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COMMISSION IMPLEMENTING REGULATION (EU) 2026/2487

of 10 November 2026

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (1) , and in particular Article 58(1) thereof,

Whereas:

(1)

In accordance with Regulation (EU) 2024/1689, AI regulatory sandboxes are intended to provide a controlled framework established by competent authorities to enable the development, training, validation and testing, including in real-world conditions, of innovative AI systems pursuant to a sandbox plan under regulatory supervision for a limited time before their placement on the market.

(2)

To avoid fragmentation across the Union, maximise the benefits of AI regulatory sandboxes for all, and guarantee the consistent implementation of Regulation (EU) 2024/1689, it is important to adopt common rules setting out the detailed arrangements regarding the establishment, development, implementation, operation and supervision of the AI regulatory sandboxes. Such rules should be in line with the objectives of the AI regulatory sandboxes and other relevant provisions set out in Regulation (EU) 2024/1689. These rules should also ensure coherence and complementarity with Union initiatives supporting data-driven innovation and with relevant Union sectoral frameworks governing the development and placing on the market of regulated products and systems.

(3)

AI regulatory sandboxes aim to enhance legal certainty for innovators and support them in achieving regulatory compliance with Regulation (EU) 2024/1689 and, as appropriate, other Union law, such as Regulation (EU) 2016/679 of the European Parliament and of the Council (2) , and Union product safety legislation. They should also promote responsible innovation and competitiveness and accelerate access of innovative AI systems to the Union market by removing barriers for small and medium enterprises ('SMEs'), including start-ups. AI regulatory sandboxes play a key role in connecting innovators with competent authorities through a collaborative approach and in enhancing the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use. Participation in AI regulatory sandboxes should focus on issues that may raise legal uncertainty for providers and prospective providers to innovate and experiment with AI in the Union.

(4)

Services provided in an AI regulatory sandbox typically constitute non-economic activities that include providing regulatory guidance, advice, and supervision by a competent authority of AI system development, testing and validation and support for conformity assessment as special supervisory and regulatory arrangement for regulatory compliance and regulatory learning purposes, to the extent they can be seen as an exercise of public powers. The AI regulatory sandbox must ensure transparent admission criteria and a fair process that focuses on regulatory challenges, time-limited participation, transparency and a wide dissemination of the outcomes for regulatory learning purposes and for the benefit of other participants, the wider (internal) market and the AI innovation ecosystem for trustworthy AI. This is without prejudice to State aid rules, as applicable, for activities and services of an economic nature by the AI regulatory sandbox (if any) provided to participants.

(5)

This Regulation lays down detailed rules as regards the establishment, development, implementation, operation and supervision of AI regulatory sandboxes by competent authorities pursuant to Article 57(1), (2), (3) and (3a) of Regulation (EU) 2024/1689. For reasons of uniform application and common interpretation concerning regulatory questions examined in the AI regulatory sandbox, as well as mutual recognition of the results, this Regulation should apply to all AI regulatory sandboxes under Regulation (EU) 2024/1689.

(6)

AI regulatory sandboxes should be widely available across the Union and enable broad and equal access to providers and prospective providers. Member States should have at least one AI regulatory sandbox at national level as required by Regulation (EU) 2024/1689. To that end, any provider or prospective provider within the scope of Regulation (EU) 2024/1689 should be able to apply and participate in the AI regulatory sandbox as long as the relevant conditions and procedures established in this Regulation are met. Such AI regulatory sandboxes should be established in the Member States by 2 August 2027. Piloting projects are also encouraged before competent authorities under Regulation (EU) 2024/1689 have been formally designated by the Member States. Joint AI regulatory sandboxes may be set up with competent authorities from other Member States for fulfilling the obligation of establishing an AI regulatory sandbox with an equivalent level of national coverage. Member States are encouraged to establish joint AI regulatory sandboxes facilitating cross-border collaboration, streamlining coordination, optimising resources and strengthening consistency in the implementation of Regulation (EU) 2024/1689. Joint AI regulatory sandboxes should be established through appropriate framework agreements, for example a memorandum of understanding. Additional AI regulatory sandboxes may also be established in specific sectors (including jointly with competent authorities of other Member States), at regional or local level, or at Union level. Sector-specific AI regulatory sandboxes may be established at different levels (regional or local, national or jointly) and can be particularly useful in industrial or public areas of particular strategic importance and

in areas of notable regulatory implementation challenges that are in need of support, including in the public sector.

