

The Digital Regulatory Framework through EU AI Act: The Regulatory Sandboxes' Approach

By Marta Boura^{*}

"If the study to which you apply yourself has a tendency to weaken your affections and to destroy your taste for those simple pleasures in which no alloy can possibly mix, then that study is certainly unlawful, that is to say, not befitting the human mind."

Mary Shelley, *Frankenstein*

In the past years, the EU political agenda has been marked with an accelerated digital transformation programme intended to provide for both a safety net for the implementation and use of technology and the regulation and democratisation of access to technology. In this context, the regulation of artificial intelligence (AI) has been flagged as a priority considering how it has contributed to a transformation on both business activities and legal practice. The EU AI Act currently under discussion has the advantage of marking a pioneer regulatory intervention laying down harmonised rules on AI, shaping both how AI is to be used as well as its risks. From a legal perspective, the EU AI Act also presents as an opportunity to launch a new digital regulatory paradigm which deals with the difficulties of the traditional regulatory framework in balancing the need to regulate a constantly changing reality alongside the creation of a regulation that is not excessively burdensome for developers and providers. On the one hand, new regulatory principles of function equivalence and technology neutrality have been implemented as application and interpretation criteria, while on the other hand, new supervisory and regulatory technologies are being experimented to align digital monitoring and reporting requirements. Accordingly, discussions around the so-called digital law philosophy, legal thinking and legal design mechanisms are to guide a new construction of how the legal field is to adapt to the digital era. Despite being a cross-cutting regulatory approach towards digital fields (as digital finance), the proposed AI regulation stands out in this domain for its assumed break with typical regulatory standards by adopting a risk-based approach (as opposed to a regulation based of rights) or implementing regulatory sandboxes aimed to test and develop new AI technologies. In this article, we propose to address the main features of the new digital regulatory paradigm having the EU AI Act in the horizon. In particular, we propose to discuss the underlying rationale of a sandbox approach and how it fits the development of emerging technologies as AI.

Keywords: *Digital regulatory framework; EU; EU AI Act; regulatory sandboxes; innovation.*

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The AI Revolution: Do we need Regulation?

New (Digital) Challenges

I. AI has coined a cross-sectional digital transformation which is shaping society. In fact, although AI first appeared as an isolated phenomenon within the digital era, as a system it has singlehandedly necessitated deep changes on how society perceives technology, and how society responds towards it. The opportunities brought or potentialized by AI have been acknowledged by organisations, public institutions and consumers that now rely on the rapid pace of AI to conduct different activities. Indeed, AI “(...) opens the way to greater operational efficiency and to reduced service and products costs, and, in general, to improving the quality of life of citizens through the possibility of automating a greater number of tasks. Furthermore, the specific uses of AI in sectors such as health or combating climate emergencies will allow us to bring greater safety and scientific evolution to this new era”¹.

Naturally, this revolution does not come without risks, such as the reinforcement of biases, automated decision-making, or the spread of misinformation, which require policymakers to pay a close look at the emergence of new technological products and how they settle into day-to-day usages.

However, and despite the risks or potential disadvantages of AI, the EU (and public agents, in general) have chosen to address it and to discuss how to control its evolution through regulation. As per our view, that finds mainly two reasons: first, because AI, together with other technologies, is already implemented in society through organisations and business sectors which inevitably is exposed to consumers and second because AI tools and platforms are overall more accessible and being appointed as a way to provide more safety and control in other technologies (as the metaverse), in particular, by intercepting or otherwise control how communication flows within the virtual world hence preventing verbal offences). Therefore, AI is not only the one responsible for the so-called digital revolution as it can lead the way of regulation of other technologies. This general success of AI over other technologies is explained both on the features of the technology *per se* (as it can capture and be of use in almost all businesses and activities) and, as per our view, on the detailed analysis that has been conducted in the past years around AI's risks. The attention EU regulators have provided to AI has contributed to increased knowledge, awareness and a sense of safety around AI, which, as per our view, summarises the most important advantage of regulation: to promote discussion and a sense of control on how technology develops and is used which, ultimately, ends up bringing people closer to technology. This is the EU's intended agenda as the EU's programme for the digital decade has been assumed as a way to “empower citizens and businesses through digital transformation”².

