

## REGULATORY LABORATORIES (SANDBOXES) AS AN OPPORTUNITY TO INCREASE THE INNOVATION POTENTIAL AND COMPETITIVENESS OF BULGARIAN COMPANIES PARTICIPATING IN GLOBAL VALUE CHAINS AMONG THE HIGH TECHNOLOGY SECTOR

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### Abstract

*The current state of high technologies Bulgarian companies are operating in an almost 'harsh' competitive environment, raising a serious question about the implementation of new regulatory approaches that would provide a suitable environment for increasing their innovative potential along the global value chains. The main goal of the paper is to analyze the experimental regulatory environment/regulatory sandboxes regulatory as part of the innovative legislation tools already implemented by the EU Member States. This approach is directly linked to supporting the unfolding of the innovative potential of European companies. In this context, issues related to the equality of economic entities in terms of access to the protected testing environment, processing personal data for experimental purposes, the responsibility of participants during testing, the impact of testing environments on the market, etc., are considered. The report outlines some of the possible risks posed by regulatory sandboxes that should be appropriately assessed in the new community regulatory framework for high technologies and the EU's new legislative framework. In this respect, the provisions related to the creation and functioning of regulatory laboratories in the proposed Artificial Intelligence Act are analyzed. Main findings of the paper are related to the competence and the need to build institutional capacity within national regulatory bodies to manage regulatory laboratories.*

**Keywords:** regulatory laboratories, sandboxes, global value chains, high technologies, artificial intelligence, experimental regulatory environment

### 1. “EX-ANTE APPROACHES”: REGULATORY SANDBOXES

Recognizing the “pacing problem”, in the context of the lagging position of legal regulation, the European Parliament notes the need to focus on “ex-ante approaches to deal with legal challenges posed by emerging technologies and supports the use of regulatory sandboxes which would give AI developers the unique chance to experiment in a fast, agile and controlled manner under the supervision of competent authorities” (ERP, 2022). The use of regulatory sandboxes as a tool to address the challenges of high technology and artificial intelligence is indicated both by the Commission (EC, 2018). and the European Parliament in the Resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics (EP, 2018). The resolution encourages the use of AI-specific regulatory sandboxes to introduce “innovative new ideas allowing safeguards to be built into the technology from the start, thus facilitating and encouraging its market entry” and to “test the safe and effective use of AI technologies in a real-world environment”.

The experimental regulatory environment (regulatory sandbox) is part of the innovative regulatory tools already being implemented by EU Member States, and it is an approach consistently promoted by the European Parliament. Regulatory sandboxes are increasingly used in a number of sectors such as finance, healthcare, legal services, aviation, transport, logistics and energy, which often feature the use of new, emerging technologies such as artificial intelligence and blockchain/distributed ledger technologies, or the innovative use of existing technologies (Attrey et al, 2020).

The experience gained by Member States underpins the first legislative initiative to create a unified legal framework for regulatory sandboxes at Community level (Artificial Intelligence Act) (EPC, 2021), as a specific measure to support artificial intelligence innovation.

The proposed framework raises substantial issues relating to the equal treatment of entities in terms of access to protected test environment, the processing of personal data for experimentation purposes, the responsibility of participants in carrying out the testing, the impact of test environments on the market, etc. In this sense are also the majority of the opinions expressed by scientists and stakeholders after the publication of the Act in April 2021, touching on issues related to the lack of liability protection for sandbox participants, the need for a more harmonised approach to regulatory sandboxes for AI and the interaction between the sandbox environment and the EU data protection rules (Madiega at al, 2022)

On the other hand, we should agree in advance with the UN Secretary-General's Special Advocate for Inclusive Finance for Development, who states that “a regulatory sandbox lowers the cost of innovation, reduces barriers to entry, and allows regulators to gather important information before deciding on whether further regulatory action is needed.” (UNSG,2020).

