



2025/0359(COD)

25.2.2026

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))

Rapporteur for opinion: Sergey Lagodinsky

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 1 a (new)

Text proposed by the Commission

Amendment

(1a) Obligations under this Regulation shall be implemented in a proportionate manner, taking into account the nature, scale and complexity of the activities concerned.

Amendment 2

Proposal for a regulation Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) This Regulation aims to simplify the implementation of Regulation (EU) 2024/1689 and to reduce unnecessary administrative burden without altering its scope. It does not introduce new legal categories of artificial intelligence systems, nor does it prejudice any future policy choices regarding systems exhibiting higher degrees of autonomy. Any such assessment should take place in the context of a dedicated legislative review.

Amendment 3

Proposal for a regulation Recital 4

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. *Nevertheless, they face* challenges *similar to SMEs* in relation to administrative burden, leading to a need for **proportionality in** the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵.

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. ***Though SMCs and SMEs have different operational and financial capabilities, the*** challenges ***they face*** in relation to administrative burden ***are in some cases similar***, leading to a need for ***a number of adjustments concerning*** the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In ***all cases, such an extension must follow a strictly proportionate approach, seeing as SMEs and SMCs are two different categories of enterprises; this approach precludes any blanket uniform treatment and, on the contrary, requires that the differences between SMEs and SMCs be emphasized in the definition of model standards, guidelines or terms for contracts for the purposes of this Regulation. For the purposes of legal certainty and in*** order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵.

⁴ Commission Recommendation of 6 May

⁴ Commission Recommendation of 6 May

2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, *pp.* 36–41, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

⁵ Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap enterprises (OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>)

2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, *p.* 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

⁵ Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap enterprises (OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>).

Justification

Extending SME-specific regulations to SMCs should not be the norm; rather, it is fundamental that such harmonisation be exceptional and implemented solely in relation to specific provisions outlined by the AI Act. Treating SMCs and SMEs in the same way entails the inevitable risk of creating a number of competition- and competitiveness-related imbalances that will harm the undertakings that are genuinely the smallest, especially micro-enterprises.

Amendment 4

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, including those of dual-use nature covered by Article 2(3) of Regulation (EU) 2024/1689. 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. These features can exacerbate associated risks for consumers stemming from the placing on the market, the putting into service or the use of AI agents. To enhance legal clarity, it is

important to clarify that AI agents fall within the definition of AI systems in Article 3, point (1), of Regulation (EU) 2024/1689, while keeping in place a risk-based and future-proof regulatory approach.

Amendment 5

Proposal for a regulation Recital 4 b (new)

Text proposed by the Commission

Amendment

(4b) To ensure that SMEs and startups can get an early understanding of their risk classification, the Commission and Member States should provide information assistance in a comprehensible manner, including through initiatives such as the AI Act Service Desk.

Amendment 6

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 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

(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.

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, ***without, however, completely eliminating the obligation of providers and implementers of AI systems to take, likewise, the necessary measures to ensure a sufficient level of knowledge in the field of AI of their staff in order to play responsible roles.*** 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.

Amendment 7

Proposal for a regulation Recital 5 a (new)

(5a) Recent developments have demonstrated the incompatibility of certain AI practices with the Union's fundamental rights framework while increasing legal uncertainty regarding them. AI systems that alter, manipulate or artificially produce images or videos depicting natural persons engaged in sexually explicit activities, displaying their intimate body parts or undresses a person without consent cause harm to victims and violate fundamental rights to dignity and privacy. While Regulation (EU) 2024/1689 establishes a framework for prohibited AI practices, the effective protection of persons, particularly women and minors who are disproportionately targeted, requires the explicit prohibition of such AI systems. Whereas Article 112 of Regulation (EU) 2024/1689 obliges the Commission to assess, on an annual basis, the necessity of amendments to the list of prohibited practices laid down in Article 5 of that Regulation and the list set out in Annex III of that Regulation, and to submit the findings of that assessment to the European Parliament and the Council, the proliferation of technologies, marketed as 'nudification' applications, has created an urgent need for explicit regulatory prohibition. This is without prejudice towards the rights, freedoms and principles recognised by Article 6 TEU and the Charter of Fundamental Rights of the European Union, and the exercise of the rights guaranteed therein to freedom of expression and information and the freedom of the arts and sciences.