¹Boura (2023).

²Recital (1) of the Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022, establishing the Digital Decade Policy Programme 2030.

II. This leads to state regulation as the necessary path and as such the EU AI Act represents a landmark of public intervention which simultaneously recognises the difficult balance between mitigation of risks and incentives for implementation. Around these difficulties, rule makers had to adjust and experience new ways of marking the regulatory AI landscape: (a) first of all, by adopting risk-based approach regulation, (b) then, by establishing legal ways of bringing the economic operators and regulators closer so the regulation suffices the market's need and the features of each type of technologies, which is being achieved by regulatory sandboxes (b) and by defying common standard principles and functions of AI governance recently proposed by the UN AI Advisory Body in the "Governing AI for Humanity" 2023 Report³.

III. In this paper, we will analyse the perspective of multistakeholder collaboration which can impact the three dimensions identified above. Indeed, it reflects the rule makers' technical understanding of technology and how the risks are known and identified in the regulation. It is a main reflection of regulatory sandboxes as controlled environments for testing and control and, ultimately, it leads to a more balanced governance focused on the users' and market's protection. In particular, we will focus on the regulatory sandboxes as a legal design revolution.

Human-machine Collaboration: Displacement vs Replacement

I. Between the lines of collaboration, the relation human-machine launches a new set of challenges that must be analysed autonomously as they depend on the type of AI. Although AI is traditionally considered for data-driven tasks and decisions⁴, generative AI has increased AI potential to the level of automation and, some might argue, creativity. At the end of the line, researchers stress out the possibility of developing human-level AI or, ultimately, artificial superintelligence which is conceptualised as a system that can overcome humans' capabilities. Indeed, following Nick Bostrom's definition:

'[...] we mean an intellect that is much smarter than the best human brains in practically every field, including scientific creativity, general wisdom and social skills. This definition leaves open how the superintelligence is implemented: it could be a digital computer, an ensemble of networked computers, cultured cortical tissue [...]. It also leaves open whether the superintelligence is conscious and has subjective experience'⁵.

³https://www.un.org/sites/un2.un.org/files/ai_advisory_body_interim_report.pdf. As Guiding Principles, the Report identifies the following: AI should be governed inclusively, by and for the benefit of all; AI must be governed in the public interest; AI governance should be built in step with data governance and the promotion of data commons; AI must be universal, networked and rooted in adaptive multistakeholder collaboration; and AI governance should be anchored in the UN Charter, International Human Rights Law, and other agreed international commitments such as the Sustainable Development Goals (16-17).

⁴Simplilearn.

⁵Bostrom (1998).

Regardless of how distant such possibilities still are from today, from a legal perspective the question of the creativity or of the AI independence from humans has been tested in multiple ways. As an example, the recently discussed *Thaler v. Comptroller-General of Patents, Designs and Trademarks* that was decided by the Supreme Court of the United Kingdom⁶ managed to bring to discussion the creativity and ownership of AI for the purposes of patent registration (the “DABUS Case”).⁷ In that case, it was unanimously decided to refuse the possibility of registering a patent whose inventor was regarded as an AI system. Therefore, human intervention was considered an essential requirement to patent a new invention⁸. This decision comes in the context of attempts to patent DABUS technology, whose registration had already been requested (and refused) in Australia, Germany, Israel, New Zealand, the United States and the European Patent Office. Registration was only accepted in Saudi Arabia and South Africa, even though the latter was only due to the automatic patent mechanism without a true assessment of subjective requirements. Within the lines of the ruling, the scope and meaning of “inventor” under Patents Act 1977 was addressed as “a person who devises a new and non-obvious product or process (the invention) which is capable of industrial application and may be protected under the patent system”⁹ therefore concluding that “the Comptroller was right to decide that DABUS is not and was not an inventor of any new product or process described in the patent applications. It is not a person, let alone a natural person and it did not devise any relevant invention. Accordingly, it is not and never was an “inventor” for the purposes of section 7 or 13 of the 1977 Act”¹⁰.

