



2025/0359(COD)

14.2.2026

AMENDMENTS 318 - 450

Draft report

Arba Kokalari, Michael McNamara
(PE782.530v01-00)

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)

Proposal for a regulation
(COM(2025)0836 – C10-0304/2025 – 2025/0359(COD))

Amendment 318

Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

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

(b) paragraph 1 is replaced by the following: **deleted**

‘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 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.

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

The authorities involved in the application of this Regulation shall cooperate actively

in the exercise of these powers, in particular where enforcement actions need to be taken in the territory of a Member State.’;

Or. en

Amendment 319

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jouvét, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

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. ***However, 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 paragraph (9) of this Regulation.***

Amendment 320
Regina Doherty

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 ***have competence*** for the supervision and enforcement of that system with the obligations of this Regulation ***in collaboration with Member State Regulators and other Authorities designated by the Member States***, in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.

Or. en

Amendment 321
Arba Kokalari

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 AI systems referred to in Annex III, point 2**, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.

Or. en

Amendment 322
Stefano Cavedagna

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***

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 ***or by providers belonging to the same group of undertakings***, the AI Office shall be exclusively competent for the supervision

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.

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

Or. en

Justification

The current wording limits AI Office competence to cases where the model and system are developed by the “same provider”. This creates a regulatory gap for vertically integrated corporate groups where different legal entities within the same group develop the model and the system respectively. Extending the scope to providers “belonging to the same group of undertakings” ensures consistent oversight of AI value chains within corporate groups, aligning with the rationale of centralised supervision for integrated AI development.

Amendment 323

Piotr Müller, Assita Kanko

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***

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 ***the*** model and ***the*** system are developed by the same provider, the AI Office shall ***have powers to monitor and supervise compliance*** of that AI system with obligations under this Regulation. ***To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and*** Regulation (EU) 2019/1020.

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

Or. en

Justification

The current experience stemming from the implementation of the DSA indicates that there should be no immediate transfer of powers from the competent national authorities to the Commission. Instead, collaboration between authorities shall be promoted. Therefore, the text reverts to the original version of Article 75, while retaining only limited changes from the Omnibus proposal.

Amendment 324

Virginie Joron, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

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 AI systems referred to in Annex III, point 2***, and that model and that system are developed by the same provider, the AI Office ***may issue non-binding recommendations to market authorities to ensure the monitoring*** of that system ***and to assess compliance*** with the obligations ***laid down in*** this Regulation.

Amendment 325
Arba Kokalari

Proposal for a regulation
Article 1 – paragraph 1 – point 25 – point b a (new)
Regulation (EU) 2024/1689
Article 75 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(ba) the following paragraph 1a is inserted:

‘1a. The AI Office and national competent authorities shall integrate innovation and competitiveness as guiding principles informing their work on this Regulation.’;

Amendment 326
Piotr Müller, Assita Kanko

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

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 be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

deleted

Justification

As per other changes to point 25.

Amendment 327

Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

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

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 be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

deleted

Or. en

Amendment 328

Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

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

Amendment

When exercising its tasks of supervision and enforcement under the first

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

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 enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis. ***The Commission shall ensure that the AI Office has the necessary technical, financial and human resources and infrastructure to fulfil its tasks effectively under this Regulation. In particular it shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, including general-purpose AI.***

Or. en

Amendment 329

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jouvét, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

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

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

mutatis mutandis.

Or. en

Amendment 330

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jovet, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

(ba) in paragraph 1, subparagraph 3a is added:

‘The AI Office shall coordinate closely with the competent national data protection authorities when the aforementioned AI systems present risks to the fundamental rights to privacy and data protection, in compliance with Article 8 of the Charter of Fundamental Rights of the EU and in line with Article 2(7) of this Regulation.’;

Or. en

Amendment 331

Piotr Müller, Assita Kanko

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3

Text proposed by the Commission

Amendment

The authorities involved in the application of this Regulation shall cooperate actively in the exercise of ***these powers, in particular where enforcement actions***

The authorities involved in the application of this Regulation shall cooperate actively in the exercise of ***this Regulation.***;

need to be taken in the territory of a Member State.;

Or. en

Justification

As per other changes to point 25.

Amendment 332

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3

Text proposed by the Commission

The authorities ***involved in the application of this Regulation*** shall cooperate actively in the exercise of these powers, in particular where enforcement actions need to be taken in the territory of a Member State.;

Amendment

The ***market surveillance*** authorities shall cooperate actively in the exercise of these powers, in particular where enforcement actions need to be taken in the territory of a Member State.;

Or. en

Amendment 333

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Juvet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

(ba) in paragraph 1, subparagraph 3a is added:

‘The AI Office shall coordinate closely with the competent national data protection authorities when the

aforementioned AI systems present risks to the fundamental rights to privacy and data protection, in compliance with Article 8 of the Charter of Fundamental Rights of the EU and in line with Article 2(7) of this Regulation.’;