Amendment 8

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. ***For that reason, Regulation (EU) 2024/1689 already 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 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 Council[2]. 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 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>).

Amendment 9

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

Amendment

(6a) *To encourage the use of new technologies for safer products and to avoid duplicative requirements in the New Legislative Framework and Regulation (EU) 2024/1689, the safety component aspect of the high risk-classification should be clarified. Additional layers of safety, where a product is already deemed safe and compliant according to product-specific rules and where the AI embedded system does not serve a safety function to the product, should not automatically lead to designation of the AI system as high-risk.*

Amendment 10

Proposal for a regulation Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) *Regulations (EU) 2024/1689 and (EU) 2024/2847 are complementary laws that ensure the safety and cybersecurity of products with digital elements. It is necessary to ensure alignment of those Regulations to allow for their smooth interplay. Where those high-risk AI systems fulfil the essential cybersecurity requirements set out in this Regulation, they should be deemed to comply with the cybersecurity requirements set out in Article 15 of Regulation (EU) 2024/1689 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under this Regulation.*

Amendment 11

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.

deleted

Amendment 12

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 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**

(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 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,

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.

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Amendment 13

Proposal for a regulation Recital 20

Text proposed by the Commission

Amendment

(20) To allow sufficient time for providers of generative AI systems subject to the marking obligations laid down in Article 50(2) of Regulation (EU) 2024/1689 to adapt their practices within a reasonable time without disrupting the market, it is appropriate to introduce a transitional period of 6 months for providers who have already placed their systems on the market before the 2 August 2026.

deleted

Amendment 14

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 Chapter III, Sections 1, 2, and 3, 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.

Amendment 15

Proposal for a regulation

Recital 23

Text proposed by the Commission

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

Amendment

(23) In light of the objective to reduce implementation challenges for citizens, businesses and public administrations, it 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 ***on*** how providers of high-risk AI systems

required to comply, the Commission should be required to publish guidance.

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Amendment 16

Proposal for a regulation Recital 23 a (new)

Text proposed by the Commission

Amendment

(23a) This Regulation shall not alter Regulation (EU) 2024/1689 as regards the scope, classification or compliance timelines applicable to AI systems.

Amendment 17

Proposal for a regulation Article 1 – paragraph 1 – point 2 a (new) Regulation (EU) 2024/1689 Article 2 – paragraph 10 a (new)

Text proposed by the Commission

Amendment

(2a) in Article 2, the following paragraph is inserted:

10a. This Regulation does not apply to AI systems or AI models that are only used intra-group and not consumer-facing with no impact on end-users or natural persons. Such activities shall be conducted in accordance with applicable Union law. The prohibited practices as outlined in Article 5 shall not be covered by that exclusion.

Amendment 18

Proposal for a regulation Article 1 – paragraph 1 – point 2 b (new) Regulation (EU) 2024/1689 Article 2 a (new)

Text proposed by the Commission

Amendment

(2b) the following article is inserted:

'Article 2a

*Proportionality and Technological
Neutrality*

*Without prejudice to explicit prohibitions
laid down in Article 5 of this Regulation
and to the protection of fundamental
rights, the national competent authorities,
the AI Office and the Commission shall
interpret, implement, apply and enforce
this Regulation in a manner that:*

*a) ensure proportionality, legal
certainty and technological neutrality;
and*

*b) minimise administrative and
compliance burdens on economic
operators*

*while ensuring that the requirements of
this Regulation, including any secondary
legislation resulting from this Regulation,
do not exceed what is strictly necessary to
achieve the objectives of this Regulation.'*

Amendment 19

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 3 – point 1 a (new)

Text proposed by the Commission

Amendment

*(2c) in Article 3, the following point is
inserted:*

*(1a) "autonomy" means the ability of
the artificial intelligence system to
operate, within constraints, without
human guidance or intervention;'*

