



2025/0359(COD)

02.2.2026

DRAFT OPINION

of the Committee on Legal Affairs

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

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))

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PA_Legam

AMENDMENTS

The Committee on Legal Affairs submits the following to the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs, as the committees responsible:

Amendment 1

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) AI agents should constitute a new category of artificial intelligence applications that can execute sophisticated real-world operations rapidly and with reduced human oversight. While conventional AI systems deliver outputs like forecasts, generated content, suggestions or judgments, AI agents distinguish themselves through their capacity to carry out concrete actions autonomously. To address this potential regulatory gap and provide legal clarity, it would be advisable to amend the definition to expressly include systems that execute autonomous actions under the jurisdiction of Regulation (EU) 2024/1689.

Or. en

Amendment 2

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

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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.

Or. en

Amendment 3

Proposal for a regulation Recital 6

Text proposed by the Commission

(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.***

Amendment

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. ***For that reason, Regulation (EU) 2024/1689 provides a legal basis authorising providers of high-risk AI systems to process special categories of personal data in certain exceptional cases and subject to strict safeguards. That legal basis is linked to those providers' obligation to establish practices concerning the detection, prevention and mitigation of biases likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law. Nevertheless, biases likely to have those effects might also result from the actions of the deployers of high-risk AI systems. Furthermore, such biases could also arise in the case of other AI systems or models. In each of those further cases, a substantial public interest exists to permit, exceptionally and where strictly necessary, the processing of special categories of personal data for the purposes of bias detection and correction. It is therefore necessary to extend the legal basis established under Regulation (EU) 2024/1689 so that it applies to the providers and deployers of other AI systems and AI models. That legal basis should be subject to the same limitations, conditions and safeguards as set out in the existing Article 10(5) of Regulation (EU) 2024/1689, thereby ensuring 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.

Furthermore, to enable providers of high-risk AI systems to lawfully undertake bias detection and mitigation activities in preparation for compliance with the high-risk requirements, including Article 10(2), points (f) and (g) of Regulation (EU) 2024/1689, the legal basis established by Article 4a of that Regulation 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

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>).

119, 4.5.2016, pp. 89–131, ELI:
<http://data.europa.eu/eli/dir/2016/680/oj>).

Or. en

Amendment 4

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

Amendment

(6a) Recent developments have demonstrated the incompatibility of certain AI practices with the Union's fundamental rights framework. The nudification of women, manipulation of intimate images without consent and generation of child sexual abuse material constitute clear breaches of fundamental rights and Union law. However, significant legal uncertainty remains as to whether AI-powered nudity applications fall within the scope of the AI practices prohibited by Article 5 of Regulation (EU) 2024/1689. Article 112 of that Regulation obliges the Commission to assess, on an annual basis, the necessity of amendments to the list of prohibited practices laid down in Article 5 and the list set out in Annex III, and to submit the findings of that assessment to the European Parliament and the Council. The Commission has failed to meet the deadline for the previous assessment period. For this reason, it seems adequate to specify that prohibited practices under Article 5 include the placing on the market, the putting into service or the use of an AI system that can generate or manipulate sexualised audio, images and videos of individuals, thereby facilitating non-consensual sharing of intimate or manipulated material as defined in Directive (EU) 2024/1385.

Or. en

Amendment 5

Proposal for a regulation Recital 9

Text proposed by the Commission

Amendment

(9) To streamline compliance and reduce the associated costs, providers of AI systems should not be required to register AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation. Given that such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless, a provider who considers that an AI system falls under Article 6(3) remains obligated to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.

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Or. en

Amendment 6

Proposal for a regulation Recital 10

Text proposed by the Commission

Amendment

(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to

(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to

high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In *particular, to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world testing plan should be integrated in the sandbox plan agreed by the providers or prospective providers and the competent authority in a single document.* In addition, it is appropriate *to provide for the possibility of* the AI Office *to establish* an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.

high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In addition, it is appropriate *that* the AI Office *establishes* an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.

