REGULATORY SANDBOXES UNDER THE DRAFT EU ARTIFICIAL INTELLIGENCE ACT: AN OPPORTUNITY FOR SMES? [*]

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ABSTRACT

More than a year after the European Commission submitted the Proposal for the Artificial Intelligence Act (AI Act), the EU institutions are still working on adopting this groundbreaking regulation. The Draft AI Act contains a uniform set of horizontal rules for the development, marketing, and use of AI systems in conformity with the Union values, applying the proportionate risk-based approach. The aim is to avoid regulatory friction and fragmentation and to create a well-functioning internal market for AI systems and technologies. However, the policy and regulatory choices should not obstruct the innovative potential and transformative impact of AI systems and technologies on the society and economy. The Draft AI Act, therefore, introduces AI regulatory sandboxes, as a testing ground for deciding what to regulate and how. This is a novel regulatory approach, fostering innovation, development, and testing of AI systems under strict regulatory oversight before these systems are placed on the market. The proposed solution from the Draft AI Act has caused both excitement and criticism in the legal doctrine and industry. This paper will explore the benefits and challenges of AI regulatory sandboxes. The draft provisions will be critically evaluated, drawing from the experience in the FinTech industry, especially considering the effect on SMEs. The EU's ambition is to set up a robust and disruption-resilient, yet flexible, innovation-friendly, and future-proof regulatory framework for AI, and the intuitive appeal of AI regulatory sandboxes for both regulators and innovators deserves an in-depth examination.

KEYWORDS: *Artificial Intelligence Act, regulatory sandboxes, SMEs*

1. INTRODUCTION

Regulating AI has become a key political priority in the EU. Developing responsible AI, with a human-centric approach, is the ultimate objective and the bottom line of all policy and regulatory initiatives in this area.[1] Disruptive technologies, such as AI, require a timely and appropriate regulatory response. At the same time, they present a challenge to the traditional regulatory paradigm.[2] The importance of "structured experimentalism"[3] and "smart regulation"[4] when it comes to regulating AI technologies is crucial for allowing their innovative character to come through for the benefit of society, while at the same time curbing their potential risks. The result of the ongoing legislative process for the adoption of the Artificial Intelligence Act[5] will show whether the EU will succeed in finding the right balance between the interest of setting up and preserving the EU's technological leadership, on the one hand, and the protection of Union values, fundamental rights and principles to the benefit of its citizens, on the other. The Draft AI Act contains a uniform set of horizontal rules for the development, marketing, and use of AI systems in conformity with the Union values, applying the proportionate risk-based approach. The aim is to avoid regulatory friction and fragmentation and to create a well-functioning internal market for AI systems and technologies. One of the proposed solutions which try to incorporate the innovative or experimental approach to law-making is the introduction of AI regulatory sandboxes. This is a novel regulatory regime and a policy instrument aimed at fostering innovation by

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[1]   On the importance of human rights-centered design for AI see more in: Yeung, K.; Howes, A.; Pogrebna, G.: AI governance by human rights-centered design, deliberation, and oversight. An end to ethics washing, in: Dubber, M. D.; Pasquale, F.; Das, S. (eds.): *The Oxford Handbook of Ethics of AI*, Oxford, 2020, pp. 77 – 106.

[2]   Barfield, W.: Towards a law of artificial intelligence, in: Barfield, W.; Pagallo, U., *Research Handbook on the Law of Artificial Intelligence*, Cheltenham - Northampton, 2018, pp. 2- 39, p. 22; Liu, H.-Y. *et al.*: *Artificial intelligence and legal disruption: a new model for analysis*, Law, Innovation and Technology, 12(2) 2020, pp. 205-258, DOI: 10.1080/17579961.2020.1815402; Brummer, C.; Yadav, Y.: *Finntech and the innovation trilemma*, The Georgetown Law Journal, 107(2) 2019, pp. 235 – 307, p. 282.

[3]   Zetzsche, D. A. *et al.*: Regulating a revolution: From regulatory sandboxes to smart regulation, in: Fordham Journal of Corporate & Financial Law 23(1) 2017, pp. 31-103, p. 64, 91; see also Wischmeyer, T.; Rademacher, T. (eds.): *Regulating Artificial Intelligence*, Cham, 2020.

[4]   Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 91; see also Leenes, R. *et al.*: *Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues*, Law, Innovation and Technology, 9(1) 2017, pp. 1 - 44, p. 41, 43, DOI: 10.1080/17579961.2017.1304921.

[5]   European Commission: Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts, COM(2021) 206 final, 21.4.2021. Further referred to as the Draft AI Act.

allowing the development and testing of AI systems under strict regulatory oversight before these systems are placed on the market. The proposed solution from the Draft AI Act has caused both excitement and criticism in the legal doctrine and industry. This paper aims to explore the benefits and challenges of AI regulatory sandboxes under the Draft AI Act.

To provide a background for our discussion, we will start by identifying the regulatory challenges associated with AI in general (2). We will then proceed with analyzing the concept of a regulatory sandbox, as a form of experimental law-making. We will outline its origins, objectives, forms, organization, and impact (3.1). The comparison with FinTech regulatory sandboxes, which are already implemented in various jurisdictions, will serve to evaluate the impact of regulatory sandboxes on SMEs (3.2). These findings will be put in perspective by providing a background for the concept of regulatory sandboxes at the EU level (4.1.) and analyzing the solution under the Draft AI Act (4.2). This is followed by an in-depth examination of the benefits and challenges of AI regulatory sandboxes to answer whether they are fit for purpose and whether their intuitive appeal for both regulators and innovators is justified (4.3). We conclude by offering some remarks and suggestions to feed into the ongoing and future discussions (5).

2. REGULATING AI

There are numerous issues associated with the regulation of AI and AI systems already identified in the literature.[6] The most obvious challenge is how to define AI, as a concept and technology. We have dealt with this question elsewhere,[7] and there is abundant academic literature dedicated to finding a workable definition of AI, especially focusing on the intersection between law and technology.[8] For the purpose of our discussion here, we can rely on a broad

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[6]   See e.g. Wischmeyer, T.; Rademacher, T. (eds.): *op. cit.* (fn. 3); Custers, B.; Fosch-Villaronga, E. (eds.): *Law and Artificial Intelligence. Regulating AI and Applying AI in Legal Prac*tice, The Hague, 2022.

[7]   See Pošćić, A.; Martinović, A.: Towards a regulatory framework for Artificial Intelligence: An EU approach. In: Drezgić, S. *et al.* (eds.): *Contemporary Economic and Business Issues*, Rijeka, 2021, pp. 49 – 62, p. 50 – 51; Pošćić, A.: *Postoji li potreba pravnog uređenja umjetne inteligencije u Europskoj uniji – razlozi za i protiv*, Zbornik Pravnog fakulteta Sveučilišta u Rijeci, 42(2) 2021, pp. 385-404, DOI:10.30925/zpfsr.42.2.7.

[8]   See e.g. Russel, S. J. and Norvig, P.: *Artificial Intelligence: A Modern Approach*, 3rd Ed., New Jersey, 2010; Nilsson, N. J.: *The Quest for Artificial Intelligence: A History of Ideas and Achievements*, Cambridge, 2010; Stone, P. *et al*.: *Artificial Intelligence and Life in 2030. One Hundred Year Study on Artificial Intelligence: Report of the 2015-2016 Study Panel*, Stanford University, Stanford [http://ai100.stanford.edu/2016-report], accessed: 18/11/2022; Pei, W.: *On*

and all-encompassing definition of AI as "a collection of technologies that combine data, algorithms and computing power"[9], whether they are purely software-based or embedded in hardware devices.[10] This approach to defining AI seems to be the most widely accepted by EU institutions.[11] Finding and relying on a workable definition of AI, despite the multi-layered complexity associated with its various applications, is necessary for creating a coherent legal framework for its use.[12]

The complexity associated with regulating AI arises from the described definitional problem, but also from the fact that AI is a source of potential public risk, with distinctive features differentiating it from other public risks and thus making it more difficult to regulate.[13] Scherer frames these distinctive features in terms of the discreetness problem, the diffuseness problem, the discreteness problem, the opacity problem, the foreseeability problem, the narrow control

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defining Artificial Intelligence, Journal of Artificial General Intelligence 10(2), 2019, pp. 1-37, DOI: 10.2478/jagi-2019-0002.

[9]   European Commission: White paper on Artificial Intelligence - A European approach to excellence and trust, COM(2020) 65 final, Brussels, 19.2.2020, p. 2.

[10]   European Commission: Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Artificial Intelligence for Europe, COM(2018) 237 final, Brussels, 25.4.2018.

[11]   See European Commission: Artificial Intelligence for Europe, *op. cit.* (fn. 10), p. 1; European Commission, White Paper on Artificial Intelligence – A European approach to excellence and trust, *op. cit.* (fn. 9), p. 2. Compare with the definition of the 'AI System' from Article 3(1) (1) of the Draft AI Act: "AI system means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with", and the definition proposed by the Independent High-Level Expert Group on Artificial Intelligence defining AI systems as "…software (and possibly also hardware) systems designed by humans…". See Independent High-Level Expert Group on Artificial Intelligence (HLEG): A definition of Artificial Intelligence: Main capabilities and disciplines, Brussels, 2018, p. 4 [https://digital-strategy.ec.europa.eu/en/library/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines], accessed 18/11/2022.

[12]   For a broader discussion see Renda, A.: *Artificial Intelligence. Ethics, governance and policy challenges*. Report of a CEPS task force, Brussels, 2019, p. 8 – 13. An analysis of stakeholders' position on the definition of AI proposed by the European Commission reveals that it is either perceived as too broad, or to narrow. See European Commission: Study to Support an Impact Assessment of Regulatory Requirements for Artificial Intelligence in Europe, Final report (D5), Luxembourg, 2021, p. 105 – 106.

[13]   Scherer, M. U.: *Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies and Strategies*, Harvard Journal of Law and Technology 29(2) 2016, pp. 353 – 400, p. 358; see also Chesterman, S.: *We, the robots? Regulating Artificial Intelligence and the limits of the law*, Cambridge, 2021, p. 13 and following.

problem, and the general control problem.[14] Whereas discreetness, foreseeability, discreteness, and opacity are related mostly to the field of AI research and development, when combined with foreseeability, the narrow and the general control problem, which are mostly associated with liability issues, create specific regulatory challenges for *ex ante* regulation. To put it plainly, it is difficult to regulate (and foresee all potential consequences of) something which can be developed by anyone with a computer or smartphone and an Internet connection i.e. without substantial resources and infrastructure (discreetness problem), when a single component can be devised by individuals located far away from one another (diffuseness problem), in different locations, at different times and without any conscious coordination (discreteness problem), where the technologies underlying the AI will be opaque to most regulators and may not be susceptible to reverse engineering (opacity problem)?[15] Building on those features is the liability gap because AI systems are designed to be autonomous and their operation may not be foreseeable even for the original programmers (foreseeability), which can lead to the loss of control by the humans who are legally responsible for their operation and supervision (narrow or local control problem), or by any human (loss of general control).[16] This description perfectly encapsulates the inherent dilemma in regulating AI: while *ex ante* regulation might be difficult, *ex post* regulation might be ineffective.

Nevertheless, the potential of AI systems to cause individual, collective, and societal harm, and the need to address this issue, is well established.[17]

The innovative potential of emerging digital technologies, such as AI and machine learning, automated decision-making, distributed ledger technology, 5G, quantum computing, etc. naturally collides with the existing norms in place. Law has a way of adapting to continuous social, economic, scientific, and technological developments. The "resilient fragility"[18] of law remains a constant, even in the face of rapidly evolving new technologies. However, AI is a disrup-

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[14]   Scherer: *op. cit.* (fn. 13), p. 359.

[15]   *Ibid.*, p. 363 – 365.

[16]   *Ibid.*, p. 366.