Amendment 20

Proposal for a regulation

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

Present text

(3) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge;

Amendment

(2d) Article 3, point (3) is replaced by the following:

(3) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge, ***excluding those that perform fine-tuning, personalisation and technical adaptation operations on AI systems on behalf of third-party clients by using data provided by the latter, unless those operations result in substantial modifications to, or changes in the intended purpose of, the AI systems in question;***

Justification

The current Regulation considers small enterprises that perform fine-tuning operations locally (i.e. on client servers) to be providers, thereby imposing totally disproportionate legal responsibilities and certification burdens on them. Among other things, this state of affairs prompts enterprises to forego local fine-tuning and instead perform this operation by means of application programming interfaces (APIs) supplied by (generally non-EU-based) large providers of general-purpose models with a view to retaining their status as deployers.

Amendment 21

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 3 – point 14

Present text

(14) ‘safety component’ means a component of a product or of an AI system

Amendment

(2e) in Article 3, point (14) is replaced by the following:

(14) ‘safety component’ means a component of a product or of an AI system

which fulfils a safety function for that product or AI system, *or* the failure or malfunctioning of which endangers the health and safety of persons or property;

which fulfils a safety function for that product or AI system, *and* the failure or malfunctioning of which endangers the health and safety of persons or property;'

Amendment 22

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EU) 2024/1689

Article 4 – paragraph 1

Text proposed by the Commission

‘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.;

Amendment

‘The Commission and Member States shall **support** 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.’

Amendment 23

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)

Amendment

1. To the extent **that is 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

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:

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 24

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4a – 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 ***also*** apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where ***strictly*** necessary and proportionate ***for bias detection and correction, subject to all the safeguards set out in this Article and applicable Union data protection law.***

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

Amendment 25

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 5 – paragraph 1

Text proposed by the Commission

Amendment

(5 a) In Article 5(1), first subparagraph, the following points are added:

‘(ha) the placing on the market, the putting into service or the use of an AI system that can generate, alter or reproduce sexually or nude content in violation of the dignity, sexual integrity or consent of natural persons, including

through the use of deep fake or other synthetic media techniques;

(hb) the placing on the market, the putting into service or the use of an AI system that generates child sexual abuse material, regardless of the nature or origin of the underlying content.'

Amendment 26

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 1

Present text

1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

(a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

(b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

Amendment

(5b) in Article 6, paragraph 1 is replaced by the following:

'1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

(a) the AI system is intended to be used as a safety component of a product and the ***AI functionality has an impact on the safety of the overall system, or the AI*** system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

(b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

A lack of harmonised standards or part thereof, the references of which have been published in the Official Journal of the European Union, leading to third-party

conformity assessment according to the applicable Union harmonisation legislation in Annex I, can in itself not lead to a product or AI system being classified as high-risk.'

Amendment 27

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 1

Present text

By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making.

Amendment

(5c) In Article 6, paragraph 3, the first subparagraph is replaced by the following:

'By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making **or by ensuring meaningful human intervention or review.**'

Amendment 28

Proposal for a regulation

Article 1 – paragraph 1 – point 6 a (new)

Regulation (EU) 2024/1689

Article 6 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

(6a) In Article 6, the following paragraph is inserted:

5a. By way of derogation from the previous paragraphs, a high-risk AI system that is developed for internal use and is employed accordingly by a micro-enterprise to optimise its company processes shall not be subject to the obligations set out in Chapter III,

Sections 2 and 3, provided that:

(a) the system is neither put on the market nor made available to third parties;

(b) the system does not process the personal data of external subjects;

(c) the system does not fall under the categories set out in Annex III, points 1,2,6 and 8;

(d) the system is only used by members of staff operating devices owned or controlled by the enterprise;

(e) the system does not implement any of the prohibited practices set out in Article 5.

Micro-enterprises making use of the derogation set out in the first subparagraph shall maintain simplified documentation in accordance with the template set out in Annex IV and shall make it available to the competent authorities upon request.