II. The implications of the DABUS case may be extended beyond the walls of the patent field. Indeed, its rationale may be exported to AI when it comes to assessing the limits of a human-machine relation.

In fact, one of the most significant challenges around AI is the concern for human replacement. Even though some may argue that AI is too expensive to replace humans, the question poses as a possibility which has not only an ethical dimension, but also a direct impact in the way regulation (and its purposes) is drafted, should the human being not be considered as a primarily object of regulation. Therefore, we are to ask: *what would then be the purpose of regulation?* The object of regulation would not change. he challenges in the digital

⁶[2023] UKSC 49 – The DABUS Case. <https://www.supremecourt.uk/cases/docs/uksc-2021-0201-judgment.pdf>.

⁷DABUS means: Device for the Autonomous Bootstrapping of Unified Sentience.

⁸Similar decisions were already discussed by the Federal Circuit Court of Appeals in *Thaler v. Vidal* 43 F.4th 1207 (2022). Indeed, as pointed out by Eden Winlow, in such case it was ruled that “Section 271 of the Patent Act requires that an inventor be a human being; permission to appeal to the Supreme Court was denied *Thaler v. Vidal* (No. 22-919). The European Patent Office reached the same conclusion in J 0008/20 (Designation of inventor/DABUS) of 21.12.2021, as did Australia’s Full Court in *Commissioner of Patents v Thaler* – [2022] FCAFC 62. Germany, Israel, New Zealand, Taiwan and South Korea have made similar findings” – cf. Eden Winlow, “The End of the Road for DABUS and Dr Thaler at the UK Supreme Court”, *Kluwer Patent Blog*, 16.01.2024. <https://patentblog.kluweriplaw.com/2024/01/16/the-end-of-the-road-for-dabus-and-dr-thaler-at-the-uk-supreme-court>

⁹Par. 57 of the DABUS Case.

¹⁰Par. 73 of the DABUS Case.

legal framework is to consider how machines are used and, ultimately, how their outputs are further assessed by humans. Therefore, regardless of the extension of AI capabilities, the focus should continue its impact on individuals and organisations.

III. In such a scenario, the “human agency” phenomenon must, however, be considered. Human agency is expressed as a concern regarding the loss of control of humans in the decision-making process as AI tends to replace human rationalisation processes by “code-driven tools”¹¹. This can be reflected in two issues: Firstly, regarding the machine's replacement of rationalisation when reaching any solution. This means, from the outset, a bias that conditions outputs by allocating to the machine the process of configuring the problem's assumptions. Secondly, in the process of human supervision of outputs, the bias manifests itself not only in the control and processing of data, but, above all, in the supervision process, as it subconsciously removes the human weight from the reach of the solution. This means that, in the same way that we trust the result achieved by the calculator to the detriment of manual calculation, in the case of AI, there will necessarily emerge a tendency to discredit the human process in favour of the machine. The difficulty will therefore lie in carrying out supervision processes in at least two phases: a first autonomous phase of achieving results without taking into account the machine's output and only then a second that has the machine's data and output as a reference.

Therefore, while human supervision as aligned in the EU AI Act is key, it has to be densified applied in a way that guarantees independent and unbiased results, for which mere confirmations of the machine's output are not enough.

From Transformation of Society to a New Paradigm on Legal Design and Interpretation

Technological Neutrality and Functional Equivalence Principles

I. Technology has forced a new way of shaping Law, mainly due to the need for regulators to adjust how regulation responds to the operator's concerns regarding technology without favouring certain products or specific technologies over others.

Therefore, and by recognizing the difficulties of regulating a universe that is continuously changing, the legal system has embraced the principle of technology and business model neutrality¹², which holds that users and organisations should have the freedom to choose which technology to use without the interference of laws and regulation.

