



Plenary sitting

A10-0073/2026

19.3.2026

*****I**
REPORT

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

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

(Joint committee procedure – Rule 59 of the Rules of Procedure)

Rapporteurs: Arba Kokalari, Michael McNamara

Symbols for procedures

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

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

Amendments to a draft act

Amendments by Parliament set out in two columns

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

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

Amendments by Parliament in the form of a consolidated text

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

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

CONTENTS

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	68
ANNEX: DECLARATIONS OF INPUT	69
OPINION OF THE COMMITTEE ON CULTURE AND EDUCATION	71
OPINION OF THE COMMITTEE ON LEGAL AFFAIRS	94
LETTER OF THE COMMITTEE ON TRANSPORT AND TOURISM	134
PROCEDURE – COMMITTEE RESPONSIBLE	139
FINAL VOTE BY ROLL CALL BY THE COMMITTEE RESPONSIBLE	140

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

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

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2025)0836),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C10-0304/2025),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 60 of its Rules of Procedure,
 - having regard to the joint deliberations of the Committee on Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs under Rule 58 of the Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs (A10-0073/2026),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation
Recital 3

Text proposed by the Commission

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

Amendment

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

Amendment 2

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission

Amendment

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

Amendment 3

Proposal for a regulation
Recital 4

Text proposed by the Commission

Amendment

(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

(4) ***99,8% of all Union companies are small and medium-sized enterprises, the majority of which are micro and small enterprises.***^{3a} 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

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.

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 *where appropriate while safeguarding the overarching objectives and level of protection afforded under Regulation (EU) 2024/1689*^{3a}. 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 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>)

^{3a} https://single-market-economy.ec.europa.eu/system/files/2023-08/Annual%20Report%20on%20European%20SMEs%202023_FINAL.pdf

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>)

Amendment 4

Proposal for a regulation Recital 5

(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***

(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 *skills* to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a solution ***imposing stringent obligations to ensure a sufficient level of AI literacy*** is not suitable for all types of providers and deployers in relation to the promotion of AI literacy. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require providers and deployers ***of AI systems to support AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf. The European Commission should promote AI literacy and competences for the wider population, and in order to support, facilitate and complement the efforts of providers, should be tasked to issue guidance on the practical implementation regarding the obligation on providers and deployers of AI systems, and should, together with the Member States, encourage and support AI literacy in society. This should include facilitating and complementing the efforts of providers and deployers of AI systems, in particular SMEs, as the implementation of the relevant obligations poses particular challenges for them. One possibility to facilitate AI literacy in the Union could be the creation of Public Private Partnerships (PPPs).***

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 5

Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) AI systems that alter, manipulate or artificially generates realistic images or videos depicting sexually explicit activities, or the intimate parts of an identifiable natural person, without that person's consent, cause harm to victims and violate fundamental rights to dignity and privacy. The proliferation of such technologies, often marketed as 'nudification' applications, has created an urgent need for explicit regulatory prohibition. Regulation (EU) 2024/1689 establishes a framework for prohibited AI practices, which is to be kept under review. 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. This prohibition should not apply to providers or deployers of AI systems who have put in place effective safety measures, such as technical and organisational measures, to prevent the generation of such depictions and to avoid continuously misuse, after the system has been placed, on the market or put into service, despite the intention of the provider or deployer. Moreover, this prohibition should not prevent AI providers from developing their technical capabilities to alter, manipulate or

artificially generate images or videos.

Amendment 6

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*** 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 Council***⁶. ***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)***

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 already provides a legal basis authorising the ***providers of high-risk AI systems to process*** special categories of personal data ***in certain exceptional cases and subject to strict safeguards. This 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. Accordingly, a substantial public interest exists to permit, 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 also applies to*** the also by providers and deployers of other AI systems and AI models. ***That*** legal basis ***should be subject to the same conditions and safeguards as apply under the existing Article 10(5), 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 and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council.

2016/680, as applicable.

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 7

Proposal for a regulation Recital 7

Text proposed by the Commission

(7) In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to the

Amendment

deleted

procedure for designating notified bodies under Regulation (EU) 2024/1689, while maintaining the same level of scrutiny, a single application and a single assessment procedure should be available for new conformity assessment bodies and notified bodies which are designated under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, such as under Regulations (EU) 2017/745⁹ and (EU) 2017/746¹⁰ of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation. The single application and assessment procedure aims at facilitating, supporting and expediting the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies under that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto.

⁹ *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).*

¹⁰ *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>).*

Amendment 8

Proposal for a regulation
Recital 8

Text proposed by the Commission

Amendment

(8) *With a view to ensuring the smooth application and consistency of Regulation (EU) 2024/1689, amendments should be made to it. A technical correction to Article 43(3), first subparagraph, of Regulation (EU) 2024/1689 should be added to align the conformity assessment requirements with the requirements of providers of high-risk AI systems in Article 16 of that Regulation. Moreover, it should be clarified that where a provider of a high-risk AI system is subject to the conformity assessment procedure under Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, and the conformity assessment extends to compliance of the quality management system of that Regulation and of such Union harmonisation legislation, the provider should be able to include aspects related to quality management systems under that Regulation as part of the quality management systems under such Union harmonisation legislation, in line with Article 17(3) of Regulation (EU) 2024/1689. Article 43(3), second subparagraph, should be amended to clarify that notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and which aim to assess high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I to that Regulation, should apply for the designation as a notified body under that Regulation within 18 months from [the entry into application of this Regulation]. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689. Moreover, Regulation (EU) 2024/1689 should be*

(8) *deleted*

amended to clarify that where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and falls within one of the use-cases listed in Annex III to that Regulation, the provider should follow the relevant conformity assessment procedure as required under that relevant harmonisation legislation.

Amendment 9

Proposal for a regulation Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) *Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847 complement each other so that the safety and cybersecurity of products with digital elements is ensured. It is necessary to ensure the alignment of Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847, to allow for their smooth implementation. Where high-risk AI systems fulfil the essential cybersecurity requirements set out in Regulation (EU) 2024/2847, 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 pursuant to Regulation (EU) 2024/2847.*

Amendment 10

Proposal for a regulation Recital 8 b (new)

Text proposed by the Commission

Amendment

(8b) *For the purposes of this*

Regulation, the fact that an AI system is integrated into, or operates within, a product subject to Union harmonisation legislation on product safety should not, in itself, imply that the AI system performs a safety function. An AI system should be regarded as performing a safety function only where its functioning is necessary to ensure that the product or the AI system complies with applicable Union safety requirements. By contrast, functionalities intended solely for user assistance, performance optimisation, service efficiency, automation, convenience, or quality control of non-safety-related aspects should not be regarded as safety functions under this Regulation, where their failure would not directly create risks to health or safety.

Amendment 11

Proposal for a regulation

Recital 9

Text proposed by the Commission

(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.

Amendment

(9) To streamline compliance and reduce the associated costs, ***the registration of*** 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 ***should be simplified by streamlining the required content in Section B of Annex VIII to that Regulation. While it remains crucial for effective market surveillance and public accountability that such AI systems are registered in the EU database, the registration requirements should be simplified and made more proportionate. This simplification will strike a better balance without undermining the protection laid down by Regulation 2024/1689.*** 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.
Furthermore, a provider **applying** 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.

Amendment 12

Proposal for a regulation Recital 10

Text proposed by the Commission

(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.

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 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. ***When discussions are held within the framework of the Board, the European Data Protection Supervisor and the AI Office, as part of their roles within the board, should provide feedback and exchange best practices on matters related to the establishment and operation of AI regulatory sandboxes that were established under their respective competences.*** By leveraging these

infrastructures and facilitating cross-border collaboration, coordination would be streamlined and resources optimally utilised. ***In order to foster innovation and facilitate the uptake of AI, SMEs, including startups, and SMCs should be provided with priority access to the AI regulatory sandboxes established by the AI Office.***

Where AI regulatory sandboxes, including the controlled environment to foster innovation, involve innovative AI systems that process personal data, the relevant national supervisory authorities should be involved in accordance with their tasks and powers.

Amendment 13

Proposal for a regulation

Recital 11

Text proposed by the Commission

(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 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

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 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.

testing of such high-risk AI systems in real-world conditions, *subject to sufficient safeguards*.

Amendment 14

Proposal for a regulation Recital 12 a (new)

Text proposed by the Commission

Amendment

(12a) In order to allow the AI Office to effectively exercise its duties under Regulation (EU) 2024/1689 and in light of the new powers conferred on it by this Regulation, adequate human, financial and technical resources should be provided, without prejudice to the budgetary procedure and existing financial instruments. In particular, the AI Office should have a sufficient number of personnel whose expertise include an in-depth understanding of AI technologies.

