

EDPS Formal comments on the draft 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

THE EUROPEAN DATA PROTECTION SUPERVISOR,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC ('EUDPR')¹, and in particular Article 42(1) thereof,

HAS ADOPTED THE FOLLOWING FORMAL COMMENTS:

1. Introduction and background

1. On 16 February, the European Commission consulted the EDPS on the draft 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 ('the draft Implementing Regulation').
2. The objective of the draft Implementing Regulation is to set common rules and detailed arrangements for the establishment, development, implementation, operation and supervision of all AI regulatory sandboxes established pursuant to Article 57 of Regulation (EU) 2024/1689 ('AI Act')².
3. The draft Commission Implementing Regulation is adopted pursuant to Article 58(1) of the AI Act.
4. The EDPS previously issued EDPB-EDPS Joint Opinion 5/2021 on the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)³ and the EDPB-EDPS Joint Opinion 1/2026 on the Proposal for a Regulation as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)⁴.

¹ OJ L 295, 21.11.2018, p. 39.

² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ, 21.11.2018, L.295, p.39.

³ [EDPB-EDPS Joint Opinion 5/2021 on the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence \(Artificial Intelligence Act\)](#), issued on 18 June 2021.

⁴ [The EDPB-EDPS Joint Opinion 1/2026 on the Proposal for a Regulation as regards the simplification of the implementation of harmonised rules on artificial intelligence \(Digital Omnibus on AI\)](#), adopted on 20 January 2026.

5. The present formal comments of the EDPS are issued in response to a consultation by the European Commission pursuant to Article 42(1) of EUDPR. The EDPS welcomes the reference to this consultation in Recital 24 of the draft Implementing Regulation. At the same time, the EDPS notes that Recital 24 refers also to a consultation with the European Data Protection Board (EDPB), whereas the request for an Opinion is addressed to the EDPS only⁵. Therefore, the EDPS recommends removing the reference to the European Data Protection Board and paragraph 2 of Article 42 EUDPR in Recital 24.
6. These formal comments do not preclude any additional comments by the EDPS in the future, in particular if further issues are identified or new information becomes available, for example as a result of the adoption of other related Implementing or Delegated acts⁶.
7. Furthermore, these formal comments are without prejudice to any future action that may be taken by the EDPS in the exercise of his powers pursuant to Article 58 of the EUDPR and are limited to the provisions of the draft Implementing Regulation that are relevant from a data protection perspective.

2. Comments

2.1. Application and selection

8. Article 3 of the draft implementing regulation sets out the application and selection criteria for participation in an AI regulatory sandbox. The EDPS considers that the objectives of the participation and the scope of the activities to be carried out in the AI regulatory sandbox, described in Article 5(2)(c) of the draft Implementing Regulation as part of the sandbox plan, should also be part of the guiding selection criteria in Article 3(3)⁷.
9. In the same vein, the need for the involvement of other relevant authorities (including data protection authorities)⁸ in the execution of the sandbox plan should also be part of the guiding selection criteria in Article 3(3).
10. The EDPS points out that national competent authorities may find it complex or even impossible to assess the “economic viability of the project proposal” as per guiding selection criteria of Article 3(3)(d) of the draft Implementing Regulation. Moreover,

⁵ In this regard, the EDPS recalls that pursuant to Article 42(2) EUDPR joint consultation of the EDPS and the EDPB are reserved for proposals that are of ‘particular importance’ for the protection of individuals’ rights and freedoms with regard to the processing of personal data.

⁶ In case of other Implementing or Delegated acts with an impact on the protection of individuals’ rights and freedoms with regard to the processing of personal data, the EDPS would like to remind that he needs to be consulted on those acts as well. The same applies in case of future amendments that would introduce new or modify existing provisions that directly or indirectly concern the processing of personal data.

⁷ Otherwise, competent authorities might find, after selecting an application, that the objectives and scope of activities envisioned do not fit within their strategic priorities, taking into account the means and resources at their disposal. In accordance with Article 3(3) of the draft implementing regulation, competent authorities may annually decide to give more priority to specific sectors in industrial or public areas of particular strategic importance and in areas of notable regulatory implementation challenges that are in need of support, for reasons of available resources and capacity of the competent authority, while still respecting the objectives of broad and equal access to the AI regulatory sandbox.

⁸ See also Article 5(2)(d) and (e) of the draft Implementing Regulation.

the EDPS notes that this criterion is not envisaged in the AI Act. If maintained, the EDPS considers that the draft Proposal should provide clear and objective criteria (e.g. specific KPIs) to enable them to assess the economic viability of the project proposal.

11. The draft Implementing Regulation specifies that AI regulatory sandboxes may be established in specific sectors or at regional or local level, as well as jointly with the competent authorities of other Member States ('joint AI regulatory sandboxes'), or at Union level⁹. The EDPS encourages to consider whether, in addition to sector-specific sandboxes, a reference should also be made to the possibility of putting in place technology-specific sandboxes, as both can present added value¹⁰. Ideally, adopting a combined approach – simultaneous application of technology and sector - specific considerations for sandboxes – would be recommendable as well.