This legal approach comprises challenges on two different levels. First of all, on the regulators' side, it requires regulation to be shaped in a way that does not favour specific types of technology or business models over others. This means that exclusions from scope must be carefully thought out so as not to discriminate

¹¹Anderson, Rainie & Luchsinger (2018).

¹²See Principle 5 of the European Interoperability Framework (EIF).

against technologies that have a similar technical basis, and that regulation of specific products should not depend on the technology that is employed. This is expressly stated as a concern in the UNIDROIT Principles on Digital Assets and Private Law¹³. As this path leads, in thesis, to a wider scope of application of each regulation, interpreters are required to analyse regulation on a case specific approach to assuring that the rules are adapted to each technology or product. The ELI Principles on Blockchain Technology, Smart Contracts and Consumer Protection¹⁴ have made it clear in Principle 3 by stating that:

‘[in] the application of the PRINCIPLES it should, for each Principle and in each specific case, be considered which type of BLOCKCHAIN is used and who the parties involved are, and which type of SMART CONTRACT is used, as referred to in Principle 2’.

Alongside technological neutrality, policymakers have opened the path for the functional equivalence, rooted in the UNCITRAL Model Law of Ecommerce, which, different from the latter, now requires assessing what the technological parallel or equivalent of non-digital rules would be as a way to extend regulation for both digital and non-digital realities¹⁵. Indeed, as David John Harvey has stated:

‘The concept of ‘functional equivalence’ in law arose primarily as a result of the development of electronic commerce (e-commerce) and the need to ensure that legal requirements prescribing the use of paper-based documentation for the purposes of recording transactions did not constitute a major or continuing obstacle to the development of e-commerce and the use of digital systems’¹⁶.

II. Both technological neutrality and functional equivalence principles respond to the issue of how rule makers and courts can design and perceive Law in the digital era (hence defining interpretation criterion), either when considering a new set of rules or by creating equivalences between the digital and non-digital universes. At its essence, both principles reflect a competition law concern which ultimately affects not only organisations but also consumers as users.

EU AI Act Landscape

I. The EU AI Act is currently shaped. Indeed, in December 2023, the EU Council announced the provisional agreement on the AI Regulation that is to be applicable 2 (two) years after its entry into force (with exception made to some provisions). Having reached this agreement, the final version is anticipated (as

¹³<https://www.unidroit.org/wp-content/uploads/2023/09/Principles-on-Digital-Assets-and-Private-Law.pdf>

¹⁴Report of the European Law Institute. https://www.europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Principles_on_Blockchain_Technology__Smart_Contracts_and_Consumer_Protection.pdf

¹⁵See Veerpalu (2019) at 141.

¹⁶Harvey (2017) at 59. See Veerpalu (2019) on the Author’s analysis.

already approved), without prejudice to some technical aspects of implementation that are expected to be discussed during this year. The last amended AI Act proposal applies to suppliers, deployers (i.e., users of AI systems in a professional context), distributors, importers of AI systems and affected persons with reference to the EU territory (or if Member States' legislation is applicable).

As we expect the AI Act final version to be released, the market is starting to adjust to it considering, in particular, implementing documentation and report processes or data control and confidentiality mechanisms.

II. From a more dogmatic approach, the AI Act has to be assessed in light of three fundamental areas that we distinguish as follows: (i) a risk-approach regarding AI usages and functionalities, which directly shape the set of obligations, (ii) the prohibition practices' rationale and its relation with the protection of EU fundamental rights and (iii) information asymmetries towards the understanding of technology which give birth to innovation and learning mechanisms.

In the next chapter, we will address this third group, mainly focusing on the regulatory sandboxes' approach under the AI Act.

Regulatory Sandboxes

An Innovation and Learning Environment

I. To address the issue of information towards both the regulation and use of technology the EU has included regulatory learning tools within the digital framework¹⁷. Regulatory sandboxes, living labs or testbeds are examples of mechanisms that may seek to fulfil the regulator's gap in relation to the technical understanding of digital realities and, in particular AI. Alongside those, lighthouses and innovation deals are also gaining influence within the international market.