[17]   Smuha, N. A.: *Beyond the individual: governing AI's societal harm*, Internet Policy Review 10(3) 2021 [https://doi.org/10.14763/2021.3.1574], p. 4. On the analysis of the risk-based approach in the EU regulation of digital technologies see De Gregorio, G.; Dunn, P.: *The European risk-based approaches: Connecting constitutional dots in the digital age*, Common Market Law Review 59(2) 2022, pp. 473–500.

[18]   Pasquale, F.: Foreword. The resilient fragility of law, in: Deakin, S.; Markou, C.: *Is law computable? Critical Perspectives on law and Artificial Intelligence*, Oxford – New York, 2020, pp. v – xvi. On legal system's adaptive complexity see: Ruhl, J. B., *Law's complexity: A primer*, Giorgia State University Law Review, 24(4) 2008, pp. 885 - 912.

tive technology,[19] amplifying the well-known Collingridge dilemma[20] in the societal control of technology, or even "accelerating the pace of a pacing problem",[21] as highlighted by the techno-libertarians.[22] As Collingridge succinctly put it, regulating technology is difficult, in the early stages because its impact cannot be easily predicted, and by the time it reaches advanced stages and undesirable consequences are discovered, technology has become so entrenched that intervention is expensive or impossible.[23] For some, this is a reason to renounce anticipatory governance and *ex ante* hard law solutions, because technological innovation outpaces the ability of laws and regulations to keep up.[24] In this view, legislators are unable to cope with the crowding-out effect of tech regulation, because "by the time policymakers start to understand one tech problem, another more pressing one crowds it out."[25]

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[19]   As a disruptive technology, AI introduces "radical changes with the possibility of rendering obsolete previous ways of performing tasks or making products". See Liu, H.-Y.: *The power structure of artificial intelligence*, Law, Innovation and Technology, 10(2) 2018, DOI: 10.1080/17579961.2018.1527480, pp. 197 – 229, p. 197. It is necessary to develop a general holistic model to respond to the legal disruption caused by new technology, because it is evident that reactive, domain-specific regulatory focus on certain activity areas is not appropriate. See Liu, H.-Y. *et al*.: *op. cit*. (fn. 2), p. 10.

[20]   Collingridge, D.: *The Societal Control of Technology*, New York, 1980: "The social consequences of a technology cannot be predicated early in the life of the technology. By the time undesirable consequences are discovered, however, the technology is often so much part of the whole economics and social fabric that its control is extremely difficult."

[21]   Thierer, A.: *Governing Emerging Technology in an Age of Policy Fragmentation and Disequilibrium*, American Enterprise Institute, 2022, available at SSRN [https://ssrn.com/abstract=4099605] or [http://dx.doi.org/10.2139/ssrn.4099605], accessed 18/11/2022; Thierer, A.: *The Pacing Problem, the Collingridge Dilemma & Technological Determinism*, 16 August 2018 [https://techliberation.com/2018/08/16/the-pacing-problem-the-collingridge-dilemma-technological-determinism/], accessed 18/11/2022.; Hagemann, R., Huddleston Skees, J.; Thierer, A.: *Soft law for hard problems: The governance of emerging technologies in an uncertain future*, Colo. Tech. L. J. 17(1) 2018.

[22]   Marchant, G. E.: The Growing Gap Between Emerging Technologies and the Law, in: Marchant, G. E.; Allenby, B. R.; Herkert, J. R. (eds.): *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight. The Pacing Problem*, Dordrecht, 2011; Thierer, A.: *Permissionless Innovation. The continuing case for comprehensive technological freedom*, Revised and expanded edition, Arlington, 2016.

[23]   Leenes, R. *et al*.: *op. cit*. (fn. 4), p. 35.

[24]   Thierer, A.: Permissionless Innovation, *op. cit*. (fn. 22), p. 110.

[25]   Thierer, A.: Governing Emerging Technology in an Age of Policy Fragmentation and Disequilibrium, *op. cit*. (fn. 21), p. 3.

However, many ways are showing that the law can (and must attempt to) cope with this regulatory challenge. The "technological push"[26] requires a smart and experimental regulatory approach.[27] For example, the principles of technological neutrality and functional equivalence are applied to overcome some of these difficulties in regulation. The principle of technological neutrality requires the adoption of neutral rules concerning technology, to be able to accommodate any future development without further legislative work,[28] as well as not to discriminate against any particular type of technology.[29] In the latter sense, it has been in application in the EU since the early 2000s.[30] Increasingly, however, the principle of technological neutrality is understood in its former sense, as "future-proof" legislation.[31] Any piece of legislation should strive to be "future-proof", but this standard is as desirable, as it is elusive when it comes to regulating rapidly advancing new technologies with unpredictable impacts. Legal futureproofing is thus just part of the formula for an antidote to legal disruption. A prerequisite for technological neutrality is the functional equivalence principle, which is based on non-discrimination and the require-

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[26] When technological innovation is taken as a solution to all societal (and economic) problems, a strong technology push entails uneasy trade-offs between values and affects the established safeguards (e.g., more security – less privacy, etc.). See Leenes, R. *et al.*: *op. cit.* (fn. 4), p. 33.

[27] Cortez argues that regulators should adapt the regulatory toolkit for disruptive innovation, and use experimental rules, regulatory sunsets, or rulemaking deadlines to calibrate their approach to novel technologies or business practices. See Cortez, Nathan, *Regulating Disruptive Innovation*, Berkeley Technology Law Journal, 29 2014, pp. 175 – 228, p. 199 and following.

[28] See e.g., UNCITRAL Model Law on Electronic Commerce [https://uncitral.un.org/en/texts/ecommerce/modellaw/electronic_commerce], accessed 18/11/2022.

[29] I.e. the regulator should not be the one to pick technological winners and losers. In the EU regulatory framework "technology neutrality" should be understood as the freedom of individuals and organisations to choose the most appropriate and suitable technology for their needs. See also Ducuing, C.: *Legal principles behind technical complexities*, 9 April 2019 [https://www.law.kuleuven.be/citip/blog/legal-principles-behind-technical-complexities-the-proposal-from-the-commission-for-a-c-its-delegated-regulation/], accessed 18/11/2022.

[30] Kamecke, U.; Körber, T.: *Technological Neutrality in the EC Regulatory Framework for Electronic Communications: A Good Principle Widely Misunderstood*, European Competition Law Review 5 2008, pp. 330 – 337, p. 331.

[31] Future-proofing is identified as the primary benefit of technology neutral legislation. See Puhakainen, E.; Väyrynen, K.: *The Benefits and Challenges of Technology Neutral Regulation - A Scoping Review*, Twenty-fifth Pacific Asia Conference on Information Systems, Dubai, UAE, 2021 [https://www.researchgate.net/publication/353143124_The_Benefits_and_Challenges_of_Technology_Neutral_Regulation_-A_Scoping_Review], accessed 18/11/2022, p. 5. Leenes et al. warn that technology-neutral norms potentially offer less legal certainty, because they tend to be more abstract than technology specific norms. See Leenes, R. *et al.*: *op. cit.* (fn. 4), p. 43.

ment for the same legal validity of digital and non-digital transactions, i.e. equivalence between different modes of activity, as well as the non-discrimination between technologies with equivalent effects.[32] Apart from that, in delivering future-proof and innovation-friendly legislation, the EU institutions are guided by the 'Innovation Principle', which entails taking into account the impact on research and innovation in the process of developing and reviewing regulation in all policy domains.[33] (Structured) flexibility and experimentation are recognized by the EU institutions as tools for regulatory learning and creating "an agile, innovation-friendly, future-proof, evidence-based, and resilient regulatory framework" to respond to disruptive challenges in the digital age.[34]

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[32]   Koops, B.-J.: Should ICT Regulation be Technology-Neutral?, in: Koops, B.-J. et al. (eds.): *Starting points for ICT Regulation. Deconstructing Prevalent Policy One-Liners*, The Hague, 2006, pp. 77 – 108; Tsokou, M.: *The insufficiency of technology neutrality and risk-based approaches: The necessity of adopting a human-rights lens when regulating AI*, [https://assets. ctfassets.net/iapmw8ie3ije/1fdlLSILUSek4D7en9eR0s/87b83b77ff283335f81e1b99e5b7c360/ MyDataIsMineAward_MachiTsokou.pdf], accessed 18/11/2022; Veerpalu, A.: *Functional equivalence: An exploration through shortcomings to solutions*, Baltic Journal of Law & Politics 12(2) 2019, pp. 134–162.

[33]   See Council of the European Union: Better Regulation to strengthen competitiveness, Brussels, 26 May 2016, 9580/16. The innovation principle compliments the precautionary principle and highlights the importance of innovation in all phases of the policy cycle. A successful innovation principle seeks to find the right balance between information, flexibility and stringency. It relies on various tools, such as research and innovation tool, innovation deals and foresight and innovation scanning, recognising that well-designed regulation can promote innovation to the benefits of society, whereas badly designed regulation can harm innovation. See European Commission: Study supporting the interim evaluation of the innovation principle, Luxembourg, 2019, p. 5, 7 [https://op.europa.eu/en/publication-detail/-/publication/e361ec68-09b4-11ea-8c1f-01aa75ed71a1]. See also European Commission: Towards an Innovation Principle Endorsed by Better Regulation, EPSC Strategic Notes (14) 2016, p. 6.

[34]   Council of the European Union: Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age, Brussels, 16 November 2020, 13026/20. Tool #22 of the Commission's Better Regulation Toolbox provides guidelines for analysing the interaction between EU initiatives and innovation in line with the innovation principle and ensures that the innovation dimension is considered when preparing and implementing EU legislation. In the preparation stage, the instruments of adaptive regulation include experimentation clauses, outcome-oriented legislation, sunset clauses, test of alternatives, top-runner approach, or any combination thereof. In the implementation stage, innovation deals as voluntary agreements with stakeholders (innovators, civil society, national/regional or local authorities) and the Commission services aim to address perceived regulatory obstacles to innovative solutions stemming from existing EU rules, when a need for clarification (instead of revision) exists. See European Commission: Better Regulation Toolbox, Tool #22, p. 170, 176 – 178 [https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox/better-regulation-toolbox-0_en], accessed 18/11/2022.

In this view, experimental regulation, such as regulatory sandboxes, intuitively fits with the innovation principle and is essential in ensuring that the emerging business models that do not comply with existing regulatory frameworks are not pre-maturely excluded from the market, without allowing them to prove that they can offer adequate levels of protection of users.[35] The aim is not to deregulate or lower the existing standards of safety and protection, but to develop an appropriate regulatory environment, capable of keeping pace with innovation, while preserving the necessary safeguards.

Experimental law-making is evidence-based law-making, and it should be designed with caution to avoid potential adverse effects.[36] In any case, the approach to regulating new and disruptive technologies, as proposed by many authors, should be "dynamic, cyclic and interactive",[37] should involve many stakeholders and quasi-regulators, and most importantly, it should involve continuous reflexive processes and re-evaluation of its effectiveness according to the observed impact, effects and further development of technology and its application.

Given the aim and the scope of this paper, we will not be able to dig deeper into all the possible approaches to regulating AI. Our starting point is that coping with technological innovation requires, at least to a certain extent, regulatory innovation as well.[38] The above discussion aims to show that applying traditional regulatory strategies to innovative technological ecosystems is difficult,[39] if achievable at all. We offer it as a background and an introduction to a relatively novel concept of experimental law-making through regulatory sand-

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[35]   See European Commission, Study supporting the interim evaluation of the innovation principle, *op. cit.* (fn. 33), p. 47. See also European Commission: Better Regulation Toolbox, Tool #69, *op. cit.* (fn. 34), p. 597 – 602.

[36]   Ranchordás identifies three common adverse effects of regulatory experimentation: limited internal and external validity of experiment's results (i.e. inability to identify whether the results ensue from the experiment or other circumstances, and the inability to draw generalised conclusions), limited scientific reasoning (which impedes evidence-based law-making and rationalisation of regulation) and methodological deficiencies (lack of objective, transparent and predictable standards which violate the principles of legal certainty, non-discrimination, and proportionality). The awareness of these shortcomings is crucial for designing better experimental legal regimes.   See Ranchordás, S.: *Experimental Regulations and Regulatory Sandboxes – Law Without Order?*, Law and Method 2021 - Special Issue: Experimental Legislation in Times of Crisis (edited by Ranchordás, S.; van Klink, B.), p. 3.

