The EU Artificial Intelligence Act: AI regulatory sandbox

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In this article, the writers examine how the regulatory sandbox is a secured space for experimentation and proactive regulatory learning ahead of the latest revisions to the European Union’s ("EU") proposed Artificial Intelligence Act (the "EU AI Act").

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AI Regulatory sandboxes – proactive learning

On 21 April 2021, the European Commission proposed the first legal framework on AI, that addressed the risks of AI and positions the European Union to play a key role globally, also known as the EU Artificial Intelligence Act ("EU AI Act"). The package consists of one legislative proposal: a new Regulation, which represents a new artificial intelligence ("AI") legislation and constitutes a new regulatory framework for the use, development, operation, deployment, importing and distribution of AI in the EU.
One of the main goals of the proposed legislative reform is to drive innovation in the AI industry. To achieve this goal, the latest version of the proposed Regulation introduces the concept of a regulatory sandbox, which provides a controlled environment that facilitates the development, testing and validation of innovative AI systems and secure processing of personal data for a limited time before their placement on the market or putting into service pursuant to a specific plan.

What is a regulatory sandbox?

In summary, a regulatory sandbox is a time-limited regulatory framework that allows the testing of innovative technologies, products, services or approaches in a real-world environment under regulatory supervision to facilitate the development and authorisation of innovative AI products.

The legal basis of a regulatory sandbox is contained under Article 53, Paragraph 1, with testing taking place under the direct supervision and guidance of the Commission in collaboration with the competent authorities with a view to identifying risks, in particular to health, safety, and fundamental rights, and ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.

The purpose of regulatory sandboxes

The purpose of regulatory sandboxes is two-pronged: it offers significant opportunities for businesses to innovate, and it also enables regulators to acquire knowledge about innovative AI-related technologies, products, services or approaches at a very early stage of development, for the purpose of finding out the right means to regulate those innovations.

The knowledge resulting from a regulatory sandbox can provide the basis for future changes to the EU AI Act, so that regulators can respond to AI innovations in a proactive manner, compared to catching up with the increasingly fast paced evolutions in AI development.
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While it is now being introduced for the first time in the context of AI development on EU level, the concept of regulatory sandboxes is well established. For over a decade now, regulatory sandboxes have been used by (mostly national) regulators to drive innovation across multiple sectors. Particularly in the field of FinTech, regulatory sandboxes have already demonstrated to have a significant impact. In September 2022, the Bank of England, HM Treasury and the Financial Conduct Authority announced an FMI sandbox focused on DLT-based securities settlement systems.

Why are regulatory sandboxes relevant?

At the time the EU AI Act is published, the flexibility offered by regulatory sandboxes is deemed especially relevant in the context of ongoing innovation in the artificial intelligence sector. The traditional regulatory framework is often not adapted to innovations in the discovery, development or administration of AI products that are spurred on by such digital technologies. Businesses such offering those types of products and services may, ultimately, be faced with regulatory constraints that could discourage their further development. In the months to follow, there may be all sorts of innovations that could benefit from a regulatory sandbox that are at present still beyond imagination.

When will an AI regulatory sandbox be possible?

The procedure for establishing an AI regulatory sandbox is set forth in Article 53 – paragraph 1 d of the latest test of the proposed Regulation.

An AI regulatory sandbox will be possible under the following conditions:

- for the competent authorities to provide guidance to AI systems prospective providers to achieve regulatory compliance with this Regulation or where relevant other applicable Union and Member States legislation;
- for the prospective providers to allow and facilitate the testing and development of innovative solutions related to AI systems; and
- regulatory learning in a controlled environment.
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The AI Office’s role in regulatory sandboxes

The AI Office ("AI Office") is designated a catalyst role in the establishment of regulatory sandboxes: it is expected to assist authorities in the establishment and development of regulatory sandboxes and to facilitate cooperation among regulatory sandboxes.