Or. en

Amendment 334
Stefano Cavedagna

Proposal for a regulation
Article 1 – paragraph 1 – point 25 – point b a (new)
Regulation (EU) 2024/1689
Article 75 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(ba) the following paragraph 1a is inserted:

‘1a. The Commission is empowered to establish an independent conformity assessment body for the purpose of carrying out third-party conformity assessments under Article 43 with respect to high-risk AI systems referred to in paragraph 1. For this purpose, the Commission shall assume the role equivalent to a notifying authority and shall comply with the requirements for notifying authorities as set out in Section 4 of Chapter III, mutatis mutandis. The conformity assessment body shall assume the role equivalent to a notified body and shall comply with the requirements for notified bodies as set out in Section 4 of Chapter III, mutatis mutandis, including as regards independence and competence. A provider who is required to undergo a third-party conformity assessment with respect to high-risk AI systems referred to in paragraph 1 may choose to use this conformity assessment body as an alternative to any other notified body designated under Section 4 of Chapter

III.;

Or. en

Justification

The Commission's original proposal grants exclusive competence to the AI Office for the supervision and enforcement of AI systems based on general-purpose AI models developed by the same provider. However, it also mandates that the Commission directly organise pre-market conformity assessments for these systems. This creates a potential conflict of interest, as the same institution would be responsible for both enforcement and conformity assessment. The proposed amendment addresses this concern by empowering the Commission to establish an independent conformity assessment body, structurally separate from the AI Office. This body would operate under the same requirements applicable to notified bodies under Section 4 of Chapter III, ensuring independence, competence, and impartiality. Crucially, providers retain the choice to use this body or any other competent notified body, thereby preserving market competition in conformity assessment services and avoiding regulatory bottlenecks. This approach aligns with the principles underlying the New Legislative Framework and ensures that providers of AI systems based on general-purpose AI models are not subject to a monopolistic conformity assessment regime.

Amendment 335

Piotr Müller, Assita Kanko

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

Text proposed by the Commission

Amendment

(c) the following paragraphs 1a to 1c are inserted: *deleted*

‘1a. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision

tasks under this Article.

1b. Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to providers of AI systems referred to in paragraph 1, without prejudice to more specific procedural rights provided for in this Regulation.

1c. 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 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.

The fees for testing and assessment activities shall be levied on the provider of a high-risk AI system who has applied for third-party conformity assessment to the Commission. The costs related to the services entrusted by the Commission to the notified bodies in accordance with this Article shall be directly paid by the provider to the notified body.’;

Or. en

Justification

Concentrating regulatory, enforcement and conformity assessment functions in the Commission risks undermining institutional impartiality, legal certainty and the system of mutual trust on which the internal market is based. EU product safety legislation relies on a functional separation between rule-making, technical standard setting, independent

conformity assessment and market surveillance. Blurring these roles creates a perception of the Commission both defining and judging compliance with its own rules and weakens the independence of notified bodies.

Amendment 336

Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

Text proposed by the Commission

Amendment

(c) *the following paragraphs 1a to 1c are inserted:* ***deleted***

‘1a. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision tasks under this Article.

1b. Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to providers of AI systems referred to in paragraph 1, without prejudice to more specific procedural rights provided for in this Regulation.

1c. 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

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.

The fees for testing and assessment activities shall be levied on the provider of a high-risk AI system who has applied for third-party conformity assessment to the Commission. The costs related to the services entrusted by the Commission to the notified bodies in accordance with this Article shall be directly paid by the provider to the notified body.’;

Or. en

Amendment 337

Zala Tomašič, Tomáš Zdechovský, Jan Farský, Alexandr Vondra, Ondřej Krutílek

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

Text proposed by the Commission

1a. The Commission shall *adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other administrative sanctions*, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-

Amendment

1a. 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 that the systems comply with the relevant requirements of this Regulation and may*

compliant with this Regulation, *in the context of its monitoring and supervision tasks* under this Article.

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. *In organising and carrying out such tests and assessments, the Commission shall ensure proportionate, SME- and SMC-friendly procedures, including simplified documentation and reduced administrative burden, without lowering the level of protection provided by this Regulation.*

Or. en

Justification

This amendment ensures that pre-market conformity assessments organised by the Commission remain proportionate in practice and do not create disproportionate procedural and documentation burdens for SMEs and small mid-caps. By requiring SME- and SMC-friendly procedures, such as simplified documentation and reduced administrative steps, it supports effective market access and avoids compliance bottlenecks, while expressly maintaining the same level of protection and regulatory objectives under the AI Act.

Amendment 338

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

Text proposed by the Commission

1a. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including

Amendment

1a. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including

its **ability** to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision tasks under this Article.

its **duty** to impose penalties, such as fines or other administrative sanctions **whenever the law is not respected**, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision tasks under this Article.