While testbeds and living labs comprise infrastructure and equipment available to organisations to provide services (mainly, to SMEs and Start-ups), integrating experimental spaces or real-life laboratories, regulatory sandboxes are not designed as proper incubators. Instead, they create technical environments that may progress without human resources, specifically to test how technologies or businesses react to real costumers, most commonly used+ by regulatory bodies. That is, therefore, it is no surprise that the AI Act has considered the regulatory sandbox approach in its Title V, as a measure in support of innovation. Indeed, as referred to in the proposed and latest amended Recital 71 of the AI Act:

'Artificial intelligence is a rapidly developing family of technologies that requires regulatory oversight and a safe and controlled space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that promotes innovation, is future-proof, and resilient to disruption, Member States should establish at least one

¹⁷European Commission, Commission Staff Working Document (2023).

artificial intelligence regulatory sandbox to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. It is indeed desirable for the establishment of regulatory sandboxes, whose establishment is currently left at the discretion of Member States, as a next step to be made mandatory with established criteria¹⁸.

II. AI regulatory sandboxes will be of greatest importance to authorities, both national and European, considering the AI Act entails the Commission's obligation to set up, maintain and control a public EU database for stand-alone high-risk AI systems¹⁹.

State of the Art: An Overview

I. Regulatory sandboxes are being designed as tools for the implementation of AI systems under the EU AI Act. Those are presented as innovative tools to assist businesses to explore and experiment new products and services under a controlled environment as a preliminary step towards regulation²⁰. Therefore, regulatory sandboxes may help shape a new way of business and regulatory learning, allowing the regulator to improve its understanding and technical knowledge of new technologies.

This solution is not, however, new to the market. On the contrary, it has been already tested in more than 50 (fifty) countries and over the past years has been used to experiment technology in different sectors. In fact, according to the 2020 World Bank paper, over 70 fintech-related sandboxes have been announced globally²¹ and regulatory sandboxes in the health industry have also been successfully implemented. Indeed, and according to the study, the "Health Data Research UK, the United Kingdom's national institute for health data services, used a sandbox environment to virtually test services and innovations for predictive early detection of neurodegenerative diseases, antidepressant treatment responses, or rare disease scanning, among other medical uses"²². Other examples are to be noted:

- (i) The first regulatory sandbox, in the financial sector, has been credited to the UK Financial Conduct Authority, in 2015;

¹⁸https://www.europarl.europa.eu/doceo/document/TA-9-2023-0236_EN.html

¹⁹See article 60, par. 1 and 5 of the AI Act. Also, in the first preliminary version of the AI Act, article 59, par. 6 contemplated the Commission would have to "facilitate the exchange of experience between national competent authorities". The said par. was, however, deleted in the amended version.

²⁰European Parliamentary Research Service (EPRS), briefing on Artificial intelligence act and regulatory sandboxes, 2022, 1. [https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/733544/EPRS_BRI\(2022\)733544_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/733544/EPRS_BRI(2022)733544_EN.pdf).

²¹World Bank Group, Global Experiences from Regulatory Experiences. Finance, Competitiveness & Innovation Global Practice, Fintech Note, no. 8, 2020, 5. <https://documents1.worldbank.org/curated/en/912001605241080935/pdf/Global-Experiences-from-Regulatory-Sandboxes.pdf>

²²World Bank Group, *ibid.*

- (ii) The Reserve Bank of India has established a working group to research the fintech sector in India, in 2016²³; or
- (iii) In Portugal, ZLT Infante D. Henrique (2022) and ZLT Matosinhos (2023) created to experiment safety/national defense systems and address the area of mobility geared towards the carbon neutrality of cities, respectively.

II. Notwithstanding, the rise of regulatory sandboxes has been deeply linked with the development of both fintech and health industries²⁴. Indeed, the fact that sandboxes allow controlling risks in a time-limited environment under regulatory watch was indeed most appealing to both areas, which have seen accelerated growth in innovation and systems over the past years. By considering the current challenges, especially with the imminent approval of the AI Act, sandboxes would definitely work as a safe environment to try different areas, as data. In fact, the Personal Data Protection Commission of Singapore started, in 2017, a regulatory operation for data, which is developed in three different stages: engagement, guidance and policy prototyping²⁵. Data sandboxes are spreading as safe spaces to “assess and experiment with new ideas involving data, including emerging technologies, data applications, and governance techniques”²⁶, which may encourage authorities in the context and for the purposes of the AI Act.