(7)

The European Data Protection Supervisor may establish an AI regulatory sandbox to support the responsible development, testing and use of AI systems provided by the EU institutions, bodies, offices and agencies. Additionally, the AI Office may establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1) of Regulation (EU) 2024/1689, which is to be implemented in close cooperation with relevant competent authorities.

(8)

It is important that the terms and conditions for the participation in an AI regulatory sandbox are made clear to the provider or prospective provider as early as possible in a transparent and non-discriminatory manner and agreed upon before entering the sandbox. These can be accepted with an electronic signature.

(9)

Participation by SMEs, including start-ups, should be free of charge unless exceptional costs are incurred in the AI regulatory sandbox. In those cases, SMEs, including start-ups, should be informed in advance and the exceptional costs recovered in a fair, transparent and proportionate manner, without prejudice to Member States making use of possibilities foreseen under the State aid rules. The same pricing regime should apply to public authorities, bodies and agencies.

(10)

For all other participants, the costs of participation must be non-discriminatory and transparent. Competent authorities may charge fees that equal the actual costs incurred for the provision of those services. This is without prejudice to State aid rules, as applicable, for services of economic nature provided in the AI regulatory sandbox (if any). The competent authority should therefore communicate the applicable fees to the provider or prospective provider in an AI regulatory sandbox as early as possible and at the latest before the participation starts and when the services are determined, as well as any exceptional costs that may arise. If the competent authority claims exceptional costs, the invoice should be sufficiently detailed that the participant understands which costs have occurred, for what services and how they have been calculated.

(11)

Competent data protection authorities 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. When the AI regulatory sandbox projects examine issues that otherwise fall under the supervisory remit of other competent authorities, including those supervising the protection of fundamental rights or those providing or supporting access to data, the latter should be associated as appropriate.

(12)

While aiming to ensure the objective of regulatory learning through the sharing of results of participation in AI regulatory sandboxes, competent authorities should respect the confidentiality of information and data obtained in carrying out tasks connected to the AI regulatory sandbox, in accordance with Article 78 of Regulation (EU) 2024/1689.

(13)

It is important to avoid fragmentation and to ensure that the necessary procedures, processes, and administrative requirements are clearly described, accessible, streamlined and easy to understand, as well as to ensure mutual recognition of the results. Competent authorities across the Union should apply uniform and common criteria as defined in this Regulation and should apply relevant available templates and guidance material adopted by the European Artificial Intelligence Board (‘the Board’) under Article 66(d) of Regulation (EU) 2024/1689 for participating in all AI regulatory sandboxes. Possible adjustments to these templates by competent authorities in specific AI regulatory sandbox projects within clearly defined cases may be done only where strictly necessary and duly justified due to the specific needs and context of the AI regulatory sandbox, while taking due account of the need to avoid fragmentation, ensure common criteria for and consistency in the implementation of the AI regulatory sandboxes across the Union, keep the process simple and streamlined for participants in an AI regulatory sandboxes and not lead to increased administrative burden. Under Article 66(d) of Regulation

(EU) 2024/1689, the Board may decide to amend or update the templates, where appropriate, in light of practical experience gained from their application and policy and technological developments.