## 2. BETTER REGULATION: REGULATORY EXPERIMENTALISM.

In the literature, an “experimental law” is defined as “a legislative or regulatory instrument of a temporary nature with limited geographic and/or subject matter application that is designed to test a new policy or legal solution and includes the prospect of an evaluation at the end of the experimental period.” (Heldeweg,2015) This includes experimentation clauses, free zones, regulatory sandboxes, etc.

In terminology, regulatory sandboxes, as part of so-called experimental legislation, refer to an isolated test environment that allows monitoring of a system and prevents damage to a computer system by malicious programmes. For regulatory purposes, the sandbox is a tool designed to test new services and products in an artificially created regulatory environment.

Regulatory sandboxes integrate the trend to promote so-called smart regulation, which can be seen as a regulatory strategy that seeks to micro-optimize the system and adapt regulation to technological advancement (Omarova,2020).

In working documents of the European Parliament, the Council and the Commission, regulatory sandboxes are defined as specific frameworks which, by providing a structured context for experimentation, enable, where appropriate, the testing of innovative technologies, products, services or approaches in a real environment – currently particularly in the context of digitisation – for a limited period of time and in a limited part of a sector or area under regulatory supervision, ensuring that appropriate safeguards are in place (EP,2020). Pointing to the lack of an agreed definition, Tambiama Madiega with Anne Louise Van De Pol note the “dual role” of regulatory sandboxes – to promote business learning, i.e. the development and testing of innovations in a real environment, on the one hand, and to support regulatory learning, i.e. the formulation of experimental legal regimes to guide and support businesses in their innovation activities under the supervision of a regulatory authority, on the other hand (Madiega at al, 2022). In practice, the approach aims to enable experimental innovation within controlled risks and supervision and to improve regulators' understanding of new technologies (Madiega at al, 2022).

Experimental lawmaking and regulatory sandboxes refer to the “digital by default” principle in the future EU law as an important tool to support digital transformation and in the context of the understanding of better lawmaking (EP,2021). To what extent and within what limits can regulatory experimentation lead to better regulation. Clearly, the flexibility of the approach, seen as its advantage, cannot be accepted as a sufficient justification for its application without a critical examination of possible deviations. Aspects such as time, scope and supervisory control, which are assessed on a case-by-case basis, are only some of the tools that warrant its safety and transparency.

Historically looking at *laissez-faire* and interventionism in legislation, Cristina Poncibò and Laura Zoboli note that for current changes and challenges, a *laissez-faire* approach is often considered too risky in the long term, given vested interests. When interventionism is adopted, on the other hand, usually the regulation remains in place indefinitely unless it is subsequently repealed or modified by some other intervention. However, the interventionist approach shows signs of tension in the market

and a society that is becoming increasingly complex with each technological step forward, and where the effects of regulatory changes have become particularly difficult to predict accurately (Poncibò at al,2022). From this perspective, regulatory sandboxes involve distancing from traditional regulatory approaches and efforts to embrace the principles of proactivity, dynamism and responsiveness of regulation (Bromberg at al,2017).

This “distancing” raises further questions of legal certainty and the need to establish clear and transparent rules, both at the level of national regulation and in the EU's legal toolbox. In this regard, Ranchordas notes the “invisibility” of the term “experimental lawmaking” and the existence of a number of uncertainties. “The definition, mode of operation, regulatory implications, as well as the design and methodology of experimental provisions and regulatory sandboxes will determine whether this experimental approach to laws and regulations will indeed be successful and help advance responsible innovation in the EU” (Ranchordas, 2021).

### **3. CHALLENGES TO REGULATORY EXPERIMENTALISM.**

A number of authors point to the possible risks of regulatory sandboxes. These risks should be properly analyzed and assessed in the new Community regulatory framework. The main risks involve the possibility of creating privileges and inequality among market participants. Cristina Poncibò and Laura Zoboli call that risk the “sandbox paradox” because the benefit to admitted companies puts them in an advantageous position that has the potential to weaken overall competition in the market (Poncibò at al,2022). In this respect, as Ranchordas points out, the very act of differentiating between market participants cannot be regarded as a breach of the principle of equal treatment if the differentiation is proportionate to the objectives set for the regulatory sandbox environment. As a guarantee of the objective nature of the demarcation of participants, the author indicates the transparency in the definition of the input and output conditions of the sandbox (Ranchordas, 2021b).