Amendment 15

Proposal for a regulation Recital 13

Text proposed by 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.

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.

(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.

Amendment 16

Proposal for a regulation

Recital 14

Text proposed by the Commission

(14) In order to strengthen the governance system for AI systems based on general-purpose AI models, it is necessary to clarify the role of the AI Office in monitoring and supervising compliance of such AI systems with Regulation (EU) 2024/1689, while excluding AI systems related to products covered by the Union harmonisation legislation listed in Annex I to that Regulation. While sectoral authorities continue to remain responsible for the supervision of AI systems related to products covered by that Union harmonisation legislation, Article 75(1) Regulation (EU) 2024/1689 should be modified to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, the AI Office should **be empowered to** take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council¹¹. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689

Amendment

(14) In order to strengthen the governance system for AI systems based on general-purpose AI models, it is necessary to clarify the role of the AI Office in monitoring and supervising compliance of such AI systems with Regulation (EU) 2024/1689, while excluding AI systems related to products covered by the Union harmonisation legislation listed in Annex I **and AI systems referred to in Annex III, point 2** to that Regulation. While sectoral authorities continue to remain responsible for the supervision of AI systems related to products covered by that Union harmonisation legislation, Article 75(1) Regulation (EU) 2024/1689 should be modified to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, the AI Office should take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council¹¹. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689

should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.

¹¹ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1020/oj>).

Amendment 17

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) To further operationalise the AI Office's supervision and enforcement set out in Article 75(1) of Regulation (EU) 2024/1689, it is necessary to further define *the* which of the powers listed in Article 14 of Regulation (EU) 2019/1020 should be conferred upon the AI Office. The Commission should therefore be empowered to adopt implementing acts to specify those powers, including the ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings referred to in Article 99, and applicable procedures. This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689.

Amendment 18

Proposal for a regulation Recital 18

should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.

¹¹ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1020/oj>).

Amendment

(16) To further operationalise the AI Office's supervision and enforcement set out in Article 75(1) of Regulation (EU) 2024/1689, it is necessary to further define which of the powers listed in Article 14 of Regulation (EU) 2019/1020 should be conferred upon the AI Office. The Commission should therefore be empowered to adopt implementing acts to specify those powers, including the ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings referred to in Article 99, and applicable procedures. This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689.

Text proposed by the Commission

(18) To enable access to Union market for AI systems which are under the supervision by the AI Office pursuant to Article 75 of Regulation (EU) 2024/1689 and subject to third party conformity assessment, the Commission should **be enabled to carry out** pre-market conformity assessments **of** those systems.

Amendment

(18) To enable access to Union market for AI systems which are under the supervision by the AI Office pursuant to Article 75 of Regulation (EU) 2024/1689 and subject to third party conformity assessment, the Commission should **ensure that** pre-market conformity assessments **are carried out for** those systems. **Furthermore, the AI Office should maintain organised records of communications with providers and deployers of general-purpose AI models with systemic risk. Such records should be documented in a consistent manner.**

Amendment 19

Proposal for a regulation

Recital 19

Text proposed by the Commission

(19) Article 77 and related provisions of Regulation (EU) 2024/1689 constitute an important governance mechanism, as they aim to enable authorities or bodies responsible for enforcing or supervising Union law intended to protect fundamental rights to fulfil their mandate under specific conditions and to foster cooperation with market surveillance authorities responsible for the supervision and enforcement of that Regulation. It is necessary to clarify the scope of such cooperation, as well as to clarify which public authorities or bodies benefit from it. With a view to reinforcing the cooperation, it should be clarified that requests to access information and documentation should be made to the competent market surveillance authority, which should respond to such requests, and that the involved authorities or bodies should have a mutual obligation to cooperate.

Amendment

(19) Article 77 and related provisions of Regulation (EU) 2024/1689 constitute an important governance mechanism, as they aim to enable authorities or bodies responsible for enforcing or supervising Union law intended to protect fundamental rights to fulfil their mandate under specific conditions and to foster cooperation with market surveillance authorities responsible for the supervision and enforcement of that Regulation. It is necessary to clarify the scope of such cooperation, as well as to clarify which public authorities or bodies benefit from it. With a view to reinforcing the cooperation, it should be clarified that requests to access information and documentation should be made to the competent market surveillance authority, which should respond to such requests **without undue delay**, and that the involved authorities or bodies should have a mutual obligation to cooperate. **It should be clarified that these provisions are without**

prejudice to the tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, those provisions do not limit any powers that those authorities and bodies have to request information pursuant to other Union or national law. Accordingly, those authorities and bodies retain any power they have to directly request information from operators pursuant to their mandate or other law.

Amendment 20

Proposal for a regulation Recital 20

Text proposed by the Commission

(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.

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 **3** months for providers who have already placed their systems on the market before the 2 August 2026.

Amendment 21

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 application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter

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 obligations.

III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. It is appropriate ***that the date of application of obligations on AI systems classified as high-risk pursuant to Article 6(2) and Annex III and on AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689 is postponed 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.*** 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.

Amendment 22

Proposal for a regulation Recital 22 a (new)

Text proposed by the Commission

Amendment

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

Amendment 23

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 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***

(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. At the same time, recognising the need to offer clarity how providers of high-risk AI systems are required to comply ***with their monitoring obligations***, the Commission should be required to publish guidance ***on the post-market monitoring plan, including a template with elements to be included***

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.

therein, by 2 February 2027.

Amendment 24

Proposal for a regulation Recital 23 a (new)

Text proposed by the Commission

Amendment

(23a) The parallel application of sectoral Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 of the European Parliament and of the Council and the requirements set out in that Regulation for high-risk artificial intelligence systems may lead to overlaps of requirements and unnecessary administrative burden for economic operators. Such overlaps could create legal uncertainty, increase compliance costs and potentially lead to competitive disadvantages, without providing additional benefits for the protection of health, safety or fundamental rights. In order to ensure a more coherent and proportionate regulatory framework and to simplify the application of requirements for artificial intelligence systems embedded in products regulated under Union harmonisation legislation, the references to the Union harmonisation legislation currently listed in Section A of Annex I to Regulation (EU) 2024/1689 should therefore be moved to Section B of that Annex. This approach clarifies that artificial intelligence systems integrated into products covered by those sectoral acts are subject to the requirements of this Regulation where relevant, while allowing the conformity assessment procedures and product safety requirements under the respective sectoral legislation to remain the primary framework. Any remaining

gaps relating to artificial intelligence systems integrated into such products should be addressed within the relevant sectoral legislation.

Amendment 25

Proposal for a regulation Recital 23 b (new)

Text proposed by the Commission

Amendment

(23b) In order to safeguard the horizontal nature of this Regulation and ensure the proper functioning of the internal market, the relevant requirements laid down in Chapter III, Section 2 of this Regulation should be deemed to constitute essential health and safety requirements for high-risk AI systems covered by Union harmonisation legislation listed in Annex I and should be applied in a consistent and coherent manner across those sectoral frameworks. For this purpose, the Commission should be entitled to adopt delegated acts taking into account the requirements set out in Chapter III, Section 2 of this Regulation as regards their application to AI systems falling within its scope as well as relevant harmonised standards. In doing so, the Commission should not go beyond the requirements laid down in Regulation (EU) 2024/1689 for this purpose and should take into account the specific context of sectorial legislation. Before adopting the acts referred to in the first subparagraph, the Commission should conduct open and transparent consultations with relevant stakeholders, including competent authorities, notified bodies, civil society and industry.

Amendment 26

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission

Amendment

(25a) When implementing and enforcing this Regulation, national competent authorities, the AI office and the Commission should take into account the objectives set out in Article 1(1) of Regulation (EU) 2024/1689 and follow the principles of necessity, proportionality, legal certainty and technological neutrality, while at the same time ensuring that unnecessary administrative and compliance burdens are minimised.