[37]   Leenes, R. *et al.*: *op. cit.* (fn. 4), p. 39-40.

[38]   On the concept of regulatory innovation see e.g. Black, J.: What is regulatory innovation?, in: Black, J.; Lodge, M.; Thatcher, M.: *Regulatory innovation. A comparative analysis*, Cheltenham – Northampton, 2005, p. 12.

[39]   Brummer, C.; Yadav, Y.: *op. cit.* (fn. 2), p. 244.

boxes. They are liable to open up an alternative avenue for risk management of disruptive technologies, such as AI, through a dynamic learning process that benefits businesses, consumers, and regulators.[40]

3. REGULATORY SANDBOXES: INNOVATIVE LEGAL REGIMES FOR INNOVATIVE TECHNOLOGIES

3.1. THE CONCEPT AND FEATURES OF REGULATORY SANDBOXES

We start from a definition of regulatory sandboxes offered by Ranchordás, who defines them as "experimental legal regimes which wave, modify national regulatory requirements (or implementation) or provide bespoke guidance on a temporary basis and for a limited number of actors in order to support businesses in their innovation endeavors".[41] Whereas experimental law-making in the EU is mostly associated with multi-level governance frameworks, regulatory sandboxes can be "much more and sometimes much less than that": they are innovation friendly, flexible and adaptable regulatory instruments.[42] Other authors refer to regulatory sandboxes as "an attempt by authorities to build supervisory capacity through engagement and state-sponsored innovation and experimentation",[43] and an opportunity for the firms to "test their products with real customers in an environment that is not subject to the full panoply of rules", creating a "collaborative relationship between regulator and regulated firm", and lifting "regulatory burdens from sandbox participants by affording flexibility in satisfying the regulatory goals of the sandbox".[44] Regulatory sandbox is praised as a forward-looking form of regulatory engagement, and a "genuinely new addition to the regulatory arsenal", as opposed to merely *ad hoc* policy responses to digital innovation.[45] The European Commission relies on a broad definition of 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".[46]

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[40]   Yordanova, K.: *The Shifting Sands of Regulatory Sandboxes for AI*, CITIP Blog, [https://www.law.kuleuven.be/citip/blog/the-shifting-sands-of-regulatory-sandboxes-for-ai/], accessed 18/11/2022.

[41]   Ranchordás, S.: *op. cit.* (fn. 36), p. 1 – 2.

[42]   *Ibid.*, p. 1.

[43]   Brummer, C.; Yadav, Y.: *op. cit.* (fn. 2).

[44]   Allen, H. J.: *Regulatory Sandboxes*, The George Washington Law Review 87(3) 2019, pp. 579-645, p. 592.

[45]   Brummer, C.; Yadav, Y.: *op. cit.* (fn. 2).

[46]   European Commission: Better Regulation Toolbox, Tool #69, *op. cit.* (fn. 34), p. 597.

The above descriptions point to several important features of regulatory sandboxes: their experimental nature, genuine innovation, temporary character, (limited) regulatory relief, controlled entry/access, close engagement, and interaction between regulators and innovators which allows mutual learning, supervision, flexibility, and adaptation. The idea is to allow the developers to test and build new ideas and inventions in a "simplified, interactive regulatory environment", "within the controlling parameters of the regulatory sandbox", but "without restrictive or complex rules that elevate regulatory risk and stifle innovation".[47] A regulatory sandbox provides a ground for experimenting with innovative technologies/products/services in an environment that will (hopefully) be able to contain or limit the consequences of a failure.

An obvious association with a sandbox in children's playground might be misleading: there is a lot more structure, control, and supervision here, and strict adherence to the rules of the game is required. Nevertheless, the process is flexible enough to let the innovators experiment and try out their innovations in real-world conditions, in a relaxed regulatory environment, whereas regulators get a direct insight into the development of innovations, and their design, and can better understand how emerging technologies, products, and services operate in the real world.[48]

A sandbox is not a novel concept in the world of computer science, where it denotes "an isolated environment meant for testing and/or preventing malicious programs from damaging a computer system or critical system resources".[49] Its testing function and risk mitigation are key features that bring this concept into the realm of regulation, where it becomes "a process and a tool for regulation", comparable to a laboratory where innovations are tested against the existing regulatory framework, through a process involving participating business entities and a regulator.[50]

Together with innovation hubs,[51] which represent another (well-established, and perhaps more familiar) concept of institutionalized supervisory outreach

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[47] Brummer, C.; Yadav, Y.: *op. cit.* (fn. 2), p. 291- 292.

[48] *Loc. cit.*

[49] Yordanova mentions the example of a web browser, see Yordanova, K.: *op. cit.* (fn. 40). See also Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 45-46.

[50] Yordanova, K.: *op. cit.* (fn. 40).

[51] There is no uniform definition of innovation hubs, but they typically encompass one-stop shops involving multi-stakeholder cooperation and serve as a "…central contact point to streamline queries and provide support, advice, and guidance to either regulated or unregulated firms, helping them navigate the regulatory, supervisory, policy, or legal environment. Support can be direct or indirect, via guidance to the market, and it does not generally include testing of products or services." See World Bank: Global Experiences from Regulatory Sandboxes,

for new and emerging technologies, regulatory sandboxes are known as "innovation facilitators".[52] Regulatory sandboxes, however, go a step further than innovation hubs: whereas innovation hubs usually provide a specific scheme or platform for firms to engage in a dialogue, and seek clarifications or non-binding guidance from the supervisory authority; regulatory sandboxes enable a direct testing environment for innovative products, services or business models, in real-world conditions, subject to the application of specific safeguards and regulatory lenience.[53] Although there is no uniform template for regulatory sandboxes and they may significantly differ in their nature and entry requirements, sometimes including also other features of experimental law-making, one shared characteristic of regulatory sandboxes is that the sandbox participants are restricted concerning the nature and scale of activities to be carried out during testing in the sandbox environment.[54]

The rise of regulatory sandboxes is associated with the development and application of new and emerging technologies, which have had a disruptive impact and have dramatically changed business models, processes, and products.[55] It started with the proliferation of FinTech regulatory sandboxes at the national level.[56] Before we take a look into their practical functioning and impact, it is important to concentrate on the common features and conceptual foundations that are applicable to regulatory sandboxes in general, regardless of the specific field in which they might operate.

Even though regulatory sandboxes may vary according to their forms, stated objectives, and practical implementation,[57] it is possible to identify several common features. Zetzsche et al. group these features around the sandboxes'

Fintech note no. 8, p. 2, [https://documents1.worldbank.org/curated/en/912001605241080935/pdf/Global-Experiences-from-Regulatory-Sandboxes.pdf], accessed 18/11/2022.

[52]   Parenti, R.: Regulatory Sandboxes and Innovation Hubs for FinTech. Impact on innovation, financial stability and supervisory convergence, Luxembourg, 2020, p. 18. See more in Zubović, A.; Derenčinović Ruk, M.: Digitalna transformacija vrijednosnih papira i aktivnosti regulatora tržišta kapitala, in: Barbić, J. (ed.): *Nove tehnologije i pravo društava*, Zagreb, 2022, pp. 95 – 137, p. 113.

[53]   Parenti, R.: *op. cit.* (fn. 52), p. 19 – 20. It is highlighted that these models are not mutually exclusive, and can be combined to effectively achieve desired objectives of regulation.

[54]   Ahern, D.: *Regulators Nurturing FinTech Innovation: Global Evolution of the Regulatory Sandbox as Opportunity Based Regulation*, EBI Working Paper Series 2020 no. 60, p. 7.

[55]   Parenti, R.: *op. cit.* (fn. 52), p. 17

[56]   The UK's Financial Conduct Authority (FCA) is known as a "sandbox pioneer", but we notice the growth of regulatory sandboxes across jurisdictions. See Allen, H. J.: *Sandbox Boundaries*, Washington College of Law Research Paper No. 2019-18, pp. 299 – 321, p. 300; Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 45-46; Zubović, A.; Derenčinović Ruk, M.: *op. cit.* (fn. 52), p. 108.

[57]   Allen, H. J.: *op. cit.* (fn. 56), p. 302.

objectives and conditions, with the latter encompassing the entry test, the scope of coverage, mandatory provisions, and reasons for removing the privilege.[58]

The objectives for introducing a regulatory sandbox may vary according to the context and regulator's mandate, but usually indicate promoting or supporting innovation, fostering effective and efficient service provision systems, market development, enhancing competition and economic growth, understanding how emerging technologies and business models interact with the legal framework, promoting inclusion of consumers, etc.[59] It is warned that the promotion of innovation cannot be the only regulatory goal, especially if it is implemented at the expense of consumer protection and other interests.[60] The entry test encompasses necessary legal and economic conditions of entry, to determine whether the entrant is qualified to "play in the sandbox".[61] These conditions may include an assessment of the innovation potential,[62] prospective risks, and benefits for markets and consumers,[63] the necessity for a sandbox approach,[64]

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[58]   Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 69 and following. Similar classifications are deployed by other authors, see e.g. Ranchordás, S.: *Experimental law-making in the EU: Regulatory sandboxes*, University of Groningen Faculty of Law Research Paper Series No. 12/2021, p. 4 - 5, available at SSRN [https://ssrn.com/abstract=3963810], accessed 18/11/2022.

[59]   Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 68 - 69; Allen, H. J.: *op. cit.* (fn. 56), p. 302 – 303.

[60]   Allen, H. J.: *op. cit.* (fn. 44), p. 581. Furthering this discussion in the field of FinTech regulation, Brummer and Yadav frame the so-called „innovation trilemma" and argue that regulators, when balancing three competing policy objectives—fostering innovation, maintaining market integrity, and offering rules simplicity—can, at best, fully achieve two out of three of these regulatory goals. See Brummer, C.; Yadav, Y.: *op. cit.* (fn. 2), p. 244.

[61]   „Eligibility to enter a sandbox is standardized and publicized, thus requiring market participants to articulate their added value in a pre-defined format. This is cost effective for participants and resource-effective for regulators, allowing easier comparison among potential entrants to the sandbox." See Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 45 – 46, 71.

[62]   A questionable characteristic, since it is debatable whether the regulator itself is capable of assessing it. See Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 69. See also Zubović, A.; Derenčinović Ruk, M.: *op. cit.* (fn. 52), p. 109. "Genuine innovation" might include anything from a new spin on the existing idea, creation of a new market for existing products, or improved access of underserved customers to existing markets. See [https://www.fca.org.uk/firms/innovation/regulatory-sandbox], accessed 18/11/2022.

[63]   The exact parameters for measuring the benefits to consumers may vary, but the proposal certainly should not expose consumers to undue risk. Through the sandbox, firms are provided with support to identify the proper consumer safeguards and ensure market transparency. See World Bank: *op. cit.* (fn. 51), p. X, 24 - 25. See also [https://www.fca.org.uk/firms/innovation/regulatory-sandbox], accessed 18/11/2022.

[64]   Firms will have to demonstrate a genuine need for a sandbox approach, mostly because their technology, service, or activity faces unnecessary regulatory burdens and does not fit neatly into the existing regulatory framework, which makes it difficult and costly to get the innovation to the market. See [https://www.fca.org.uk/firms/innovation/regulatory-sandbox],

as well as the entrants' preparedness test (i.e. whether technology has entered a development phase, whether the entrants understand the laws and regulation governing their conduct, and whether they engage in appropriate risk management).[65] As to the scope of coverage, the existing examples across the globe in the FinTech industry show considerable variations, from sectoral limitations, or limits to the engagement of licensed entities, to defining designated customers, and/or possible time and size constraints.[66] The scope can be limited geographically (e.g. to the national market),[67] according to the specific themes or policy priorities,[68] type of sandbox (i.e. product, policy, cross-sectoral),[69] number of participants, duration of testing, access model,[70] etc. In addition, testing restrictions may apply, e.g. restrictions concerning the number and/or type of customers a firm may serve during the testing period.