At the same time, there is a risk of disturbing the balance between measures to support innovation and the safeguards provided against infringement of public interest and consumer rights. In this context, the possibility of “misuse” of sandboxes is linked to the potential negative impacts on consumer protection caused by reduced safeguards and supervisors’ requirements for attracting innovators, which is particularly visible in the “race” for innovation in the fintech sector (Allen,2020). With regard to the proposal for an artificial intelligence act, the experts also draw attention to the risk posed by the right of private data processors to deviate from the applicable data protection rules when testing their AI systems (Truby at al, 2022). Also, the possibility of testing the parameters in the regulatory sandbox to differ significantly across Member States leads to the risk of fragmentation of the EU single market (Madiaga at al, 2022).

These risks imply the establishment of EU-wide, strict, clear and transparent rules for regulatory experimentation (compliance with the principle of legality in administrative activity) to ensure equal treatment of participants, transparency, protection of public interest and consumers, including protection of personal data used for the purposes of testing in a controlled environment.

### **4. REGULATION OF REGULATORY SANDBOXES IN THE PROPOSAL FOR AN ARTIFICIAL INTELLIGENCE ACT.**

The European legislator's approach to the regulation of experimental lawmaking is in line with the accepted view that relations in the field of high-tech regulation should be provided for at Community level through regulations, being a legal instrument that provides direct applicability in accordance with Article 288 TFEU, reduces legal fragmentation and facilitates the development of a single market for lawful, safe and trustworthy AI systems (Artificial intelligence act). This aims to harmonise the general rules that each Member State will apply and to overcome the possibility of looking for “more attractive” test environments in different Member States. In this sense is the opinion expressed by many experts (Parenti, 2020). In this regard, the EU digital finance strategy envisages the development of a “procedural framework for launching cross-border testing and other mechanisms facilitating the

interaction of firms with supervisory authorities from different Member States” by mid-2021. The ESA’s 2019 Joint Report sets out key requirements for the establishment and operation of regulatory sandboxes, such as having “clearly defined and published eligibility criteria for entry” and “clearly defined and published key information to be provided from the companies in support of the application to participate in the regulatory sandbox” (ESAs,2019).

Within the legislative procedure for discussion of the Commission's Proposal for an Artificial Intelligence Act adopted on 21 April 2021, attention continues to be focused on the search for an optimal legal regime for the implementation of regulatory sandboxes, and a number of correction proposals are likely to be adopted in the final version. An indication of this is provided in the published compromise proposal of 25 November 2022, prepared by the Czech Presidency, which takes into account the final written comments of the Member States (EPC,2021). The proposal was confirmed in the common position (“common approach”) of the Council on the Artificial Intelligence Legislation, published on 6 December 2022 (EC, 2022). The pace of technological development is so fast that substantial amendments were necessary to the Commission's original proposal of 21 April 2021 (adopted by the European Parliament on 14 June 2023). The agreement reached in December 2023 concerns new provisions related to general-purpose AI systems, specific rules for foundation models (including generative AI).

It reiterates the relevance of establishing common rules for the deployment of regulatory sandboxes, as well as a framework for cooperation between relevant authorities to ensure uniform application across the EU. The version in the compromise proposal sets out the legal definition of a regulatory sandbox, delineating more clearly than the original version the range of participants (suppliers and potential suppliers), its scope (development, training, validation and testing of artificial intelligence systems), as well as the conditions (under a specific plan for a limited period of time under regulatory supervision).<sup>1</sup> Testing in a regulatory environment takes place before the systems are placed on the market or put into service. What sets the new proposal apart is the possibility for regulatory sandboxes to include real-world testing under the supervision of national competent authorities. In addition, the wording of Article 53 (Regulatory AI sandboxes) has been amended and supplemented by specifying “general, basic principles” that should be included in the implementing acts, through which the issues related to the terms and conditions for establishment and management of regulatory sandboxes are to be defined. The compromise text preserves the established regime of liability of participants for damages caused in the course of participation in a regulatory sandbox.