Justification

Micro-enterprises (companies with fewer than 10 employees and an annual turnover that does not exceed EUR 2 million, see Commission Recommendation 2003/361/EC of 6 May 2003) often use AI tools for simple international automation processes (stock management, sales projections, shift optimisation). Making these undertakings subject to the same obligations as multinational corporations or SMCs is disproportionate and discourages digital uptake. The internal use exemption, combined with proportionate guarantees, drastically reduces red tape while maintaining essential protections.

Amendment 29

Proposal for a regulation

Article 1 – paragraph 1 – point 6 b (new)

Regulation (EU) 2024/1689

Article 9 – paragraph 2 – point b

Present text

Amendment

(b) the estimation and evaluation of the

(6a) in Article 9(2), point b is replaced by the following:

'(b) the estimation and evaluation of the

risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse;

risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse, ***including cybersecurity specific threat modelling;***

Amendment 30

Proposal for a regulation

Article 1 – paragraph 1 – point 8 a (new)

Regulation (EU) 2024/1689

Article 11 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(8a) in Article 11, the following paragraph is inserted:

'1a. The Commission's simplified form shall be digital-by-default, machine-readable, interoperable (so the same info can be reused for other reporting/authority requests), and enable pre-filling /re-use of previously submitted information.'

Amendment 31

Proposal for a regulation

Article 1 – paragraph 1 – point 9 a (new)

Regulation (EU) 2024/1689

Article 17 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(9a) In Article 17, the following paragraph is added:

'2a. If the provider is an SMC or an SME, including start-ups, the national authorities shall provide appropriate guidance and advice, so that the necessary technical documentation and quality management system requirements are tailored to the organisational size and capacity of these categories of providers;'

Amendment 32

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 40 – paragraph 2 – subparagraph 1

Present text

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.

Amendment

(12a) In Article 40, paragraph 2, the 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.'

Amendment 33

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission **may** adopt,

Amendment

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

'1. The Commission **shall** 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 Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:

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

Amendment 34

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 35

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 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.’

Amendment 36

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 meet the requirements set out in Section 2 or, as applicable, comply with obligations set out in Sections 2 and 3 of

‘6. Where **the European Parliament** or a Member State considers that a common specification does not entirely meet the requirements set out in Section 2 or, as applicable, comply with obligations

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.

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.'

Amendment 37

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.'

Amendment 38

Proposal for a regulation

Article 1 – paragraph 1 – point 14

Regulation (EU) 2024/1689

Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Amendment 39

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

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 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).; ***The Commission shall ensure that any implementing act adopted pursuant to this paragraph is limited to what is strictly necessary to ensure interoperability and effective implementation of the marking obligations.***

Amendment 40

Proposal for a regulation

Article 1 – paragraph 1 – point 15 a (new)

Regulation (EU) 2024/1689

Article 50 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

(15a) in Article 50, the following paragraph is added:

'7a. The AI Office, in cooperation with the European Union Agency for

Cybersecurity (ENISA), shall develop non-binding technical guidance on emerging AI-specific cybersecurity threats, risks including from autonomous operational capabilities and secure-by-design AI development practices in accordance with the NIS2 and Cyber Resilience Act frameworks.'

Amendment 41

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.;

Amendment 42

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

'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.;

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 43

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.;

Amendment 44

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

Amendment

14. National competent authorities, ***the***

coordinate their 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.;

European Commission, the European Data Protection Supervisor and the AI Office shall coordinate their 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.

Amendment 45

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point e a (new)

Regulation (EU)2024/1689

Article 57 – paragraph 14 a (new)

Text proposed by the Commission

Amendment

(ea) in Article 57 the following paragraph is inserted:

'(14a) The Commission and the AI Office shall ensure transparent and non-discriminatory criteria for accessing the EU-level sandbox and shall support the participation of SMEs and the public administrations of Member States with developing administrative capacity and innovation ecosystems, including by providing technical assistance and procedural guidance.'

