REGULATORY SANDBOXES AND INNOVATION-FRIENDLY REGULATION: BETWEEN COLLABORATION AND CAPTURE

Sofia Ranchordas[*] *and Valeria Vinci*[**]

Abstract

Regulatory sandboxes, controlled regulatory environments for the testing of novel products or processes, have garnered an increasing amount of attention over the last decade and have been recently presented as innovation-friendly instruments. This article contends that fostering responsible innovation through regulatory sandboxes presents significant challenges. First, there is no consensus on what the advancement of innovation entails, how to achieve it, and what the role of regulations and regulatory sandboxes should be in it. Second, there is a lack of clarity regarding the definition and functioning of regulatory sandboxes. Third, there is a risk of regulatory capture due to the close collaboration between regulators and regulates and potential lack of transparency regarding the choice of regulatory interventions within the sandbox.

Drawing on Italy's initial experiences with general and sector-specific regulatory sandboxes and existing scholarship on experimental regulatory instruments, this article contributes to the ongoing debate on regulation and innovation by critically examining the interplay between regulatory sandboxes and the promotion of responsible innovation. Furthermore, it explores the impact of regulatory sandboxes on the evolving collaborative dimensions of public law and provides policymakers and regulators with actionable insights for navigating this innovative regulatory tool.

[*] Full Professor of Administrative Law, Tilburg Law School, The Netherlands and Professor of Public Law, Innovation, and Sustainability at Luiss Guido Carli, Rome, Italy.

[**] PhD candidate in Law and Business, Luiss Guido Carli, Rome, Italy.

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1. Introduction

Regulatory sandboxes, controlled regulatory environments for the testing of novel products or processes, have attracted considerable attention over the last decade[1]. Regulatory sandboxes emerged in the financial sector where they were first used as a safe testbed for Fintech[2]. More recently, regulatory sandboxes have expanded to other

[1] See T. Madiega, A.L. Van De Pol, *Artificial intelligence act and regulatory sandboxes*, European Parliamentary Research Service (2022); W. G. Johnson, *Caught in quicksand? Compliance and legitimacy challenges in using regulatory sandboxes to manage emerging technologies*, 17 Regul. & Governance 709 (2023); P. Vallance, *Pro-innovation Regulation of Technologies Review - Digital Technologies*, Report to the Chancellor of the Exchequer and to HM Government (2023); *Regulatory sandboxes in artificial intelligence*, OECD Digital Economy Papers, No. 356 (2023).

[2] B. Lim, C. Low, *Regulatory Sandboxes in Fintech*, in J. Madir (ed.), *Fintech* 302 (2019); D.A. Zetzsche, R.P. Buckley, J.N. Barberis & D.W. Arner, *Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation*, 23 Fordham J. Corp. & Fin. L. 31 (2017); A. Alaassar, A.L. Mention & T.H. Aas, *Exploring a new incubation model for FinTechs: Regulatory sandboxes*, 103 Technovation 1 (2021); D. Ahern, *Regulators Nurturing Fintech*

sectors such as energy, healthcare, and telecommunications[3]. An important illustration of this expansion is the proposed AI Act ('AIA')[4] which enables Member States to establish general AI regulatory sandboxes[5]. Regulatory sandboxes have also been considered for the promotion of sustainable development and responsible innovation in the last 'Green Deal Industrial Plan for the Net-Zero Age'[6]. This Plan presents regulatory sandboxes as instruments likely to contribute to a predictable, flexible, and simplified regulatory environment[7]. More recently, the European Commission published a Commission Staff Working Document on "Regulatory Learning in the EU. Guidance on regulatory sandboxes testbeds, and living labs in the EU, with a focus section on energy"[8], which acknowledges that experimentation spaces such as regulatory sandboxes may help improve the regulatory governance of innovation and accelerate the deployment of innovative solutions. But is this as simple as it is presented? Can regulatory sandboxes truly foster innovation?

This article acknowledges the flexible and potentially innovation-friendly character of regulatory sandboxes. However, it also offers a critical perspective, arguing that the advancement of responsible

Innovation: Global Evolution of the Regulatory Sandbox as Opportunity-Based Regulation, 15 Indian J. L. Tech. 345 (2019).

[3] See, for example, *https://energy.ec.europa.eu/publications/regulatory-sandboxes-energy-sector_en*.

[4] *Proposal for a Regulation laying down harmonized rules on artificial intelligence ("Artificial Intelligence Act") and amending certain Union legislative acts*, COM/2021/206 final. On December 9 2023, Parliament reached a provisional agreement with the Council on the AI Act. The agreed text will now have to be formally adopted by both Parliament and Council.

[5] European Parliament, P9_TA(2023)0236, Artificial Intelligence Act, Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)) available at *https://www.europarl.europa.eu/doceo/document/TA-9-2023-0236_EN.html*.

[6] Brussels, 1.2.2023 COM(2023) 62 final, Communication from the European Commission, *A Green Deal Industrial Plan for the Net-Zero Age*.

[7] Id., Section 2.1.

[8] 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*, SWD(2023) 277 final.

innovation through general-purpose regulatory sandboxes is challenging, particularly when the shortcomings of these instruments are not adequately considered. In addition, it also delves into the collaborative nature of sandboxes, discussing both their regulatory potential and shortcomings.

First, there is no consensus on what the advancement of responsible innovation entails in practice, how to achieve it, and what the role of laws and regulations should be[9]. Second, there is limited empirical evidence on the ability of general-purpose regulatory sandboxes to promote responsible innovation, particularly when compared to sector-specific regulatory sandboxes. Third, close collaboration between regulators and regulatees is a double-edged sword. A fruitful and open regulatory collaboration requires extensive exchange of information among sandbox participants and the regulator as well as the publication of evaluation reports. This is a process that many regulatees are not willing to embrace. However, regulatory opacity also has several downsides. Limited transparency and openness in the context of a regulatory sandbox may limit the ability of stakeholders outside the sandbox to scrutinize the equity of its measures, potential competitive advantages conferred to sandbox participants, and hold regulators accountable for agency drift. Furthermore, as described by the theory of regulatory capture, there is the risk that in the context of regular exchanges between regulators and regulatees, market actors may try to influence regulators to make decisions that benefit their own narrow special interests rather than the collective welfare. This article cautions against this effect by offering guidance on how to avoid this outcome[10].

The article reflects upon existing scholarship on experimental regulations and the advancement of innovation, as well as the recent operationalization of *Sperimentazione Italia*, a general-purpose regulatory sandbox that aims to advance responsible innovation in the public sector[11]. Drawing partly on the Italian experience with regulatory sandboxes, we show that the goal to promote responsible innovation

[9] A. Butenko, P. Larouche, *Regulation for innovativeness or regulation of innovation?*, 7 Law Innovation & Tech. 52 (2015).
[10] G. Stigler, *The theory of economic regulation*, 2 Bell J. Econ. & Manage. Sci. 3 (1971).
[11] Introduced by article 36 of Law Decree No. 76 dated 16 July 2020 converted by Law No. 120 dated 11 September 2020.

with this regulatory instrument is more complex than it seems. While *Sperimentazione Italia* is compatible with EU policies on responsible innovation, this sandbox provides its stakeholders with limited information, predictability, and clarity. The results of *Sperimentazione Italia* are limited at the time of writing, but the potential of this sandbox is far from being fulfilled. Despite the limited available evidence, this preliminary discussion aims to shed light on the potential and shortcomings of sandboxes to promote responsible innovation. Since regulatory sandboxes are a relatively novel instrument, much can be learned from similar forms of experimental regulations which have been implemented for centuries and about which there is more available legal, methodological, and practical knowledge[12].

This article is organized as follows. Section 1 distinguishes between different types of experimental regulatory instruments. Section 2 discusses the Italian experience with experimental legislation and regulations, including the initial results of *Sperimentazione Italia*. Section 3 delves into the intricacies of regulating technological change and the strategic use of regulation to foster responsible innovation. Section 4 discusses the potential and challenges of employing regulatory sandboxes to advance responsible innovation, including the risk of regulatory capture . Lastly, we conclude and draw broader implications of this discussion for Italian and EU public law.