(14)

When selecting participants, competent authorities should review the eligibility of the candidates and the selection criteria laid down in this Regulation, where competent authorities may take into account the available resources and capacity for the number of applicants they can accept. For the selection criteria, this includes the specific regulatory and practical challenges in the proposed sandbox project, such as the lack of (physical, digital or hybrid) testing environments or when there are regulatory challenges related to potential unclarity or challenges for an AI system to meet specific legal requirements. Competent authorities should also review the potential for and scalability of regulatory learning for the specific sector, such as to what extent participation in the AI regulatory sandbox will lead to more regulatory knowledge about the specific sector and the technology, and to what extent the legal questions examined in the sandbox will enhance the learning and the potential of broader uptake and development of AI in the specific sector. When assessing the extent to which the project will contribute to the public interest or societal benefit and Union policy, competent authorities may consider the collective interest, the positive impact to a specific sector and its contribution to competitiveness, which may encompass the benefit to the Union's AI ecosystem. There may be different levels of maturity in the proposals for an AI regulatory sandbox project, where competent authorities may consider the maturity of the proposal in light of the authority's available capacity and the other selection criteria. When assessing the innovative character of an AI system in a proposal for an AI regulatory sandbox project, competent authorities should take into account the novelty of the AI system, with such novelty arising in particular either from novel or improved technologies, design, methods, or architectures or other elements throughout any stage of the AI system's life cycle relative to the current state of the art, or from the novel application or adaptation of existing technology to a new domain or use case. The innovative character may also arise from novel measures aimed to ensure compliance with applicable legal requirements, enhanced fundamental rights safeguards or improved safety performance of the AI system. Any additional selection criteria that may be added by competent authorities should be reasonable, proportionate and duly justified due to the context and objectives of the AI regulatory sandbox and broader national strategies and priorities, while taking into account the aim of AI regulatory sandboxes allowing broad and equal access through national coverage and having uniform and common selection criteria in the Union.

(15)

The right to appeal decisions made by competent authorities may cover non-compliance with the eligibility criteria or the outcome of the selection procedure. The appeal should be filed in accordance with the relevant Union or national legislation and procedures for appeal of administrative decisions. The appeal procedure should include the right of every person to be heard, the right of every person to have access to his or her file, and the obligation of the administration to give reasons for its decision.

(16)

Due to their limited administrative resources to navigate the legal landscape and ensure compliance with Regulation (EU) 2024/1689, SMEs, including start-ups, should have priority access to AI regulatory sandboxes if they meet the eligibility and selection criteria, and have a registered office or a branch in the Union. The AI regulatory sandboxes that may be established by the AI Office should provide priority access to SMEs, including start-ups, and small mid-cap enterprises ('SMCs'), pursuant to Article 57(3a) of Regulation (EU) 2024/1689.

(17)

In line with broader Union and national AI strategies and priorities, while respecting the aim of achieving national coverage in the AI regulatory sandbox, competent authorities may, in the selection of participants, choose to periodically focus on multiple, specific sectors that are in industrial or public areas of particular strategic importance and in areas of notable regulatory implementation challenges that are in need of support, depending on their capacities, especially in the early implementation phases of the AI regulatory sandbox.

(18)

Competent authorities are encouraged to offer or refer to digital, physical or hybrid testing infrastructure in the AI regulatory sandbox. In order to adequately leverage available resources and infrastructure at the Union and national level and promote synergies with the AI regulatory sandboxes, competent authorities should, as appropriate, ensure cooperation with and facilitate the involvement of relevant AI ecosystem actors, such as the

Testing and Experimentation Facilities, the European Digital Innovation Hubs, AI Factories, and other AI innovation initiatives. Competent authorities should, where appropriate, facilitate involvement of actors such as national or European standardisation organisations, notified bodies, research and experimentation labs and relevant stakeholder and civil society organisations. Involvement of notified bodies in an AI regulatory sandbox should not compromise their tasks nor their compliance with the requirements to which they are subject to under Regulation (EU) 2024/1689, while facilitating early knowledge of the activities performed in the AI regulatory sandbox and their general alignment with the state of the art benchmarks and testing methodologies. Where appropriate, there should be supervision by the competent authority of specific projects within the AI regulatory sandboxes that may be carried out in existing Union and national AI ecosystem initiatives and infrastructure. Member States are encouraged to establish joint AI regulatory sandboxes leveraging these infrastructures and facilitating cross-border collaboration and testing.