2.2. Further processing of personal data and legal basis in the AI regulatory sandbox

12. Article 5(2) of the draft Implementing Regulation enumerates the elements that should be specified in the AI regulatory sandbox plan. In point (e) it requires that the sandbox plan indicates whether the AI system specified in the selected application involves the processing of personal data and the need for involving the competent data protection authority. In this regard, the EDPS welcomes recital 10 of the draft Implementing Regulation clarifying that a competent data protection authority should be associated to the operation of the AI regulatory sandbox and supervise when personal data is processed for the development, training or testing of the AI system in the context of the AI regulatory sandbox, in line with Article 57(10) AIA.
13. In cases where processing of personal data is foreseen, the EDPS recommends that the sandbox plan also determines the scope and the modalities of the processing, including the categories of personal data that may be processed in the context of the sandbox and appropriate safeguards for the protection of the rights and freedoms of natural persons in line with the GDPR and the EUDPR.
14. While Article 59 of the AI Act provides specific rules related to the further processing of personal data for developing AI systems in the public interest in the sandbox, this is not the case for other AI systems to be tested in the regulatory sandboxes. The EDPS also notes that Article 2(7) AI Act provides that it shall not affect data protection legislation, without prejudice to Article 59 of the AI Act.
15. To help minimise risk of legal uncertainty and disparities in the implementation of regulatory sandboxes, the EDPS invites the Commission to explicitly state in a recital of the draft Implementing Regulation that a valid legal basis should still be identified

⁹ See: Recital 5 of the draft Implementing Regulation.

¹⁰ While sector-specific approach reveals sector-specific challenges, the technology-centric lessons-learned are transferable across different sectors - for instance, understanding how hallucination and bias occurs in the context of LLMs application is relevant to multiple sectors. A sandbox that would be limited to 'sectoral' pilots only may potentially observe only the surface manifestation of a risk, and miss the structural causes that generate those risks and the means how to address them so to achieve compliance.

under the relevant data protection law for AI sandboxes operated under Articles 57 of the AI Act.

2.3. AI regulatory sandbox to be established by the EDPS

16. According to Article 57(3) of the AI Act, the European Data Protection Supervisor may also establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies (EUIs), and may exercise the roles and the tasks of national competent authorities. In this regard, the EDPS welcomes recital 6 of the draft Implementing Regulation recalling that the EDPS may establish an AI regulatory sandbox to support the responsible development, testing and use of AI systems provided by the EUIs.
17. In order to enhance legal certainty and clarity with regard to the sandboxes established by the EDPS for the EUIs, in particular as regards the scope of the mandatory requirements applicable to such sandboxes and the role and tasks of the EDPS as the competent authority, the EDPS invites the Commission to consider adding to recital 6 the following clarifications:
 - references in this Implementing Regulation to “national competent authorities” and “competent authorities” shall be construed as references to the European Data Protection Supervisor and other relevant Union authorities,
 - references to “national legislation” shall be construed as references to the applicable Union law.
 - references to “national annual reports” shall be construed as “EDPS annual reports”.
18. Such a clarification would, most importantly, ensure legal certainty by making it explicit that applicants (EUIs) have the right to appeal the sandbox selection decisions adopted by the EDPS, in accordance with the relevant Union legislation and the procedures governing appeals against the EDPS administrative decisions.

2.4. Cooperation mechanism between National Competent Authorities and authorities protecting fundamental rights

19. Article 77 of the AI Act grants to Supervisory Authorities (SAs), specifically national public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, the power to request documentation from National Competent Authorities (NCAs) regarding high-risk AI systems.
20. While this provision establishes a cooperation channel to help such authorities (including data protection authorities) to exercise their supervisory powers, it does not provide explicit guidance for mutual cooperation, namely the NCAs consulting other authorities on matters concerning fundamental rights’ risks that may arise in the context of the regulatory sandbox. This is particularly relevant in the context of the AI regulatory sandbox, since under Article 57 (11), the NCA can take a decision to temporarily or permanently suspend an activity based on risks to fundamental rights.

21. The EDPS therefore suggests clarifying the need for mutual assistance and consultation between NCAs and other authorities (including data protection authorities) in the specific context of regulatory sandboxes.

2.5. Other comments

22. The EDPS suggests considering the following points to ensure greater clarity and consistency between the provisions of the AI Act and the draft Implementing Regulation:

- the need to clarify the distinction between the “terms and conditions of participation” to be accepted via electronic signature by providers or prospective providers (as referred to in Recital 8 of the draft Implementing Regulation), “the general terms and conditions” set out in Article 2 of the draft Implementing Regulation and “the participation conditions and parameters set out in the sandbox plan” (as referred to in Article 8(2)(i) of the draft Implementing Regulation).
- the need to clarify the relationship between Articles 6(5) and 6(6) of the draft Implementing Regulation as both refer to the possibility to publish exit reports or their key findings by competent authorities. In particular, it may be worth clarifying whether Article 6(6) applies only when the participant does not agree to publish its sandbox exit report on the dedicated interface referred in Article 57(17) of the AI Act under Article 6(5).
- the need to ensure consistency between Article 9(1) of the draft Implementing Regulation and Article 57(16) of the AI Act, as the former refers to the duty of national competent authorities to publish “annual reports” online while the latter refers to the duty to publish “annual reports or abstracts thereof”.
- the need to ensure consistency between the terms “suspension” and “termination” as used in Article 8 of the draft Implementing Regulation and Article 57(11) of the AI Act, and to clarify that competent authorities are obliged to notify the AI Office in the event of both temporary or permanent suspension of the testing process or participation in the AI regulatory sandbox.

23. It is further suggested that the title of Article 8 reflect both the suspension and the potential extension of an AI regulatory sandbox project.

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(e-signed)

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