Amendment 27

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

Text proposed by the Commission

Amendment

2. For AI systems classified as high-risk AI systems in accordance with Article 6(1) related to products covered by the Union harmonisation legislation listed in **Section B of Annex I**, only Article 6(1), Article 60a, Articles 102 to 109 and Articles 111 and 112 shall apply. Article 57 shall apply only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.;

2. For AI systems classified as high-risk AI systems in accordance with Article 6(1) related to products covered by the Union harmonisation legislation listed in Annex I, only Article 6(1), Article 60a, Articles 102 to 109, **Articles 110a-110l** and Articles 111 and 112 shall apply. Article 57 shall apply only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.;

Amendment 28

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

1. ‘Providers and deployers of AI systems ***shall*** take measures to ***support the improvement*** 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, 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. ***This obligation does not cover any guarantee of a specific level of AI literacy of any individual.***;

Amendment 29

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EU) 2024/1689

Article 4 – paragraph 1a (new)

Text proposed by the Commission

Amendment 30

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EU) 2024/1689

Article 4 – paragraph 1b (new)

Text proposed by the Commission

Amendment

(1a) ***The Commission shall issue guidance on the practical implementation of the obligation on providers and deployers of AI systems under paragraph 1.***

Amendment

(1b) ***The Commission and the Member States shall encourage and support AI literacy in society and among the general population and support, facilitate and complement the efforts of providers and***

deployers of AI systems, in particular SMEs, for example via the creation of Public Private Partnerships in fulfilling their obligation under paragraph 1.;

Amendment 31

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4 a (new) – paragraph 1

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 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 32

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4 a (new) – 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***

Amendment

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

safeguards set out in this paragraph.;

(a) processing is 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 of 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.'

Amendment 33

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 5 – paragraph 1 – subparagraph 1 – point ha (new)

Text proposed by the Commission

Amendment

(5a) in Article 5, paragraph 1, subparagraph 1 the following point is added:

(ha) the placing on the market, the putting into service or the use of an AI system that alters, manipulates or artificially generates realistic images or videos so as to depict sexually explicit activities or the intimate parts of an identifiable natural person, without that person's consent.

This prohibition does not apply to providers or deployers of AI systems who have put in place effective safety measures to prevent the generation of such depictions and to avoid misuse continuously, after the system has been placed, on the market or put into service despite the intention of the provider or deployer.

This prohibition shall not prevent AI providers from developing any capabilities referred to in the first subparagraph.

Amendment 34

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) Article 6(1) is amended as follows:

"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 whose functioning is necessary to ensure that the product or AI system complies with applicable Union safety requirements***, 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.

"

(Regulation (EU) 2024/1689)

Amendment 35

Proposal for a regulation
Article 1 – paragraph 1 – point 5 c (new)
Regulation (EU) 2024/1689
Article 6 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(5c) In Article 6, paragraph 1a is added:

‘1a. For the purposes of this Regulation, functionalities intended solely for user assistance, performance optimisation, service efficiency, automation, convenience, or quality control of non-safety-related aspects shall not be regarded as safety functions under this Regulation, where their failure would not directly create risks to health or safety.’

Amendment 36

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, 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.;

Amendment 37

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 25 – paragraph 2

Present text

2. Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation. That initial provider shall closely cooperate with new providers and shall make available the necessary information and provide the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems. This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation.

Amendment

(9a) Article 25(2) is replaced by the following:

"2. Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation.

That initial provider, as well as providers of general-purpose AI models whose models are integrated into high-risk AI systems, shall closely cooperate with new providers and shall make available the necessary information and provide the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems.

This obligation shall include:

(a) the provision of technical documentation sufficient to assess compliance with Article 16 requirements;

(b) the disclosure of known limitations and failure modes that could affect high-risk applications;

(c) the provision of reasonable technical access for testing and validation purposes.

This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation.’

”

(Regulation (EU) 2024/1689)

Amendment 38

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 27 – paragraph 4

Present text

Amendment

4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the ***fundamental rights impact assessment referred to in paragraph 1 of this Article*** shall ***complement that data protection impact assessment. to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680,*** the fundamental rights impact assessment referred to in paragraph 1 of this Article ***shall complement*** that data protection impact assessment.

(9b) in Article 27, paragraph 4 is replaced by the following:

"4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the ***deployer*** shall, ***when conducting*** the fundamental rights impact assessment referred to in paragraph 1 of this Article ***include cross references to the relevant sections of*** that data protection impact assessment ***or include relevant parts of that data protection impact assessment into the fundamental rights impact assessment.***

”

(Regulation 2024/1689)

Amendment 39

Proposal for a regulation

Article 1 – paragraph 1 – point 10

Regulation (EU) 2024/1689

Article 28 – paragraph 8 (new)

Text proposed by the Commission

Amendment

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

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

Amendment 40

Proposal for a regulation

Article 1 – paragraph 1 – point 10

Regulation (EU) 2024/1689

Article 28 – paragraph 8 (new) – subparagraph 1

Text proposed by the Commission

Amendment

The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed *deleted*

in Section A of Annex I, when those notified bodies apply for designation under this Regulation, provided that the relevant Union harmonisation legislation provides for such a procedure.

Amendment 41

Proposal for a regulation

Article 1 – paragraph 1 – point 10

Regulation (EU) 2024/1689

Article 28 – paragraph 8 (new) – subparagraph 2

Text proposed by the Commission

Amendment

The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation.;

deleted

Amendment 42

Proposal for a regulation

Article 1 – paragraph 1 – point 11

Regulation (EU) 2024/1689

Article 29 – paragraph 4 – second subparagraph

Text proposed by the Commission

Amendment

Notified bodies, which are designated under any of the Union harmonisation legislation listed in Section A of Annex I and which apply for the single assessment referred to in Article 28(8), shall submit the single application for assessment to the notifying authority designated in accordance with that Union harmonisation legislation.

deleted

Amendment 43

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 42 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(12a) In Article 42, the following paragraph is inserted:

'2a. Where an AI system is subject to the requirements of Regulation (EU) 2024/2847 as well as requirements set out in Article 15, and where those high-risk AI systems fulfil the essential cybersecurity requirements set out in Regulation (EU) 2024/2847, they shall be presumed to comply with the cybersecurity requirements set out in Article 15 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued pursuant to Regulation (EU) 2024/2847.'

Amendment 44

Proposal for a regulation

Article 1 – paragraph 1 – point 13

Regulation (EU) 2024/1689

Article 43 – paragraph 3

Text proposed by the Commission

Amendment

(13) in Article 43, paragraph 3 is replaced by the following:

deleted

‘

For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI

systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.

For the purposes of that conformity assessment, notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I shall have the power to assess the conformity of high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with the requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under the relevant Union harmonisation legislation. Without prejudice to Article 28, such notified bodies which have been notified under the Union harmonisation legislation in Section A of Annex I, shall apply for designation in accordance with Section 4 at the latest [18 months from the entry into application of this Regulation].

Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option to opt out from a third-party conformity assessment, provided that that manufacturer has applied harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.

Where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I and it falls within one of the categories listed in Annex III, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation listed in Section

A of Annex I;

,

Amendment 45

Proposal for a regulation

Article 1 – paragraph 1 – point 13

Regulation (EU) 2024/1689

Article 43 – paragraph 4 – subparagraph 3

Text proposed by the Commission

Amendment

Where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I and it falls within one of the categories listed in Annex III, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation listed in Section A of Annex I;

deleted

Amendment 46

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 47

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

Text proposed by the Commission

Amendment

7. The **AI Office** shall encourage and

7. The **Commission** shall encourage

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).;

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 *shall* 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 48

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 56 – paragraph 6

Text proposed by the Commission

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

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 *and other relevant competent authorities*, 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 49

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a

Regulation (EU) 2024/1689

Article 57 – paragraph 3 a (new)

Text proposed by the Commission

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

Amendment

(3a) The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to *SMEs, including startups*.;

The AI Office shall ensure that, to the extent innovative AI systems referred to in paragraph 5 involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities, the EDPB and those other national or competent authorities are associated with the operation of the AI regulatory sandbox established at Union level and involved in the supervision of those aspects to the extent that they relate to their respective tasks and powers, in accordance with Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2018/680.

Amendment 50

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

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. 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.;

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

Amendment 51

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

Amendment

14. National competent authorities 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.;

When discussions are held within the framework of the Board, the European Data Protection Supervisor and the AI office shall, as part of their roles within the Board, also provide their feedback and exchange best practices on matters related to the establishment and operation of AI regulatory sandboxes established under their respective competences.;

Amendment 52

Proposal for a regulation

Article 1 – paragraph 1 – point 18

Regulation (EU) 2024/1689
Article 58 – paragraph 1 – point d (new)

Text proposed by the Commission

(d) the detailed rules applicable to the governance of AI regulatory sandboxes covered under Article 57, including as regards the exercise of the tasks of the competent authorities and the coordination and cooperation at national and EU level.;

Amendment

(d) the detailed rules applicable to the governance of AI regulatory sandboxes covered under Article 57, including as regards the exercise of the tasks of the competent authorities, ***the involvement and supervision by the competent data protection authorities*** and the coordination and cooperation at national and EU level.;

Amendment 53

Proposal for a regulation

Article 1 – paragraph 1 – point 19 – point a

Regulation (EU) 2024/1689

Article 60 – paragraph 1

Text proposed by the Commission

Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III ***or covered by Union harmonisation legislation listed in Section A of Annex I***, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.;

Amendment

1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.;

Amendment 54

Proposal for a regulation

Article 1 – paragraph 1 – point 19 – point b

Regulation (EU) 2024/1689

Article 60 – paragraph 2

Text proposed by the Commission

2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III ***or covered***

Amendment

2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III in real

by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.;

world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.;

Amendment 55

Proposal for a regulation

Article 1 – paragraph 1 – point 20

Regulation (EU) 2024/1689

Article 60 a (new) – paragraph 3

Text proposed by the Commission

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.