2. Experimental Regulations and Regulatory Sandboxes

Experimental laws and regulations are far from being new phenomena in Italy or in the rest of the world[13]. Experimental legislation, a general term used to denote primary legislation authorizing legal experiments, has existed for centuries, dating back to 17th-century French law[14]. However, experimental laws and regulations remained relatively obscure and underused for centuries. Over the last two

[12] S. Ranchordás, *Experimental Regulations and Regulatory Sandboxes – Law Without Order?*, Law and Method 1 (2021).
[13] N. Maccabiani, *An empirical approach to the rule of law: the case of regulatory sandboxes*, 13 Osservatoriosullefonti.it 741 (2020).
[14] F. Crouzatier-Durand, *Réflexions sur le concept d'expérimentation législative (à propos de la loi constitutionnelle du 28 mars 2003 relative à l'organisation décentralisée de la République)*, 56 RFDC 675 (2003).

decades, there has been a growing scholarly, political, and legislative interest in the broader use of experimental legislation, experimental regulations, pilots, and policy experiments. This interest has been partly fueled by debates on the need to improve the quality of legislation and regulation[15]. This section begins with a brief distinction between different experimental legislative and regulatory measures. It then reviews the first experiences with experimental regulatory measures in Italy.

2.1. Experimental legislation and other experimental measures

There is no single definition of 'experimental legislation' or 'experimental law'. Instead, this term may be used loosely to refer to a wide range of legislative, regulatory, and policy instruments with a temporary nature[16].

First, there are few experimental statutes stricto sensu. Rather, in unitary states, legal experiments occur through a derogation or waiving mechanism, that is, there is a legislative disposition in a statute (experimental clause) authorizing a derogation from existing legislation. Experimental clauses establish the central requirements for the experiment, which will then be further developed in secondary legislation. Examples of these requirements are the duration of the experiment, the group or geographical area to which the experiment is applicable, the scope of the derogation, the objectives of the experiment, and the evaluation criteria. In most cases, experimental clauses apply to a limited number of dispositions and only allow for experiments within a specific sector or legal area. There are however examples of general experimental clauses or experimental laws that have a broader scope and allow for the adoption of experimental regulations in a large number of sectors. This is the case of the Flemish government decree of 7 December 2018 (*Bestuursdecreet*) which, in its chapter 4, allows the Flemish government to adopt experimental regulations and regulatory free zones (*regelluwe zones*).

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[15] R. Van Gestel, G. Van Dijck, *Better regulation through experimental legislation*, 17 EPL 539 (2011).

[16] See, for example, M.A. Heldeweg, *Experimental Legislation Concerning Technological & Governance Innovation – An Analytical Approach*, 3 Theory Pract. Legis. 169 (2015).

Experimental regulations and regulatory sandboxes have recently been regarded as regulatory tools that can be employed to stimulate innovation[17]. They are also perceived as strong alternatives to more cautious regulatory approaches to the regulation of novel phenomena and regulatory change, namely by the OECD[18].

The European Commission defined in the November 2023 Better Regulation Toolbox, regulatory sandboxes as "schemes that enable firms to test innovations in a controlled real-world environment, under a specific plan developed and monitored by a competent authority" and which are "usually organised on a case-by-case basis, include a temporary loosening of applicable rules, and feature safeguards to preserve overarching regulatory objectives, such as safety and consumer protection"[19]. Regulatory sandboxes enable a direct testing environment for innovative products, services, or business models, under a specific testing plan. This plan typically involves some degree of regulatory leniency combined with certain safeguards. This may include waiving existing rules, modifying otherwise applicable regulations, providing additional compliance assistance, or implementing other measures designed to support innovative market actors. In a regulatory sandbox, regulators work collaboratively with a small group of regulatees for a limited amount of time, furthering the trend to redefine regulation through collaborative negotiation[20].

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[17] "A regulatory sandbox brings the cost of innovation down, reduces barriers to entry, and allows regulators to collect important insights before deciding if further regulatory action is necessary." *Briefing on Regulatory Sandboxes*, UNSGSA Fintech Sub-Group on Regulatory Sandboxes, June 3, 2018. See also *G20 Survey on agile approaches to the regulatory governance of innovation*, Report for the G20 Digital Economy Taskforce, August 2021, available at *https://www.oecd.org/gov/g20-survey-on-agile-approaches-to-the-regulatory-governance-of-innovation-f161916d-en.htm*.

[18] OECD, Recommendation of the Council for Agile Regulatory Governance to Harness Innovation (Adopted by the Council at Ministerial level on 6 October 2021), recommendation IV.4, available at *https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0464#mainText*. See *infra*, Section 4.

[19] European Commission, *Better Regulation Toolbox*, July 2023, tool #69 (Emerging methods and policy instruments).

[20] See A.C. Amato Mangiameli, *Tecno-regolazione e diritto. Brevi note su limiti e differenze*, 32 Dir. inf. 147 (2017). The Author reflects on the enhanced negotiating nature of the law "*Il diritto si presenta sempre più come negoziato*". The Author makes reference to French literature on the issue, see F. Ost, *Le role du droit: te la vérité révélée à la réalité*

Regulatory sandboxes differ from experimental regulations on several grounds. First, sandboxes do not always entail the disapplication of existing laws and regulations[21]. Rather, sandboxes can be limited to providing customized or bespoke compliance assistance to regulatees or collaborating with them on the design of products to ensure compliance with regulations (e.g., Norwegian DPA regulatory sandbox for privacy-friendly AI systems; Spanish regulatory sandbox for AI)[22].

Second, a large part of regulatory sandboxes consists of policy decisions on eligibility, objectives, entry and exit requirements, and evaluation criteria which aim to promote innovation. Experimental regulations may be used for a number of other goals. Sector-specific regulatory sandboxes have sought to assist mainly startups to develop their products, allowing them to participate in a testbed for a short period of time (six months on average), and collaborate closely with the regulator and sometimes with each other[23]. In other words, regulatory sandboxes typically allow for customization of regulatory measures

négociée, in G. Timsit, A. Claisse & N. Belloubet-Frier (eds.), *Les administrations qui changent. Innovations techniques ou nouvelles logiques?* 73 ff. (1996).

[21] See 2023 Better Regulation Toolbox which refers to regulatory/legislative barriers. See also G. Lo Sapio, *Il regolatore alle prese con le tecnologie emergenti. La regulatory sandbox tra principi dell'attività amministrativa e rischio di illusione normativa*, 20 Federalismi.it 16 (2022).

[22] The Norwegian regulatory sandbox is established under the supervision of the Norwegian Data Protection Authority and aims at promoting the development of innovative artificial intelligence solutions that, from a data protection perspective, are both ethical and responsible (*https://www.datatilsynet.no/en/regulations-and-tools/sandbox-for-artificial-intelligence/*). This sandbox operates with three main principles for responsible artificial intelligence: lawfulness, ethic and robustness. These principles are based on the "Ethics guidelines for trustworthy AI" presented in 2019 by the High-Level Expert Group on AI appointed by the European Commission (see *https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai*). Spain has also recently established a regulatory sandbox for AI, aimed at creating a testing environment for the implementation of the legal requirements for certain AI systems that may pose risks to security, health, and fundamental rights. The sandbox allows the cooperation between authorities and AI developers for the implementation of those requirements (*Real Decreto 817/2023, de 8 de noviembre, que establece un entorno controlado de pruebas para el ensayo del cumplimiento de la propuesta de Reglamento del Parlamento Europeo y del Consejo por el que se establecen normas armonizadas en materia de inteligencia artificial*).

[23] S. Ranchordás, *Experimental Regulations and Regulatory Sandboxes*, cit. at 12.

and aim to reduce regulatory burdens of innovative companies. Regulatory sandboxes may thus not be experimental in the traditional sense of creating a completely different set of conditions to try a new measure. Rather, regulatory sandboxes' key feature is their aim to establish a stronger collaboration between regulators and innovators through regulatory flexibility. Therefore, regulatory sandboxes can be defined as collaborative regulatory instruments where regulators interact closely with a selected group of market actors (usually startups) to create a safe testbed to understand how to best regulate new types of services or products[24]. All types of experimental regulations and regulatory sandboxes are required to comply with existing constitutional, EU, and international law frameworks, including the principles of legality, equal treatment, legal certainty, and proportionality[25]. Experimental regulations and regulatory sandboxes and their implementation perils are—at the resemblance of many other instruments—grasped better when analyzed in practice. Therefore, the following subsection introduces the experience of Italy first with experimental regulations, and second, with regulatory sandboxes, including a general-purpose regulatory sandbox[26].