The ability to conduct a live test of innovative products or services under real-world conditions, supported by the relevant market authority and applying the sandbox tools which can relax the regulatory regime and thus lower the costs of market entry is what draws the firms to try out their innovations in regulatory sandboxes. However, the regulatory sandbox is not a "regulatory-exempt space".[71] To retain the necessary flexibility, most existing regulatory sandboxes do not prescribe in advance which mandatory provisions can be waived, but there is usually a core of rules which cannot be subject to adaptation and relaxation (such as requirements concerning the prevention of

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accessed 18/11/2022.

[65]   FCA, e.g., highlights that the entrants should have a clear vision of the objectives of the sandbox, understand the applicable regulations, consider the risks and impact of (successful) testing, and ensure voluntary participation of the testing partners. See [https://www.fca.org.uk/firms/innovation/regulatory-sandbox], accessed 18/11/2022.

[66]   Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 71 – 76.

[67]   See   FCA   [https://www.fca.org.uk/firms/innovation/regulatory-sandbox],   accessed 18/11/2022.

[68]   E.g., enhancing blockchain technology, innovations in insurance technology, supporting remote authentication, etc. Available data shows that the share of thematic sandboxes in 2020 was around 40 %. See World Bank: Key data from regulatory sandboxes across the Globe, [https://www.worldbank.org/en/topic/fintech/brief/key-data-from-regulatory-sandboxes-across-the-globe], accessed 18/11/2022.

[69]   *Loc. cit.*

[70]   For example, in 2021 the UK's FCA regulatory sandbox has moved from a cohort to an always open model, allowing firms to submit their applications and access the testing services at any point throughout the year. See [https://www.fca.org.uk/firms/innovation/regulatory-sandbox], accessed 18/11/2022.

[71]   See [https://www.fca.org.uk/firms/innovation/regulatory-sandbox], accessed 18/11/2022.

money laundering, customer confidentiality, etc.).[72] Ahern observes a hierarchy or sliding scale of models of the regulatory relief in different sandbox systems: From the most strict (no relaxation of applicable rules), over the moderation of the strict approach (relaxation of applicable rules permitted only within the discretionary scope of existing rules), and customized approach for pre-determined sandboxes with pre-determined parameters including those relating to regulatory relief (block exemption license), to the most radical model (tailor-made sandbox based on the relaxation of specific rules).[73] The last, but not least common feature involves the prescribed conditions for the forced exit,[74] or the requirement to elaborate an exit strategy in advance.[75]

Having in mind these common features, many authors point out that regulatory sandboxes might help reduce the pervasive information uncertainties attached to the growth of algorithms and AI, as well as to the viability of new data, particularly at an early stage of innovation.[76] Ideally, they should keep pace with AI development, without unduly restricting its innovative potential. In the next section, we will briefly touch upon the existing examples of FinTech regulatory sandboxes to investigate whether this experimentation – innovation – dialogue triad in regulatory sandboxes is capable of increasing competitiveness, especially for innovative SMEs.

3.2. *DRAWING FROM THE EXPERIENCE OF FINTECH REGULATORY SANDBOXES*

Having taken a look at the distinctive features of regulatory sandboxes, we now turn to the example of regulatory sandboxes in the FinTech industry to establish their impact on SMEs. The term FinTech denotes a diffuse set of

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[72] Zetzsche, D. A. *et al*.: *op. cit*. (fn. 3), p. 75 – 76. For example, the MAS FinTech Regulatory sandbox guidelines enumerate the list of "to maintain" and "possible to relax" requirements in an exemplary manner, to be determined in accordance with the specifics of each case. See [https://www.mas.gov.sg/-/media/MAS-Media-Library/development/Regulatory-Sandbox/Sandbox/FinTech-Regulatory-Sandbox-Guidelines-Jan-2022.pdf?la=en&hash=0136A576014D8B13D-16264CDFDA2C66791F6E8CA], accessed 20/11/2022.

[73] Ahern, D: *op. cit*. (fn. 54), p. 17 – 20.

[74] E.g., if the risks outweigh benefit, if the participant does not comply with rules and obligations, or if the purpose of the sandbox is not achieved. See Zetzsche, D. A. *et al*.: *op. cit*. (fn. 3), p. 77.

[75] See Ahern, D.: *Regulatory Lag, Regulatory Friction and Regulatory Transition as FinTech Disenablers: Calibrating an EU Response to the Regulatory Sandbox Phenomenon*, EBI Working Paper Series 2021 no. 102, p. 15; Zubović, A.; Derenčinović Ruk, M.: *op. cit*. (fn. 52), p. 108.

[76] Brummer, C.; Yadav, Y.: *op. cit*. (fn. 2), p. 291 – 292.

technology-enabled financial services with a profound and sometimes disruptive impact on financial markets, institutions, and the financial sector in general,[77] including, but not limited to, digital banking or payment services, platform-based financing, robo-advisers, blockchain and distributed ledger technologies (DLT), smart contracts, application programming interfaces (APIs), etc. FinTech regulatory sandboxes are applicable either in the traditionally regulated financial sector or across sectors.[78] Their growing popularity across the globe is evident: in 2017, there were 16 regulatory sandboxes in operation,[79] whereas in 2020, 73 FinTech-related regulatory sandboxes were recorded.[80] About one-fifth of all regulatory sandboxes was created in the first half of 2020, suggesting a rapid growth in the use of sandboxes to test FinTech innovation and regulation.[81]

The main *ratio* behind existing FinTech sandboxes seems to be in the increase of supervisory knowledge and capacity to understand FinTech activities and their business models, risks and incentives.[82] By analogy, the same logic can be extended to the creation of AI regulatory sandboxes.

In addition to their proliferation in the last decade, the functioning of FinTech regulatory sandboxes has also diversified. The Monetary Authority of Singapore (MAS), for example, has started differentiating several sandbox regimes according to risk and necessity: there are (traditional) Sandbox, Sandbox Express, and Sandbox Plus options in place.[83] This is a perfect example of a mutual learning experience in the sandbox, which results in the regulator's better

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[77] See Parenti, R.: *op. cit.* (fn. 52), p. 14 and following; Allen, H. J.: *op. cit.* (fn. 44), p. 585.

[78] Parenti, R.: *op. cit.* (fn. 52), p. 14.

[79] Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 64.

[80] See World Bank: *op. cit.* (fn. 68).

[81] See World Bank: *op. cit.* (fn. 68).

[82] Parenti, R.: *op. cit.* (fn. 52), p. 8.

[83] FinTech Regulatory Sandbox framework was implemented in Singapore in 2016, enhanced with Sandbox Express in 2019 and Sandbox Plus in 2022. Whereas Sandbox option is aimed for more complex business models where customisation is required to balance the risks and benefits of the experiment, Sandbox Express provides firms with a faster option to test certain innovative financial products and services in the market, where the risks are low and well-understood by the market. It allows eligible applicants to begin market testing within 21 days of applying to MAS. See MAS Sandbox Express Guidelines (updated January 2022), [https://www.mas.gov.sg/-/media/MAS-Media-Library/development/Regulatory-Sandbox/Sandbox-Express/Sandbox-Express-Guidelines-1-Jan-2022.pdf?la=en&hash=08F99C6216499D-FCED58489B5C0B3C8A8139CC57], accessed 20/11/2022. Express Plus, on the other hand, provides a one-stop assistance designed to support early adopters and first movers of technology innovation concerning eligibility criteria and streamlining application with financial grants. See [https://www.mas.gov.sg/development/fintech/regulatory-sandbox], accessed 20/11/2022.

understanding of innovators and their needs, and the corresponding ability to adapt to the sandbox environment.

Various regulatory sandbox tools can be applied, depending on the needs and nature of specific business tests conducted, sometimes combining the functions of innovation hubs with regulatory sandboxes. For example, the UK's Financial Conduct Authority (FCA) applies an arsenal of tools, from restricted authorization, signposting, informal steer, individual guidance, waivers or modification to rules, and 'no enforcement action' letters.[84] Similar tools are applied in other jurisdictions, with so-called "innovation waivers", or waivers from existing rules during the sandbox testing, as the most commonly used tool.[85] The same tools and the lessons learned from their application should be catered to the needs of AI regulatory sandboxes.[86] The Norwegian Data Protection Authority's Sandbox for Responsible AI, for example, offers free guidance for companies selected to participate in the sandbox, in exchange for full openness about the assessments that are made.[87] The sandbox is not intended to grant exemptions from regulations, but the Data Protection Authority will not initiate corrective measures during the test – the focus is on helping the participants comply with the existing regulations.[88] In the context of AI sandboxes, the tools will depend on the sector and market for which the

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[84] Restricted authorisation includes support and tailored authorisation process for non-authorised entities, but it is restricted to testing innovative product or service as agreed. Signposting is not tailored to a particular firm, but it is nevertheless helpful since it includes identifying existing rules and offering guidance that might be relevant to the firm and the proposed business model. Informal steer is a tool to help firms understand the potential regulatory implications of their innovative product or business model at an early stage of development, but without guarantees – it is followed at firm's own risk. Individual guidance might be available to explain how the authority should interpret prescribed requirements in the context of a specific test, whereas waivers or modifications to rules include waiving or modifying overly difficult rules for the purpose of the test, but cannot include waivers from national or international law. The 'no enforcement action' letters are applied where the FCA cannot issue individual guidance or waivers, they are limited for the duration of the test and to FCA's own disciplinary actions, without affecting the liability to consumers. See [https://www.fca.org.uk/firms/innovation/regulatory-sandbox], accessed 18/11/2022.

[85] See e.g., [https://www.natlawreview.com/article/hardly-child-s-play-north-carolina-joins-growing-number-states-fintech-regulatory], accessed 18/11/2022.

[86] Ranchordás refers to temporary derogations, bespoke guidance, regulatory comfort and confirmations as typical sandbox tools. See Ranchordás, S.: *op. cit.* (fn. 58), p. 4.

[87] See [https://www.datatilsynet.no/en/regulations-and-tools/sandbox-for-artificial-intelligence/; https://www.datatilsynet.no/en/regulations-and-tools/sandbox-for-artificial-intelligence/framework-for-the-regulatory-sandbox/], accessed 18/11/2022.

[88] See [https://www.datatilsynet.no/en/regulations-and-tools/sandbox-for-artificial-intelligence/framework-for-the-regulatory-sandbox/], accessed 18/11/2022.

sandbox is created (i.e. whether it is a regulated market), the powers vested in the supervising body implementing the sandbox, the objectives of the sandbox, etc. The mentioned Norwegian Data Protection Authority's Sandbox for Responsible AI enumerates the 'activities' offered in the sandbox, which boil down to signposting, informal steer, individual guidance, and mutual learning and involve an interdisciplinary team of experts depending on the needs of each participant (lawyers, technologists, social scientists, communication consultants, etc.).[89] The bottom line is that there is no "one-size-fits-all" solution, and that the chosen collection of sandbox tools should accommodate the specific objectives pursued.

There are still no clear signals as to the impact of FinTech sandboxes on the competitiveness of SMEs. Analyzing the viability of its sandbox model following the first year of its application, the UK FCA found clear evidence that the sandbox has been most popular with start-up companies and those that are not yet authorized by the FCA, whereas the share of participation of SMEs is roughly equal to that of large firms.[90] Further empirical findings support the conclusion that sandbox reduces information asymmetries and regulatory costs, thus helping sandbox participants raise more capital after entry.[91] With AI regulatory sandboxes, there might be more incentives for innovative SMEs to participate, should the EU follow through on its commitment to boost the competitiveness of SMEs.