Essential to the topic under consideration is the new possibility of uncontrolled (outside a regulatory sandbox) real-world testing of high-risk AI systems listed in Annex III (as opposed to regulatory sandboxes where innovative AI systems are indicated as the subject). To this end, the proposal introduces new provisions (Articles 54a and 54b) allowing this test by laying down a number of cumulative conditions. In practice, a notification regime has been adopted for this type of testing (which is not subject to supervision), which, given the lack of control, is incompatible with the general concept of ensuring fundamental rights, health and safety. On the other hand, this could lead to the creation of “free zones” in individual Member States and exacerbates one of the problems identified for the regulatory sandboxes themselves.

Expressing her concerns about the regulation of regulatory sandboxes, K. Yordanova notes: “As the implementation of the sandbox is not uniform among EU countries and is not mandatory for it, the European Commission’s proposal may cause confusion in the market. It may also encourage AI developers to choose EU countries with less stringent sandbox regimes, at least for regulatory compliance purposes.” (Yordanova,2019)

In this respect, the text of the compromise proposal creates two regimes for the subsequent processing of personal data. The first regime relates to the hypothesis of subsequent processing of personal data (lawfully collected for other purposes) for the purpose of developing, testing and training of innovative

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<sup>1</sup> Initial proposal in Article 53, paragraph 1 “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 putting into service pursuant to a specific plan”.

AI systems within the regulatory sandbox. The proposal provides the legal basis for the such processing in cases of development of artificial intelligence systems in the public interest, under certain, cumulatively stated conditions. In this case, participants in the regulatory sandbox (including testing in a real environment) cooperate with supervisory authorities to limit possible risks, and their behaviour will be taken into account when imposing fines under Article 83, paragraph 2 of the General Data Protection Regulation.

The second regime applies to testing high-risk AI systems in real-world settings outside AI regulatory sandboxes. Here, no condition is set that the system is to be developed in the public interest, and the legal basis for the processing is the informed consent of individuals to participate in tests. Recital 72a of the compromise proposal notes that such consent is distinct from data subjects' consent to have their personal data processed under relevant data protection legislation and does not affect that consent. For the purpose of ensuring awareness, the proposal sets out the minimum requirements for the content of the privacy notice. The application of the General Data Protection Regulation to date has revealed serious challenges in using the subject's consent for the purposes of specific processing. The principle is that this ground is applied exceptionally when one of the other grounds specified in Article 6 of the GDPR is not applicable, subject to provided guarantees for exercising the rights of data subjects. In this sense, testing in real conditions, outside the supervision of the competent authorities, would create an additional risk in this regard.

## 5. CONCLUSIONS

The flexibility sought by the European legislator in terms of the legal regime for regulation of artificial intelligence systems and, in particular, the relevant opportunities created for testing in a regulated environment and outside it, are reflected in the powers of national competent authorities to create and manage their regulatory sandboxes. To this end, they should take into account the specific circumstances and capacity of those involved, and create a procedure and conditions that ensure the protection of fundamental rights, health and safety. Given the complexity of the subject matter and the rapid development of these relations, national competent authorities will need to build up a strong institutional capacity in a short time to be able to adequately address the responsibilities assigned to them. Considering the fact that not all Member States have applied the capabilities of the regulatory sandboxes until now, cooperation becomes an absolutely necessary prerequisite for aligning the practice and preventing differences that affect the degree of control over the legality of the actions of participants in regulatory sandboxes and beyond.

In this regard, the “pacing problem” continues to be extremely relevant in terms of the possibilities for development of technologies in the EU in compliance with the principle of legality, but it should not be allowed to become dominant in defining the Community legislative policy. In this case, a clear definition of the scope of the controlled risk and supervision would be a guarantee for better management.

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