



Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs

2025/0359(COD)

5.2.2026

***I

DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)
(COM(2025)0836 – C10-0304/2025 – 2025/0359(COD))

Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs

Rapporteurs: Arba Kokalari, Michael McNamara

(Joint committee procedure – Rule 58 of the Rules of Procedure)

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Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the **■** symbol or ~~strikeout~~. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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Agence Europe

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

(COM(2025)0836 – C10-0304/2025 – 2025/0359(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2025)0836),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C10-0304/2025),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 60 of its Rules of Procedure,
 - having regard to the joint deliberations of the Committee on Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs under Rule 58 of the Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs (A10-0000/2026),
1. Adopts its position at first reading hereinafter set out;
 2. Approves its statements annexed to this resolution;
 3. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective application of the relevant rules.

Amendment

(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective, ***simple and uniform*** application of the relevant rules.

Or. en

Amendment 2

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission

Amendment

(3 a) Additionally, the Commission, the AI Office and Member States' competent authorities should ensure that supervision, enforcement and monitoring of sectorial and national laws do not create overlaps, inconsistent interpretations or divergent enforcement in order to enable AI innovation in the private and public sector.

Or. en

Amendment 3

Proposal for a regulation
Recital 5

Text proposed by the Commission

Amendment

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared

by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, **rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas** AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. **In light of that**, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to **provide a sufficient level of** AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, **including** through offering training opportunities, providing informational resources, **and** allowing exchange of good practices **and other non-legally binding initiatives**. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. **This amendment is without prejudice to the broader measures taken by** the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.

by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, **and different types of activities will require different competencies**. AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. **To ensure that AI literacy requirements are effective**, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, to **support implementation by** individually, collectively and in cooperation with relevant stakeholders **providing guidance to help** encourage providers and deployers to **promote** AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, **for example** through offering training opportunities, providing informational resources, **or** allowing exchange of good practices. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. The Commission and the Member States **should continue** to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.

Or. en

Amendment 4

Proposal for a regulation Recital 6

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of Regulation (EU) 2024/1689 already provides a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council⁶. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷ and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council⁸ provides a legal basis allowing, where necessary for the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of Regulation (EU) 2024/1689 already provides a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council⁶. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷ and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council⁸ provides a legal basis allowing, where necessary for the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable. ***Furthermore, to enable providers of high-risk AI systems to lawfully undertake bias detection, monitoring and mitigation activities in preparation for compliance with the high-risk requirements, including the requirements laid down in Article 10(2), points (f) and (g), of Regulation (EU) 2024/1689, the legal basis established by***

Article 4a should apply from the entry into application of this Regulation.

⁶ 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>).

⁷ 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>).

⁸ Directive (EU) 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

⁶ 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>).

⁷ 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>).

⁸ Directive (EU) 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

Or. en

Amendment 5

Proposal for a regulation Recital 18 a (new)

(18 a) Without prejudice to the budgetary procedure and existing financial instruments, adequate human, financial and technical resources should be allocated to the AI Office to ensure that it can effectively perform its duties and exercise its powers in respect of the enforcement of Regulation (EU) 2024/1689, in particular in light of the new powers conferred on it in this Regulation.

Or. en

Amendment 6

Proposal for a regulation Recital 22

Text proposed by the Commission

Amendment

(22) Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, notably that the general date of application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. **Building on experience**, it is appropriate **to put in place a mechanism that links the entry into application to the availability of measures in support of compliance with Chapter III, which may include harmonised standards, common specifications, and Commission guidelines. This should be confirmed by**

(22) Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, notably that the general date of application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. It is appropriate **that the obligations on AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689 are postponed** until 2 December 2027 as regards AI systems

the Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case.

The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations.

classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations.

Or. en

Amendment 7

Proposal for a regulation Recital 22 a (new)

Text proposed by the Commission

Amendment

(22 a) In order to ensure legal certainty and to avoid further application delays, the Commission should ensure that measures in support of compliance with regard to Chapter III, Sections 1, 2, and 3 are in place in due time to ensure timely and effective implementation of the necessary provisions;

Or. en

Amendment 8

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EU) 2024/1689

Article 4 – paragraph 2 (new)

Text proposed by the Commission

Amendment

(2) The Commission and the Member States shall support the AI literacy in society and support the providers and deployers of AI systems in fulfilling their obligation under paragraph 1.