Amendment

3. Member States, the Commission, ***and national competent authorities such as*** 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.

Amendment 56

Proposal for a regulation

Article 1 – paragraph 1 – point 21

Regulation (EU) 2024/1689

Article 63 – paragraph 1

Text proposed by the Commission

1. SMEs, including start-ups, may comply with certain elements of the quality

Amendment

1. SMEs, including start-ups, ***and micro enterprises*** may comply with certain

management system required by Article 17 in a simplified manner. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.;

elements of the quality management system required by Article 17 in a simplified manner. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of SMEs and *micro enterprises*, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.;

Amendment 57

Proposal for a regulation

Article 1 – paragraph 1 – point 21 a (new)

Regulation (EU) 2024/1689

Article 64 – paragraph 2a (new)

Text proposed by the Commission

Amendment

(21a) In Article 64, paragraph 2a is added:

‘(2a) Without prejudice to the budgetary procedure and through existing financial instruments, the AI Office shall be allocated with adequate human, financial and technical resources, and with infrastructure to fulfil their tasks, to effectively perform its duties and exercise its powers in respect of the enforcement of Regulation (EU) 2024/1689. In particular, the AI Office shall have a sufficient number of personnel permanently available with in-depth competences and technical expertise. The AI Board shall assess competence and resource requirements.’

Amendment 58

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 59

Proposal for a regulation

Article 1 – paragraph 1 – point 24

Regulation (EU) 2024/1689

Article 72 – paragraph 3

Text proposed by the Commission

Amendment

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan.;

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan, ***including a template with elements to be included by 2 February 2027.***;

Amendment 60

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 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***

1. Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I ***and AI systems referred to in Annex III, point 2,*** and that model and that system are developed by the same provider ***or by providers belonging to the same group of undertakings,*** the AI Office shall ***have powers to supervise and enforce*** the obligations of this Regulation in accordance with the tasks and

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.

responsibilities assigned by it to market surveillance authorities. The AI Office shall also *have powers to supervise and enforce* the obligations under this Regulation in relation to AI *systems* 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. *Where the Commission has not initiated proceedings for the same infringement, the competent authority of a Member State in which the main establishment of the provider of very large online platform or of very large online search engine is located, or where their legal representative is established, may have the powers to supervise and enforce the obligations under this Regulation.*

Notwithstanding the first subparagraph, the supervision and enforcement powers of the AI Office, do not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of this Regulation.

Amendment 61

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 2

Text proposed by the Commission

When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall *be empowered to* take appropriate measures and decisions to adequately exercise its supervisory and

Amendment

When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers.

enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

Amendment 62

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b a (new)

Regulation (EU) 2024/1689

Article 75 – paragraph –1a (new)

Text proposed by the Commission

Amendment

(ba) in Article 75, paragraph -1a is inserted:

‘-1a. In the implementation and enforcement of this Regulation, the AI Office shall promote innovation, competitiveness and the protection of fundamental rights, taking them into consideration in the exercise of their functions. The AI Office shall coordinate closely with the competent data protection authorities designated pursuant to Regulation (EU) 2016/1679 in matters involving the processing of personal data falling within the scope of that Regulation.’

Amendment 63

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75 – paragraph – 1c

Text proposed by the Commission

Amendment

The Commission shall **organise and carry out** pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify

1c. The Commission shall, **subject to Article 28(8), ensure that** pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 **are carried out** before such AI systems are placed on the market or put into

that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission *may* entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply *mutatis mutandis* to the Commission when exercising its powers under this paragraph.

service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission *shall* entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply *mutatis mutandis* to the Commission when exercising its powers under this paragraph.

Amendment 64

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point b

Regulation (EU) 2024/1689

Article 77 – paragraph 1 – point b

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 of their jurisdiction.;

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 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 *machine-readable* format *by electronic means* where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. *This paragraph is without prejudice to the tasks, powers and independence of the relevant national public authorities or bodies under their mandates in accordance with Union and national law;*

Amendment 65

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c – introductory part

Regulation (EU) 2024/1689

Article 77 – paragraph 1a (new)

Text proposed by the Commission

(c) the following paragraph 1a **and 1b** are inserted:

Amendment

(c) the following paragraph 1a, **1b and 1ba** are inserted:

Amendment 66

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c

Regulation (EU) 2024/1689

Article 77 – paragraph 1a (new)

Text proposed by the Commission

1a. Subject to the conditions specified in this Article, the market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer, where necessary.

Amendment

1a. Subject to the conditions specified in this Article, the market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer, where necessary **and without undue delay**.

Amendment 67

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c

Regulation (EU) 2024/1689

Article 77 – paragraph 1b (new)

Text proposed by the Commission

1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with mutual assistance necessary for fulfilling their respective mandates, with a view to ensuring coherent application of this Regulation and Union

Amendment

1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with mutual assistance necessary for fulfilling their respective mandates, with a view to ensuring coherent application of this Regulation and Union

law protecting fundamental rights and streamlining procedures. This shall include, in particular, exchange of information where necessary for the effective supervision or enforcement of this Regulation and the respective other Union legislation.;

law protecting fundamental rights and streamlining procedures ***while respecting their respective competences, tasks, powers and independence***. This shall include, in particular, exchange of information where necessary for the effective supervision or enforcement of this Regulation and the respective other Union legislation.;

Amendment 68

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c

Regulation (EU) 2024/1689

Article 77 – paragraph 1b a (new)

Text proposed by the Commission

Amendment

1ba. Requests for assistance shall contain all the necessary information, including the purpose of and reasons for the request.

Amendment 69

Proposal for a regulation

Article 1 – paragraph 1 – point 28 – introductory part

Regulation (EU) 2024/1689

Article 96 – paragraph 1

Text proposed by the Commission

Amendment

(28) in Article 96(1), the second subparagraph ***is*** replaced by the following:

(28) in Article 96(1), ***point (a) and*** the second subparagraph ***are*** replaced by the following:

Amendment 70

Proposal for a regulation

Article 1 – paragraph 1 – point 28

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – point a

Text proposed by the Commission

(a) the application of the requirements and obligations referred to in Articles 8 to 15 and in Article 25;

Amendment

-1. (a) the application of the requirements and obligations referred to in Articles 8 to 15 and in Articles **25 and 26**;

Amendment 71

Proposal for a regulation

Article 1 – paragraph 1 – point 28

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

-1a. *in Article 96, paragraph 1, subparagraph 1, the following point is inserted:*

‘(fa) the application of the obligations referred to in Article 27, including the possibility to reference or include relevant sections or parts of the data protection impact assessment into the fundamental rights impact assessment pursuant to Article 27(4) of this Regulation, using, where relevant, standardised templates. ’

Amendment 72

Proposal for a regulation

Article 1 – paragraph 1 – point 29 – point a a (new)

Regulation (EU) 2024/1689

Article 99 – paragraph 4 – point da (new)

Text proposed by the Commission

Amendment

(aa) *in paragraph 4 the following point (da) is inserted:*

‘(da) obligations of providers and third parties, including providers of general purpose AI models, pursuant to Article 25(2), (3) and (4); ’

Amendment 73

Proposal for a regulation

Article 1 – paragraph 1 – point 29 – point b

Regulation (EU) 2024/1689

Article 99 – paragraph 6

Text proposed by the Commission

6. In the case of **SMCs** and SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.;

Amendment

6. In the case of and SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.;

Amendment 74

Proposal for a regulation

Article 1 – paragraph 1 – point 29 – point b

Regulation (EU) 2024/1689

Article 99 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. In Article 99, paragraph 6a is inserted:

‘In the case of SMCs, with the exception of providers of general-purpose AI models with systemic risk, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 4 and 5, whichever is lower.’