[24] See S. Ranchordás, *Innovation Experimentalism in the Age of the Sharing Economy*, 19 Lewis & Clark L. Rev. 871 (2015). The Author notes that "innovation is both a public and private activity which benefits highly from collaboration between the State and the private actors".

[25] S. Ranchordás, *Experimental Regulations and Regulatory Sandboxes*, cit. at 12; Id., *Experimental lawmaking in the EU: Regulatory Sandboxes*, EU Law Live (Oct. 22, 2021), University of Groningen Faculty of Law Research Paper No. 12/2021, Nov. 18, 2021 (last revised Feb. 2, 2022), available at *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3963810*.

[26] It should be mentioned that in June 2022 the Spanish government introduced the first AI regulatory sandbox which aims to "look at operationalising the requirements of the future AI regulation as well as other features such as conformity assessments or post-market activities". See *https://digital-strategy.ec.europa.eu/en/news/first-regulatory-sandbox-artificial-intelligence-presented*.

3. Experimental regulations and regulatory sandboxes in Italy

Literature on experimental legislation in Italy is still in its infancy[27]. The enactment of experimental regulations was initially linked to the development of flexible regulatory approaches in social policy[28]. More recently, experimental regulations and regulatory sandboxes have expanded to the regulation of emerging technologies. This section discusses the Italian experience with experimental regulations and regulatory sandboxes.

3.1. Experimental laws and regulations in Italy

In June 1998, Law No. 449/1997 introduced one of Italy's first legal experiments with the so-called minimum integration income ("*reddito minimo di inserimento*"), which established the provision of economic and social support measures for individuals at risk of those risking social exclusion and unable to survive or support their families due to illness, disabilities or social reasons[29]. This form of welfare benefit was approved on an experimental basis and was part of the reform of the Italian social security system initially conducted in limited areas of the country. This new measure also aimed to combat poverty by providing an income support contribution of up to ITL 500,000 per month and personalised assistance programs. The experiment lasted two years. A few years later, Law No. 10/2011 introduced another 12-month experiment concerning a 'social card' for individuals and families in need of financial assistance[30]. Experimental regulations were also adopted in the 1990s. Law No. 127/1997 introduced an experimental regulation with the goal of promoting digitalization, allowing for the testing of the Electronic Identity Card[31].

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[27] See E. Longo, *Time and Law in the post-COVID-19 Era: the usefulness of Experimental Law*, in S. Ranchordàs & B. van Klink (eds.), *Experimental Legislation in Times of Crisis*, Law and Method – Special Issue 1 (2021). See also F. Laviola, *Regolazione della tecnologia e dimensione del tempo*, 14 Osservatoriosullefonti.it 1163 (2021).

[28] See *infra*, Subsection 2.1.

[29] Article 59, par. 47 of Law No. 449 dated 27 December 1997.

[30] Article 2, paragraphs 46-49 of Law Decree No. 225 dated 29 December 2010 converted by Law No. 10 dated 26 February 2011.

[31] Known as Law "Bassanini-bis", the measure was introduced under Article 2, par. 10 and then implemented by different measures starting with the Decree of the President of the Council No. 437 dated 22 October 1999. Actual implementation of the measure started in 2001 with pilot projects in 83 municipalities.

While the mentioned experimental regulations introduced new legal regimes, not all experimental laws in Italy have followed this model. For instance, a different approach was embraced in the regulation of the 'micro-mobility', such as electronic hoverboards and e-scooters, under Law 145/2018[32]. This law allowed for possible derogations from existing legislation to test the introduction of new forms of sustainable electric transport.

Although experimental regulations have existed for a number of years, it was only with the approval of the fintech sandbox that Italian scholars and policymakers began devoting more attention to experimental regulations and in particular to regulatory sandboxes[33].

3.2. Italian *Regulatory Sandboxes*

In the next subsections, we introduce two different regulatory sandboxes currently active in Italy at the time of writing: a sector-specific regulatory sandbox concerning financial innovation (Fintech) and a general-purpose sandbox known as "*Sperimentazione Italia*"[34]. While the scope of the first is limited to a specific sector, the second one represents an interesting attempt to set up general-purpose sandboxes[35].

[32] Art. 1, paragraph 101, of Law No. 145 dated 30 December 2018 concerning State budget forecast for year 2019 and multiannual budget for the triennium 2019-2022.

[33] Experimental legislation in labour law has been examined by P. Ichino, *Come il metodo sperimentale può contribuire al progresso del diritto del lavoro*, 30 Riv. it. dir. lav. 393 (2011).

[34] See E. Longo, *Time and Law in the post-COVID-19 Era*, cit. at 27; N. Maccabiani, *An empirical approach to the rule of law*, cit. at 13; A. Merlino, *Il* regulatory sandbox *e la teoria delle fonti*, 17 Dir. pubbl. eur. Rass. online 111 (2022); E. Corapi, *Regulatory Sandbox nel Fintech?*, in E. Corapi, R. Lener (eds.*), I diversi settori del fintech*, 13 ff. (2019); M.T. Paracampo, *Dalle regulatory sandboxes al network dei facilitatori di innovazione tra decentramento sperimentale e condivisione europea*, 18 Riv. dir. banc. 219 (2019); F. Di Porto, A. Signorelli, *Regolare attraverso l'intelligenza artificiale*, in A. Pajno, F. Donati & A. Perrucci (eds.), Intelligenza artificiale e diritto: una rivoluzione?, vol. I, 617 ff. (2022). For first comments on *Sperimentazione Italia*, see G. Lo Sapio, *Il regolatore alle prese con le tecnologie emergenti*, cit. at 21; M. Trapani, *L'utilizzo delle sandboxes normative: una ricognizione comparata delle principali esperienze di tecniche di produzione normativa sperimentali e il loro impatto sull'ordinamento*, 15 Osservatoriosullefonti.it 215 (2022).

[35] A. Merlino, *Il* regulatory sandbox *e la teoria delle fonti*, cit. at 34.

3.2.1. The Italian Fintech Regulatory Sandbox

FinTech has pushed the boundaries of traditional regulatory frameworks in the financial world and revolutionized how traditional markets operate[36]. The Italian Fintech sandbox was introduced by Law Decree No. 34/2019[37], drawing on the UK experience with sandboxes in the financial sector. This sandbox is designed for operators in the banking, insurance, and finance sectors who wish to experiment with innovative services or products within a protected area under the monitoring of banking and financial supervising authorities, namely the Bank of Italy, IVASS, and Consob[38]. The Italian Fintech sandbox allows selected participants to operate in an experimental regulatory space where certain provisions under regulations issued by the supervising authorities can be derogated for a maximum period of 18 months, all under constant supervision and dialogue with supervising authorities[39].

The experimental provision is implemented by a ministerial decree, specifically Decree No. 101/2021 of the Ministry of Economy and Finance. This Decree establishes the criteria for admission to the sandbox and specific timeframes for the submission of admission requests. By outlining these requirements, the ministerial decree delineates the types of innovations intended to be promoted through the experiment[40]. Among these requirements, it is provided that the proposed activity shall be "significantly innovative." Furthermore, the innovation should be "responsible", delivering added value to end users and enhancing the overall efficiency of the financial system. This sandbox incorporates a "governance" element since it allows supervising

[36] S.T. Omarova, *Technology v Technocracy: Fintech as a Regulatory Challenge*, 6 J. Fin. Regul. 75 ff. (2020).

[37] Article 36, paragraph 2-bis of Law Decree No. 34/2019, converted with amendments into Law No. 58/2019 on the regulation of Fintech Committee and Experiment and implemented by Decree No. 101/2021 of the Ministry of Economy and Finance.