Amendment 46

Proposal for a regulation

Article 1 – paragraph 1 – point 18

Regulation (EU)2024/1689

Article 58 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) the terms and conditions applicable to the participants;

(c) the terms and conditions applicable to the participants, ***in particular those concerning SMEs and SMCs;***

Amendment 47

Proposal for a regulation

Article 1 – paragraph 1 – point 20 a (new) – point a (new)

Regulation (EU) 2024/1689

Article 62 – paragraph 1 – point d

Present text

(d) facilitate the participation of SMEs and other relevant stakeholders in the standardisation development process.

Amendment

(20a) Article 62 is amended as follows:

(a) in paragraph 1, point (d) is replaced by the following:

(d) facilitate the participation of SMEs and other relevant stakeholders in the standardisation development process, **including through appropriate dedicated financial support mechanisms to reimburse the cost of SME experts participating in European bodies;**

Justification

Compliance with the regulation will depend on the appropriate tools being made available to small businesses for regulatory compliance. In this regard, it is essential to step up support for SMEs in the process of setting authorised standards. As it stands, participation in technical committees is sustainable only for large companies. What is more, it will be essential to relieve SMEs from overly complex audits on open-source components developed by third parties. In this regard, a 'safe harbour' linked to an EU repository must be established.

Amendment 48

Proposal for a regulation

Article 1 – paragraph 1 – point 20 a (new) – point b (new)

Regulation (EU) 2024/1689

Article 62 – paragraph 3 – point d a (new)

Text proposed by the Commission

Amendment

(b) in paragraph 3, the following point is added:

(da) establish and maintain a public repository of certified open-source AI components; also for the purposes of the obligations referred to in Article 16, the use of these components shall be presumed to be consistent with the requirements laid down in Section 2.

Justification

Compliance with the regulation will depend on the appropriate tools being made available to small businesses for regulatory compliance. In this regard, it is essential to step up support for SMEs in the process of setting authorised standards. As it stands, participation in technical committees is sustainable only for large companies. What is more, it will be essential to relieve SMEs from overly complex audits on open-source components developed by third parties. In this regard, a 'safe harbour' linked to an EU repository must be established.

Amendment 49

Proposal for a regulation

Article 1 – paragraph 1 – point 22 – point b

Regulation (EU) 2024/1689

Article 69 – paragraph 3

Text proposed by the Commission

Amendment

(b) *paragraph 3 is deleted.*

deleted

Amendment 50

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU)2024/1689

Article 75 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

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

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.

are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. ***The competent national authorities may refer signs of non-compliance or systemic risks that have arisen in their country to the AI Office and the AI Office shall, within a reasonable time, inform the referring authority about follow-up measures. The AI Office shall, in exercising its duties, work with the competent national authorities and with the relevant authorities under Regulation (EU) 2022/2065, in accordance with the principles of proportionality and ne bis in idem.***

Justification

While centralised supervision by the AI Office enhances consistency, national competent authorities must retain an effective right to notify potential non-compliance or systemic risks identified on their territory. The amendment strengthens cooperative enforcement without creating duplication of competences or additional administrative burden.

Amendment 51

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point b

Regulation(EU)2024/1689

Article 77 – paragraph 1

Text proposed by the Commission

1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits

Amendment

1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, ***shall have direct access to the technical documentation necessary for the exercise of their duties and*** shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where

of their jurisdiction.;

access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction.;

Amendment 52

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 August 2029.'

Amendment 53

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

Regulation (EU) 2024/1689

Article 111 – paragraph 4

Text proposed by the Commission

(b) the following paragraph 4 is added:

‘4. Providers of AI systems, including general-purpose AI systems, generating

Amendment

deleted

synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;'

Amendment 54

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 1 – introductory part

Text proposed by the Commission

Amendment

(d) 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:*

(d) Chapter III, Sections 1, 2, and 3, shall apply:

Amendment 55

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 1 – point i

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

Amendment 56

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 1 – point ii

Text proposed by the Commission

Amendment

(ii) *12 months after the adoption of*

deleted

the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.