Or. en

Amendment 7

Proposal for a regulation Recital 11

Text proposed by the Commission

Amendment

(11) *To foster innovation, it is also appropriate to extend the scope of real-world testing outside AI regulatory sandboxes in Article 60 of Regulation (EU) 2024/1689, currently applicable to high-risk AI systems listed in Annex III to that Regulation, and allow providers and prospective providers of high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation to also test such systems in real-world conditions. This is without prejudice to other Union or national law on the testing in real-world conditions of high-risk AI systems related to products covered by that Union harmonisation legislation. To address the*

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specific situation of high-risk AI systems covered the Union harmonisation legislation listed in Section B of Annex I to that Regulation, it is necessary to allow the conclusion of voluntary agreements between the Commission and Member States to enable testing of such high-risk AI systems in real-world conditions.

Or. en

Amendment 8

Proposal for a regulation Recital 13

Text proposed by the Commission

(13) Article 69 of Regulation (EU) 2024/1689 should be amended to simplify the fee structure of the scientific panel. If Member States call upon the panel's expertise, the fees they may be required to pay the experts should be equivalent to the remuneration the Commission is obliged to pay in similar circumstances.

Furthermore, to reduce the procedural complexity, Member States should be able to consult the experts of the scientific panel directly, without involvement of the Commission.

Amendment

(13) Article 69 of Regulation (EU) 2024/1689 should be amended to simplify the fee structure of the scientific panel. If Member States call upon the panel's expertise, the fees they may be required to pay the experts should be equivalent to the remuneration the Commission is obliged to pay in similar circumstances.

Or. en

Amendment 9

Proposal for a regulation Recital 22

Text proposed by the Commission

(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

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 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

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. ***Against that background***, it is appropriate to ***align the implementation timeline and set the date for the application of Section 1,2 and 3 of Chapter III to 2 December 2027 for AI systems classified as high-risk pursuant to Article 6(1) and Annex I. 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.***

obligations.

Or. en

Amendment 10

Proposal for a regulation Recital 22 a (new)

Text proposed by the Commission

Amendment

(22a) To ensure a sufficient degree of legal clarity in the event of continued delays in the availability of harmonised standards, it is necessary to mitigate potential legal uncertainty resulting from their absence. To that end, the Commission should be required to adopt common specifications by 2 December 2027. This deadline aligns with the deferred application date of Sections 1, 2, and 3 of Chapter III of Regulation (EU) 2024/1689 for AI systems classified as high-risk under Article 6(1) and Annex I of that Regulation, which has also been postponed to 2 December 2027. Additionally, the Commission should be required to issue standardisation requests covering the obligations set forth in Chapter V, Sections 2 and 3, of that Regulation by 2 December 2027, as it has not proceeded without undue delay.

Or. en

Amendment 11

Proposal for a regulation Recital 23

Text proposed by the Commission

Amendment

(23) In light of the objective to reduce implementation challenges for citizens, businesses and public administrations, it

deleted

is essential that harmonised conditions for the implementation of certain rules are adopted only where strictly necessary. For that purpose, it is appropriate to remove certain empowerments bestowed on the Commission to adopt such harmonised conditions by means of implementing acts in cases where those conditions are not met. Regulation (EU) 2024/1689 should therefore be amended to remove the empowerments conferred on the Commission in Article 50(7), Article 56(6), and Article 72(3) thereof to adopt implementing acts. The removal of the empowerment to adopt a harmonised template for a post-market monitoring plan in Article 72(3) of Regulation (EU) 2024/1689 has as an additional benefit that it will offer more flexibility for providers of high-risk AI systems to put in place a system for post-market monitoring that is tailored to their organisation. At the same time, recognising the need to offer clarity how providers of high-risk AI systems are required to comply, the Commission should be required to publish guidance.

Or. en

Amendment 12

Proposal for a regulation

Article 1 – paragraph 1 – point 2 a (new)

Regulation (EU) 2024/1689

Article 3 – point 1

Text proposed by the Commission

(1) ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives,

Amendment

(2a) In article 3, point 1 is replaced by the following:

(1) ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives,

infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, *or* decisions that can influence physical or virtual environments;

infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, decisions, *or actions* that can influence physical or virtual environments;

Or. en

Amendment 13

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EU) 2024/1689

Article 4

Text proposed by the Commission

Amendment

(4) *Article 4 is replaced by the following:*

deleted

Article 4

AI literacy

‘The Commission and Member States shall encourage providers and deployers of AI systems to take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, level of education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.;