[38] *Regulatory sandbox lessons learned report*, UK Financial Conduct Authority (2017), available at *https://www.fca.org.uk/publications/research/regulatory-sandbox-lessons-learned-report*; B. Lim, C. Low, *Regulatory Sandboxes in Fintech*, cit. at 2; T.F. Hellmann, A. Montag, N. Vulkan, *The Impact of the Regulatory Sandbox on the FinTech Industry* (2022), available at *https://ssrn.com/abstract=4187295*.

[39] See *supra*, Subsection 1.1.

[40] Direction of the experiment should be explicitly indicated, See S. Ranchordás, *Constitutional Sunsets and Experimental Legislation: A Comparative Perspective* (2014).

authorities to select – within the legal requirements– which innovation can be tested and then potentially introduced to the market. Additionally, it promotes informal dialogues between supervising authorities and market operators, providing guidance to private actors and fostering regulatory learning. Following the experiment's successful completion and a favorable assessment of the sandbox, regulators may propose targeted amendments to sector-specific regulations in order to govern the tested products or services and their equivalents.

Other EU Member States have applied the described structure of fintech sandboxes to other regulated areas, such as transport, environment and energy[41]. Italy, on the contrary, has decided to promote innovation in these sectors through a general-purpose regulatory sandbox called *Sperimentazione Italia*.

3.2.2. *Sperimentazione Italia*

Sperimentazione Italia is an initiative that invites startups, companies, universities, and research centers to test their innovative projects for a limited period of time through a temporary waiver of existing regulations[42]. This general-purpose sandbox opens the way to experiments in the public sector, provided that the proposed innovation cannot be implemented under another existing law and certain legal requirements are met[43]. This general-purpose regulatory sandbox is part of the Italian Strategic Plan on AI for 2022- 2024 which aims to test innovative AI solutions in the Italian market and boost the digitalisation of private and public sectors. The ultimate aim of this Strategic Plan is to increase at least by 30% the presence of AI products and services in the market[44]. *Sperimentazione Italia* is the first general-purpose sandbox

[41] Germany introduced sandboxes under the Passenger Transportation Act: § 2(7) and §16 with regard to regulations on the operation of motor vehicles with automated and autonomous driving (adopted by the Fed. Cabinet in February 2022); France introduced regulatory sandboxes ("*bac a sable réglementaire*") in the energy sector under the supervision of the *Commission de Régulation de l'Energie*.

[42] *Sperimentazione Italia* was introduced by Law Decree No. 76/2020, converted into Law No. 120/2020.

[43] The most advanced Member States is France, which introduced an experimental clause in the Constitution in 2003: Art. 37, par. 1, of French Constitution.

[44] Italian Strategic Plan on AI for 2022- 2024 is an ambitious programme – jointly elaborated by the then Ministry of University and Research, Ministry of Economic Development, and Ministry for Technological Innovation and Digital Transition – to

adopted in Europe and could be an interesting point of reference for both future EU and national policies[45]. *Sperimentazione Italia* starting point is the identification of regulatory barriers to proposed innovations. Therefore, applicants ('innovators') should explain to regulators why existing rules hinder their innovative activity and why regulatory simplification is needed[46]. Despite its positive intent, this step may potentially discourage participation as it places the burden on innovators to initiate the procedure with evidence of the existence of regulatory barriers.

Law Decree No. 76/2020 identifies "urgent measures for simplification and digital innovation" and introduces under Title IV "provisions for innovation". Article 36 provides administrative simplification measures for innovation to favour the digital transformation of public administration, as well as the development, diffusion, and use of emerging technologies through the creation of regulatory sandboxes. Application requests should be submitted to the Department of the Presidency of the Council of Ministers in charge of digitalization and should include details on the requesting entities, characteristics of the proposed innovation, suggested duration of the sandbox, list of regulatory barriers, objectives and scope of the experiment as well as the expected benefits and risks, including relevant mitigation measures (Article 36). Furthermore, for the sandbox to be authorized, proposed innovations must have "a positive impact on the quality of the environment or life" and should have the potential to become successful.

promote the development and use of AI applications in Italy. It sets a series of specific objectives and identifies 11 priority sectors where investments should be addressed as well as 24 policies to be adopted in the next 3 years to promote the digitalization of Italian public and private sectors through AI applications.

[45] See G. Lo Sapio, *Il regolatore alle prese con le tecnologie emergenti*, cit. at 21; M. Trapani, *L'utilizzo delle sandboxes normative*, cit. at 34.

[46] "Two approaches are theoretically possible to set up a sandbox: one where the request (and identification of a regulatory barrier) is initiated by innovators, and another, where the regulator identifies legislative provisions for testing and calls for applications by interested organisations9 first, the sandbox reflects the paradigm of responsible innovation since only innovations having a positive impact on the quality of life and the environment can be admitted to the experiment." European Commission, *2021 Better Regulation Toolbox*.

These experiments cannot exceed one year and can be extended only once[47].

Given the simplification scope of the provision, the Decree sets a very strict (and optimistic) timeline for the procedure, establishing a maximum duration for each phase: 30 days for the assessment of the admission request and an additional period of 30 days for issuing the authorization or rejection decision. The Decree also establishes continuous monitoring obligations for the competent office of the Presidency of the Council, in collaboration with the Ministry of Economic Development. The cohort of applicants admitted to the regulatory sandbox is also required to submit a report at the end of the experiment. The Presidency of the Council and other responsible ministries are then expected to assess the outcomes of the experiment, considering the benefits the innovation can bring to the quality of life and environment. In case of positive evaluation, the involved authorities can propose permanent revisions to the temporarily derogated regulation based on the data collected during the experiment.

The Decree specifies that it is not possible to experiment with certain regulated sectors, some of which are already covered by specific sectorial experiments. This includes financial activities subject to authorization (Fintech), national security, birth registry, marital status and electronic identity card, elections and referenda, as well as any preventive measures related to public security. These exclusions are justified by the fact that these areas are typical representations of state authority, which cannot be subject to derogations on an experimental basis.

Based on publicly available documents, at the time of writing, two projects have been admitted to *Sperimentazione Italia*: the first project concerns the testing of autonomous driving buses in a restricted area of Turin (around 5 km), and the second one concerns an experiment with autonomous robots for last-mile delivery in a specific area of Milan[48].

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[47] The cooperation among Ministries is carried out through the institute of "Conferenza di servizi" under Law No. 241/1990.

[48] The approval of the two projects was announced by press releases on the webpage of the Department for Digital Transition: *https://innovazione.gov.it/notizie/articoli/innovazione-via-libera-alla-sperimentazione-di-navette-a-guida-autonoma-su-strada/*; *Al via la sperimentazione di Yape, il primo robot-fattorino per le consegne a guida autonoma*

While this general-purpose regulatory sandbox has great potential and it is still in its infancy, some shortcomings are already visible. First, there is limited information on the already approved experiments: the measures authorizing the sandboxes are not publicly available. While the protection of confidential information of market actors is a legitimate concern, the lack of openness can also be problematic. This may dissuade eligible participants from joining the regulatory sandbox and regulators from learning from existing experiments. This issue should be addressed to better balance the protection of innovations admitted to the experiment and transparency requirements. Since the actual authorization and the structuring of the sandbox ultimately depend on the authorizing measure issued by the Presidency of the Council, access to these documents would help us understand the functioning of the regulatory sandbox. Additionally, this would help shed light on the sandbox's compliance with constitutionally protected rights. Furthermore, information on successful sandbox experiences could promote the wider adoption of this regulatory instrument.

Second, *Sperimentazione Italia* is the first general-purpose sandbox within the EU and it contains some elements which could inspire future regulatory sandboxes at EU level if more guidance is provided. The exercise to reflect upon regulatory barriers and the close collaboration with innovators are two aspects to be considered, but additional guidance is required to avoid regulatory fragmentation. As others have remarked, generic sandboxes risk being 'devoid of defined admission thresholds and sufficient expertise or skills for some technologies relative to others'[49].

Third, the ambition to advance responsible innovation with a general-purpose regulatory sandbox overlooks the complexity of regulating technological change as well as the challenge of promoting responsible innovation with regulatory instruments. The next sections will delve into this point.

(*https://innovazione.gov.it/notizie/articoli/al-via-la-sperimentazione-di-yape-il-primo-robot-fattorino-per-le-consegne-a-guida-autonoma/*). The documentation concerning the projects and their approval is not publicly available.