Amendment 75

Proposal for a regulation

Article 1 – paragraph 1 – point 29 a (new)

Regulation (EU) 2024/1689

Article 110 a (new)

Text proposed by the Commission

Amendment

(29a) The following articles: Article 110a – Article 110l are inserted:

Article 110a

***Amendment to Regulation (EU)
2023/1230***

***In Article 8 of Regulation (EU)
2023/1230, the following paragraphs 2
and 3 are added:***

‘2. The Commission is empowered to adopt delegated acts in accordance with Article 48 to amend the essential health and safety requirements set out in Annex III in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 20 of this Regulation concerning machinery and related products that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.’

Article 110b

***Amendment to Regulation (EU)
2025/2509***

***In Article 5 of Regulation (EU)
2025/2509, the following paragraphs 4
and 5 are added:***

‘4. The Commission is empowered to adopt delegated acts in accordance with Article 53 to amend the essential safety

requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

5. When adopting delegated acts pursuant to paragraph 4 of this Article or Common Specifications pursuant to Article 16 of this Regulation concerning toys that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'

Article 110c

Amendment to Directive 2013/53/EU

In Article 4 of Directive 2013/53/EU, the following paragraphs 3 and 4 are added:

'3. The Commission is empowered to adopt delegated acts in accordance with Article 50 to amend the essential requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the

purpose of this Regulation.

4. When adopting delegated acts pursuant to paragraph 3 of this Article or Common Specifications pursuant to Article 14a of this Regulation concerning products that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'

Article 110d

Amendment to Directive 2014/33/EU

In Article 5 of Directive 2014/33/EU, the following paragraphs 3 and 4 are added:

'3. The Commission is empowered to adopt delegated acts in accordance with Article 42 to amend the essential health and safety requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

4. When adopting delegated acts pursuant to paragraph 3 of this Article or Common Specifications pursuant to Article 14a of this Regulation concerning lifts and safety components for lifts that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission

shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'

Article 110e

Amendment to Directive 2014/34/EU

In Article 4 of Directive 2014/34/EU, the following paragraphs 2 and 3 are added:

'2. The Commission is empowered to adopt delegated acts in accordance with Article 39 to amend the essential health and safety requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 12a of this Regulation concerning products that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'

Article 110f

Amendment to Directive 2014/53/EU

In Article 3 of Directive 2014/53/EU, the

following paragraphs 5 and 6 are added:

‘5. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend the essential requirements in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

6. When adopting delegated acts pursuant to paragraph 5 of this Article or Common Specifications pursuant to Article 16a of this Regulation concerning radio equipment that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.’

Article 110g

Amendment to Directive 2014/68/EU

In Article 4 of Directive 2014/68/EU, the following paragraphs 4 and 5 are added:

‘4. The Commission is empowered to adopt delegated acts in accordance with Article 44 to amend the general safety and performance essential safety requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems

referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

5. When adopting delegated acts pursuant to paragraph 4 of this Article or Common Specifications pursuant to Article 12a of this Regulation concerning products that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'

Article 110h

*Amendment to Regulation (EU) 2016/424
In Article 6 of Regulation (EU) 2016/424, the following paragraphs 2 and 3 are added:*

'2. The Commission is empowered to adopt delegated acts in accordance with Article 44 to amend the essential requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

3. When adopting delegated acts pursuant to paragraph 2 of this Article or

Common Specifications pursuant to Article 12a of this Regulation concerning cableway installations, subsystems and safety components that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'

Article 110i

Amendment to Regulation (EU) 2016/425

In Article 5 of Regulation (EU) 2016/425, the following paragraphs 2 and 3 are added:

'2. The Commission is empowered to adopt delegated acts in accordance with Article 44 to amend the essential health and safety requirements set out in Annex II in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 14a of this Regulation concerning personal protective equipment that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements

set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.’

Article 110j

Amendment to Regulation (EU) 2016/426

In Article 5 of Regulation (EU) 2016/426, the following paragraphs 2 and 3 are added:

‘2. The Commission is empowered to adopt delegated acts in accordance with Article 41 to amend the essential requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

3. When adopting delegated acts pursuant to paragraph 2 of this Article or Common Specifications pursuant to Article 13a of this Regulation concerning appliances or fitting that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.’

Article 110k

Amendment to Regulation (EU) 2017/745

In Article 5 of Regulation (EU) 2017/745, the following paragraphs 7 and 8 are added:

‘7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.’

Article 110l

Amendment to Regulation (EU) 2017/746

In Article 5 of Regulation (EU) 2017/746, the following paragraphs 7 and 8 are added:

‘7. The Commission is empowered to adopt delegated acts in accordance with Article 107 to amend the general safety and performance requirements set out in

Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. For high-risk AI systems referred to in Article 6(1) of Regulation (EU) 2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation as well as relevant harmonised standards. With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in Regulation (EU) 2024/1689.'

Amendment 76

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

Regulation (EU) 2024/1689

Article 111 – paragraph 4 (new)

Text proposed by the Commission

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

4. Providers of AI systems, including general-purpose AI systems, generating 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 **November 2026**;

Amendment 77

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d (new)

Text proposed by the Commission

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

Amendment

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

Amendment 78

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point i (new)

Text proposed by the Commission

(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

Amendment 79

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point ii (new)

Text proposed by the Commission

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

deleted

Amendment

Amendment 80

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

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 81

Proposal for a regulation

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

Regulation (EU) 2024/1689

Annex I – Section A

Text proposed by the Commission

Amendment

(31 a) In Annex I, Section A is deleted

Amendment 82

Proposal for a regulation

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

Regulation (EU) 2024/1689

Annex I – Section B – point 20 a (new)

Text proposed by the Commission

Amendment

(31b) In Annex I, Section B, the following points are added:

‘20a. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);

20b. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ

L 170, 30.6.2009, p. 1);

20c. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

20d. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);

20e. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);

20f. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

20g. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);

20h. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);

20i. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81,

31.3.2016, p. 51);

20j. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

20k. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

20l. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

20m. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council Directive 73/361/EEC.’

Amendment 83

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Regulation (EU) 2024/1689

Annex VIII – section B

Text proposed by the Commission

(32) in Annex VIII, section B **is** deleted;

Amendment

(32) in Annex VIII, section B, **points 7 and 9 are** deleted;

EXPLANATORY STATEMENT

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

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

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

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

ANNEX: DECLARATIONS OF INPUT

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

1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register
AI Sweden
Allied for Startups
Applia (Home Appliance Europe)
Mistral
Coimisiún na Meán
Google Ireland
TIC Council
DOT Europe
TAM Ireland
Home Appliance Europe
Minister of Digitalisation and Public Governance – Norway
Ada Lovelace
Microsoft
The Future Society
Access Now
Orgalim
IBM
European Banking Federation
European Digital Rights (EDRi)
Black Forest Labs
Center for Countering Digital Hate
Confederation of Industry of Czech Republic
Confederation of Swedish Enterprise
Hetch
Mouvement des Entreprises de France
Orgalim (Europe's Technology Industries)
Save the Children Europe
2. Representatives of public authorities of third countries, including their diplomatic missions and embassies

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

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).

Where natural persons are identified in the list by their name, by their function or by both, the rapporteurs declare that they have submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484 (<https://www.europarl.europa.eu/data-protect/index.do>), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

6.3.2026

OPINION OF THE COMMITTEE ON CULTURE AND EDUCATION

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: Emma Rafowicz

AMENDMENTS

The Committee on Culture and Education 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 2 a (new)

Text proposed by the Commission

Amendment

(2a) Effective implementation of Regulation (EU) 2024/1689 requires that the adjustments introduced to facilitate its application in practice do not reduce the clarity and accessibility of the regulatory framework for those required to apply it. In particular, where the Regulation is applied in the fields of education, culture and media, a clear understanding of the obligations and safeguards related to the use of AI systems remains essential to ensure its effective and consistent application, with a particular attention

given to rightholders from the cultural and creative sectors. The measures introduced to support timely and proportionate compliance with this Regulation should therefore continue to support clarity and accessibility of its requirements, thereby contributing to informed use of AI systems and trust in their deployment.

Amendment 2

Proposal for a regulation

Recital 3

Text proposed by the Commission

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

Amendment

(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective application of the relevant rules. *As AI systems are increasingly used in education and in the cultural and creative sectors, their deployment might raise specific considerations linked to learning processes, cultural expression and media pluralism. When applying this Regulation, particular attention should therefore be paid to these sectors in order to support informed use of AI and maintain trust in its deployment. In the field of education, this specifically requires safeguards to ensure that the deployment of AI systems preserves pedagogical autonomy, guarantees high standards of data privacy for learners, and prevents dependency on proprietary ecosystems (vendor lock-in).*

Amendment 3

Proposal for a regulation

Recital 5

Text proposed by the Commission

Amendment

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

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competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.