Or. en

Amendment 9

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Article 4 a – Paragraph 1

Text proposed by the Commission

Amendment

1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

1. To the extent ***strictly*** necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Or. en

Amendment 10

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Article 4 a – Paragraph 2

Text proposed by the Commission

2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;

Amendment

2. Paragraph 1 may **exceptionally** apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;

Or. en

Amendment 11

Proposal for a regulation

Article 1 – paragraph 1 – point 10 – introductory part

Text proposed by the Commission

(10) in Article 28, the following **paragraph 8** is added:

Amendment

(10) in Article 28, the following **paragraphs 8 and 8 a** are added:

Or. en

Amendment 12

Proposal for a regulation

Article 1 – paragraph 1 – point 10 a (new)

Article 28 – paragraph 8

Text proposed by the Commission

Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall be established, organised and operated in such a way that ensures that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated under this Regulation and Union harmonisation legislation listed in Section

Amendment

8. Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall be established, organised and operated in such a way that ensures that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated under this Regulation and Union harmonisation legislation listed in Section

A of Annex I, where the relevant Union harmonisation legislation provides for such single application and single assessment procedure.

A of Annex I, where the relevant Union harmonisation legislation provides for such single application and single assessment procedure. ***Notifying authorities designated under this Regulation and under Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments, in particular to avoid inconsistent or divergent interpretation of Union law.***

Or. en

Amendment 13

Proposal for a regulation

Article 1 – paragraph 1 – point 10 b (new)

Article 28 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8 a. A notifying authority that has been designated under the Union harmonisation legislation listed in Section A of Annex I is also the notifying authority for the application of the single application and single assessment procedure referred to in paragraph 8, unless the Member State designates another notifying authority for this Regulation.

Or. en

Amendment 14

Proposal for a regulation

Article 1 – paragraph 1 – point 12 a (new)

(EU) 2024/1689

Article 42

Present text

Amendment

Article 42

(12 a) "Article 42

Presumption of conformity with certain

Presumption of conformity with certain

requirements

1. High-risk AI systems that have been trained and tested on data reflecting the specific geographical, behavioural, contextual or functional setting within which they are intended to be used shall be presumed to comply with the relevant requirements laid down in Article 10(4).

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to comply with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements

requirements

1. High-risk AI systems that have been trained and tested on data reflecting the specific geographical, behavioural, contextual or functional setting within which they are intended to be used shall be presumed to comply with the relevant requirements laid down in Article 10(4).

2. High-risk AI systems that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to comply with the cybersecurity requirements set out in Article 15 of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements

3. Where an AI system is subject to the requirements of Regulation (EU) 2024/2847 as well as requirements set out in Article 15, and where those high-risk AI systems fulfil the essential cybersecurity requirements set out in the Regulation (EU) 2024/2847, they shall be deemed to comply with the cybersecurity requirements set out in Article 15 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under Regulation (EU) 2024/2847.

"

(paragraph 3 is inserted:)

Or. en

(2024/1689)

Amendment 15

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Article 50

PE782.530v01-00

14/21

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Text proposed by the Commission

7. The **AI Office** shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, in accordance with the procedure laid down in Article 56(6), first subparagraph. If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).;

Amendment

7. The **Commission** shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, in accordance with the procedure laid down in Article 56(6), first subparagraph. If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).;

Or. en

Amendment 16

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a
Article 57

Text proposed by the Commission

The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to **SMEs**.;

Amendment

The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to **SMCs and SMEs, including startups**.;

The AI Office shall ensure that, to the extent the innovative AI systems involve the processing of personal data, the competent data protection authorities are associated with the operation of the AI

regulatory sandbox established at Union level and involved in the supervision of those aspects to the extent of their respective tasks and powers, in accordance with Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU)2018/680.