(19)

In order to frame a specific set of actions for developing, training, testing or validating concrete projects of innovative AI systems in the controlled environment of an AI regulatory sandbox and to allocate the necessary resources, the sandbox plan should address the needs of the participants, specifying their objectives, as well as the relevant risk management safeguards and the support to be provided by the competent authorities, and other entities involved.

(20)

Participation in an AI regulatory sandbox should support a path towards conformity with Regulation (EU) 2024/1689. Participation in and exiting from an AI regulatory sandbox should not be considered an approval by the competent authorities to the provider or prospective provider to place on the market or put into service the AI system supervised in the AI regulatory sandbox under Regulation (EU) 2024/1689. Since exiting an AI regulatory sandbox does not grant presumption of conformity with the legal requirements of Regulation (EU) 2024/1689, market surveillance authorities and notified bodies should positively take into account the exit reports and the written proof provided by the competent authority with a view to accelerating conformity assessment procedure to a reasonable extent.

(21)

In order to facilitate and accelerate the placing of AI systems onto the Union internal market, testing in real-world conditions may be conducted within the framework of an AI regulatory sandbox. Such testing should not affect other Union and national law on the testing in real-world conditions. With the involvement of the sectoral competent authority under the Union harmonisation legislation listed in Annex I to Regulation (EU) 2024/1689, testing of high-risk AI systems embedded in regulated products or systems that constitute products themselves subject to specific requirements set out in the relevant Union harmonisation law could also be conducted, as appropriate. For AI systems classified as high-risk AI systems in accordance with Article 6(1) or Regulation (EU) 2024/1689 related to products covered by the Union harmonisation legislation listed in Section B of Annex I, such testing may be conducted only in so far as the requirements for high-risk AI systems under Regulation (EU) 2024/1689 have been integrated in that Union harmonisation legislation.

(22)

Exit reports are useful for regulatory learning and contribute to the dissemination of lessons learned. It is necessary to lay down rules regarding the content of the exit report referred to in Article 57(7) of Regulation (EU) 2024/1689. Publication and dissemination of the results of a specific sandbox project for the benefit of everyone should encourage dialogue among competent authorities, participants and non-participants, such as relevant stakeholders. In order to enable regulatory learning in the Union and the ability of competent authorities in other Member States to consider, among others, the key findings and lessons learned, whenever the written proof and exit report are published, it should be done in one or more of the official languages of the institutions of the Union, as indicated by the competent authority. Competent authorities should possibly ensure that one of the languages determined by them is one which is broadly understood by the largest possible number of cross-border providers or prospective providers.

(23)

The Board and the Commission should collaborate on the evaluation of the AI regulatory sandboxes established in the Member States or at Union level. This should be done by taking into account the impact an AI regulatory

sandbox has had, including the lessons learned, and in terms of evaluating the processes and governance. Such an evaluation may be done by an independent body.

(24)

AI regulatory sandboxes established under this Regulation are without prejudice to other legislation allowing for the establishment of other sandboxes aiming to ensure compliance with laws other than Regulation (EU) 2024/1689.

(25)

The European Data Protection Supervisor was consulted in accordance with Article 42(1) and (2) of Regulation (EU) 2018/1725 of the European Parliament and of the Council (3) and delivered an opinion on 6 March 2026.

(26)

The measures provided for in this Regulation are in accordance with the opinion of the Artificial Intelligence Committee,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation sets out 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.

2. The rules set out in this Regulation shall fully apply to AI regulatory sandboxes established in accordance with Article 57(1), (2), (3) and (3a) of Regulation (EU) 2024/1689 and to the competent authorities referred therein.

CHAPTER II

PARTICIPATION IN AN AI REGULATORY SANDBOX

Article 2

General terms and conditions for access to and participation in an AI regulatory sandbox

1. The terms and conditions set out in paragraphs 2 to 6 shall apply to the participation in an AI regulatory sandbox.

2. Providers and prospective providers shall have non-discriminatory and transparent access to clear and publicly available information about the scope of the AI regulatory sandbox, and the services offered by the competent authorities within the AI regulatory sandbox.