Amendment 4

Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) The promotion of AI literacy plays an important role in supporting citizens' understanding of AI and its impact on society, including awareness of the opportunities and risks associated with AI, in particular the ability to identify and counter algorithmic bias, discrimination, and the amplification of disinformation, thereby contributing to its democratic governance and public oversight. In practice, such understanding is fostered through education, training, skilling and reskilling programmes, as well as through culture, media literacy and public awareness initiatives. These broader initiatives complement the organisational AI literacy measures taken by providers and deployers of AI systems for their staff and other persons acting on their behalf. Member States should therefore be encouraged, in the context of promoting AI literacy, to involve education providers, cultural institutions, media organisations and civil society actors, in order to ensure that AI literacy initiatives are accessible, inclusive and adapted to different audiences and age groups.

Amendment 5

Proposal for a regulation Recital 5 b (new)

Text proposed by the Commission

Amendment

(5b) AI literacy, together with media and digital literacy, is especially important for children and young people, who are often exposed to AI systems from an early age without sufficient awareness of bias, inaccuracies, or misleading outputs, and of the effects such systems may have on trust in information, privacy, and the shaping of opinions and behaviour. Measures to promote these literacies should support critical thinking, digital autonomy, and informed decision-making, and should be tailored to different ages and learning contexts.

Amendment 6

Proposal for a regulation Recital 5 c (new)

Text proposed by the Commission

Amendment

(5c) Artificial intelligence is increasingly present in the digital environments used by children and young people, including in education, social media, online gaming, and cultural and creative platforms. Regulation (EU) 2024/1689 should therefore be applied in a manner that reflects how children and young people interact with AI systems and their specific need for protection and age-appropriate information.

Amendment 7

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

Amendment

(6a) 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. 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 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.

Amendment 8

Proposal for a regulation Recital 9

Text proposed by the Commission

(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

Amendment

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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.

Amendment 9

Proposal for a regulation Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) Extending opportunities for real-world testing can support innovation, but it should not result in vulnerable groups becoming default test populations. Where real-world testing involves AI systems intended for use in education and vocational training, or is carried out in environments where minors are likely to be affected, the real-world testing plan should set out safeguards that are specific to that setting, including clear information for affected persons and meaningful involvement of deployers such as schools and other public-interest organisations responsible for those environments.

Amendment 10

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.

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Amendment 11

Proposal for a regulation Recital 21

Text proposed by the Commission

Amendment

(21) To provide sufficient time for providers of high-risk AI systems and to clarify applicable rules to the AI systems already placed on the market or put into service before the entry into application of relevant provisions of the Regulation (EU) 2024/1689, it is appropriate to clarify the application of a grace period provided in Article 111(2) of that Regulation. The grace period, for the purpose of Article 111(2), should apply to a type and model of AI systems already placed in the market. This means that if at least one individual unit of the high-risk AI system has been lawfully placed on the market or put into service before the date specified in Article 111(2), other individual units of the same type and model of high-risk AI system are subject to the grace period provided in Article 111(2) and thus may continue to be placed on the market, made available or put into service on the Union market without any additional obligations, requirements or the need for additional certification, as long as the design of that high-risk AI system remains unchanged. For the purposes of application of the grace period provided in Article 111(2), the

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decisive factor is the date on which the first unit of that type and model of high-risk AI system was placed on the market or put into service on the Union market for the first time. Any significant change to the design of that AI system after the date specified in Article 111(2) should trigger the obligation of the provider to comply fully with all relevant provisions of this Regulation applicable to high-risk AI systems, including the conformity assessment requirements.

Amendment 12

Proposal for a regulation

Recital 22

Text proposed by the Commission

Amendment

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

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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 obligations.

Amendment 13

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

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 how providers of high-risk AI systems are required to comply, the Commission should be required to publish guidance.

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. *In that context, codes of practice encouraged by the AI Office pursuant to Article 50(7) should, where relevant, provide guidance on how appropriate user information and awareness can be ensured in a proportionate manner, including in situations where AI systems present lower risks, in particular in education and training, media and information services, cultural and creative activities, or the provision of public services.*

Amendment 14

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.’;

Amendment 15

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4a – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) for the sole purpose of detecting and mitigating algorithmic biases that may affect media pluralism and the diversity of information, providers of high-risk AI systems used in the media ecosystem may, in exceptional and strictly limited circumstances, process special categories of personal data, provided that:

(i) such processing is strictly necessary and cannot be effectively achieved through the use of anonymised, aggregated or synthetic data;

(ii) the processing is limited in scope, duration and access, and does not lead to the identification, profiling or categorisation of individual users;

(iii) no inferences are drawn regarding political opinions, religious beliefs or other protected characteristics of natural persons;

(iv) appropriate technical and organisational measures are implemented in accordance with Union data protection law to ensure confidentiality, security and accountability;

(v) the personal data are deleted without undue delay once the bias has been detected and mitigated;

(vi) users are informed in a clear and accessible manner that their personal data may be processed, in exceptional circumstances, for the sole purpose of detecting and mitigating algorithmic biases, and are provided with information on the scope, safeguards, and rights applicable to such processing.

Amendment 16

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4a – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Children's personal data is explicitly prohibited from being collected, processed or used any other way.

Amendment 17

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

'(ha) the placing on the market, the putting into service or the use of an AI system that can alter, manipulate or generate images or videos so as to depict sexually explicit activities or the intimate parts of a natural person, or that undresses that person, and can facilitate non-consensual sharing of intimate or manipulated material as defined in Article 5 of Directive 2024/1385^{1a}.

*^{1a} 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>)
'*

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.’;

Amendment 19

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 20

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 ***adopt implementing acts to approve*** those codes of practice in accordance with the procedure laid down in Article 56(6). 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). ***Those codes of practice shall, where relevant, address how appropriate user information and awareness can be ensured in a proportionate manner, including in cases where AI systems are considered to present lower risks, in particular when used in education and training, media and information services, cultural and creative activities, or the provision of public services.***

Amendment 21

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 56 – paragraph 6 – subparagraph 1

Text proposed by the Commission

6. The ***Commission*** and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes

Amendment

6. The ***AI office*** 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.

of practice by the participants and their contribution to the proper application of this Regulation. The **AI office and the Board**, 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. **They** shall publish **their** assessment of the adequacy of the codes of practice.

Justification

This amendment seeks to ensure that the monitoring, evaluation and disclosure of the adequacy of codes of practice are fully consistent with the governance arrangements set out in this Regulation. Entrusting these responsibilities to the AI Office and the Board places oversight in the hands of the bodies specifically mandated for technical supervision. In addition, restoring this role to the Board is necessary to maintain an appropriate institutional balance.

Amendment 22

Proposal for a regulation

Article 1 – paragraph 1 – point 23

Regulation (EU) 2024/1689

Article 70 – paragraph 8

Text proposed by the Commission

8. National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMCs and SMEs, including start-ups, taking into account the guidance and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union law, the national competent authorities under that Union law shall be consulted, as appropriate.

Amendment

8. National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMCs and SMEs, including start-ups, **and, where relevant, to public sector deployers, including local public authorities and publicly funded education, training and cultural institutions**, taking into account the guidance and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union law, **including data protection, consumer protection and audiovisual media services**, the national competent authorities under that Union law

shall be consulted, as appropriate.

Amendment 23

Proposal for a regulation

Article 1 – paragraph 1 – point 24

Regulation (EU) 2024/1689

Article 72 – paragraph 3

Text proposed by the Commission

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan.

Amendment

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan, ***including practical examples for high-risk AI systems deployed in education and vocational training and other public services, and on monitoring indicators that may signal adverse impacts on fundamental rights, including discriminatory outcomes.***

Amendment 24

Proposal for a regulation

Article 1 – paragraph 1 – point 27

Regulation (EU) 2024/1689

Article 95 – paragraph 4

Text proposed by the Commission

4. The AI Office and the Member States shall take into account the specific interests and needs of SMCs and SMEs, including start-ups, when encouraging and facilitating the drawing up of codes of conduct.

Amendment

4. The AI Office and the Member States shall take into account the specific interests and needs of SMCs and SMEs, including start-ups, ***as well as the operational needs of local public authorities and public-interest organisations, including education, training and cultural institutions, where they are expected to use or benefit from such codes,*** when encouraging and facilitating the drawing up of codes of

conduct.

Amendment 25

Proposal for a regulation

Article 1 – paragraph 1 – point 28

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 2

Text proposed by the Commission

When issuing such guidelines, the Commission shall pay particular attention to the needs of SMCs and SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation.