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[89]   I.e. assisting in the performance of a data protection impact assessment, contributing to the identification of data protection challenges, providing feedback on relevant technical and legal solutions to data protection challenges, exploring options for the implementation of privacy by design, conducting informal inspections to highlight relevant requirements, contributing input to various assessments and considerations of the balance between necessity and potential adverse effects on user privacy, providing an arena for knowledge exchange and network-building for other sandbox participants, external experts, and other authorities, and sharing preliminary and final sandbox experiences. See [https://www.datatilsynet.no/en/regulations-and-tools/sandbox-for-artificial-intelligence/framework-for-the-regulatory-sandbox/what-happens-in-the-sandbox/], accessed 18/11/2022.

[90]   Financial Conduct Authority (FCA): *Regulatory Sandbox Lessons Learned Report*, 2017, p. 9 [https://www.fca.org.uk/publication/research-and-data/regulatory-sandbox-lessons-learned-report.pdf], accessed 18/11/2022.

[91]   Cornelli, G. *et al*.: Inside the regulatory sandbox: effects on fintech funding, BIS Working Papers No. 901, 2020, p. 26 [https://www.bis.org/publ/work901.pdf], accessed 20/11/2022.

4. AI REGULATORY SANDBOXES

4.1. THE EU POLICY APPROACH TO REGULATORY SANDBOXES

The growing recognition of regulatory sandboxes as innovation facilitators is apparent in policy and strategy papers of EU institutions in recent years. In its AI Strategy from 2018, the European Commission mentions regulatory sandboxes only in the passing, and describes them as "testing grounds for new business models that are not (yet) regulated".[92] The ensuing Coordinated Action Plan for AI and its Annex from the same year further elaborates the idea of establishing AI regulatory sandboxes, as part of a wider effort for supporting start-ups and innovative SMEs.[93] The accompanying reasoning was that regulatory sandboxes "can play an important role to encourage AI-based innovation for areas where the law provides regulatory authorities with a sufficient margin of maneuver".[94] The latter caveat puts obvious boundaries to sandboxing approach, and the Commission acknowledged that, depending on the circumstances, innovation can be supported with "softer approaches", i.e. other methods for policy experimentation and development, such as digital innovation hubs, innovation deals, innovation centers, and policy labs.[95] Surprisingly, the idea of regulatory sandboxes is completely absent in the White Paper on AI from 2020, which focuses primarily on digital innovation hubs as facilitators for access and use of AI by SMEs.[96] In this view, SMEs should be empowered to understand and adopt AI, but are not recognized as innovation leaders requiring the testing ground for their innovative solutions. Nevertheless, policy experimentation, especially in the context of regulatory sandboxes, is identified as a useful strategy to unleash the potential of SMEs in the digital transition.[97]

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[92]   See European Commission: Artificial Intelligence for Europe, *op. cit.* (fn. 10), p. 9. This definition might not accurately convey the meaning and purpose of regulatory sandboxes. While the business model may be new and innovative, it is the fact that its impact upon entering a regulated territory may be unknown or unforeseeable in advance, or that the costs of compliance with the existing regulation is liable to impede the application of the innovative model that cause the need for a testing ground.

[93]   European Commission: Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Coordinated Plan on Artificial Intelligence, COM/2018/795 final, Brussels, 7.12.2018, p. 3; and Annex, p. 8 - 9.

[94]   *Ibid.*, Annex, p. 17.

[95]   *Ibid.*, Annex, p. 18.

[96]   European Commission: White paper on Artificial Intelligence, *op. cit.* (fn. 9), p. 7.

[97]   European Commission: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the

In the broader EU regulatory and policy setting, it should be stressed that the Commission's Better Regulation Toolbox 2021 dedicates particular attention to regulatory sandboxes as emerging policy instruments and the most recent tools of adaptive regulation, identifying their main characteristics, benefits and challenges, as well as providing examples of existing sandboxes and a blue-print for their set-up.[98] It is highlighted that the findings from a regulatory sandbox can be used to inform *ex ante* impact assessments and consideration of various policy options, as well as *ex post* evaluation of existing legislation or fitness checks, but that other forms of experimentation may be more appropriate in a particular case. [99]

The European Parliament has already in 2019 embraced the idea of using regulatory sandboxes to introduce, in cooperation with regulators, innovative new ideas, allowing safeguards to be built into the technology from the start, thus facilitating and encouraging its market entry.[100] It also highlighted the necessity to introduce AI-specific regulatory sandboxes "to test the safe and effective use of AI technologies in a real-world environment."[101] In the context of digital financial services, the European Parliament has called on the Commission to establish a common Union framework for a pan-European sandbox for digital financial services,[102] recognizing that it would provide additional benefits for financial innovation and stability, and reduce supervisory fragmentation.

The Council has also been openly endorsing regulatory sandboxes and experimentation clauses, as part of a better regulation toolbox contributing to an innovation-friendly, future-proof, sustainable, and resilient EU regulatory framework.[103] The Council affirms that regulatory sandboxes can offer significant

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Regions. An SME Strategy for a sustainable and digital Europe, COM/2020/103 final, Brussels, 10.3.2020. The draft AI Act gives effect to this by prioritising access of SMEs to AI regulatory sandboxes. This will be further elaborated under 4.2.

[98]   European Commission: Better Regulation Toolbox, *op. cit*. (fn. 34), Tool #69.

[99]   I.e. those under Tool #22. See: European Commission: Better Regulation Toolbox, *op. cit*. (fn. 34), Tool #22 and Tool #69.

[100]   European Parliament: Resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics (2018/2088(INI)).

[101]   *Ibid*., para. 32.

[102]   European Parliament: Resolution of 8 October 2020 with recommendations to the Commission on Digital Finance: emerging risks in crypto-assets - regulatory and supervisory challenges in the area of financial services, institutions and markets (2020/2034(INL)).

[103]   Council of the European Union: Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age, *op. cit*. (fn. 34). Regulatory sandboxes are defined as "concrete frameworks which, by providing a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies,

opportunities particularly to innovate and grow for all businesses, especially SMEs, including micro-enterprises as well as start-ups, in industry, services, and other sectors.[104]

It is important to mention that the current financial envelope for the Digital Europe Programme for the period 2021-2027[105] does not expressly include the financing of AI regulatory sandboxes at the national or EU level.[106] This is not surprising, given that they are still not a widespread phenomenon in the EU Member States,[107] and that the common rules for their establishment are yet to be implemented with the adoption of the Draft AI Act. Instead, the Digital Europe Programme focuses on support and financing for the European Digital Innovation Hubs,[108] as bespoke legal entities for achieving the goals of the

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products, services or approaches – at the moment especially in the context of digitalisation – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place." Often serving as the legal basis for regulatory sandboxes, experimentation clauses are defined as "legal provisions which enable the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in relation to testing innovative technologies, products, services or approaches." Compare with the stated purpose of experimentation clauses as provided under Better Regulation Tool #22 (European Commission: Better Regulation Toolbox, *op. cit.* (fn. 34)). See more on regulatory sandboxes and experimentation clauses in Štefanek, Š.: *Regulatory sandboxes and experimentation clauses: An attempt to make the (Croatian) legal system more entrepreneurial*, EU and Comparative Law Issues and Challenges (ECLIC) (6) 2022 [https://doi.org/10.25234/eclic/22416], pp. 213 – 235.

[104] Council of the European Union: *op. cit.* (fn. 102).

[105] Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240 (OJ L 166, 11.5.2021).

[106] This does not mean that the financing for the projects including AI regulatory sandboxes cannot be obtained either under the framework of the Digital Europe Programme, or other financing instruments of the EU.

[107] In 2020, only 7 Member States have implemented some type of sandbox (see World Bank: *op. cit.* (fn. 68)); whereas in 2021, more than half of EU Member States have set up sandboxes, mostly in areas of finance, transport and energy, with additional in the pipeline. See Science, research and innovation performance of the EU 2022. Building a sustainable future in uncertain times 2022, p. 552 [https://op.europa.eu/en/publication-detail/-/publication/52f8a759-1c42-11ed-8fa0-01aa75ed71a1/], accessed 19/11/2022. A "state-of-play" fact-finding mission was initiated during the Slovenian Presidency of the Council in July 2021, but there is no public report available on key findings. See Council Presidency: State of play on the use of regulatory sandboxes in the EU Member States, Brussels, 5 July 2021, 10338/21.

[108] European Digital Innovation Hubs are defined as legal entities selected under the prescribed procedures to fulfil the tasks of the Digital Europe Programme, by directly providing, or ensuring access to, technological expertise and experimentation facilities, such as equipment and software tools to enable the digital transformation of industry, as well as by facilitating access to finance and it is open to businesses of all forms and sizes, in particular to

Programme, which is to support and accelerate the digital transformation of the European industry, economy, and society. However, the explicit operational objectives under Specific Objective 2 – Artificial Intelligence support the establishment of testing and experimentation facilities (TEFs), as specialized large-scale reference sites open to all technology providers across Europe to test and experiments with state-of-the-art AI-based soft- and hardware solutions and products, in real-world environments and at scale.[109] In turn, the TEFs (as technological "playgrounds") can support the establishment of regulatory sandboxes (as regulatory "playgrounds"), with the goal of developing a dialogue with competent national authorities for supervised testing and experimentation under real or close to real conditions.[110] Compliance with the ethical requirements for AI systems is a prerequisite for all funding actions. The concern for the ethical aspects of AI systems has culminated in the work and recommendations of the High-Level Expert Group on AI. The Ethics Guidelines for Trustworthy AI[111] have significantly informed and influenced the work of the European Commission in preparing the text of the Draft AI Act.[112] The Guidelines set up a voluntary framework and guidance for all AI stakeholders, including but not limited to companies, organizations, researchers, public services, government agencies, institutions, civil society organizations, individuals, workers, and consumers. They can be relevant in the setting up and operation of regulatory sandboxes, and they should serve as a key reference point, particularly for those Member States which have not yet developed national AI strategies. The Guidelines set up a framework and identify seven key requirements for Trustworthy AI (1) human agency and oversight, (2) technical robustness and safety, (3) privacy and data governance, (4) transparency, (5) diversity, non-discrimination and fairness, (6) environmental and societal

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SMEs, mid- caps and scale-up companies, and to public administrations across the Union. See Article 2(5) of the Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240 (OJ L 166, 11.5.2021).

[109] See Article 5, Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240 (OJ L 166, 11.5.2021).

[110] See Testing and experimentation facilities under the Digital Europe Programme [https://digital-strategy.ec.europa.eu/en/activities/testing-and-experimentation-facilities], accessed 18/11/2022.

[111] Independent High-Level Expert Group on Artificial Intelligence (HLEG): Ethics Guidelines for Trustworthy AI [https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai], accessed 18/11/2022.

[112] See European Commission: Draft AI Act, *op. cit.* (fn. 5), Explanatory Memorandum, para. 3.2.

well-being and (7) accountability.[113] These considerations should guide the national authorities in assisting the sandbox entities to develop, deploy and use AI systems in a way that adheres to the ethical principles of respect for human autonomy, prevention of harm, fairness, and explicability.[114] The advocated human-centric approach to AI, consistently emphasized throughout legislative and policy-making activities of the EU, can only be achieved if AI sandboxes adhere to these principles to maximize the benefits and minimize the risk of AI systems.

Bearing in mind the generally positive attitude of EU institutions, we now turn to analyzing the proposed provisions on AI regulatory sandboxes in the draft AI Act.

4.2. AI REGULATORY SANDBOXES UNDER THE DRAFT AI ACT

The Draft AI Act, presented by the European Commission in April 2021 aims to set up a robust, yet flexible legal framework for trustworthy AI, encompassing harmonized rules for the development, placement on the market, and use of AI systems in the Union. One of the most important features underlying the Draft AI Act is its proclaimed human-centric approach, based on respect for EU values and human rights. The rules are meant to ensure that people can embrace AI solutions and technology trusting that it is safe and that it complies with the law, including the respect for human rights.

Its stated specific objectives include ensuring that AI systems placed on the Union market and used are safe and respect existing law on fundamental rights and Union values; ensuring legal certainty to facilitate investment and innovation in AI; enhancing governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems; and facilitating the development of a single market for lawful, safe and trustworthy AI applications, as well as preventing market fragmentation.[115] The AI Act

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[113] HLEG: *op. cit.* (fn. 111), p. 2.