3. Access to and participation in an AI regulatory sandbox for SMEs, including start-ups, shall be prioritised and free of charge for services of regulatory guidance, advice and supervision concerning (the compliance with) Regulation (EU) 2024/1689 and other Union and national law supervised in the AI regulatory sandbox, including supervision of the testing in real-world conditions, support for conformity assessment, reliance on relevant regulatory privileges in accordance with Article 57(12) and Article 59 of Regulation (EU) 2024/1689, redirection to pre-deployment services, and supervision of the testing and validating of AI systems. The AI regulatory sandboxes that may be established by the AI Office shall provide priority access to SMEs, including start-ups, and SMCs, pursuant to Article 57(3a) of Regulation (EU) 2024/1689.

Competent authorities may still recover exceptional costs exceeding those of the services listed in the first subparagraph for which the authority requires additional financial capacity. Such costs shall concern other services that shall be agreed upon between the competent authority or competent authorities and the participant in the sandbox plan.

The recovery of exceptional costs for other services shall be carried out in a fair, transparent and proportionate

manner without prejudice to Member States making use of possibilities foreseen under State aid rules, as applicable. When charging SMEs, including start-ups, a fee for exceptional costs, the invoice shall be sufficiently detailed in order for the participant to understand which exceptional costs have occurred and how they have been calculated. Prospective participants shall be informed about the possibility that exceptional costs might be incurred as early as possible and at least before the participation starts.

Public authorities, bodies and agencies shall also benefit from the pricing regime specified in this paragraph.

4. Competent authorities may charge undertakings other than SMEs, including start-ups, a fee equal to the full costs incurred for the services and without prejudice to State aid rules as applicable for services provided in the AI regulatory sandbox of economic nature. In such case, competent authorities shall define and publish the list of fees that apply for participation, when opening the application phase pursuant to Article 3.

5. Providers or prospective providers who do not have a registered office or a branch in the Union and who have been selected following the fulfilment of the eligibility and selection criteria referred to in Article 3(2) and (3) of this Regulation, shall pay to the competent authority a participation fee and include in the application to participate in an AI regulatory sandbox information about the designated authorised representative established in the Union, through a written mandate, who can represent the provider or prospective provider and be held responsible and liable as a guarantee for the compliance of the provider or prospective provider's activities in the AI regulatory sandbox.

6. Without prejudice to their participation in the AI regulatory sandbox, participants in the AI regulatory sandbox remain responsible for ensuring compliance with applicable Union legislation.

Article 3

Application and selection

1. Any provider or prospective provider may apply to participate in an AI regulatory sandbox. Competent authorities shall facilitate the application procedure with a form to be made available through easily accessible means. This form shall be filled in with information on the applicant and the project proposed for participation in the AI regulatory sandbox.

2. A proposal for a sandbox project shall be eligible for consideration in the application procedure for participation in the AI regulatory sandbox if it meets the following cumulative criteria:

(a)

the application is made by a provider or prospective provider, or by an authorised representative for providers or prospective providers who do not have a registered office or a branch in the Union jointly with the third country provider or prospective provider. Providers and prospective providers may also submit applications in partnerships with deployers or other relevant third parties needed for the participation in the AI regulatory sandbox;

(b)

the application relates to (1) an AI system which is not placed on the market or put into service; or (2) to an AI system that has already been placed on the market or put into service, but will be subject to substantial modification pursuant to Article 3(23) of Regulation (EU) 2024/1689; or (3) to an AI system that according to its intended purpose has not been classified as high-risk, but has then been placed on the market or put into service in such a way that the AI system concerned becomes a high-risk AI system pursuant to Article 25(1)(c) of Regulation (EU) 2024/1689.

Providers or prospective providers are not restricted to apply to an AI regulatory sandbox only in the Member State they are established or located in.