Concept, Features and Operation

I. Notwithstanding the development of regulatory sandboxes’ systems across the globe, these are still new tools to the legal industry. Indeed, sandboxes reflect the innovation demanded and promoted by the digital decade, which is rapidly evolving around technology.

The increased use and implementation of technology in society – which has expanded throughout all business activities and sectors – has determined the need for a regulatory action that is difficult to accomplish: first of all, due to the technical particularities involving such mechanisms and how it reflects a need for a specialised knowledge of the legislator when drafting a framework; second, because the innovation is not certain – it depends on tests, on how the users react to new products and services, meaning that from a practical point of view, a regulation may not be required to last for more than one month; third, because technology has an inherent accelerated rhythm, which may not be compatible with the time required for a regulation to be put in place; and lastly, surely there are different addressees and uses to be taking into account and from which a unitary regulation may not be deemed appropriate. Indeed, the risks of use of technology differ depending on the purpose of its use (e.g., in health industry for the purpose

²³See Chandra (2022).

²⁴On this regard, see Sherkow (2022).

²⁵See Datasphere Initiative, Sandboxes for data: creating spaces for agile solutions across borders, UK Government, 2022. <https://www.thedatasphere.org/wp-content/uploads/2022/05/Sandboxes-for-data-2022-Datasphere-Initiative.pdf>.

²⁶Kalkar, Saxena & Verhulst (2022).

of diagnose or in gaming) and on its users or main addresses (e.g., consumers and minors shall entail more information requirements and protection when compared to sophisticated and professionalised users).

This comes to state This means that the existence of regulation for technology (AI, metaverse or other) cannot spare a joint assessment based on traditional regulation in relation to the agents or sectors in discussion. Should we, for example, discuss the use of AI in the banking sector, the potential liabilities and information requirements shall be read in addition to the existent framework applicable to banking products and services. By doing so, we are to conclude that any tech regulation shall be always a *plus*, rather than replacing the framework in place.

II. In light of this, sandboxes are ways to bring regulators and operators together allowing (i) business operators to safely experiment new tools, products and services and (ii) regulators to learn and understand the features and mechanics of such technology. In this sense, regulatory sandboxes are mainly isolated learning and experimental environments. This approach is quite innovated: on one hand, brings lawyers and business agents together in new learning fields and, on the other hand, are based on a fact that legal players do not have the required know-how to accomplish regulation drafts.

Although particularly suitable for the experimentation of emerging technologies, regulatory sandboxes can indeed be used for all types of new products and services as a way to develop technology and keep tracking with the accelerated pace of innovation. As a result, with a sandbox approach we get to accomplish a new security layer which benefits not only the product and services to be tested, but the future regulation to be drafted, and also a safe ground for experiments to take place, allowing features of technology to be tested before being provided to society. For example, should we consider software testing, we have a preliminary stage of technical and legal development allowing the players to align their relevant components and prevent threats or hacking attacks. Indeed, these sandboxes are being particularly successful in software development and cybersecurity sectors precisely due to these benefits.

III. From its sphere of activity point of view, regulatory sandboxes may be national or cross-border. The particularities of cross-border testing are, from a legal perspective, more complex. Those may contemplate either (i) multi sandbox testing, involving tests conducted in two or more jurisdictions or (ii) observing sandbox testing, meaning the tests, *per se*, will be conducted in one jurisdiction, but will be provided visibility to national authorities of other(s) jurisdiction(s).

The challenges of involving different authorities and jurisdictions relate not only with the observance of the legal requirements and applicable law for the prosecution of the tests, but also with the relevant coordination among authorities. When within the EU space, these challenge – although existing – are mitigated. However, should we consider a multi sandbox testing combined with multiple sandboxes, the complexity arises.