Amendment

When issuing such guidelines, the Commission shall pay particular attention to the needs of SMCs and SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation, ***including education and vocational training, cultural and creative activities, and media and information services.***

Amendment 26

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

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 ***deployers and providers*** 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

2 August 2030.

down in this Regulation by 2 August 2030.

Amendment 27

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

Amendment

(b) the following paragraph 4 is added:

deleted

‘4. Providers of AI systems, including general-purpose AI systems, generating 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 28

Proposal for a regulation

Article 1 – paragraph 1 – point 31

Regulation (EU) 2024/1689

Article 113

Text proposed by the Commission

Amendment

(31) Article 113 is amended as follows:

deleted

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

‘(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:

(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.;

(b) in the third paragraph, point (e) is added:

‘(e) Articles 102 to 110 shall apply from [the date of entry into application of this Regulation].;’

Amendment 29

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Text proposed by the Commission

Amendment

(32) in Annex VIII, section B is deleted;

deleted

ANNEX: DECLARATION OF INPUT

The rapporteur for opinion declares under her exclusive responsibility that she did not include in her opinion input from interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register¹, or from representatives of public authorities of third countries, including their diplomatic missions and embassies, to be listed in this Annex pursuant to Article 8 of Annex I to the Rules of Procedure.

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_interinstit/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	CULT 19.1.2026	
Rapporteur for the opinion Date appointed	Emma Rafowicz 20.1.2026	
Rule 59 – Joint committee procedure Date announced in plenary	19.1.2026	
Discussed in committee	9.2.2026	
Date adopted	5.3.2026	
Result of final vote	+: –: 0:	18 0 3

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

18	+
NI	Nikolaos Anadiotis
PPE	Maravillas Abadia Jover, Niels Geuking, Eleonora Meleti, Matej Tonin, Bogdan Andrzej Zdrojewski, Milan Zver
Renew	Laurence Farreng, Hristo Petrov, Brigitte van den Berg
S&D	Maria Guzenina, Nikos Papandreou, Emma Rafowicz, Birgit Sippel, Krzysztof Śmiszek
The Left	Carolina Morace
Verts/ALE	Diana Riba i Giner, Nela Riehl

0	-

3	0
ECR	Ivaylo Valchev
ESN	Irmhild Boßdorf
PfE	Catherine Griset

Key to symbols:

+ : in favour

- : against

0 : abstention

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

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

Text proposed by the Commission

(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

Amendment

(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*

to Commission Recommendation 2025/3500/EC⁵.

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 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>).

⁴ Commission Recommendation of 6 May 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>).

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

(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

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 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***

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.

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)

Text proposed by the Commission

Amendment

(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

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)***

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 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***

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.

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

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>).

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

(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.

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, coordination would be better streamlined and resources optimally utilised.

Amendment 13

Proposal for a regulation Recital 20

Text proposed by the Commission

(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.

Amendment

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

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

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

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

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)

(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)

Regulation (EU) 2024/1689

Article 3 – point 3

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 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;

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, **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

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 ***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 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

Amendment

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;

(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***

(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.

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

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

(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;

Amendment

(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, **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

Amendment

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

(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.

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, 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:

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

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

(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

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 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

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

‘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 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

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

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

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

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).;

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

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

Amendment

‘The AI Office *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.’;

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*

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.;

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 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 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

14. National competent authorities, ***the 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

Amendment

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

(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

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

Amendment

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. ***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

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 of their jurisdiction.;

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 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***

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.***'

obligations laid down in this Regulation
by 2 August 2030.;

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

Amendment

(b) *the following paragraph 4 is added:* **deleted**

‘4. Providers of AI systems, including general-purpose AI systems, generating 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 the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I. *deleted*

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

Amendment

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

(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 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

18.3.2026

LETTER OF THE COMMITTEE ON TRANSPORT AND TOURISM

Ms Anna Cavazzini
Chair
Committee on the Internal Market and Consumer Protection
BRUSSELS

Mr Javier Zarzalejos
Chair
Committee on Civil Liberties, Justice and Home Affairs
BRUSSELS

Subject: Opinion on 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))

Dear Chairs,

Under the procedure referred to above, the Committee on Transport and Tourism (TRAN) has been asked to submit an opinion to the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs. At their meeting of 11 February 2026, TRAN Coordinators decided to send the opinion in the form of a letter. TRAN adopted the following opinion at its meeting of 18 March 2026¹.

¹ The following were present for the final vote: Elissavet Vozemberg-Vrionidi (Chair), Sophia Kircher (Vice-Chair), Elena Kountoura (Vice-Chair), Virginijus Sinkevičius (Vice-Chair), Vivien Costanzo (rapporteur for opinion), Daniel Attard, Adrian-George Axinia, Rachel Blom, Nina Carberry, Benoit Cassart, Anna Maria Cisint, Johan Danielsson, Valérie Devaux, Carlo Fidanza, Jens Gieseke, Borja Giménez Larraz, Sérgio Gonçalves, Roman Haider, Dariusz Joński, François Kalfon, Martine Kemp, Willemien Koning, Merja Kyllönen, Elżbieta Katarzyna Łukacijewska, Milan Mazurek, Ștefan Mușoiu, Cynthia Ní Mhurchú, Jan-Christoph Oetjen, Philippe Olivier, Ana Miguel Pedro, Arash Saeidi, Marjan Šarec, Lena Schilling, Volker Schnurrbusch, Rosa Serrano Sierra, Stanislav Stoyanov, Maciej Wąsik, Roberts Zile.

General Remarks

1. The Committee on Transport and Tourism (TRAN) welcomes the objective of simplification under the Digital Omnibus on artificial intelligence (AI), hereafter ‘AI Omnibus’, and recognises the need to support a risk-based EU regulatory framework that is operational and innovation-friendly, while maintaining effective safeguards to ensure that AI systems are safe, transparent, accountable and respectful of fundamental rights.
2. Technological innovation in the EU transport sector is essential to strengthen its global competitiveness, to deliver safe, efficient, and sustainable transport systems for citizens and businesses, and to contribute to improved working conditions for the millions of workers who underpin the European mobility system.
3. AI is emerging as an important enabling technology to support EU transport policy objectives. AI is not a new phenomenon in the transport sector as it has been embedded in driver assistance systems, traffic management and operational optimisation tools for many years now. Examples of safety relevant systems already in use or in project phases include predictive maintenance systems in all transport modes, risk prediction and foreign object detection on runways in aviation, on track obstacle detection and train positioning in rail, autonomous vessels and collision detection systems in the maritime sector as well as advanced driver assistance systems and automated driving in road transport. Its role is expected to expand further, where it demonstrably contributes to improvements in safety and efficiency. In tourism, AI is reshaping the interaction between consumers, intermediaries and businesses.

Impact of the AI Omnibus on transport

4. The AI Omnibus introduces amendments to two key pieces of legislation: the AI Act (Regulation (EU) 2024/1689), which sets the regulatory framework for the use of AI across the EU, and the EASA Basic Regulation (Regulation (EU) 2018/1139) to ensure that AI integration in aviation maintains the highest standards of safety, efficiency, and accountability.
5. The extension of regulatory privileges from small and medium-sized enterprises (SMEs) to small-mid cap companies (SMCs) helps smaller and innovative EU companies active in AI-enabled transport systems, to scale up beyond the start-up phase without facing increased compliance burdens.
6. The extension of real-world testing possibilities to AI systems covered by Annex I, Section B, has a direct operational impact on transport. For technologies such as automated vehicles, exposure to complex traffic environments is essential to achieve technological maturity and for validating safety performance under real-world conditions. Facilitating these controlled operational scenarios is a decisive step toward accelerating the innovation cycle and the subsequent deployment of AI across European transport networks. They complement regulatory sandboxes by enabling a progression from controlled testing environments to real-world conditions once safety has been demonstrated. This approach strengthens public and consumer confidence and supports the rapid development and market uptake of innovative AI applications.
7. The Committee welcomes the amendments proposed by the AI Omnibus to the EASA Basic Regulation. These amendments would ensure that the existing safeguards for the use of high-risk AI systems, as set out in Chapter III, Section 2 of Regulation 2024/1689, also apply to

delegated or implementing acts provided for in seven additional articles of the EASA Regulation (Articles 27, 31, 32, 36, 39, 50 and 53). Despite the recent adoption of the AI Act, this update is necessary in light of the accelerating evolution of AI technologies and their potential deployment in additional civil aviation domains, including, for example, the medical assessment of air traffic controllers, ground-handling services and training.