Or. en

Amendment 14

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4a – paragraph 1 – introductory part

Text proposed by the Commission

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:

Amendment

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 **provisions on** 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 15

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4a – paragraph 1 – point b

Text proposed by the Commission

(b) the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, **including pseudonymisation**;

Amendment

(b) the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures;

Or. en

Amendment 16

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

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. Providers and deployers of high-risk AI systems ***may exceptionally process special categories of personal data to the extent that:***

(a) such processing is strictly necessary to ensure bias detection and correction in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations; and

(b) all the conditions and safeguards set out in paragraph 1 are applied.

This paragraph does not create any obligation to conduct such bias detection and correction with special categories of personal data.

Or. en

Amendment 17

Proposal for a regulation

Article 1 – paragraph 1 – point 5 a (new)

Regulation (EU) 2024/1689

Article 5 – paragraph 1 – subparagraph 1 – point h a (new)

Text proposed by the Commission

Amendment

(5a) In Article 5(1), first subparagraph, the following point is added

‘(ha) The placing on the market, the putting into service or the use of an AI system that can generate or manipulate sexualised audio, images and videos of

*individuals, thereby facilitating non-consensual sharing of intimate or manipulated material as defined in Directive (EU) 2024/1385**.

** Directive (EU) 2024/1385 of the European Parliament and of the Council of 14 May 2024 on combating violence against women and domestic violence, OJ L, 2024/1385, 24.5.2024, ELI: <http://data.europa.eu/eli/dir/2024/1385/oj>.*

Or. en

Amendment 18

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

Amendment

(6) in Article 6(4), paragraph 4 is replaced by the following:

deleted

4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.;

Or. en

Amendment 19

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 40 – paragraph 2 – subparagraph 1

In accordance with Article 10 of Regulation (EU) No 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, **as applicable**, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum.

(12a) In Article 40, paragraph 2, first subparagraph is replaced by the following:

‘In accordance with Article 10 of Regulation (EU) (No) 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, **by 2 December 2027**, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum.

Or. en

Amendment 20

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 – introductory part

1. The Commission **may** adopt, implementing acts establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the obligations set out in

(12b) In Article 41, the introductory wording is replaced by the following:

‘1. The Commission **shall** adopt, implementing acts **by 2 December 2027** establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the

Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:

obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:’

Or. en

Amendment 21

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(12c) in Article 41, the following paragraph is inserted

‘1a. When there is no harmonised standard that enable compliance with the essential requirements set out in Section 2 of this Chapter and no reference in the Official Journal of the European Union is expected to be published within a reasonable period, the Commission shall by means of implementing acts adopt common specifications in order to address an urgent concern with regard to non-compliant AI systems, which cannot be adequately mitigated by alternative measures. A situation shall be considered to constitute an urgent concern when the suspension of cooperation with international standardisation organisations impedes the development of relevant harmonised standards by European standardisation organisations. In such a situation the Commission shall adopt common specifications only after prior authorisation of the Council. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2). When preparing those implementing acts, the Commission shall be assisted by an expert group that includes relevant stakeholder representatives.

Amendment 22

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

(12d) in Article 41, the following paragraph 1b is inserted

‘1b. The Commission shall provide the European Parliament, in a timely manner, with all relevant information concerning the implementing acts referred to in paragraph 1. That shall include, in particular, details on the drafting process of the implementing act, details on the composition of the expert groups supporting the process, details on the timeline and, where the drafting of an implementing act is outsourced, information on the main contractual aspects of such outsourcing, including the name of the entity responsible for the drafting, the total value of the contract and its duration.’

Or. en

Amendment 23

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 6

Text proposed by the Commission

Amendment

(12e) in Article 41, paragraph 6 is replaced by the following:

6. Where a Member State considers that a common specification does not entirely

‘6. Where **the European Parliament** or a Member State considers that a

meet the requirements set out in Section 2 or, as applicable, comply with obligations set out in Sections 2 and 3 of Chapter V, it shall inform the Commission thereof with a detailed explanation. The Commission shall assess that information and, if appropriate, amend the implementing act establishing the common specification concerned.

common specification does not entirely meet the requirements set out in Section 2 or, as applicable, comply with obligations set out in Sections 2 and 3 of Chapter V, it shall inform the Commission thereof with a detailed explanation. The Commission shall assess that information and, if appropriate, amend the implementing act establishing the common specification concerned.’