3. When evaluating a proposal for a sandbox project, the competent authority shall take into consideration at least the following selection criteria:

(a)

the need to participate in the AI regulatory sandbox, due to specific regulatory and other practical challenges in relation to Regulation (EU) 2024/1689 and, where relevant, other applicable Union and national law;

(b)

the potential for and scalability of regulatory learning, including the expected impact and benefits for the specific sector;

(c)

the extent to which the project will contribute to objectives of public interest or societal benefit and Union policy;

(d)

the maturity of the proposal;

(e)

the innovative character of the AI system.

4. Competent authorities may periodically decide to give more priority to specific sectors in industrial or public areas of particular strategic importance and to 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.

5. When complying with their obligations under this Article, competent authorities shall apply available templates and guidance material adopted by the Board under Article 66(d) of Regulation (EU) 2024/1689.

6. The selection procedures shall be transparent, fair and equal while allowing priority access for SMEs, including start-ups, and, where applicable, for SMCs, pursuant to Article 62(1), point (a) and Article 57(3a) of Regulation (EU) 2024/1689.

7. Competent authorities shall inform the applicant about the outcome of the selection procedure no later than three months after the submission of the complete application to the competent authority or after the submission deadline of a call for application. The applicant has the right to appeal such decisions made by competent authorities, taking into account relevant national legislation and procedures for appeal of administrative decisions.

Article 4

Participation

1. Competent authorities shall record in a secure manner in accordance with applicable Union and national law the activities related to participation in an AI regulatory sandbox, and maintain records related to AI systems developed or tested in that sandbox. Where necessary for their monitoring and supervisory tasks, competent authorities shall also be entitled to request additional relevant information from the participants.

2. Competent authorities shall provide the Commission with all relevant information related to AI regulatory sandboxes as referred to in Article 57(17) of Regulation (EU) 2024/1689 for publication on the single information platform.

3. Competent authorities may share with the Commission for publication on the single information platform as referred to in Article 57(17) of Regulation (EU) 2024/1689 tools for compliance with Regulation (EU) 2024/1689, such as technical specifications, benchmarks and testing tools developed in AI regulatory sandboxes, provided that those means demonstrate proven relevance for compliance with Regulation (EU) 2024/1689 as confirmed by the Commission after consultation of the Board, without prejudice to the need to observe and protect intellectual property rights and confidential business information and trade secrets in accordance with Union and national law.

4. The duration of the participation in the AI regulatory sandbox shall be proportionate to the set-up and operation of the sandbox, taking into account, in particular, the following elements:

(a)

the available capacity, resources and priority defined by the competent authorities;

(b)

whether the sandbox project will cover several or all aspects of the conformity assessment referred to in Article 43 of Regulation (EU) 2024/1689 or other obligations set out in that Regulation;

(c)

the complexity, scale and specific needs of the selected sandbox project.

5. Competent authorities shall cooperate, as appropriate, with and facilitate the involvement of the relevant actors within the AI ecosystem referred to in Article 58(2)(f) of Regulation (EU) 2024/1689, such as the Testing and Experimentation Facilities, the European Digital Innovation Hubs, centres of excellences, and AI Factories. In the implementation of the AI regulatory sandboxes, competent authorities shall, as appropriate, leverage the existing Union and national AI ecosystem initiatives and infrastructure, including through regulatory supervision of specific projects within the AI regulatory sandboxes that may be carried out in those facilities, where appropriate.

6. Competent authorities shall ensure that any person involved in an AI regulatory sandbox project is bound by appropriate confidentiality obligations, without prejudice to Article 57(7), (8), (16) and (17) of Regulation (EU) 2024/1689 and applicable Union or national law on transparency and access to documents.

CHAPTER III

OPERATION OF AN AI REGULATORY SANDBOX PROJECT

Article 5

Sandbox plan

1. Following the selection of applications in accordance with Article 3, a sandbox plan shall be agreed upon between the provider or prospective provider and the competent authority or authorities supervising the AI regulatory sandbox, as applicable, without undue delay following the selection.