[49] J. McCarthy, *From childish things: the evolving sandbox approach in the EU's regulation of financial technology*, 15 Law Innovation & Tech. 1 (2023).

4. Regulating (Responsible) Innovation

Can regulation truly advance innovation? Should regulation only promote responsible innovation? This section discusses existing scholarly perspectives that have sought to shed light on these two questions.

4.1. The Challenge of Regulating Technological Change

The regulation of technological change has been described as a wicked problem which requires alternative governance systems and an interdisciplinary reflection on innovation[50]. The regulation of technological change and innovation is indeed complex for a number of reasons[51]. First, innovation is an elusive concept which is hard to define, measure, and thus regulate. One of the most commonly used definitions of innovation has been proposed by the OECD Oslo Manual of Innovation. In its latest version (2018), innovation is defined as: 'a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)'[52]. This definition of innovation contains three elements: (i) innovation can refer to both novelties or ameliorations, (ii) of existing products and processes; (iii) that have been made available to users. In other words, a brilliant new idea that has never exited a laboratory is thus not an innovation until it has reached its users.

Innovation has been too easily heralded by policymakers as a goal to strive for, a measurement of economic success, and a reason to

[50] G.E. Marchant, *Governance of Emerging Technologies as a Wicked Problem*, 73 Vand. L. Rev. 1861 (2020). See also M.A. Staner, G.E. Marchant, *Proactive International Regulatory Cooperation for governance of emerging technologies*, 55 Jurimetrics 153 (2015).

[51] While there is a broad agreement in the literature that new technologies create challenges for law and regulation, innovation law is mainly limited to Intellectual Property law, while too little is known and researched about "the most adequate and efficient mix of legal and policy instrument to promote innovation" and on "how different legal instrument can be employed to regulate and facilitate innovation". S. Ranchordás, *Innovation Experimentalism in the Age of the Sharing Economy*, cit. at 24; see also Id., *Constitutional Sunsets and Experimental Legislation*, cit. at 40; L. Bennett Moses, *Regulating in the Face of Sociotechnical Change*, in R. Brownsword, K. Yeung & E. Scotford (eds.), *The Oxford Handbook of Law, Regulation and Technology* 573 ff. (2017).

[52] OECD, Eurostat, *Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation*, 4th ed. (2018), available at *https://doi.org/10.1787/9789264304604-en*.

relax regulatory frameworks. This position has often been advanced with little regard for its shortcomings and potential side-effects to sustainability, the rule of law, and human rights. As we explain later, responsible innovation does not always coincide with this general and primarily economic definition of innovation.

Second, it is challenging to regulate technological change because innovative products may disrupt the wider regulatory order, triggering concerns about its adequacy and regulatory legitimacy[53]. Differences in the timing of technology and regulation explain this difficulty. The literature has claimed there is sometimes a 'pacing gap' between the slow-going nature of regulation and the speed of technological change[54]. Technological innovations have specific development trajectories, investment and life cycles, and path dependencies that do not go well with the speed of technology[55]. Fast changing technologies challenge traditional regulatory techniques not only because regulators regulate slowly but also because there may be information asymmetries due to the reluctance of firms to disclose relevant information. This has been captured in the so-called Collingridge dilemma which explains that when an innovation emerges, regulators hesitate to regulate due to the limited availability of information[56]. Later when they have gathered enough information, it may be too late as technology may have changed or regulation may no longer be able to contain its risks and side-effects. In simple terms, regulators can typically only shape the development of a technology when it is at an early stage of development. However, at this stage, regulators do not know yet how a novel technology will affect society. Later, when technology has become societally embedded and regulators have gathered more information about their implications, it may no longer be possible to influence its development. Alternatively, this timing and information asymmetry problem can also result in overregulation which stifles

[53] R. Brownsword, K. Yeung & E. Scotford (eds.), *The Oxford Handbook of Law, Regulation and Technology*, cit. at 51.
[54] G.E. Marchant, *Governance of Emerging Technologies as a Wicked Problem*, cit. at 50.
[55] B.-J. Koops, *The Concepts, Approaches, and Applications of Responsible Innovation*, in B.-J. Koops, I. Oosterlaken, H. Romijn, T. Swierstra & J. van den Hoven (eds.), *Responsible Innovation 2*, 1 ff. (2015).
[56] D. Collingridge, *The Social Control of Technology* (1980).

investment in R&D and ultimately innovation due to the imposition of heavy burdens on businesses[57].

In most cases, however, regulation offers sufficient flexibility to accommodate new technological developments. However, it remains unclear how regulation can be employed to truly support and advance innovation. Legal and interdisciplinary scholarship as well in grey literature have offered different perspectives on how regulation can play an important role for innovation. We review in the following section the most common set of arguments.

4.2. Perspectives on the Regulation of Technological Change and Responsible Innovation

Regulation is a multilevel, multi-instrument, and complex phenomenon that is in permanent dialogue with society. Innovation and regulation have thus a reflexive relationship and depending on how they engage, the results will be different. A number of scholars have posited that regulation can steer innovation in a specific direction[58]. As noted by Butenko and Larouche, innovation is partially pre-determined (intentionally or unintentionally) by the existing structure of the regulatory environment[59]. Lobel has demonstrated that labor regulation, in particular non-competition clauses, may have a negative impact on the innovation process, as human capital relocates to areas with fewer mobility constraints[60].

At the same time, Ford has also argued that innovation will affect regulation no matter how it is structured: 'in its design, regulation constitutes the spaces in which innovation happens. It creates loopholes, opportunities, boundaries, and incentives. Different tradeoffs will make sense in different circumstances'[61]. Regulators aiming to deepen

[57] L. Bennett Moses, *Regulating in the Face of Sociotechnical Change*, cit. at 51.
[58] A. Butenko, P. Larouche, *Regulation for innovativeness or regulation of innovation?*, cit. at 9, 62. See also N.A. Ashford, R.P. Hall, *The Importance of Regulaton-Induced Innovation for Sustainable Development*, 3 Sustainability 270 (2011).
[59] A. Butenko, P. Larouche, *Regulation for innovativeness or regulation of innovation?*, cit. at 9. See also E. Longo, *Time and Law in the post-COVID-19 Era*, cit. at 27.
[60] O. Lobel, *Noncompetes, Human Capital Policy & Regional Competition*, 45 J. Corp. L. 931 (2020); Id., *Talent Wants to Be Free* (2013).
[61] C. Ford, *Making Regulation Robust in the Innovation Era*, in M. Maggetti, F. Di Mascio & A. Natalini (eds.), *Research Handbook on Regulatory Authorities* (2022).

their understanding of how innovation interacts with regulation need to consider the specific context in which innovation occurs. As innovation manifests differently across sectors, so too must the regulatory response be tailored. Ford identifies three main issues that arise from the misalignment of innovation with regulation: First, information and data gaps where regulators may lack sufficient knowledge about the potential risks associated with new products or practices[62]. Second, the issue of visibility, often a consequence of incremental innovation, where gradual changes remain unnoticed until a regulatory concern becomes critical. As technology changes, unforeseen risks, uncertainty, and opportunities may emerge. Despite the inevitable differences between different new technologies, uncertainty as to how and when to regulate is a common regulatory challenge. Third, the legibility challenge, which encompasses the difficulty in comprehending one's surroundings and forming accurate judgments.