8. Considering these points, the Committee stresses that swift adoption of the updated legal framework is essential to ensure legal certainty and a simplified regulatory environment.

9. TRAN notes that, given that most transport systems already fall under sectoral Union harmonization legislation, the effective implementation of AI safeguards will largely depend on how these requirements interact with and are integrated into existing regulatory frameworks and supervisory practices. It underlines that differences in regulatory structures and capacities across transport modes and Member States may result in uneven application of AI-related safeguards.

AI's potential for the transport and tourism sectors

10. AI's success as a key technology for the future of the transport and tourism sectors, contributing to important safety and efficiency gains must also go hand in hand with careful consideration of its social and environmental impacts. In particular, the use of natural resources and the outsourcing of skills and jobs outside Europe are important factors that should be taken into account when evaluating the overall cost-benefit of AI deployment in the sector.

Risks and safeguards

11. The contribution of AI to safety and sustainability will depend on responsible deployment, effective oversight and alignment with broader transport and tourism policy objectives. While AI can support efficiency gains in transport operations, its overall environmental impact must be carefully assessed.

12. The increasing integration of AI systems into transport and tourism operations represents not only technological innovation but also changes in the organisation of work, including the potential to optimise workflows and reduce routine or repetitive tasks. Automated driving systems and remote supervision models may significantly reshape the roles of drivers, dispatchers and operational staff, including through the emergence of remote monitoring, operation or control functions that can be performed from anywhere in the world.

13. As AI deployment progresses, it is important to consider its implications for work organisation, workforce skills and job profiles. Any organisational changes, including new operational and outsourcing models involving third countries, should ensure that the development of AI in the sector does not lead to the relocation of skills and jobs outside the Union and should contribute to upholding high working conditions and standards. Maintaining and developing a strong EU-based jobs and skills ecosystem within the EU is essential to supporting the Union's strategic autonomy and competitiveness.

Access to funding, capital and scale-up capabilities to support EU AI innovation

14. While the Committee notes that several initiatives exist at EU level that aim to stimulate and accelerate AI innovation in key industrial sectors, particularly in terms of autonomous

driving, such as the European Connected and Autonomous Vehicle Alliance and the Autonomous Drive Ambition Cities initiative announced in the Apply AI strategy to accelerate autonomous vehicle deployment, important barriers in accessing capital may hinder European companies from scaling up their businesses to compete on a par with other global companies.

15. While Europe has strong industrial players and innovative technology firms, many companies in AI and transport automation remain in the start-up, early scale-up phase or leave the EU at an early stage. TRAN therefore calls on the Commission and the Member States to examine instruments and mechanisms allowing public-private partnerships and incentivising venture capital to bridge the gap between the start-up and SME phase, while ensuring that public and private investment promotes energy-efficient, safe, interoperable and open AI solutions that strengthen sustainability, resilience and Europe's technological sovereignty.

Strategic autonomy

16. Given that the AI Act, notably its rules on high-risk systems, affects transport, TRAN calls for coherence with EU transport objectives and digital sovereignty. As AI increasingly becomes integral to critical transport infrastructure, safeguards are needed to protect data sovereignty, avoid strategic dependencies and ensure enforceability of EU law.

17. In procurement for critical infrastructure, authorities should be able to require interoperable solutions, effective cyber security and operational control within the Union to ensure strategic security of supply and resilience.

National fragmentation

18. The Committee emphasises that the EU type-approval framework (Regulation (EU) 2018/858) and the General Safety Regulation (Regulation (EU) 2019/2144) provide a strong harmonised safety regime for the deployment of automated driving and other AI-enabled transport systems.

19. The extension of real-world testing in the AI Omnibus is a welcome step that creates greater opportunities for innovation. Well-designed safeguards help uphold safety standards while reinforcing trust in new AI technologies. Divergent national or regional testing and operational regimes may continue to hinder large-scale testing and deployment. Further harmonisation and convergence would strengthen legal certainty and the functioning of the internal market. Supporting the EU transport sector in fully benefiting from Europe's increasing digital competitiveness and more integrated data ecosystems is a priority.

Yours sincerely,

Elissavet Vozemberg-Vrionidi

ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur for opinion declares that she included in her opinion input on matters pertaining to the subject of the file that she 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
Bitkom e.V.
Bureau Européen des Unions de Consommateurs
Einride AB
European Transport Safety Council
Robert Bosch GmbH
TUI AG
2. Representatives of public authorities of third countries, including their diplomatic missions and embassies
None

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 she 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 RESPONSIBLE

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)			
Date submitted to Parliament	19.11.2025			
Committee(s) responsible Date announced in plenary	IMCO 19.1.2026	LIBE 19.1.2026		
Committees asked for opinions Date announced in plenary	BUDG 19.1.2026	ITRE 19.1.2026	TRAN 19.1.2026	CULT 19.1.2026
	JURI 19.1.2026			
Not delivering opinions Date of decision	BUDG 11.12.2025	ITRE 28.1.2026		
Rapporteurs Date appointed	Arba Kokalari 21.1.2026	Michael McNamara 21.1.2026		
Rule 59 – Joint committee procedure Date announced in plenary	19.1.2026			
Date adopted	18.3.2026			
Result of final vote	+: -: 0:	101 9 8		
Date tabled	19.3.2026			

**FINAL VOTE BY ROLL CALL
BY THE COMMITTEE RESPONSIBLE**

101	+
ECR	Michał Dworczyk, Assita Kanko, Piotr Müller, Gheorghe Piperea, Sebastian Tynkkynen, Ivaylo Valchev, Maciej Wąsik, Charlie Weimers
ESN	Tomasz Froelich, Milan Mazurek, Milan Uhrík, Petar Volgin, Ewa Zajączkowska-Hernik
NI	Malika Sorel
PPE	Magdalena Adamowicz, Peter Agius, Pablo Arias Echeverría, Hildegard Bentele, Krzysztof Brejza, Paulo Cunha, Dóra Dávid, Salvatore De Meo, Regina Doherty, Christian Doleschal, Arba Kokalari, Jeroen Lenaers, Lukas Mandl, Verena Mertens, Ana Miguel Pedro, Jessica Polfjård, Emil Radev, Oliver Schenk, Andreas Schwab, Tomislav Sokol, Susana Solís Pérez, Alice Teodorescu Măwe, Tomas Tobé, Dimitris Tsiodras, Adina Vălean, Sabine Verheyen, Loránt Vincze, Axel Voss, Elissavet Vozemberg-Vrionidi, Marion Walsmann, Isabel Wiseler-Lima, Javier Zarzalejos, Tomáš Zdechovský
PfE	Jorge Buxadé Villalba, Jaroslav Bžoch, Klara Dostalova, Marieke Ehlers, Catherine Griset, Virginie Joron, Fabrice Leggeri, Pierre Pimpie, Petra Steger, Alexandre Varaut
Renew	Jeannette Baljeu, Raquel García Hermida-Van Der Walle, Bart Groothuis, Anna-Maja Henriksson, Fabienne Keller, Moritz Körner, Morten Løkkegaard, Michael McNamara, Cynthia Ni Mhurchú, Hristo Petrov, Marie-Agnes Strack-Zimmermann, Jana Toom, Michal Wiezik, Sophie Wilmès
S&D	Marc Angel, Daniel Attard, Biljana Borzan, José Cepeda, Adnan Dibrani, Isilda Gomes, Elisabeth Grossmann, Maria Guzenina, Evin Incir, François Kalfon, Marina Kaljurand, Murielle Laurent, Juan Fernando López Aguilar, Matjaž Nemeč, Christel Schaldemose, Krzysztof Śmiszek, Marco Tarquinio, Carla Tavares, Georgia Tramacere, Kristian Vigenin, Alessandro Zan
The Left	Gaetano Pedulla'
Verts/ALE	Jaume Asens Llodrà, Anna Cavazzini, Daniel Freund, Katrin Langensiepen, Erik Marquardt, Leoluca Orlando, Tineke Strik, Kim Van Sparrentak

9	-
NI	Kateřina Konečná
PPE	Inese Vaidere
The Left	Konstantinos Arvanitis, Pernando Barrena Arza, Damien Carême, Leila Chaibi, Özlem Demirel, Luke Ming Flanagan
Verts/ALE	David Cormand

8	0
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ECR	Stefano Cavedagna, Paolo Insevlvini, Daniele Polato
NI	Erik Kaliňák
Renew	Sandro Gozi
S&D	Katarina Barley, Birgit Sippel, Cecilia Strada

Key to symbols:

+ : in favour

- : against

0 : abstention