Amendment 57

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – introductory part

Text proposed by the Commission

Amendment

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:

deleted

Amendment 58

Proposal for a regulation

Article 1 – paragraph 1 – point 31 a (new)

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

(31a) in Article 11 , the following paragraph is added:

By way of derogation from the deadlines referred to in the the third paragraph, micro-enterprises established in the Union shall benefit from an additional transition period of 24 months for the application of the provisions of Chapter II, Sections 1, 2 and 3. During this additional period:

(a) the placing on the market of high-risk AI systems by those undertakings shall continue to be permitted, provided that the supplier demonstrates that it has taken proportionate risk self-assessment measures based on harmonised standards or recognised good practices;

(b) national supervisory authorities

shall adopt a non-sanctioning monitoring regime, giving priority to technical assistance and guided correction of non-compliance, without prejudice to provisions on public safety and the protection of fundamental rights;

(c) the Commission shall, within ... [36 months of the date of entry into force of this amending regulation], submit a report on the compliance capacity of micro-enterprises, assessing the need for further support measures or an adjustment of the requirements in accordance with the principle of proportionality;

Justification

Micro-enterprises and smaller enterprises (often made up of one to three individuals) do not have dedicated compliance resources. Often, the owner accumulates technical, commercial and administrative roles. The standard timelines are unrealistic. The extension requested is in line with the precedent set with GDPR: many Member States granted up to 36 months in an effort to provide soft enforcement for SMEs. A 2024 study by the Commission notes that micro-enterprises need 3.5 times longer than large certified companies. A gradual, assisted approach reduces business failures.

Amendment 59

Proposal for a regulation

Article 1 – paragraph 1 – point 31 b (new)

Regulation (EU) 2024/1689

Annex 1: List of Union Harmonisation Legislation

Present text

Annex I

Section A. List of Union harmonisation legislation based on the New Legislative Framework as amended as follows:

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending

Amendment

(31b) The Machinery Regulation (EU) 2023/1230 is moved from Annex I Section A to Section B

"Annex I

(2) Section B, the following points are added from section A:

13. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and

Directive **95/16/EC (OJ L 157, 9.6.2006, p. 24)**;

repealing Directive 2006/42/EC of the European Parliament and of the Council **and Council Directive 73/361/EEC"**

(32024R1689)

Justification

Particularly in the area of self-learning machines and software, the AI Act contains a number of safety requirements that are already included in the Machinery Regulation. To avoid double regulation, the Machinery Regulation contained in Annex I Section A is to be moved to Section B.

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 opinion input on matters pertaining to the subject of the file that he received, in the preparation of the opinion, prior to the adoption thereof in committee, 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).

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	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)	
References	COM(2025)0836 – C10-0304/2025 – 2025/0359(COD)	
Committee(s) responsible Date announced in plenary	IMCO 19.1.2026	LIBE 19.1.2026
Opinion by Date announced in plenary	JURI 19.1.2026	
Rapporteur for the opinion Date appointed	Sergey Lagodinsky 3.12.2025	
Rule 59 – Joint committee procedure Date announced in plenary	19.1.2026	
Discussed in committee	12.2.2026	
Date adopted	24.2.2026	
Result of final vote	+: -: 0:	18 6 0

**FINAL VOTE BY ROLL CALL
BY THE COMMITTEE ASKED FOR OPINION**

18	+
ESN	Mary Khan
PPE	Maravillas Abadía Jover, Lukas Mandl, Emil Radev, Axel Voss, Adrián Vázquez Lázara, Marion Walsmann, Michał Wawrykiewicz
Renew	Ilhan Kyuchyuk, Dainius Žalimas
S&D	José Cepeda, Victor Negrescu, René Repasi, Krzysztof Śmiszek, Lara Wolters
The Left	Mario Furore
Verts/ALE	Sergey Lagodinsky, Tineke Strik

6	-
ECR	Alberico Gambino, Chiara Gemma, Mario Mantovani
PfE	Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

0	0

Key to symbols:

+ : in favour

- : against

0 : abstention