Notwithstanding, the proper features of the sandbox shall vary depending on its purposes, which are usually divided into four categories: regulatory or policy

sandboxes, innovation sandboxes, software development sandboxes and data sandboxes²⁷.

IV. In terms of its operation, sandboxes work as public-private partnerships aiming at reproducing the production environment, even though isolated from the technical operators' facilities (e.g., company servers and location). Depending on the product or service to be tested, these can run in virtual or physical spaces.

The sandbox's set up, however, depends on the purpose for which it is created. Most commonly, we find regulatory sandboxes run in a virtual space, for which VirtualBox serves as an example as it allows users to install it so they can try virtual spaces for other systems.

All in all, sandboxes work as a cycle²⁸ in 4 (four) stages²⁹: (i) the set-up phase that provides for the configuration of the environment, (ii) the operation within the timeframe defined, (iii) the evaluation of the results and (iv) finally, conclusion of the experimentation.

Challenges: Innovation over Sustainability?

I. The potential of regulatory sandboxes cannot be considered without their risks or challenges. Among those, we point out specifically the pressure on resources for regulatory authorities and, above all, the risks for environmental sustainability.

Indeed, as pictured above, the operation of sandboxes will require the reproduction of new and parallel environment that suffice identical safety and control requirements as the real-life ones. For example, attention has to be made to consumer protection, safety and data control and governance while conducting tests³⁰. To accomplish that, regulatory authorities, together with organisations, will have to be deeply invested in innovation, which entails human resources and definitely money. This shall be conducted by the same authorities already involved in the supervision and control of regulatory requirements under AI Act (and, in fact, other legal instruments that currently compose the EU digital framework, as DORA or the DSA). This means that “[sandbox] programmes may therefore put pressure on the time and resources of already over-burdened regulatory authorities”³¹.

From an operational and practical perspective, these costs must be absorbed by public authorities so as to avoid the risk of having experimental environments compromising the implementation and success of technology or otherwise pressuring regulatory entities.

²⁷Kalkar, Saxena & Verhulst (2022).

²⁸United Nations, Department of Economic and Social Affairs, “Sandboxing and experimenting digital technologies for sustainable development”, Policy Brief no. 123, 2021, 4.

²⁹United Nations, Department of Economic and Social Affairs, “Sandboxing and experimenting digital technologies for sustainable development”, Policy Brief no. 123, 2021, 6-7.

³⁰Attrey, Leshner & Lomax (2020) at 10.

³¹Attrey, Leshner & Lomax (2020) at 12.

II. Also, when discussing technology, sustainability is usually forgotten. Despite its (significant) benefits, the sandboxes' approach must be assessed considering its impact on allocation of environmental resources.

There is, first and foremost, an evident multiplication of resources as sandboxes are to replicate the operation model. Therefore, the system on which the product is tested shall have the same resources as the operation system. A strong balance between costs and benefits is to be made in light of the EU environmental goals.

III. SupTech and ReghTech may be important tools when addressing these challenges, seeking to create more technological efficiency within the context of supervisory authorities and regulatory compliance mechanisms, respectively. In particular, it can address the “regulatory pressure and budget limitations”³², even though still burdening the planet resources as high energy consumption tools.

