandboxes_-_winnovation_analytical_paper_may_2020.pdf.

Wiseman, H.J. (2014), "Regulatory Islands", *New York University Law Review Vol. 89:1661*. [57]

Wolfe, D. (2018), *Experimental Governance: Conceptual approaches and practical cases. Background paper for an OECD/EC Workshop on 14 December 2018 within the workshop series "Broadening innovation policy: New insights for regions and cities", Paris.*, https://www.oecd.org/cfe/regionaldevelopment/Wolfe(2018)ExperimentalGovernanceConceptualApproaches.pdf. [13]

World Economic Forum (2020), *Agile Regulation for the Fourth Industrial Revolution. A toolkit for regulators*, https://www.weforum.org/about/agile-regulation-for-the-fourth-industrial-revolution-a-toolkit-for-regulators. [8]

Zetzsche, D. et al. (2017), "Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation", *SSRN Electronic Journal*, https://doi.org/10.2139/ssrn.3018534. [30]

Notes

[1] According to the European Commission's Joint Research Centre, as of early 2023, regulatory experimentation initiatives had been adopted or were under development in 12 EU Member States, with 3 additional Member States considering their adoption (Gangale et al., 2023[63]).

[2] From a methodological standpoint, the best approach consists in the creation a control group to provide a counterfactual.

[3] In practice, RE forms do present variable degrees of hybridisation and overlaps.

[4] In the context of experimental settings, controlled conditions notably refer to regulators' ability to gather relevant data and information to be able to account for the results of the experiment.

[5] https://www.thegfin.com/.

[6] Interoperability Test Bed | Joinup (europa.eu).

[7] https://www.ofgem.gov.uk/energy-policy-and-regulation/policy-and-regulatory-programmes/innovation-link-share-your-energy-ideas.

[8] https://www.kela.fi/web/en/news-archive/-/asset_publisher/lN08GY2nIrZo/content/results-of-the-basic-income-experiment-small-employment-effects-better-perceived-economic-security-and-mental-wellbeing.

[9] This initiative is referred to as a (regulatory) sandbox, in an example of the increasingly large and diverse array of experiments being designated under this term. Regulatory sandboxes are discussed later in this section.

[10] Moreover, a variety of related terms that may fit into the definition of regulatory sandbox have sometimes been used interchangeably, e.g. exceptions, derogations, special rules, legal instructions, special agreements…

[11] http://www.sra.org.uk/

[12] The authors assess the main advantages and disadvantages of the various approaches under consideration. They also propose a "smart regulation process" approach building on that assessment.

[13] This section draws on (Centre for Regulatory Innovation, 2021[5]).

[14] https://www.researchgate.net/publication/345950608.

[15] For additional relevant examples, the reader may consult the list of relating to technological innovations that the German government has identified in an annex to its Handbook for regulatory sandboxes (Federal Ministry for Economic Affairs and Energy (BMWi), 2019[38]).

[16] According to the CRI, RE initiatives should meet the following conditions if they are to bring tangible benefits: prioritise learning (i.e. generate information and evidence by systematically testing ideas); test or trial a defined learning objective or hypothesis; clarify the potential outcomes of the experiment and how these would be interpreted and acted on.

[17] Procedural Framework for Innovation Facilitator Cross-Border Testing (europa.eu).

[18] The authors note, however, that "this form of risk management should however not put at stake the meaningful character of the experiment: while some experiments may deliver results after one or two years, in some sectors, the effectiveness of new policies and laws may only be visible after a decade".

[19] Part B (pp. 19-27) of the CRI's Experimentation Toolkit provides step-by-step guidance to help policymakers determine whether RE should be privileged based on existing needs and constraints.

[20] For further elements on this topic, the reader may also refer to Schittekatte et al., who discuss trade-offs at play along six design dimensions when implementing a regulatory experiment (Schittekatte et al., 2021[25]).

[21] Since some regulatory experiments involve only a small number of companies, concerns might be raised that the government is "picking winners" or otherwise unduly favouring certain actors. External oversight of the whole process is therefore key to avoid regulatory capture.