[114] *Loc. cit.*

[115] See European Commission: Draft AI Act, *op. cit.* (fn. 5), Explanatory Memorandum, para. 1.1. See more on AI Act in e.g., Veale, M.; Frederik Zuiderveen Borgesius, F.: Demystifying the Draft EU Artificial Intelligence Act, Computer Law Review International 22(4) 20221, p. 97 – 112 [https://doi.org/10.9785/cri-2021-220402]; Ebers, M.: Standardizing AI – The Case of the European Commission's Proposal for an Artificial Intelligence Act, in: DiMatteo, L. A.; Cannarsa, M.; Poncibò, C. (eds.): *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics*, Cambridge, 2022, p. 321 – 344; Bogucki, A. *et al.: The AI Act and emerging EU digital acquis*, CEPS In-Depth Analysis, Brussels, 2022 [https://www.ceps.eu/wp-content/uploads/2022/09/CEPS-In-depth-analysis-2022-02_The-AI-Act-and-emerging-

adopts a proportionate risk-based approach, differentiating between uses of AI that create an unacceptable risk, a high risk, and low or minimal risk. Whereas AI systems that create an unacceptable risk[116] are prohibited, because they contravene Union values and violate fundamental rights, high-risk AI systems[117] are permitted, subject to compliance with certain mandatory requirements and an *ex ante* conformity assessment.

AI system for the purposes of the AI Act is defined as "software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with".[118] Without going into further discussions about this

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EU-digital-acquis.pdf], accessed 20/11/2022; Raposo, V. L.: *Ex machina: Preliminary critical assessment of the European Draft Act on artificial intelligence*, International Journal of Law and Information Technology, 30 2022, pp. 88–109 [https://doi.org/10.1093/ijlit/eaac007].

[116]   Article 5 of the Draft AI Act contains an exhaustive list of specific prohibited AI practices, such as those applying manipulative or exploitative practices through subliminal techniques beyond a person's consciousness or exploit vulnerabilities of specific vulnerable groups; or AI-based social scoring for general purposes by public authorities, or the use of 'real time' remote biometric identification systems in public spaces for the purposes of law enforcement, with certain exceptions. In their Opinion on the Draft AI Act, the IMCO and LIBE committees of the European Parliament have suggested adding the predictive policing AI systems to the list. See European Parliament, Committee on the Internal Market and Consumer Protection (IMCO), Committee on Civil Liberties, Justice and Home Affairs (LIBE): Draft Report on the proposal for a Regulation of the European Parliament and of the Council on harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts, 2021/0106, 22 April 2021.

[117]   Classification of an AI system as high-risk is based on its intended purpose, function and modalities for which it is used. Two main categories of high-risk AI systems are those intended to be used as a safety component of other products; and stand-alone AI systems with mainly fundamental rights implications that are explicitly listed in Annex III of the Draft AI Act (such as AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons; AI systems used to determine access or assigning natural persons to educational and vocational training institutions; or a recruitment or selection of natural persons for job vacancies). The European Commission is empowered to expand this list in line with the emerging uses and applications of AI, and in accordance with the defined criteria and risk assessment methodology. High-risk AI systems have to comply with the minimum legal requirements concerning data and data governance, documentation and record keeping, transparency and provision of information to users, human oversight, robustness, accuracy and security. See Article 6 et seq., Draft AI Act.

[118]   Article 3(1) Draft AI Act. The AI techniques and approaches referred to in this provision are listed in Annex I, and include (a) machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; (b) logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning

legislative definition, it is apparent that it could cause some doubts in practice, especially concerning a delineation between (purely) software and hardware-embedded AI systems.[119]

Being that this is the first comprehensive regulatory framework for AI, the expectations are high. We will analyze the draft provisions[120] concerning the AI regulatory sandboxes to check whether they can support the ambitious goals of the Draft AI Act.

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and expert systems; (c) statistical approaches, Bayesian estimation, search and optimization methods. Under Article 4 of the Draft AI Act, the European Commission is empowered to adopt delegated acts to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein. This provision is likely to be expanded with additional requirements and specifications for the Commission, especially concerning general purpose AI systems, as evident from the procedure and standpoint of delegations in the Council. See Council of the European Union: Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts - Third Presidency compromise text (Title IA, Articles 30-85 and the relevant recitals, Annexes V-IX) Brussels, 23.9.2022, 12549/22 [https://artificialintelligenceact.eu/wp-content/uploads/2022/09/AIA-CZ-3rd-Proposal-23-Sept.pdf], accessed 18/11/2022.

[119] See, e.g., the definition by the Independent High-Level Expert Group on Artificial Intelligence (HLEG) that proposes to use the term AI system to "…mean any AI-based component, software and/or hardware. Indeed, usually AI systems are embedded as components of larger systems, rather than stand-alone systems." Independent High-Level Expert Group on Artificial Intelligence (HLEG): *op. cit.* (fn. 11), p. 1. For a conceptual comparison between the interchangeable terms "AI systems" (in the Draft AI Act) and "automated decision systems" (in the proposed U.S. Algorithmic Accountability Act), and the preference for the latter, see Mökander, J. *et al.*: *The US Algorithmic Accountability Act of 2022 vs. The EU Artificial Intelligence Act: what can they learn from each other?*, Minds and Machines 2022 [https://doi.org/10.1007/s11023-022-09612-y], published online 18 August 2022. Analysing the definition of AI systems in the Draft AI Act, Schwemer *et al.* advocate for a narrower reading, in light of the overall context and provisions of the AI Act. See Schwemer, S. F.; Tomada, L.; Pasini, T.: *Legal AI Systems in the EU's proposed Artificial Intelligence Act*. Proceedings of the Second International Workshop on AI and Intelligent Assistance for Legal Professionals in the Digital Workplace (LegalAIIA 2021), held in conjunction with ICAIL 2021, June 21, 2021, Sao Paulo, Brazil, available at SSRN [https://ssrn.com/abstract=3871099], accessed 18/11/2022.

[120] We will rely primarily on the text of the relevant provisions, as proposed by the European Commission. Since the legislative process is well under way, in addition to the text of the Draft AI Act proposed by the European Commission, we will also refer to the currently available positions of the Council and the European Parliament committees on specific aspects of the draft proposal, where relevant and appropriate. For the sake of clarity, any reference to 'Draft AI Act' or 'AI Act' in this paper means the version of the text as proposed by the European Commission.

Title V ('Measures in support of innovation') of the Draft AI Act, in the version proposed by the European Commission, contains three provisions (Articles 53 – 55). Although one might be (mis)lead by the title to expect an arsenal of measures, these provisions are primarily concentrated on regulatory sandboxes. The proclaimed objective of this Title is to create a "legal framework that is innovation-friendly, future-proof and resilient to disruption."[121] The addressees are national competent authorities from one or more Member States, as well as the European Data Protection Supervisor.[122] To ensure uniform implementation across the Union, the Draft AI Act provides minimum common rules for regulatory sandboxes (Article 53).[123] The Draft AI Act further offers additional safeguards in terms of data protection (Article 54), as well as measures to reduce the regulatory burden on SMEs and start-ups (Article 55).

Under the Draft AI Act, AI regulatory sandboxes establish a controlled environment that facilitates the development, testing, and validation of innovative AI systems for a limited time before their placement on the market or put into service, based on a specific testing plan agreed with the competent authorities. The competent authorities provide direct supervision and guidance to sandbox entities, to ensure compliance with the requirements of the AI Act and, where relevant, other Union and Member States' legislation supervised within the sandbox.[124]

The content of Article 53 of the Draft AI Act is limited to the basic requirements for AI sandboxes, concerning:

– Purpose and objectives: As can be discerned from the definition of AI regulatory sandboxes under Article 53(1) of the Draft AI Act, their purpose is to facilitate innovation while ensuring regulatory compliance. Recital 72 offers further guidance by citing three objectives: fostering innovation,

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[121] European Commission: Draft AI Act, *op. cit*. (fn. 5), Explanatory Memorandum, para 5.2.5.

[122] The Council proposes to circumscribe the authority of the European Data Protection Supervisor to establish only those AI regulatory sandboxes which are connected with the AI systems provided by the EU institutions, bodies and agencies. See Council of the European Union: *op. cit*. (fn. 118), p. 93.

[123] See Recital (72) and Article 53 Draft AI Act.

[124] Article 53(1) Draft AI Act. Strict regulatory oversight in the sandbox environment is necessary to ensure a safe space for experimentation, and to promote responsible innovation and integration of appropriate safeguards and risk mitigation measures, see Recital (71) of the Draft AI Act. Yordanova points out that the definition of AI sandbox is significantly broadened, encompassing "development, testing and validation and therefore combining the traditional function of a regulatory sandbox with those of other tools such as testing and pilots." See Yordanova, K.: *The EU AI Act – Balancing human rights and innovation through regulatory sandboxes and standardization*, TechREG Chronicle, March 2022, p. 7.

enhancing legal certainty for innovators and competent authorities alike, and accelerating access to the markets, with a special focus on removing barriers for small and medium enterprises (SMEs) and start-ups.[125]

− Data protection: The Draft AI Act recognizes the obvious connection of AI use with data protection and privacy concerns, which necessitates co-operation between the relevant authorities involved in the supervision of the sandboxes. It is therefore required to involve national data protection authorities or other competent national authorities in the operation of the AI regulatory sandbox, if and to the extent that the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data.[126]

− Powers of competent authorities: It is highlighted that AI regulatory sandboxes do not affect the supervisory and corrective powers of the competent authorities.[127]

− Risk mitigation: Immediate mitigation of any significant risks to health and safety and fundamental rights identified during the development and testing of such systems is required. In case of failure to take mitigation measures, the development and testing process shall be suspended until such mitigation takes place.[128]

− Liability: Experimentation in the sandbox does not exonerate the participants from liability under applicable Union or national legislation for any harm inflicted on third parties as a result of the experimentation taking place in the sandbox.[129]

− The EU dimension: The new European Artificial Intelligence Board[130] and the European Commission provide a reference point for all national compe-

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[125] Recital (72) Draft AI Act. The changes to Recital (72) under the Third Presidency compromise text in the Council specifically highlight the "contribution to evidence-based regulatory learning" as a benefit of the sandbox exercise, and place focus on issues that raise legal uncertainty for providers and perspective innovators to innovate. See Council of the European Union: *op. cit.* (fn. 118). The Council proposes to insert the sandbox objectives into the text of Article 53 as well.

[126] Article 53(2) Draft AI Act.

[127] Article 53(3) Draft AI Act.

[128] Article 53(3) Draft AI Act.

[129] Article 53(4) Draft AI Act.

[130] The tasks of the European Artificial Intelligence Board are to provide advice and assistance to the Commission and contribute to the effective cooperation with the national supervisory authorities; to coordinate and contribute to guidance and analysis by the Commission

tent authorities. National competent authorities will be required to submit annual reports to the Board and the Commission on the results from the implementation of a sandbox, including good practices, lessons learned, and recommendations. This ensures coordination, cooperation, and mutual learning from best practices.[131]

Specific modalities and the conditions of the operation of the AI regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation, and exiting from the sandbox, and the rights and obligations of the participants shall be set out in an implementing act, to be subsequently adopted by the European Commission.[132]

An important addition to the version proposed by the European Commission suggested by the Council concerned the clarification of the relationship between the AI sandboxes set up to ensure compliance with the AI Act, and other national AI regulatory sandboxes that already exist, or will be established in Member States to ensure compliance with legislation other than the AI Act. AI regulatory sandboxes set up under the AI Act should be without prejudice to existing legislation allowing for the establishment of those other sandboxes.[133] Potentially, 'other' regulatory sandboxes could switch to the AI regulatory sandbox operated and supervised under the framework of the AI Act, provided that such agreement between national competent authorities and sandbox participants exists. Such explanations are missing in the text proposed by the European Commission, but they are extremely valuable in view of the fact that many Member States have already introduced, or are in the process of adopting their legal frameworks for AI sandboxes and/or other digital testing grounds.[134] This means that, given the optional character of AI sandboxes under the AI Act, diverging experimental legal regimes will continue to exist

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and the national supervisory authorities and other competent authorities on emerging issues covered by the AI Act; and to assist the national supervisory authorities and the Commission in ensuring the consistent application of the AI Act. See Articles 56 – 58 Draft AI Act.

