# Regulatory Sandboxes: A Wager on Europe's AI Strategy

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## 1. Introduction

In recent years, the demand for innovation-enabling regulation has permeated nearly every domain of governance, encompassing areas such as food and medicine, financial services, and artificial intelligence (AI). The 2024 EU Regulation on AI (AI Act) exemplifies this trend: it seeks to reconcile the objective of fostering technological innovation with the imperative of safeguarding health, fundamental rights and freedoms, which remain the primary concern of regulatory intervention. Within this broader trend, one of the most prominent instruments is the "regulatory sandbox" (RS). RSs are frameworks established by public authorities that permit the live testing of new products, services, business models, or delivery mechanisms in a controlled environment and for a limited period. The metaphor of a "sandbox" and the adjective "regulatory" recall a safe space for experimentation and capture their dual nature: on the one hand, they lower barriers to market entry by reducing regulatory uncertainty and administrative burdens; on the other, they offer regulators an opportunity to observe, adjust, and refine the enforcement of rules in light of technological change. In this sense, sandboxes respond to longstanding demands from innovators, reformists, and policy think tanks - most of which are making considerable clamour today in Europe - for more agile mechanisms capable of combining legal certainty for businesses with adequate consumer protection.

The concept was pioneered by the UK's Financial Conduct Authority (FCA) in 2016, primarily to support the burgeoning fintech sector. Since then, the model has been adopted by numerous countries and adapted for a wide array of industries beyond finance, including healthcare, energy, transportation, food, and indeed AI.

The rationale for such frameworks is clear. Many disruptive technologies do not fit neatly within existing legal categories, creating compliance challenges and potential risks for both innovators and end-users. Sandboxes provide a "safe space" for experimentation (at least an innovative form of administrative framework), helping to mitigate these risks, adjust the enforcement of regulations, while preserving the pace of innovation. In the field of AI, their necessity is particularly evident for four reasons. First, they encourage investment by offering a predictable and supervised environment in which high-risk – but not only – technologies can be trialled. Second, they reduce regulatory burdens for small and medium-sized enterprises, enabling them to test compliance pathways that would otherwise be prohibitively costly. Third, they foster structured networks between regulators, industry, and other stakeholders, thus improving mutual understanding and building trust. Finally, they represent a novel tool of regulatory enforcement, allowing authorities to test and calibrate either new or old rules in practice before they are fully operational. Recognising these benefits, the AI Act places RS at the centre of its innovation strategy (Article 57-60), making it one of the most promising instruments for the effective implementation of the new regime.

## 2. The Academic Debate on Regulatory Sandboxes

In academic literature, RSs are often discussed within the broader category of "experimental regulation" and administrative frameworks created by agencies. Scholars debate whether

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sandboxes are a subset of experimental legislation (in some jurisdictions, RS are created through experimental clauses) or a distinct phenomenon. The distinction generally rests on four dimensions. *First*, experimental statutes define *ex ante* the experiment's scope, duration, and evaluation, whereas sandboxes are built on policy decisions regarding eligibility, entry and exit, and assessment. *Second*, experimental statutes derogate from existing rules, while sandboxes temporarily relax requirements through waivers, guidance, or "no-action" letters for the singular experimentation, without implying deregulation. *Third*, experimental clauses apply generically to categories of products (e.g. procurement). At the same time, sandboxes are established on a case-by-case basis in specific sectors (e.g. finance), either by innovators facing barriers or regulators testing new rules. *Fourth*, experimental clauses are not necessarily participatory, whereas sandboxes foster collaboration between regulators and industry.

Despite these differences, both instruments facilitate legal experimentation and may complement each other. They help overcome the limits of traditional regulatory approaches in digital innovation, where policymakers have increasingly relied on alternative instruments such as economic incentives, self-regulation, and information-based strategies.

Today, technological complexity, exemplified by AI, demands flexible governance rather than static solutions. Regulatory experimentation appeals because it strikes a balance between innovation and the public interest through adaptive policies that involve direct engagement between regulators and industry. Its benefits include avoiding regulatory gaps and fostering both business innovation and regulatory learning. A key development has been the shift from delayed to real-time supervision, particularly in finance,

which requires data-driven oversight and advanced computational tools.

Sandboxes allow regulators and companies to pilot innovative products in real-world conditions. They enable refinement, compliance testing, and risk identification within controlled environments, thereby improving both market safety and regulatory understanding.

## 3. Regulatory Sandboxes in the AI Act

In recent years, the sandbox approach has gained traction across the EU as a way to address emerging technologies. They promise to accelerate innovation, foster stakeholder collaboration, and enhance legal certainty.

The AI Act has invested in RS since the proposal was published. The approved text of the regulation obliges Member States to establish, either nationally or jointly among different Member States, at least one RS. This entails not only issuing rules but also creating, resourcing, and budgeting RSs to operate effectively. The main purpose is to facilitate market access, particularly for small and medium-sized enterprises, while ensuring that AI systems are safe, secure, and compliant with the Act. However, those who attempt to grasp all the practicalities of RS directly from the AI Act may be misled. Although the recitals and articles are sufficiently detailed to appear dense, the regulation does not provide a comprehensive and final picture of this new instrument. Indeed, the AI Act remains at a helicopter view, offering only limited coordinates, such as the principles guiding national regulators' activity at this stage, which should be seen as an opening framework. What is still missing—yet expected to be clarified through a specific "implementing act"—are the operational procedures to be followed, including application, preparation, validation, and exit. This should not come as a surprise to regulators, who are already

familiar with such legal and policy technicalities from other experiences with RSs.

Will this framework be effective? This is perhaps the most delicate point. Will the RS framework truly make a difference? At the EU level, the conditions appear—at least for now—to be favourable. A distinctive advantage of the AI Act's regulatory sandbox framework lies in its explicit multi-level governance structure, which combines local, national, and EU-level oversight and coordination. Unlike many traditional sandbox models, which rely on single-level governance with limited coordination, the AI Act RS benefits from harmonised guidelines and oversight by both the European Commission (AI Office) and the European AI Board.

Moreover, the essence of RS there appears to rest on a win–win rationale between providers and regulators. RS are designed to support both during the entire phases of creation and supervision. For regulators in particular, they represent an instrument of evidence-based regulatory learning (Recital 139 AI Act), making a significant leap forward from traditional approaches.

Nevertheless, four advancements remain crucial.

First. Sandboxes must be understood as ongoing processes, extending beyond isolated procedures or activities—an essential element for the functioning of the entire EU market.

Second. The framework will only prove effective if it is embraced as a genuine pathway to make responsible AI a reality. At the policy level, structured environments are needed to support firms throughout the innovation cycle, facilitating their participation in RSs. In this regard, the Commission is deploying new infrastructures across Europe—most notably AI factories, Testing and Experimentation Facilities (TEFs), and European Digital Innovation Hubs (EDIHs)—as key players both inside and outside the sandbox.

Third. Effectiveness requires not only investment but also a renewed alliance between industry and research. A continuous channel of communication—particularly with universities—should tackle not only technical challenges but also the regulatory and governance dimensions of innovation.

Fourth. There is no one-size-fits-all sandbox model. Their design will inevitably depend on multiple factors, including the underlying technology, the relevant sector, and the supervising authority. In Italy, for example, the National Cybersecurity Agency will act as the competent authority, and it will likely leverage its expertise to focus—though not exclusively—on the sandboxing of cybersecurity products.

Whether they succeed or fail, the establishment of AI regulatory sandboxes remains a wager on Europe's AI strategy.