The previous perspectives could suggest that innovation-friendly regulation should be flexible. Research has shown that while excessive regulation can indeed impact negatively R&D investment, rigid legal systems may be preferable at early stages of the technological development when legal certainty is essential to ensure commitment[63]. Scholarship has, nonetheless, cautioned against the impact of excessive regulation and obsolete regulation. On the one hand, excessive regulation, fuelled by special interest groups, has been found to stifle innovation in some sectors such as the legal profession, where the development of novel integrated legal products (for example, tax and accounting processes) and LegalTech (e.g., online divorce platforms), have been restricted by regulatory perceptions of how legal services should be delivered[64]. On the other, excessive regulation can be the result of the accumulation of regulations, including obsolete rules. This may impose significant costs on businesses and hinder innovation. This issue often stems from regulations that are predicated on outdated technological assumptions, owing to regulatory agencies' insufficient investment in

[62] Ibidem.
[63] L. Anderlini, L. Felli, G. Immordino & A. Riboni, *Legal Institutions, Innovation, and Growth*, 54 Int. Econ. Rev. 937 (2013).
[64] G.K. Hadfield, *Legal Barriers to Innovation: The Growing Economic Cost of Professional Control over Corporate Legal Markets*, 60 Stan. L. Rev. 1689 (2008).

resources and staff training[65]. The lack of dialogue between regulators and firms has also been blamed for this disconnect between regulators and the innovation process. Stamford has argued that public regulators could stimulate innovation by creating collaborative initiatives between government, stakeholders, and innovators[66]. This would expand the role of governments in the innovation process beyond the financing of research through subsidies, tax incentives, and intellectual property rights[67]. By engaging more actively with innovators, public regulators can offer support with legal compliance, promote the refinement of outdated regulation, and contribute to the improvement of regulation while driving the innovation process forward.

The adoption of regulatory sandboxes and other innovation-friendly policies reflects the growing academic consensus on the symbiotic relationship between regulatory frameworks and technological change and the need to address some of the mentioned challenges. This scholarly and policy position is also supported by the argument that the EU's competitive edge and capacity for innovation can be significantly enhanced by adopting a regulatory stance that actively fosters and accommodates innovation. The adoption of the controversial innovation principle occurred within this context[68].

The proposed "European Declaration on Digital Rights and Principles for the Digital Decade" recognizes the need for an appropriate regulatory framework to underpin a responsible digital transformation[69]. This is confirmed in other policy documents developed at the EU level, such as the "New European Innovation Agenda" and the

[65] P. Ibáñez Colomo, *Future-Proof Regulation against the Test of Time: The Evolution of European Telecommunications Regulation*, 42 Oxford J. Legal Stud. 1170 (2022).
[66] S. Samford, *Innovation and public space: The developmental possibilities of regulation in the global south*, 9 Regul. Gov. 294 (2015).
[67] See also C. Goanta, *How Technology Disrupts Private Law: An Exploratory Study of California and Switzerland as Innovative Jurisdictions*, TTLF Working Papers No. 38, Stanford-Vienna Transatlantic Technology Law Forum 1 (2018).
[68] European Commission, Directorate-General for Research and Innovation, F. Simonelli, F., A. Renda, *Study supporting the interim evaluation of the innovation principle: final report*, Publications Office, 2019, *https://data.europa.eu/doi/10.2777/620609*.
[69] *European Declaration on Digital Rights and Principles for the Digital Decade*, COM(2022) 28 final, paragraph 6 of the Preamble.

Green Deal Industrial Plan for the Net-Zero Age[70]. These policy documents highlight some of the complexities of regulating innovation and reveal a growing attention towards the shortcomings of only considering innovation from an economic and business perspective. The focus of traditional scholarship on the relationship between regulation and economic innovation has ignored the potential downsides of unconstrained innovation on sustainability, the rule of law and human rights. This has resulted in a reformulation of the debate which is now focused on regulation and responsible innovation.

Responsible innovation redefines innovation in light of a set of values and moral considerations. There is a wealth of literature on responsible innovation which describes it as the incorporation of societal values, ethics and ideas of societal desirability, acceptability, and sustainability within the innovation process[71]. This strand of scholarship turns moral and public values (e.g., sustainability, privacy, autonomy) into requirements for design, research and development at an early stage of technology[72]. Responsible innovation seeks to contribute to sustainable development by advancing governance schemes that support innovation that avoid harm and promote products that protect the Earth's life-support system and improve living conditions (e.g., alleviate poverty)[73]. Responsible innovation entails a wide range of interests to be considered when regulating innovation. It is therefore important to reflect upon the most suited regulatory instruments to reach these objectives.

The regulation of innovation and in particular responsible innovation has been framed both by the longstanding scholarship on risk management, innovation studies, and the more recent ecological, public health, and political crises. To illustrate, both natural disasters and the pandemic have urged us to reflect on the relation with our

[70] Communication from the European Commission, *A New European Innovation Agenda*, COM(2022) 332, 5.7.2022. This is also recognized by Advocate General Pitruzzella in one of the first cases where the European Court of Justice addressed automated decision-making.

[71] B.-J. Koops, *The Concepts, Approaches, and Applications of Responsible Innovation*, cit. at 55.

[72] Ibidem.

[73] C. Voegtlin, A.G. Scherer, *Responsible Innovation and the Innovation of Responsibility: Governing Sustainable Development in a Globalized World*, 143 J. Bus. Ethics 227 (2017).

ecosystem and reconsider the role of scientific expertise as a resource against ecological and health catastrophes and disinformation about them[74]. These phenomena have also changed our relationship with "physical" spaces: they accelerated the evolution of the digital dimension and contributed to the development of technologies allowing us to interact in completely digitalized environments[75]. In the next section, we discuss how regulatory sandboxes engage with these new perspectives and contribute to the regulation of responsible innovation.

5. Regulatory Sandboxes and (Responsible) Innovation: Potential and Critique

This section explores how regulatory sandboxes can be instrumental in promoting responsible innovation. However, considering existing proposals to expand the use of this regulatory instrument, this section also presents a set of objections against it and words of caution.

5.1. Regulatory Sandboxes and Responsible Innovation: Potential

By strategically timing interventions, fostering dynamic partnerships between regulators and innovators, and adapting to shifts in societal values and needs, regulatory sandboxes hold the potential of effectively guiding the development of responsible innovation[76].

[74] See A.C. Amato Mangiameli, *Tecno-regolazione e diritto*, cit. at 20. The Author offers interesting reflections on the relationship between technology, law and regulation and society. See also O.W. Lembcke, *Techno-regulation and law: rule, exception or state of exception?: A comment to Han Somsen and Luigi Corrias*, 40 Rechtfilosofie & Rechtstheorie 131 (2011); L. Bennett Moses, *Regulating in the Face of Sociotechnical Change*, cit. at 51.

[75] The evolution of the digital sphere is currently causing a debate around the concept of "metaverse". See the study from the European Parliamentary Research Service, *Metaverse Opportunities, risks and policy implications*, June 2022, where the Metaverse is described as "an immersive and constant virtual 3D world where people interact through an avatar to enjoy entertainment, make purchases and carry out transactions with crypto-assets, or work without leaving their seat"; L. Floridi, Metaverse: a Matter of Experience, 35 Philos. Technol., No. 73, 1 (2022).

[76] See P. Vallance, *Pro-innovation Regulation of Technologies Review*, cit. at 1, 7-8.

Time: Temporary Character and Regulatory Flexibility

First, regulatory sandboxes set temporary measures that can respond to new challenges. This timing element helps address the critique that regulation may become, at some point, obsolete and disconnected from society, generating costs for firms, uncertainty, and creating a competitive disadvantage for businesses[77]. Nonetheless, Leenes et al. also remind us that the critique that regulation lags behind innovation often is exaggerated. Regulatory and legal frameworks tend to be relatively flexible and able to accommodate to most technological changes[78]. Nevertheless, temporary and experimental regulatory systems tend to offer the additional flexibility that may be required for the development of disruptive innovation[79].

Collaboration

Second, regulatory sandboxes reshape the relationship between regulators and market actors. They enable a closer public-private collaboration which benefits both innovators and regulators. Innovators can benefit from the artificially created regulatory environment to test the introduction of their products in the market. Within the sandbox, they do so under the supervision of the competent supervisory authority and may profit from bespoke guidance and regulatory comfort. Regulators, on the other side, have the chance to get to know a certain innovation, address the information asymmetries that are inherent to the innovation process, and shape an ad hoc testing environment. Here they can ensure that certain values are protected and specific objectives are pursued. The regulation and compliance that emerge from regulatory sandboxes are born out of a dialogue between regulators and innovators. Moreover, sandboxes can benefit society at large as they facilitate the testing of innovations that would otherwise not be granted access to markets[80]. This collaborative nature can reduce power asymmetries between regulators and regulatees.

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[77] P. Ibáñez Colomo, *Future-Proof Regulation against the Test of Time*, cit. at 65.