Where the AI Office considers it appropriate, for AI products that may fall within the scope of the Regulation proposal, to set up an AI regulatory sandbox, it shall provide a recommendation to the European Commission, listing the products or category of products covered by the sandbox and including a sandbox plan based on data provided by the developers. The sandbox plan shall set out a commercial, technical and regulatory justification for the sandbox, including an overview of the regulatory requirements that cannot be complied with (and, where appropriate, a proposal for an alternative or mitigation measures). Moreover, the plan shall include a proposed timeline for the duration of the sandbox.

Based on the suggestion made from the AI Office, the European Commission shall subsequently decide on the set up of an AI regulatory sandbox. A Commission Decision establishing an AI regulatory sandbox shall be limited in time and shall prescribe detailed conditions for its implementation. Specifically, the Commission Decision shall include (a) the proposed sandbox plan, (b) the duration of the regulatory sandbox and its expiry and (c) as a part of the sandbox plan, the regulatory requirements (of the proposed Regulation) that cannot be complied with, together with appropriate measures to mitigate potential risks caused by AI systems.

The Commission may decide to suspend or revoke a regulatory sandbox if the requirements and conditions for the sandbox are no longer met or if such suspension or revocation is appropriate to protect the fundamental rights or safety and security of individuals.

If certain risks are identified after the establishment of the AI regulatory sandbox, the Commission may, to the extent possible, also mitigate those risks by imposing supplementary conditions, after consultation with the AI Office. The Commission may furthermore also extend the duration of an AI regulatory sandbox.
Consequences for the further AI system lifecycle

The fact that a product was developed in a regulatory sandbox will have some consequences for the further product lifecycle:

- when authorising an AI system, the competent authorities should take the sandbox plan into account;

- an AI system developed in a regulatory sandbox may only be placed on the market when authorised in accordance with the procedure described in the proposed Regulation and such marketing authorisation shall, in first instance, only be valid for the duration of the regulatory sandbox. Nonetheless, at the request of the marketing authorisation holder, the authorisation may be withdrawn. Moreover, if the regulatory sandbox is suspended or revoked by the European Commission, the marketing authorisation shall also be suspended.

- the marketing authorisation of a AI system developed under a regulatory sandbox may include derogations from the requirements under the EU AI Act;

- the summary of AI system characteristics and the package leaflet of the AI system shall indicate that it was developed as part of a regulatory sandbox; and

- the marketing authorisation should also reflect any mitigation measures that are implemented for the regulatory sandbox.

Supervision of AI regulatory sandboxes

Although AI regulatory sandboxes are established by a decision from the European Commission, it is the responsibility of the competent authorities of the Member States to supervise the AI regulatory sandboxes and to ensure their compliance with the EU AI Act.
The national competent authorities shall immediately notify to the Commission and to the AI Office, any violation of the conditions of the decision on the implementation of a regulatory sandbox or the identification of fundamental rights or safety and security risks. The national competent authorities will be able to suspend or restrict the use of AI systems in a sandbox in case of fundamental rights or safety and security risks. They can also suspend the development and testing in a AI regulatory sandbox until effective mitigation takes place.

The AI office is expected to submit annual reports to the Commission on the results of the regulatory sandbox. Based on the insights generated from those reports, the Commission can, where deemed appropriate, make legislative proposals with a view to update the regulatory framework. Additionally, such regulatory sandbox framework does not have the effect of exonerating the marketing authorisation holder from its liability with regards to the AI system concerned.

To summarise, many aspects of the AI regulatory sandbox will still require further clarification, in particular the consequences for products that will be developed under such temporary framework. Moreover, it is yet to be seen how the text of the EU AI Act will evolve in the course of the legislative process. However, one thing can be said with certainty: the flexibility offered by a AI regulatory sandbox will provide businesses with significant opportunities to grow and innovate. Additionally, the fact that regulators will be able to learn and respond proactively to such AI innovations should lead to a more innovation-friendly and future proof regulatory framework.

How AI & Partners can help

We can help you start assessing your AI systems using recognised metrics ahead of the expected changes brought about by the EU AI Act. Our leading practice is geared towards helping you identify, design, and implement appropriate metrics for your assessments.

Website: https://www.ai-and-partners.com/