Or. en

Amendment 24

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 42 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(12f) In Article 42, the following paragraph is added

‘2a. Where an AI system is subject to the requirements of Regulation (EU) 2024/2847 as well as requirements set out in Article 15 of this Regulation, 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 of this Regulation in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under Regulation (EU) 2024/2847.’

Or. en

Amendment 25

Proposal for a regulation

Article 1 – paragraph 1 – point 14

Text proposed by the Commission

Amendment

(14) in Article 49, paragraph 2 is deleted; **deleted**

Or. en

Amendment 26

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

Text proposed by the Commission

Amendment

(15) in Article 50, paragraph 7 is replaced by the following: **deleted**

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).;

Or. en

Amendment 27

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 56 – paragraph 6

Text proposed by the Commission

Amendment

(16) in Article 56(6), the first subparagraph is replaced by the following:

deleted

6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking utmost account of the opinion of the Board, shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. The Commission shall publish its assessment of the adequacy of the codes of practice.;

Or. en

Amendment 28

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a

Regulation (EU) 2024/1689

Article 57 – paragraph 3a

Text proposed by the Commission

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

‘The AI Office **shall** 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.;

priority access to SMEs.’;

Or. en

Amendment 29

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point b

Regulation (EU) 2024/1689

Article 57 – paragraph 5

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 authority, ensuring that appropriate safeguards are in place.’

Or. en

Amendment 30

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point e

Regulation (EU) 2024/1689

Article 57 – paragraph 14

Text proposed by the Commission

14. National competent authorities shall coordinate their activities and cooperate within the framework of the Board. They

Amendment

14. ‘National competent authorities, ***the European Data Protection Supervisor, and the AI Office*** shall coordinate their

shall support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.;

activities and cooperate within the framework of the Board. They shall support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.’

Or. en

Amendment 31

Proposal for a regulation

Article 1 – paragraph 1 – point 20

Regulation (EU) 2024/1689

Article 60a

Text proposed by the Commission

Amendment

(20) the following Article 60a is inserted:

deleted

Article 60a

Testing of high-risk AI systems covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions outside AI regulatory sandboxes

1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I, in accordance with this Article and a voluntary real-world testing agreement, without prejudice to the prohibitions under Article 5.

2. The voluntary real-world testing agreement referred to in paragraph 1 shall be concluded in writing between interested Member States and the Commission. It shall set the requirements for the testing of those AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions.

3. *Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.*

4. *The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish detailed elements of the real-world testing plan for AI systems covered by Union harmonisation legislation listed in Section B of Annex I.*

5. *Article 60(2), (5) and (9) shall apply.;*

Or. en

Amendment 32

Proposal for a regulation

Article 1 – paragraph 1 – point 22 – point b

Regulation (EU) 2024/1689

Article 69 – point 3

Text proposed by the Commission

Amendment

(b) *paragraph 3 is deleted.*

deleted

Or. en

Amendment 33

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a

Regulation (EU) 2024/1689

Article 111 – paragraph 2

Text proposed by the Commission

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to **operators** of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, **the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.**;

Amendment

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to **providers and deployers** of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, **they shall be brought into compliance with this Regulation by 31 December 2030.**'

Or. en

Amendment 34

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

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

Amendment

(a) in the third paragraph, point (d) is added:
'Chapter III, Sections 1, 2, and 3, shall apply:

available, from the following dates:

(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

(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.

In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, 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.’

(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

ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur for opinion declares that he included in his draft opinion input on matters pertaining to the subject of the file that he received, in the preparation of the draft opinion, 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
Volkswagen
Logitech
DKB
Indeed
Adobe
Vzbv
Mozilla Foundation
Bitkom
Cocir
E-on
Milestones Systems
Volkswagen
German Chamber of Commerce
German Association of Local Public Utilities
Philips
OpenAI
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 rapporteur for opinion.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteur for opinion declares that he has 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_interinst/2021/611/oj).