[78] R. Leenes, E. Palmerini, B-J. Koops, A. Bertolini, P. Salvini & F. Lucivero, *Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues*, 9 Law Innovation & Tech. 1 (2017).

[79] C. Ford, *Making Regulation Robust in the Innovation Era*, cit. at 61.

[80] Regulatory sandboxes have also been defined as "schemes that enable firms to test innovations in a controlled real- world environment, under a specific plan developed

The demand for more flexible and collaborative regulation emerged in the late 90s as a response to less state-centered approaches to regulation. This concept has been depicted as a legal framework that creates "regulatory scaffolding," where public entities or regulators set the broad parameters, underpinnings, and institutional contours of a regulated domain, whilst deliberately leaving certain areas open within pre-defined, structured spaces. Flexible regulation was envisioned as porous and permeable to inputs coming from outside the regulatory structure and in particular by non-State actors[81]. Regulatory sandboxes contribute to this collaborative view of the regulatory process.

Evolving societal needs

Regulatory sandboxes enable regulation to adapt to changing societal values and overarching objectives. Regulating innovation with the "incorporation of societal values, ethics and ideas of societal desirability, acceptability, and sustainability" requires regulators to identify and balance such values and consider an extremely wide range of interests when defining the regulatory framework, increasing (and necessarily clearly defining) the space for the involvement of non-state actors in the policy making process. In the Communication 'A new European innovation agenda,' the European Commission underlines the importance of innovation for the achievement of the twin green and digital transition as well as the UN Sustainable Development Goals[82]. One of the five pillars of this agenda is the development of 'framework conditions for deep tech innovation'. This includes experimental approaches to regulation including regulatory sandboxes. Additionally,

and monitored by a competent authority. They are usually organised on a case-by-case basis, include a temporary loosening of applicable rules, and feature safeguards to preserve overarching regulatory objectives", European Commission, *2021 Better Regulation Toolbox*, tool #69. In the compromise text of the AIA, regulatory sandbox means "a controlled environment established by a public authority that facilitates the safe development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan under regulatory supervision" (amendment to Article 3 – paragraph 1 new point 44 g).

[81] C. Ford, *Innovation and the State: Finance, Regulation, and Justice* (2017).

[82] Communication from the European Commission, *A New European Innovation Agenda*, cit. at 70.

the OECD recently considered regulatory sandboxes for the regulation of artificial intelligence and digital transformation[83].

5.2. General Critique

The employment of regulatory sandboxes to advance responsible innovation can be criticized on multiple fronts. First, in the EU, regulatory sandboxes lack a single definition and institutional framework for their establishment[84]. This could lead to confusion among regulators and the fragmentation of the European single market[85]. Furthermore, there is a general misinterpretation of the functions of regulatory sandboxes and the differences between sandboxes and other regulatory and non-regulatory experimental instruments[86]. As recently stressed by the OECD with regarding AI, regulatory sandboxes can be used to govern and regulate technology alongside other tools, but this requires a clear understanding of the different mechanisms available and their potential applications. Currently, there is still a lack of an internationally agreed definition of these instruments and standard typologies[87]. In the mentioned publication, OECD attempted for the first time to provide a classification of regulatory sandboxes and other mechanisms, trying to offer internationally shared criteria. Similarly, the European Commission, in July 2023, published a Staff Working Document offering guidance on the distinction between regulatory sandboxes, pilots, living labs, testbeds and other forms of experimentation.

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[83] *Regulatory sandboxes in artificial intelligence*, OECD Digital Economy Papers, cit. at 1.

[84] For a comparison among the different forms of regulatory sandboxes developed in Europe, see M. Trapani, *L'utilizzo delle sandboxes normative*, cit. at 34.

[85] S. Ranchordás, *Experimental Regulations for AI: Sandboxes for Morals and Mores*, University of Groningen Faculty of Law Research Paper No. 7/2021, May 6, 2021 (last revised Jul. 12, 2021), available at *https://ssrn.com/abstract=3839744*. Literature also points out that the precise definition of regulatory sandboxes varies depending on the jurisdiction using it, see B.R. Knight, T.E. Mitchell, *The Sandbox Paradox: Balancing the Need to Facilitate Innovation with the Risk of Regulatory Privilege*, 72 S.C. L. Rev. 445 (2020).

[86] See *supra*, Section 2.

[87] "The newness of these mechanisms and lack of standard typologies means every sandbox is different". *Regulatory sandboxes in artificial intelligence*, OECD Digital Economy Papers, cit. at 1.

OECD classifies regulatory sandboxes based on the sphere of application (private/public/hybrid) and scope (law-specific; technology-based; generic/cross-sectorial; and regthech/govtech). However, current sandboxes proposals show a lack of understanding by regulators of these different approaches/applications. A shared and clear definition of regulatory sandboxes represents the first necessary step toward the possible creation of pan-European sandboxes[88], as planned within the proposed AI Act and recently attempted with Distributed Ledger Technologies[89].

A second line of critique concerns the experimental nature of regulatory sandboxes and their methodological validity. Regulatory sandboxes are often tailored to a specific sector, addressing a particular regulatory challenge, and meeting the needs of participants. This also means that those selected in a regulatory sandbox may benefit from a better market position, as they do not have to comply with the same regulatory burdens as other market actors. This could result in an uneven level-playing field. This possible "personalization" of the instrument and the resulting experiment may hinder the generalization of obtained results and, consequently, limit market-wide benefits[90]. In other words, the results obtained may only be valid for that specific sector, cohort, and regulatory project and a methodologically responsible generalization to other circumstances may not be possible. The proposed AI Act seeks to address some of these concerns with regards to the actual implementation of regulatory sandboxes, such as the risk of internal market fragmentation, lack of transparency and negative impacts on competition[91]. Article 53a (at the time of writing) provides for the Commission to adopt a delegated act "detailing the modalities for the establishment, development, implementation functioning and supervision of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation

[88] Ibidem.

[89] In February 2023, the European Commission launched a regulatory sandbox for innovative use cases involving Distributed Ledger Technologies (DLT).

[90] A. Attrey, M. Lesher, C. Lomax, *The role of sandboxes in promoting flexibility and innovation in the digital age*, Going Digital Toolkit, Policy Note, No. 2 (2020), available at *https://goingdigital.oecd.org/data/notes/No2_ToolkitNote_Sandboxes.pdf*.

[91] S. Ranchordás, *Experimental lawmaking in the EU*, cit. at 25, 7; Id., *Experimental Regulations for AI*, cit. at 85.

and exiting from the sandbox, and the rights and obligations of the participants, based on the provisions set out [in the AI Act]". Furthermore, Article 53 requires establishing authorities (i.e. authorities who set up and supervise the sandbox) to inform the AI Office (the Brussels-based 'European Artificial Intelligence Office' under Article 56 of the AI Act) of the establishment of a sandbox. The AI Office is then in charge of making publicly available a list of "planned and existing sandboxes". Lastly, paragraph 3 of article 53a, links sandboxes to "other Digital Single Market initiatives such as Testing & Experiment Facilities, Digital Hubs, Centres of Excellence, and EU benchmarking capabilities" thus acknowledging that there are other experimental mechanisms.

Many uncertainties concerning the use of sandboxes remain. For example, the scope and nature of AI regulatory sandboxes does not clearly emerge from the AI Act. At the time of writing, Article 53 lists the objectives of AI regulatory sandboxes such as the facilitation of the testing and development of innovative solutions related to AI systems as well the promotion of regulatory learning in a controlled environment[92]. However, further clarification may be needed regarding the design and classification of regulatory sandboxes, as some may have an experimental nature while others may primarily serve as collaborative compliance instruments.

A third source of concerns is the governance of regulatory sandboxes. The OECD mentions experimental regulation as governance frameworks susceptible of enabling the development of agile and future-proof regulation[93]. This governance element is particularly interesting with regard to responsible innovation and the necessary balancing of the different interests at stake. Regulatory sandboxes have the potential of giving direction to the innovation process so as to align it with overarching social, economic, and technological objectives and regulatory concerns. This governance element warrants further attention for several reasons. First, it relies on the active engagement and collaboration between regulators and innovators, setting them apart from other experimental regulations. Second, effective governance is

[92] See also recital 72.