2. The sandbox plan shall specify at least the following elements concerning the participation in the AI regulatory sandbox:

(a)

information about the applicant and the AI system specified in the selected application;

(b)

the estimated timeline of the sandbox project, including an estimated end date;

(c)

the objectives of the participation, scope of the activities, roles and responsibilities assigned to the provider or prospective provider and, where applicable, to deployers and other third parties participating in the sandbox, and services to be provided by the competent authority or competent authorities, or other actors of the AI ecosystem, including those subject to exceptional costs for SMEs or fees for other participants, to be carried out in the AI regulatory sandbox;

(d)

a description of the requirements and obligations laid down in Regulation (EU) 2024/1689 and, where relevant, in other national or Union legislation, that are supervised and addressed in the context of the sandbox project;

(e)

an indication 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;

(f)

risk management safeguards and a procedure for monitoring, managing and reporting serious incidents that could occur during the participation in the AI regulatory sandbox, when considered necessary and appropriate given the risks that are likely to arise;

(g)

where applicable, a plan on testing in real world conditions, supervised within the framework of the AI regulatory sandbox.

3. The provider or prospective provider shall, to the best of their ability, identify which information or data included in the sandbox plan might be confidential pursuant to Article 78 of Regulation (EU) 2024/1689.

4. The sandbox plan may be updated during the participation in the AI regulatory sandbox if both the competent authority or competent authorities and the provider or prospective provider agree.

5. When complying with their obligations under this Article, competent authorities shall apply available templates and guidance material adopted by the Board under Article 66(d) of Regulation (EU) 2024/1689.

6. Subject to Article 2(2) of Regulation (EU) 2024/1689, and as regards testing in real world conditions of AI systems covered by Union harmonisation legislation listed in Section B of Annex I to Regulation (EU) 2024/1689, the design and implementation of sandbox projects and sandbox plans shall take into account the specificities of the AI systems and products tested. Member States may enable testing in real world conditions of those products, including by providing, as necessary, access to physical public infrastructure, with a view of assessing and verifying the conformity with the requirements laid down in Articles 8 to 15 of Regulation (EU) 2024/1689.

Article 6

Written proof and exit report

1. After completion of a provider's or a prospective provider's participation in the AI regulatory sandbox, the competent authority or competent authorities shall evaluate the admitted project with respect to the activities carried out and the progress in their implementation, in accordance with the objectives in the sandbox plan.

2. The written proof provided for under Article 57(7) of Regulation (EU) 2024/1689 may, where appropriate, be drafted in collaboration with other relevant authorities and be signed by each authority involved. The written proof shall serve as documentation evidence informing notified bodies and relevant market surveillance authorities, but it shall not have the same status or legal effect as a declaration of conformity within the meaning of Article 47 of Regulation (EU) 2024/1689 or any other legislation supervised in the AI regulatory sandbox where similar declarations of conformity are issued. The written proof shall include at least the following elements:

(a)

types of activities successfully carried out in the sandbox in terms of development, training, validation, and testing of the AI system, as applicable, indicating the sector or sectors in which the AI regulatory sandbox operated;

(b)

the legal requirements and obligations evaluated in the context of the AI regulatory sandbox;

(c)

proof of whether the admitted sandbox project has been completed.

3. The exit report provided for under Article 57(7) of Regulation (EU) 2024/1689 shall serve for regulatory learning purposes and include at least the following:

(a)

a description of the key regulatory issues examined in the AI regulatory sandbox, how those issues were addressed or resolved, including specific recommendations, good practices, tools, benchmarks or measures tested that could be replicated;

(b)

if applicable, a record of serious incidents within the AI regulatory sandbox;

(c)

best practices and lessons learned that can be scaled up in similar cases.

The exit report shall be drafted and signed by the competent authority or competent authorities supervising the AI regulatory sandbox project.

4. When complying with their obligations under this Article, competent authorities shall apply available templates and guidance material adopted by the Board under Article 66(d) of Regulation (EU) 2024/1689.