[131] Article 53(5) Draft AI Act.

[132] The blueprint is already provided in the broader context of a Better Regulation Toolbox, where regulatory sandboxes are viewed as an emerging method and policy instrument for *ex ante* policy assessments, or *ex post* fitness checks. See European Commission: Better Regulation Toolbox, *op. cit.* (fn. 34), Tool #69.

[133] See Council of the European Union: *op. cit.* (fn. 118), p. 36 – 37.

[134] See, e.g. in Germany, Bundesministerium fur Wirtschaft und Energie, Neue Raume fur Innovation zu proben, Konzept fur ein Reallabore-Gesetz [https://www.bmwk.de/Redaktion/ DE/Publikationen/Digitale-Welt/konzept-fur-ein-reallabore-gesetz.pdf?__blob=publication-File&v=6], accessed 18/11/2022. See also Federal Ministry for Economic Affairs and Climate Action: [https://www.bmwk.de/Redaktion/EN/Downloads/I/info-reallabore.pdf?__blob=-publicationFile&v=4], accessed 18/11/2022.

even after the adoption of the Draft AI Act, and it is necessary to address their potential intersections.

Article 54 of the Draft AI Act prescribes strict conditions for further processing of personal data, which are lawfully collected for other purposes, in the AI regulatory sandbox. The conditions for further processing attach to the purpose of the processing,[135] effective monitoring and mitigation mechanisms,[136] as well as data storage, usage, transmission, and deletion.[137] There are additional requirements concerning the obligatory content of the technical documentation referred to in Annex IV of the Draft AI Act,[138] and transparency of the AI project developed in the sandbox.[139] These obligations are without prejudice to Union or Member States legislation excluding processing for other purposes than those explicitly mentioned in that legislation.[140] The additional

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[135] When processing is necessary for the development and testing of certain innovative AI systems aimed at safeguarding substantial public interest (Article 54(1)(a) (i) – (iii) Draft AI Act), and where such data is necessary for complying with one or more requirements on data governance for high-risk AI systems under Title III, Chapter II of the Draft AI Act, if those requirements cannot be effectively fulfilled by processing anonymised, synthetic or other non-personal data (Article 54(1) (b) Draft AI Act). There is no guidance as to the required standard for constituting a 'substantial' public interest.

[136] There are effective monitoring mechanisms to identify if any high risks to the fundamental rights of the data subjects may arise during the sandbox experimentation as well as response mechanism to promptly mitigate those risks and, where necessary, stop the processing (Article 54 (1) (c) Draft AI Act).

[137] Any personal data to be processed in the context of the sandbox are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to that data (Article 54 (1) (d) Draft AI Act). Any personal data processed shall not be transmitted, transferred or otherwise accessed by other parties (Article 54 (1) (e) Draft AI Act). Any processing of personal data in the context of the sandbox shall not lead to measures or decisions affecting the data subjects (Article 54 (1) (f) Draft AI Act). Any personal data processed in the context of the sandbox shall be deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period (Article 54 (1) (g) Draft AI Act). The logs of the processing of personal data in the context of the sandbox are kept for the duration of the participation in the sandbox and 1 year after its termination, solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under this Article or other application Union or Member States legislation (Article 54 (1) (h) Draft AI Act).

[138] A complete and detailed description of the process and rationale behind the training, testing and validation of the AI system shall be kept together with the testing results as part of the technical documentation (Article 54 (1) (i) Draft AI Act).

[139] A short summary of the AI project developed in the sandbox, its objectives and expected results has to be published on the website of the competent authorities (Article 54 (1) (j) Draft AI Act).

[140] Article 54 (2) Draft AI Act.

legal basis and permission to process personal data specified in the context of AI innovation, apart from that regulated under the GDPR, might prove problematic in practice.[141]

The Draft AI Act pays particular attention to the position of small-scale providers[142] and users in the context of regulatory sandboxes, and other activities aimed at supporting them to comply with the AI Act. This entails specific obligations of Member States to provide small-scale providers and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfill the eligibility conditions,[143] and to undertake specific awareness raising activities about the application of the AI Act tailored to the needs of the small-scale providers and users.[144] Where appropriate, Member States shall establish a dedicated channel for communication with small-scale providers and user and other innovators to provide guidance and respond to queries about the implementation of the AI Act.[145] When setting the fees for conformity assessment under Article 43 of the Draft AI Act (applicable for high-risk AI systems), the specific interests and needs of the small-scale providers shall be taken into account, with appropriate reduction in those fees according to their size and market size. [146]

The Draft AI Act acknowledges and attempts to mitigate its negative impact in terms of compliance costs on competitiveness of SMEs, especially those supplying high-risk AI systems.[147] It is not surprising that the support for regulatory sandboxes during stakeholder consultations primarily came from businesses and business associations, which have recognized their potential

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[141]   See Bomhard, D.; Merkle, M.: *Regulation of Artificial Intelligence*, Journal of European Consumer and Market Law, 10(6) 2021, pp. 257-261, p. 259; Smuha, N. *et al.*: *How the EU can achieve legally trustworthy AI: A response to the European Commission's proposal for an Artificial Intelligence Act*, available at SSRN: [https://ssrn.com/abstract=3899991] or [http://dx.doi.org/10.2139/ssrn.3899991], accessed 18/11/2022, p. 42.

[142]   See Article 3 (1) (3) Draft AI Act: 'Small-scale provider' means a provider that is a micro or small enterprise within the meaning of the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (notified under document number C(2003) 1422), OJ L 124, 20.5.2003. Within the SME category, a small enterprise is an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million; whereas a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.

[143]   Article 55 (1) (a) Draft AI Act.

[144]   Article 55 (1) (b) Draft AI Act.

[145]   Article 55 (1) (c) Draft AI Act.

[146]   Article 55 (2) Draft AI Act.

[147]   See Recital (73) Draft AI Act.

for the promotion of innovative business models.[148] Ensuring priority access for small-scale providers and lowering the fees for conformity assessment are examples of such measures and the embodiment of the "Think Small First"[149] principle. However, even though these measures are useful and welcome, their effect is doubtful, given that the scope of regulatory requirements for AI systems is not reduced.[150]

Some Member States are already piloting projects aimed at ensuring regulatory compliance with the future AI Act. In June 2022, the Spanish Government launched an initiative for a pilot AI sandbox, aiming to "provide companies, especially SMEs and start-ups with certainty when they start implementing the requirements and other features such as conformity assessments or post-market activities" of the future AI Act.[151] It will connect authorities with companies developing AI solutions in a joint effort to operationalize future obligations under the AI Act and to create know-how, guidance, and good practice examples for similar ventures in the years to come. The European Commission will work closely with the Spanish authorities, and all other Member States can participate or follow the development of this exercise and its outcome, which could reinforce its potential to develop into a pan-European AI sandbox and feed into the harmonized guidelines and standards to be prepared by the Commission for the implementation of the AI Act. The organizational structure of this pilot AI sandbox is typical for regulatory sandboxes: it will be based on a public call, based on transparent eligibility and selection criteria for the participating companies. Parallelly, a focus group will be established, with the task of preparing the overall framework for the sandbox, monitoring, documenting, and systematizing its progress, and based on its results, developing a set of guidelines and standards for future use. With the work on adopting the AI Act still in progress, the experiences from this and similar ventures might contribute to identifying the gaps and challenges requiring further fine-tuning.

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[148] European Commission: Draft AI Act, *op. cit*. (fn. 5), Explanatory Memorandum, para, para. 3.1.

[149] See European Commission: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Better regulation for better results - An EU agenda, COM(2015) 215 final, Strasbourg, 19.5.2015.

[150] Bomhard, D.; Merkle, M.: *op. cit*. (fn. 141), p. 259. See also European Parliamentary Research Service (EPRS): Auditing the quality of datasets used in algorithmic decision-making systems, p. 40 [https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729541/EPRS_STU(2022)729541_EN.pdf], accessed 18/11/2022

[151] Bringing the AI Regulation Forward [https://digital-strategy.ec.europa.eu/en/events/launch-event-spanish-regulatory-sandbox-artificial-intelligence], accessed 18/11/2022.

4.3 BENEFITS AND CHALLENGES OF AI REGULATORY SANDBOXES

The existing contours of AI regulatory sandboxes under the Draft AI Act provide a solid background for contemplating the benefits and challenges of the proposed regulatory regime.

Once adopted, the AI Act will be the first horizontal piece of legislation regulating the use of AI. Although it aspires to provide innovative and comprehensive solutions, any new regulation puts additional, although undoubtedly necessary, regulatory pressure on innovators. It will certainly take time and substantial effort to fully comprehend and comply with its requirements, during which time the innovative AI systems will continue to evolve and emerge. This pressure can be alleviated by engaging in regulatory sandboxes. One of the most obvious benefits is that experimenting in the sandbox might help the companies adapt to the new framework, and at the same time reveal whether the new regulation itself needs to be refined and adapted in response to unforeseen effects of experimental technologies.[152]

The common approach to AI sandboxes might help overcome regulatory fragmentation and regulatory friction, and the resulting legal uncertainty. Different Member States currently have different sandbox rules or no rules at all. Since the AI sandbox regime under the Draft AI Act is optional, whether it will prevail over national options depends on its design and clearly formulated benefits for Member States and businesses alike. In addition, the AI sandboxes might provide a necessary jumpstart for those Member States that are lagging behind in supporting innovation.

Sandbox might help in protecting from the risk inherent in the operation of AI systems, especially those identified as high-risk AI systems. The testing environment allows for risk containment, advance preparation and implementation of risk mitigating strategies, thus insulating the consumers and market from large-scale adverse effects of AI technologies.

The existence of sandbox regime sends a positive signal to businesses and creates an innovation-friendly environment, which in turn increases competitiveness. Nevertheless, competitiveness is not an automatic consequence, it will depend on the sandbox conditions. When entry and testing conditions are too relaxed, bad, or even harmful innovation can sneak in. The sandbox conditions should therefore serve an important gatekeeping function.[153] So far, the AI sandbox framework under the Draft AI Act does not appear either overly permissive or too strict. The proposed provisions provide a general framework and organizational

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[152]   See also Brummer, C.; Yadav, Y.: *op. cit.* (fn. 2), p. 295.

[153]   *Loc. cit.*

principles, whereas the particularities concerning eligibility and selection criteria, the procedure for application and participation, monitoring, exit strategies, etc. are to be adopted by the European Commission. The solutions adopted in the implementing act will have a decisive impact on the success of this legal regime in the context of the AI Act and will provide ground for further assessment.

The benefits and challenges of AI sandboxes are often intertwined. A sandbox by definition creates a closed environment for safe(r) experimentation and mutual learning, but the inherent limits of the sandbox testing experience might reflect negatively on the lessons drawn from the experiment. The question is, whether the sandbox offers sufficiently informative evidence as to how the approved innovation is likely to work outside of the shielded environment, i.e. in the main market.[154] The scaling-up of the results observed in the testing environment to the wider market is a well-known challenge.[155] The national competent authorities that will operate the sandbox will have to design it keeping in mind that the outcome of the testing will have to be relevant in the wider context and sufficiently informative, which will be a difficult task. This is where the EU added value, arising under the coordination and cooperation tenets under the Draft AI Act for the Member States' authorities and EU bodies and institutions, could prove helpful. Mutual learning, exchange of best practices, and cross-border sandbox implementation and cooperation might help to overcome the scale-up challenge.

On the other hand, there is not much guidance as to how multi-jurisdictional[156] AI sandboxes should be implemented in practice.[157] Another issue that will be challenging in practice concerns the relationship between overlapping experimental regimes at European and local levels.[158] The intersection between

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[154] Brummer, C.; Yadav, Y.: *op. cit.* (fn. 2), p. 295.