[93] OECD, *Recommendation of the Council for agile regulatory governance to harness innovation* (Adopted by the Council at Ministerial level on 6 October 2021).

critical to understanding the potential and risks of regulatory sandboxes, particularly the risk of them being co-opted as vehicles for private interest lobbying. This last point merits further consideration.

5.3. Regulatory Capture

Despite its benefits, close collaboration between regulators and regulatees can generate regulatory capture and creating 'revolving door' effects[94]. While, in many cases, only smaller market actors (startups, SMEs) and hence, in theory, less powerful regulatees are eligible to participate in regulatory sandboxes, these instruments require by design close collaboration between regulators and firms and regular exchange of information. As discussed in the context of *Sperimentazione Italia* (see Section 2.2.2.), regulators invite regulatees to express their regulatory needs and identify solutions for regulatory burdens. This general-purpose sandbox also opens the door to an extensive regulatory discussion of the firms' position regarding a large number of perceived regulatory burdens and solutions on how to alleviate them.

The regulatory dialogue generated by general-purpose sandboxes like *Sperimentazione Italia* can create scenarios where regulators are systematically exposed to arguments from firms that may not align with the public interest. While this phenomenon may have many invisible ramifications in the case of general-purpose sandboxes, capture is also a risk in sector-specific sandboxes.

Firms participating in sandboxes have thus more opportunities to influence regulatory outcomes to reshape the regulatory environment in their favor, potentially at the expense of competitors, consumers, and, more generally, the public interest. The example of *Sperimentazione Italia* also reveals another aspect of regulatory sandboxes that can make regulators more prone to regulatory capture: as explained above, there is limited transparency regarding the operationalization of this regulatory environment. This lack of transparency contrasted with other sector-specific sandboxes where, at times, openness requirements can be perceived as excessive and discouraging to firms wishing to protect their business models. If the operations within a regulatory sandbox lack transparency, there is a greater chance for

[94] See also I. H-Y Chiu, *A Rational Regulatory Strategy for Governing Financial Innovation*, 8 Eur. J. Risk Regul. 743 (2017); J. McCarthy, *From childish things*, cit. at 49.

regulatory capture. This occurs as the public and other stakeholders outside the sandbox are not able to understand the fairness of the sandbox measures. For outsiders, it may difficult to discern if the issued bespoke guidance, tailored regulations, and waivers were solely justified by the experimental character of the regulatory sandbox or may grant an unwarranted benefit to certain firms which will not be shared by others. Furthermore, this lack of transparency makes it more complex to hold regulators accountable for their decisions in the context of regulatory sandboxes.

Regulatory capture has been loosely defined and misused over the last decades. Therefore, at first sight, it may seem difficult to imagine that regulatory sandboxes, with their limited duration, small cohorts, and restricted scope, can result in regulatory capture. However, in regulation, there is not one but many degrees of regulatory capture. Indeed, not all forms of regulatory influence generate the same capture dynamics or resulting impact. It is thus important to distinguish between strong and weak capture: while strong capture impairs the goal of regulation of pursuing the public interest; weak capture is, in some cases, the outcome of a compromise between regulators and market actors and it may still serve the public interest[95]. Furthermore, capture has a subjective dimension: as Coglianese has explained, "different people see different things. Those on the political left see signs of capture in weak laws or lax law enforcement, while those on the right see capture in strict laws imposing burdens on smaller businesses and new competitors"[96]. Capture is difficult to define, prove, and grasp. However, regulatory capture is mostly defined by the exercise of influence on regulators, for the benefit of the industry, and in detriment of the public interest. In other words, collaboration between firms and regulators in the context of a sandbox does not necessarily result in capture. Rather, regulation should be collaborative and should be the result of a regulatory conversation, rather than a monologue. Most regulations are indeed the result of information exchange, regulatory

[95] D. Carpenter, D.A. Moss, *Introduction*, in Id. (eds.) *Preventing Regulatory Capture* (2014).

[96] C. Coglianese, *The Elusiveness of Regulatory Capture*, The Regulatory Review, Jul. 5, 2016, available at *https://www.theregreview.org/2016/07/05/coglianese-the-elusiveness-of-regulatory-capture/*.

conversations, compromises, and a balancing of costs and benefits. A regulation has only been captured, at some level, if the regulation no longer serves the public interest.

McCarthy argues that the shortcomings of regulatory capture can be mitigated by legislative and policy considerations such as the ones proposed in the AIA[97]. This regulation, in its current proposed version, requires guided coordination of national authorities by a European AI Board. Enhanced transparency requirements such as publication of evaluation reports and justification of adopted measures can help address some of the concerns on regulatory capture, helping stakeholders understand better the reasons underlying certain regulatory interventions. The short duration of sandboxes and diversity of cohorts can also minimize regulatory capture. Ultimately, capture can be countered if regulators turn sandboxes into open, collaborative, and transparent conversational spaces from which the whole industry and consumers can benefit.

6. Conclusion and Broader Implications for Public Law

Regulation is a multilevel, multi-instrument, and complex phenomenon that is in permanent dialogue with society. The regulation of technological change and innovation is particularly challenging and requires the use of novel and more flexible instruments that can address the uncertainty and risks that often accompany the innovation process[98]. Regulatory sandboxes have emerged in this context as a responsive, temporary, and collaborative instrument that can help regulators and innovators reshape the regulatory process. This article discussed this subject both in Italy and in the European contexts. While regulatory sandboxes have the potential to reduce regulatory burdens and redesign more innovation-friendly regulatory frameworks, this instrument is not a panacea. We can distinguish two sets of key takeaways from our analysis.

First, there is an important difference between sector-specific and general-purpose regulatory sandboxes. Sector-specific

[97] J. McCarthy, *From childish things*, cit. at 49.
[98] R. Romano, *Regulating in the Dark and a Postscript Assessment of the Iron Law of Financial Regulation*, 43 Hofstra L. Rev. 25 (2014).

regulatory sandboxes establish specific criteria, objectives, and allow market actors to be supervised directly by the regulator that is the closest to them. General-purpose regulation aim to pursue more general goals. However, pursuing innovation on general terms is a complex task. *Sperimentazione Italia* is an example of the latter: designed with the best of intentions to promote responsible innovation in the public sector, it has yet to attract broader market attention. Limited information, transparency, the imposition of numerous burdens on applicants, and its broader scope have not allowed the market to fully engage with the intended benefits of the regulatory sandbox. Regulatory sandboxes that offer limited guidance risk generating regulatory fragmentation, disregarding the risk of creating market inequalities among market participants, and generating legal uncertainty and may thus not be able to deliver fair and generalizable results.

Also, when regulating technological change, regulators should be aware of the possibility that the use of regulatory sandboxes instead of generally applicable regulations may change the regulatory message. Some regulatory burdens may be unnecessary while compliance with others may be essential to address certain risks. This should also not be forgotten when seeking to promote responsible innovation. Regulation should prioritize the rule of law and fundamental rights over technology or notions of economic innovation. Acknowledging the role of regulatory sandboxes in fostering responsible innovation is critical, yet it is equally important to address legal and regulatory challenges, including the risk of regulatory capture and disparities in market competition. Implementing comprehensive guidelines and ensuring transparency can effectively mitigate these issues.

The second set of takeaways concerns the broader implications of regulatory sandboxes to public law, both in Italy and in the EU. Moving forward, the growing adoption of regulatory sandboxes asks us to rethink the relationship between regulators and market actors and the need to continue to promote regulatory dialogues. Indeed, for decades, regulation has been losing its national, top-down, and authoritative character[99]. Regulators regulate now also through reputation, information and data, and the establishment of closer connections with market actors. Beyond discussed criticalities and necessary

[99] S. Cassese, Public law in crisis?, 15 ICON 585 (2017).

improvements, this is one of the key promises of regulatory sandboxes to public law: both sector-specific and general-purpose regulatory sandboxes enhance the collaborative dimension of public law, underlining the need for regulatory conversations with market actors. We have learned from *Sperimentazione Italia* and existing scholarship on sandboxes that initiating these regulatory conversations does not suffice. It is important to ensure that regulatees are provided with clarity, transparent information, and certainty.