References

- Anderson, J. Rainie, L. & A. Luchsinger (2018). ‘Artificial Intelligence and the Future of Humans’, Pew Research Center 3. https://elondn.blob.core.windows.net/eu3/sites/964/2020/10/AI_and_the_Future_of_Humans_12_10_18.pdf
- Armstrong, P. & H. Alexander (2019). ‘Financial innovation, ReghTech and SupTech – change for markets and authorities’, ESMA Report on Trends, Risks and Vulnerabilities. No. 1, 2019, 42-46, 42. https://www.esma.europa.eu/sites/default/files/trv_2019_1-regtech_and_suptech_change_for_markets_and_authorities.pdf
- Attrey, A., Leshner, M. & C. Lomax (2020). ‘The role of sandboxes in promoting flexibility and innovation in the digital age’, Going Digital Toolkit Note, No. 2, 2020, 10. https://goingdigital.oecd.org/data/notes/No2_ToolkitNote_Sandboxes.pdf.
- Bostrom, N. (1998). ‘How Long Before Superintelligence?’ in *International Journal of Futures Studies*, 2. [observatory/glossary/term/technological-neutrality-and-data-portability](https://www.observatory/glossary/term/technological-neutrality-and-data-portability) <https://nickbostrom.com/superintelligence>
- Boura, M. (2023). ‘Inteligência Artificial. Quadro jurídico e reflexões sobre a Proposta de Regulamento de Inteligência Artificial’ [Artificial intelligence. Legal framework and reflections on the Proposed Artificial Intelligence Act – in Portuguese]. *CIJ*, Vol. 32(3), no. 3, 2023, p. 102. Free translation. <https://cij.up.pt/pt/red/edicoes-antiores/2023-nordm-3/inteligencia-artificial-quadro-juridico-e-reflexoes-sobre-a-proposta-de-regulamento-de-inteligencia-artificial>
- Chandra, A. (2022). ‘Regulatory Sandbox: History, Uses & Key Takeaways’, 25.07.2022. <https://ksandk.com/regulatory/regulatory-sandbox-history-and-uses>.
- Datasphere Initiative, Sandboxes for data: creating spaces for agile solutions across borders, UK Government, 2022. <https://www.thedatasphere.org/wp-content/uploads/2022/05/Sandboxes-for-data-2022-Datasphere-Initiative.pdf>
- European Commission, Commission Staff Working Document, Regulatory learning in the EU, *Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy*, SWD (2023) 277/2 final, Brussels, 29.08.2023.
- Harvey, D.J. (2017). *Collisions in the Digital Paradigm: Law and Rule Making in the Internet Age*, Bloomsbury Publishing
<https://eur-lex.europa.eu/eli/dec/2022/2481/oj>

³²Armstrong & Harris (2019).

- Kalkar, U., Saxena, S. & S. Verhulst (2022). 'Data Sandboxes: Managing the Open Data Spectrum', A Primer by the Open Data Policy Lab. <https://incubator.opendatapolicylab.org/files/DataSandboxesPrimer.pdf>
- Recital (1) of the Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022, establishing the Digital Decade Policy Programme 2030.
- Report of the European Law Institute. https://www.europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Principles_on_Blockchain_Technology_Smart_Contracts_and_Consumer_Protection.pdf
- Sherkow, J.S. (2022). 'Regulatory Sandboxes and the Public Health' in *University of Illinois Law Review*, 2022(1): 357-410.
- Simplilearn, 'Artificial Intelligence vs. Human Intelligence'. <https://www.simplilearn.com/artificial-intelligence-vs-human-intelligence-article#:~:text=Will%20AI%20Replace%20Humans%3F,and%20making%20data%2Ddriven%20decisions>
- United Nations, Department of Economic and Social Affairs, "Sandboxing and experimenting digital technologies for sustainable development", Policy Brief no. 123, 2021, 6-7. https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/PB_123.pdf
- United Nations, Department of Economic and Social Affairs, 'Sandboxing and experimenting digital technologies for sustainable development', Policy Brief no. 123, 2021, 4. https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/PB_123.pdf
- Veerpalu, A. (2019). 'Functional Equivalence: An Exploration Through Short Comings to Solutions' in *Baltic Journal of Law & Politics* 12(2):134-162.
- Winlow, E. (2024). 'The End of the Road for DABUS and Dr Thaler at the UK Supreme Court'. Kluwer Patent Blog.

Cases

Australia

Commissioner of Patents v Thaler [2022] FCAFC 62.

UK

Thaler v Comptroller-General of Patents, Designs and Trademarks [2023] UKSC 49 - The DABUS Case.
<https://www.supremecourt.uk/cases/docs/uksc-2021-0201-judgment.pdf>

USA

Thaler v. Vidal 43 F.4th 1207 (2022).