5. The exit report shall not have the same status or legal effect as a declaration of conformity within the meaning of Article 47 of Regulation (EU) 2024/1689 or any other legislation supervised in the AI regulatory sandbox where

similar declarations of conformity are provided. The relevant competent authority shall provide the participant of the AI regulatory sandbox with the exit report within a reasonable period, but no later than 45 working days after completing participation.

6. The written proof and exit report shall be drafted in one or more of the official languages of the institutions of the Union, as indicated by the competent authority.

7. In case both the participant and the competent authority explicitly agree, the exit report may be shared by the competent authority with the Commission for publication on the single and dedicated interface referred to in Article 57(17) of Regulation (EU) 2024/1689.

8. In cases where the participant does not agree and without prejudice to Union and national law on access to documents, the competent authority may still publish relevant key findings and lessons learned from the exit report, containing only non-confidential information, in order to contribute to legal clarity, regulatory learning and innovation within the internal market. The exchange of information as well as the non-confidential information will not include any sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities. Unless stated as confidential in the sandbox plan in accordance with Article 5(3) or explicitly indicated as such by the participant before the end of the sandbox project, information shall be presumed to be available for disclosure.

9. Market surveillance authorities and notified bodies from any Member State shall recognise the exit report and written proof as referred to in Article 57(7) of Regulation (EU) 2024/1689 as documentation of the activities carried out, the related results and the learning outcomes of participation in any AI regulatory sandbox to ensure that this participation is mutually and uniformly recognised across the Union.

Article 7

Follow-up activities after participation

A competent authority or competent authorities may decide to undertake follow-up activities for providers or prospective providers having formerly participated in the AI regulatory sandbox and who may agree to engage on a voluntary basis. These follow up activities shall aim to: (i) assess the effectiveness of their participation in the AI regulatory sandbox; (ii) gain relevant information to boost AI innovation and uptake after exiting from the AI regulatory sandbox; and (iii) contribute to the national annual report.

Article 8

Extension and suspension of an AI regulatory sandbox project

1. Until 30 calendar days before the planned participation end date, the competent authority and the provider or prospective provider may decide to extend the duration of the sandbox project if they both agree and such an extension is justified.

2. Competent authorities may temporarily or permanently suspend the testing process or the participation in an AI regulatory sandbox if no mitigation is possible. Competent authorities may consider that no mitigation is possible if one or more of the following conditions apply:

(a)

where the participation conditions and parameters set out in the sandbox plan have been breached;

(b)

when the conditions for temporary or permanent suspension of the testing process or the participation in the AI regulatory sandbox under Article 57(11) of Regulation (EU) 2024/1689 are fulfilled due to significant risks to health, safety or fundamental rights identified during the development and testing of AI systems that cannot be effectively mitigated;

(c)

at the motivated request of the participant in an AI regulatory sandbox project.

The competent authorities shall inform the AI Office without undue delay of such a decision and the reasons thereof.

Article 9

Evaluation

1. When drafting the annual report under Article 57(16) of Regulation (EU) 2024/1689, the competent authority shall apply the available elements and template provided by the Board under Article 66(d) of Regulation (EU) 2024/1689. These annual reports shall be submitted to the AI Office and the Board.

2. The competent authorities shall publish the annual reports referred to in paragraph 1 of this Article or abstracts thereof online, and may share the annual reports with the Commission for publication on the single information platform as referred to in Article 57(17) of Regulation (EU) 2024/1689.

3. The general annual reports from the AI Office shall be made publicly available online by the Commission on the single and dedicated interface referred to in Article 57(17) of Regulation (EU) 2024/1689.

4. The reports as referred to in this Article will not cover any sensitive operational data in relation to the activities of law enforcement, border control, immigration or asylum authorities.

CHAPTER IV

FINAL PROVISION

Article 10

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union .

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 November 2026.

For the Commission

The President

Ursula VON DER LEYEN

(1) OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj .

(2) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1 , ELI: http://data.europa.eu/eli/reg/2016/679/oj).

(3) 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 L 295, 21.11.2018, p. 39 , ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

ELI: http://data.europa.eu/eli/reg_impl/2026/2487/oj

ISSN 1977-0677 (electronic edition)

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