

**Statement**

*on the*

*Draft of a Commission Implementing Regulation, laying down rules for the application of Regulation (EU) 2024/1689 of the European Parliament and of the Council as regards the establishment, development, implementation, operation and supervision of AI regulatory sandboxes*

**LawCom.Institute**

LawCom.Institute GmbH is a private company specializing in advising public administration. In 2025 one of several assignments regarding the adoption of the AI-Act was to develop a concept for a regulatory AI sandbox based on Art. 57,58 AI-Act. Drawing on this experience, we have reviewed the draft of the EU Implementing Regulation laying down rules for the application of Regulation (EU) 2024/1689 of the European Parliament and of the Council, specifically regarding the establishment, development, implementation, operation, and supervision of AI regulatory sandboxes.

We appreciate the opportunity to share our insights and would like to offer the following observations:

**General Observations**

Article 58(1) of the AI Act mandates the Commission to adopt implementing acts specifying detailed arrangements for the establishment, development, implementation, operation, and supervision of AI regulatory sandboxes, with the aim of avoiding fragmentation across the Union. The current draft addresses most of the issues outlined in Article 58 of the AI-Act. However, we would like to draw your attention to some instances which might be understood as if the draft would:

- Introduce new regulations not rooted in the AI-Act or other EU regulations,
- Repeat the content of existing provisions without adding meaningful specification,
- Fail to clarify rules that urgently require further specification.

Below, we provide detailed comments on individual provisions of the draft:

## **Article 2(2)**

This provision is intended to specify Article 58(2)(d) AI-Act, which states:

*"Access to the AI regulatory sandboxes is free of charge for SMEs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner."*

It is essential for competent authorities to understand:

- What costs may be considered "exceptional" and
- Under what circumstances cost recovery would be deemed unfair or disproportionate.

The draft does not provide a specification but instead alters the original rule by suggesting that only costs "exceeding what the competent authority can reasonably expect from the sandbox plan associated with the specific sandbox project" may be recovered. This approach may force authorities to reject sandbox plans for projects with high anticipated costs (e.g., for testing or training), as there would be no opportunity to recover such costs once the sandbox plan is accepted. There is also no provision for reaching an agreement with applicants willing to cover extensive use of training or testing facilities.

Regarding the second question (unfair or disproportionate recovery), the draft merely repeats the phrase "in a fair, transparent, and proportionate manner," which does not constitute a meaningful specification.

So our proposition is that the draft should keep close to Article 58(2)(d) AI-Act by not referring to the costs expected from a specific sandbox plan, but by referring to the average of projects participating in an AI regulatory sandbox.

## **Article 2(3)**

This paragraph seems to restrict the possibilities for charging applicants larger than SMEs with fees to cover full costs. Art. 58(2)(d) AI-Act only regards fees for SMEs. There is no reason for restricting the possibilities of the authorities to charge the full costs incurred to applicants larger than SMEs. "Proportionate" implies that only a part of the costs may be covered, not the entire amount of costs. This paragraph should either be deleted, or the words "proportionate to" (the costs incurred) should be replaced by "covering" (the costs incurred).

## **Article 2(5)**

This paragraph is unnecessary. Its content is self-evident (i.e., European law applies to participants), and it interferes with Article 57(12) of the AI Act without providing further specification. It could be deleted.

## **Article 3(3)**

This provision regards criteria for selection of a sandbox project. Among the criteria to be taken into consideration, the prospective costs or capacities consumed by the sandbox plan are not mentioned.

This might be inconsistent with Article 4(3) of the draft, which allows explicitly to take into consideration available capacity and resources when determining the duration of the sandbox plan. Since Article 2(2) of the draft prohibits SMEs from covering the costs of the plan, the prospective costs must necessarily be considered by the public authority when deciding whether a project can reasonably be admitted to a sandbox with limited resources.

Therefore, the following should be added:

*"f) the costs and capacities consumed for the execution of the Sandbox Plan."*

#### **Articles 3(5) and 3(6)**

These provisions add no substantive information, merely referring to the AI-Act itself. Such references are redundant in a regulation intended to specify the AI-Act. These paragraphs should be deleted.

#### **Article 4(4)**

This provision concerns real-world testing under the supervision of a regulatory sandbox (Article 58(4) AI Act). The only guidance provided is that "the real-world testing plan shall be part of the sandbox plan." The real issue is that Article 58(4) AI-Act is inconsistent with the regulation of real-world testing in Article 60 of the AI-Act, which assigns responsibility for approval to the market surveillance authority. Real-world testing of AI systems is generally governed by Article 60 and is not typically linked to regulatory sandboxes. For practical purposes, clearer guidance is needed on how to allocate responsibilities under Articles 57, 58 and 60 of the AI-Act.