[155] European Commission: Better Regulation Toolbox, *op. cit.* (fn. 34), Tool #69, p. 600. See also Attrey, A.; Lesher, M.; Lomax, C.: *The role of sandbox in promoting flexibility and innovation in the digital age*, Going Digital Toolkit Policy Note, No. 2, 2020 [https://goingdigital. oecd.org/data/notes/No2_ToolkitNote_Sandboxes.pdf], accessed 18/11/2022.

[156] Under the current version of Article 53(1) of the Draft AI Act, AI regulatory sandboxes may be established by one or more Member States.

[157] Yordanova warns that without standardisation, the sandboxed activity is unfit for cross-border provision of services, which brings into question this type of sandboxes. See Yordanova, K.: *op. cit.* (fn. 124), p. 7. Evidence from Latin America and the Caribbean shows that cross-border, multi-jurisdictional sandbox is an attractive option for small markets, but the harmonization required from different jurisdictions may prove to be an insurmountable obstacle. See World Bank: *op. cit.* (fn. 51), p. 14. For an in-depth analysis of advantages and challenges of multi-jurisdictional FinTech sandboxes see Ahern, D.: *op. cit.* (fn. 75), p. 22 – 24.

[158] See European Parliamentary Research Service (EPRS): Artificial Intelligence Act and Regulatory Sandboxes, Briefing, p. 5 [https://www.europarl.europa.eu/RegData/etudes/ BRIE/2022/733544/EPRS_BRI(2022)733544_EN.pdf], accessed 18/11/2022.

regulatory sandboxes and other experimental legal regimes aimed to support digital innovation is still not adequately addressed. There is a growing variety of such regimes in the Member States and the at EU level (such as living labs, test beds, innovation hubs, etc.), and the concept of AI sandboxes under the AI Act partly incorporates similar functions (i.e. testing, valid,ation and piloting). Given the competing and overlapping regimes, the obvious question is whether some of the minimum requirements for AI sandboxes might apply to them by analogy. This is especially important given experiments involving high-risk AI systems. The Council has suggested inserting an additional provision under Title V of the Draft AI Act, to recognize and regulate experimenting which takes place outside of a fully-fledged AI regulatory sandbox.[159] It requires the development of a real-world testing plan, with similar minimum requirements and safeguards as those applicable in the sandbox regime. Another addition by the Council concerns the obligation to design and implement AI sandboxes in such a way as to facilitate cross-border cooperation.[160] The AI sandboxes certainly add to the complexity of different legal regimes, and more effort should be put into ensuring minimal standardisation of sandbox rules across different Member States.

Likewise, there might be confusion between different types of sandboxes at EU level, depending on the area where they apply and the corresponding legal framework. For example, the purpose of AI sandboxes under the Draft AI Act is to facilitate innovation, while ensuring regulatory compliance. This seems to imply that, apart from suspension of the authorities' corrective powers during sandbox testing, there will be no regulatory waivers available. Thus, the AI sandbox type comes close to innovation deals, that aim to clarify regulatory barriers perceived by innovators, instead of revising or suspending them.[161] Since AI is a pervasive, general-purpose technology that may be applicable across sectors and in combination with other technologies,[162] the question is whether other types of sandboxes, such as those based on experimentation clauses (as instruments of adaptive regulation), might be allowed under the horizontal legal framework, as well.

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[159] Council of the European Union: *op. cit.* (fn. 118), p. 98 – 101 (Articles 54a and 54b).

[160] See Council of the European Union: *op. cit.* (fn. 118), p. 95-96.

[161] See European Commission: Better Regulation Toolbox, *op. cit.* (fn. 34), Tool #22. See also Leimüller, who identifies sandbox type 1 as that based on explicit experimentation clause and possible waiver options, and sandbox type 2 as that including supervision comparable to Innovation Deals, i.e. without regulatory waivers. Leimüller, G.: *Regulatory Sandboxes*, Analytical paper for Business Europe, Vienna, 2020, p. 10 [https://www.businesseurope.eu/sites/buseur/files/media/other_docs/regulatory_sandboxes_-_winnovation_analytical_paper_may_2020.pdf], accessed 18/11/2022.

[162] Think of FinTech related AI applications in connection with e.g., robo-advice, APIs or DLTs.

Whereas the "sandbox concept itself is easy to copy",[163] the results are not easily replicable in different contexts and AI ecosystems. The national authorities should avoid the "copy-paste" trap and instead attempt to cultivate an in-depth understanding and knowledge exchange with the innovators, to better understand the implications of the testing experience.

Another connected challenge is the rapid pace of the development of technological solutions. Once the sandbox exercise is completed, the AI system under scrutiny and its application might have already evolved, thus making the tested model irrelevant, or in need of further examination. This can be overcome by resorting to a combination of different, even looser forms of experimentation, in and around the sandbox itself. Currently, the Draft AI Act offers no solution for this issue.

An important benefit of sandboxes in general is the regulatory lenience. It means that competent authorities might refrain from using their corrective powers against a sandbox participant during the experiment, as long as the participant adheres to the rules of play agreed upon in the sandbox. According to the version of the text proposed by the European Commission, AI sandboxes shall not affect the supervisory and corrective powers of the competent authorities.[164] The vagueness of this provision has prompted the Council to suggest changes that would provide specific safeguards for sandbox participants during the experiment: the authorities should flexibly use supervisory powers, with a view to supporting innovation. No administrative fines for infringement of applicable Union or Member State legislation shall be imposed during the testing period, provided that the participant respects the agreed sandbox plan and follows the guidance given by the authorities in good faith.[165]

Regulatory lenience does not extend to liability issues: Under the Draft AI Act, sandbox participants are not shielded from liability under applicable Union or national legislation for any harm inflicted on third parties as a result of the experimentation taking place in the sandbox.[166] Truby et al. criticize this approach as "eroding the very essence of sandbox regulation".[167] According to

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[163] Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 79. On the importance of the regulator's reputation for sandbox success and appeal, see Fahy, L.: Regulator reputation and stakeholder participation: A case study of the UK's regulatory sandbox for Fintech, European Journal of Risk Regulation (13) 2022, pp. 138-157, p. 155, DOI: 10.1017/err.2021.44.

[164] Article 53 (3) Draft AI Act.

[165] See Council of the European Union: *op. cit.* (fn. 118), p. 95.

[166] Article 53(4) Draft AI Act.

[167] Truby, J. et al.: *A Sandbox Approach to Regulating High-Risk Artificial Intelligence Applications*, European Journal of Risk Regulation (13) 2022, pp. 270–294, p. 291, DOI:10.1017/err.2021.52.

them, sandbox participants run a considerable risk: they are exposed to compliance and setup costs, an added layer of regulatory scrutiny and supervision, and their classified and commercially sensitive information and trade secrets are exposed to regulators and third parties. These risks should at least be offset by a diversified approach to liability issues. We cannot agree with such proposition. A sandbox should not be seen as a way of escaping from responsibility inflicted to third parties. Quite the contrary, it should facilitate the development of safe AI systems, and motivate the developers to map out and resolve any potential liability issues in advance, before the harm is inflicted and before the product or service is placed on the market.

Sandboxes are designed with the aim of supporting innovation and increasing competitiveness. To increase competitiveness without distorting competition, a transparent, level-playing field for all potential participants should be created. This means that all rules of play should be disclosed clearly and allow participation under the same conditions, and the abstention from using corrective powers by the authorities should not be applied arbitrarily, to prevent any issues arising from the competition law perspective,[168] as well as the principle of equality.[169]

It is worth highlighting that the promotion of innovation should never be the only or predominant regulatory goal, as it is liable to lead to a regulatory race to the bottom, attracting innovation and investment at the expense of human rights and consumer protection safeguards. Furthermore, this could amplify the danger of forum shopping. Given that the AI sandbox regime under the Draft AI Act is optional and left for implementation to Member States, AI developers might be encouraged to choose those Member States with less stringent sandbox regimes.[170]

One important aspect of the sandbox environment is that it presents an opportunity for a mutual-learning experience. This is not limited to regulators and participants but should include a wide range of different stakeholders within the AI ecosystem. It would therefore be appropriate, as suggested by the Council,[171] to underline the possibility of cooperation between national competent

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[168]   See Ahern, D.: *op. cit.* (fn. 54), p. 9; Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 80.

[169]   Ranchordás warns that the assessment of compliance of the sandbox regime with the principle of equal treatment should take into account the temporary character of the regime, whether the sandbox was established in accordance with objective criteria, whether it is proportionate to the goals pursued (i.e. the applied sandbox tools should be least disruptive for the legal order and necessary for the achievement of sandbox objectives), and whether the conditions of entry and exit are transparent. See Ranchordás, S.: *op.cit.* (fn. 58), p. 8.

[170]   EPRS: *op. cit.* (fn. 158), p. 5.

[171]   Council of the European Union: *op. cit.* (fn. 118), p. 36. Similar proposition is made in the Joint Report by the IMCO and LIBE Committees, see European Parliament: *op. cit.* (fn. 116).

authorities establishing AI regulatory sandbox with other relevant authorities, including those supervising the protection of fundamental rights, as well as other actors, such as national or European standardization organizations, notified bodies, testing and experimentation facilities, research and experimentation labs, innovation hubs and relevant stakeholder and civil society organizations.

5. CONCLUDING REMARKS

The potential of AI sandboxes to encourage innovation and enhance the competitiveness of SMEs is still unclear. The underlying question is whether the cost of regulatory compliance, which will certainly affect SMEs will be offset with clear benefits and opportunities arising for SMEs' business models under the Draft AI Act. As recognized in the Impact Assessment, "whether the additional costs can at the margin discourage some SMEs from entering into certain markets for high-risk AI applications will depend on the competitive environment for the specific application and its technical specificities".[172] It is too early to assess whether innovative SMEs will seize the regulatory flexibility in the sandbox as an opportunity for placing their products and services in the market. The allure of the sandbox for individual SMEs will certainly depend on the actual cost-benefit analysis within the sandbox environment, and upon exit.[173] One thing is certain, regulatory flexibility cannot substitute for market demand.[174] This is a challenge for small markets. In addition, establishing and running a sandbox is a costly exercise, both in terms of financial and institutional resources.[175] On the other hand, if applied with due care and without engaging in the race to the bottom, it can also be turned into an asset, to kickstart the innovative potential of such economies.

AI systems form complex value chains and may be applicable in a plurality of contexts, across different sectors, and for a range of different purposes. This entails further considerations, such as those concerning the identification of competent authorities for the operation of an AI sandbox, their powers and

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[172] European Commission: Staff Working Document. Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts. SWD/2021/84 final, Brussels, 21.4.2021, p. 70.

[173] See Ahern, D.: *op. cit.* (fn. 75), p. 10.

[174] Zetzsche, D. A. *et al.*: *op. cit.* (fn. 3), p. 90.

[175] Bajakić, I.: *Transformation of financial regulatory governance through innovation facilitators - case study of innovation hub in Croatian capital markets*, EU and Comparative Law Issues and Challenges Series (ECLIC) (4) 2020 [https://doi.org/10.25234/eclic/1193], pp. 917–946, p. 917.

mutual relationship, as well as cooperation and coordination mechanisms to ensure the smooth functioning of the sandbox experiment. This requires capacity building for regulators, to understand the potential and the purpose of a sandbox, as well as the innovative solutions it is supposed to support. Undoubtedly, deeply experienced regulators will have sufficient expertise to facilitate innovative business models even in the absence of a regulatory sandbox.[176]

The sandbox will work only under carefully calibrated conditions. Most importantly, the sandbox procedure has to be transparent, with easily accessible and user-friendly rules and guidelines, clearly explaining the benefits of sandbox testing, i.e., how the procedure and its outcome enhance legal certainty and alleviate concerns that firms might have when placing an innovative AI system on the market. This will create a climate of mutual trust between the innovators and regulators, as well as increase the consumers' trust in the AI systems. Otherwise, the concept of an AI sandbox might not live up to its full potential.

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