Or. en

Amendment 17

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point b

Article 57

Text proposed by the Commission

5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent **authority**, ensuring that appropriate safeguards are in place. Such sandboxes may include testing in real world conditions supervised therein. When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan.;

Amendment

5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent **authorities**, ensuring that appropriate safeguards are in place. Such sandboxes may include testing in real world conditions supervised therein. When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan.;

Or. en

Amendment 18

Proposal for a regulation

Article 1 – paragraph 1 – point 18

Article 58

Text proposed by the Commission

(d) the detailed rules applicable to the governance of AI regulatory sandboxes covered under Article 57, including as

Amendment

(d) the detailed rules applicable to the governance of AI regulatory sandboxes covered under Article 57, including as

regards the exercise of the tasks of the competent authorities and the coordination and cooperation at national and EU level.;

regards the exercise of the tasks of the competent authorities, ***the involvement and supervision by the competent data protection authorities*** and the coordination and cooperation at national and EU level.;

Or. en

Amendment 19

Proposal for a regulation

Article 1 – paragraph 1 – point 22 – point b

Text proposed by the Commission

(b) paragraph 3 is deleted.

Amendment

deleted

Or. en

Amendment 20

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Article 75

Text proposed by the Commission

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.

Amendment

(1) Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I ***and AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies which are subject to the supervision of the European Data Protection Supervisor pursuant to Article 74(9)***, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in

relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.

Or. en

Amendment 21

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a – introductory part

Text proposed by the Commission

(a) in the third paragraph, point **(d)** is added:

Amendment

(a) in the third paragraph, point **(c)** is added:

Or. en

Amendment 22

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a Article 113

Text proposed by the Commission

Chapter III, Sections 1, 2, and 3, shall apply ***following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates:***

Amendment

Chapter III, Sections 1, 2, and 3, ***with the exception of Article 6(5)***, shall apply:

- (i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and***
- (ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.’;***

Or. en

Amendment 23

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a Article 113

PE782.530v01-00

18/21

PR1336193EN.docx

Text proposed by the Commission

Amendment

(i) 6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and *deleted*

Or. en

Amendment 24

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a
Article 113

Text proposed by the Commission

Amendment

(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I. *deleted*

Or. en

EXPLANATORY STATEMENT

The digital omnibus on artificial intelligence is a welcome step to make the implementation and enforcement of Regulation (EU) 2024/1689 (AI Act) simpler, effective and uniform. The Co-Rapporteurs support the Commission's ambitions to clarify and simplify certain provisions of the AI Act.

The Co-Rapporteurs consider that a postponement of the application date is necessary, considering the delayed preparation of standards, which are necessary to support compliance, as well as the delayed guidelines, governance and conformity assessment frameworks. This is a central part of the AI omnibus.

In order to ensure legal certainty and predictability, the report suggests to replace the Commission's proposal of linking the date of application to a decision by the Commission with a set timeline of 2 December 2027 for Annex III systems and 2 August 2028 for Annex I systems. The report also states that the Commission should ensure that measures in support of compliance are in place in due time to avoid further application delays.

Besides the postponement, the Co-Rapporteurs have introduced some targeted adjustments to the Commission's proposal related to AI literacy, processing of special categories of personal data for bias detection and mitigation, notified bodies, cybersecurity and sandboxes.

ANNEX: DECLARATIONS OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteurs declare that they included in their report input on matters pertaining to the subject of the file that they received, in the preparation of the draft report, from the following interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register¹, or from the following representatives of public authorities of third countries, including their diplomatic missions and embassies:

1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register
AI Sweden
Allied for Startups
Applia
Mistral
Coimisiún na Meán
2. Representatives of public authorities of third countries, including their diplomatic missions and embassies

The list above is drawn up under the exclusive responsibility of the rapporteurs.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteurs declare that they have submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484

(<https://www.europarl.europa.eu/data-protect/index.do>), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

¹ Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register (OJ L 207, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/agree_interinsttit/2021/611/oj).