#### **Article 4(5)**

This provision is intended to specify Article 58(2)(f) of the AI-Act, which requires regulatory sandboxes to "facilitate the involvement of other relevant actors within the AI ecosystem." However, Article 4(5), sentence 1, shifts responsibility from the regulatory sandbox to the competent authority, which is not supported by the AI-Act. The term "competent authorities" should be replaced by "regulatory sandboxes"

#### **Article 5(2)(g)**

This provision conflates the authority to supervise real-world testing (assigned to the market surveillance authority under Article 60) with the supervision of regulatory sandbox projects (Articles 57 and 58). The mutual tasks of the regulatory sandbox / competent authority according to Art. 58 (4) AI-Act vs. the market surveillance authority according to Art. 60 (6) AI-Act should be specified more precisely.

#### **Article 5(2)**

This paragraph does not mention the costs that the competent authority can reasonably expect from the sandbox plan, despite Article 2(2) highlighting the importance of this figure. An additional point should be added:

*"the costs that can reasonably be expected from the execution of the sandbox plan."*

#### **Article 5(6)**

This paragraph imposes obligations on Member States regarding real-world testing of AI systems. As the draft is intended to specify regulations on regulatory sandboxes, it should not

attempt to regulate real-world testing under Article 60 AI-Act, which is outside the scope of Article 58(1) AI-Act.

Furthermore, the obligations stated in paragraph 6 are not supported by Articles 57, 58, or 60 AI-Act. There is no obligation for Member States to "enable the testing in real-world conditions of those products, including by providing, as necessary, access to physical public infrastructure." Otherwise, any provider of an AI system listed in Section B of Annex I could claim access to public infrastructure (e.g., airport runways or railway tracks), potentially disrupting essential services. This paragraph or at least the words: *"including by providing, as necessary, access to physical public infrastructure"* should be deleted.

#### **Article 6**

The importance of both the proof and the exit report, to be issued by the competent authority, is clear. However, the competent authority cannot have adequate evidence of the sandbox process unless it receives the necessary information from the sandbox organization. Therefore, it is important to establish that the competent authority may rely on a report from the sandbox organization, which must include the elements specified in Article 6(2)(a)-(c) and Article 6(3)(a)-(c) of the draft. This should be reflected in paragraph 1 as follows:

*"After completion of a provider's or prospective provider's participation in the AI regulatory sandbox, the relevant competent authority shall, **based on a report from the sandbox organization**, evaluate the admitted project with respect to the activities carried out and the progress achieved, in accordance with the objectives set out in the sandbox plan."*

#### **Article 6(4)**

This paragraph states that the exit report does not have the same status or legal effect as a declaration of conformity under Article 47 of Regulation (EU) 2024/1689. This is unnecessary, as Article 57(7) of the AI-Act already clarifies that neither the exit report nor the written proof constitutes a declaration of conformity, but rather serves as evidence of compliance for the conformity assessment process. This paragraph should be deleted.

#### **Article 7(1)**

This article describes the possibility of voluntary post-production research efforts by the national authority. As there is no obligation for the national authority to undertake such efforts, nor for providers to support them, this provision is unnecessary and not covered by the Commission's mandate under Article 58(1). It should be deleted.

#### **Article 7(2)**

This provision introduces a new obligation for national authorities to provide evidence and reporting regarding sandbox documents to the market surveillance authority, as referenced in Article 74 of the AI-Act. The powers of market surveillance authorities are established in Regulation (EU) 2019/1020 and specified for AI in Article 74 of the AI-Act. The new rule in paragraph 2 is not supported by these regulations and would exceed the Commission's authority under Article 58(1). It should be deleted.

## Missing Elements

### 1. AI-regulatory sandboxes as part of the EU AI-Ecosystem

As AI regulatory sandboxes will add a new kind of player to the existing AI-ecosystem, it should be clarified which tasks have to be fulfilled by the regulatory sandboxes and which tasks shall remain with already existing players as EDIHs, TEFs, AI Factories:

Here are some questions arising in this context:

- According to 3.2 AI Continent Action Plan of the Commission

*“The Network of European Digital Innovation Hubs will ... facilitate companies’ access to ... other AI initiatives such as regulatory sandboxes and Testing and Experimentation Facilities.*

It might be helpful to detail which roles in the application and selection process lie with the sandbox organization and which should be done by the EDIH.

- EU has established TEFs for testing AI-Systems.

It might be useful to clarify if this task remains with TEFs or if the regulatory sandboxes have to take over.

- Training of AI-Models needs great amounts of data processing capacities. For this purpose, AI-(Giga-) Factories are (to be) established in Europe.

It would be helpful to point out if AI regulatory sandboxes really are expected to establish training facilities.

Art. 3 of the draft might be used to clarify the role

### 2. Governance of AI regulatory sandboxes

Any Member State intending to establish a regulatory AI sandbox must determine the most suitable legal entity to fulfill the requirements of the AI-Act. Neither the AI-Act nor the draft provides guidance on the organization of regulatory sandboxes. It appears that there are no restrictions regarding organizational structure. On the other hand, the draft itself does not mention the regulatory sandbox as an acting entity, as it addresses the “competent authorities”. It would be helpful if the following could be confirmed by the Commission in a new article of the draft:

*"A regulatory sandbox may be operated by the national competent authority itself. The national competent authority may also approve the operation of the regulatory sandbox by another legal entity, which may be a different public authority or a private company, provided that it agrees to fulfill the obligations arising from the AI-Act and this implementing regulation."*