Or. en

Amendment 339

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a a (new)

Text proposed by the Commission

Amendment

1aa. Where the Commission has not initiated proceedings for the same infringement, the 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 resides or is established, shall have powers to supervise and enforce the obligations under this Regulation, with respect to those providers.

Or. en

Amendment 340

Michael McNamara, Svenja Hahn

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Text proposed by the Commission

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 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.

Amendment

The Commission **may, where it deems it necessary and subject to Article 28(8),** 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 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. **Where it does not deem it necessary to carry out the pre-market conformity assessment itself,** 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.

Or. en

Amendment 341
Regina Doherty

Proposal for a regulation
Article 1 – paragraph 1 – point 25 a (new)
Regulation (EU) 2024/1689
Article 75 a (new)

Text proposed by the Commission

Amendment

(25a) The following article is inserted:

‘Article 75a

The AI Office shall have the promotion of innovation, competitiveness, and

economic growth as central objectives informing its work and integrated into its activities. The AI Office shall report annually on how it met these objectives.’;

Or. en

Amendment 342

Leila Chaibi, Pernando Barrena Arza
on behalf of The Left Group

Proposal for a regulation

Article 1 – paragraph 1 – point 26

Regulation (EU) 2024/1689

Article 77

Text proposed by the Commission

Amendment

(26) Article 77 is amended as follows:

deleted

(a) the heading is replaced by the following:

‘Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities’

(b) paragraph 1 is replaced by the following:

‘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.’;

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

‘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.

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.’;

Or. en

Amendment 343

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jovet, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point b

Regulation (EU) 2024/1689

Article 77 – paragraph 1

Text proposed by the Commission

1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this

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

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 is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, this article does 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.***;

Or. en

Amendment 344

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Juvet, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 345

Stefano Cavedagna

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c

Regulation (EU) 2024/1689

Article 77 – paragraph 1 a

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. ***In this case, the request must take into account the size and capabilities of the deployer.***

Or. en

Justification

While welcoming the strengthening of cooperation provided for in Article 77, it is considered essential that requests for information by the competent authorities remain targeted and proportionate to the size and capacity of the companies from which the information is requested.

Amendment 346

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jovet, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c

Regulation (EU) 2024/1689

Article 77 – paragraph 1 a

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. 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 ***without delay and no later than one month after receiving the request.***

Or. en

Amendment 347

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jovet, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c

Regulation (EU) 2024/1689

Article 77 – paragraph 1 b

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 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.;

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

Or. en

Amendment 348

Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jovet, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point c

Regulation (EU) 2024/1689

Article 77 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

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

the request. The market surveillance authority shall not refuse to comply with the request unless: a) the requesting authority is not competent for the subject-matter of the request or for the measures it is requested to execute; or b) compliance with the request would infringe this Regulation or Union or Member State law to which the market surveillance authority receiving the request is subject.

Or. en

Amendment 349
Piotr Müller, Assita Kanko

Proposal for a regulation
Article 1 – paragraph 1 – point 26 a (new)
Regulation (EU) 2024/1689
Article 80 a (new)

Text proposed by the Commission

Amendment

(26a) The following article is inserted:

‘Article 80a

Record-keeping and transparency of supervisory communications

Competent national authorities and the AI Office shall maintain organised and retrievable records of communications with providers and deployers of general-purpose AI models with systemic risk concerning the application or interpretation of obligations under this Regulation, in particular those laid down in Article 55(1), point (b). Such records shall be documented in a consistent manner and made available, where appropriate and without prejudice to trade-secret protections, for the purposes of parliamentary oversight, cooperation between authorities and judicial review.’;

Or. en

Justification

Establishing a clear obligation to record and systematically organise supervisory communications is necessary to ensure transparency, accountability, democratic oversight and equal treatment of economic operators, in particular with regard to the interpretation and application of the notion of systemic risk and related obligations. Furthermore, it would enable effective judicial and parliamentary scrutiny, while fully preserving the protection of trade secrets.

Amendment 350

Henrik Dahl

Proposal for a regulation

Article 1 – paragraph 1 – point 26 a (new)

Regulation (EU) 2024/1689

Article 82

Text proposed by the Commission

Amendment

(26a) Article 82 is deleted.

Or. en

Justification

The article undermines legal certainty and predictability for providers, because an AI system that is compliant may still face further requirements or restrictions from national authorities. This could lead to fragmentation of the internal market, as different Member States may introduce various additional requirements.

Amendment 351

Piotr Müller, Assita Kanko

Proposal for a regulation

Article 1 – paragraph 1 – point 26 b (new)

Regulation (EU) 2024/1689

Article 92 – paragraph 3

Present text

Amendment

(26b) in Article 92, paragraph 3 is amended as follows:

3. For the purposes of paragraph 1, the

‘3. For the purposes of paragraph 1, the

Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools, ***including source code***.

Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools.’;

Or. en

Justification

Compulsory disclosure of proprietary source code would expose sensitive security and trade-secret information, yet add only marginal oversight benefits given the existing transparency, documentation and audit tools already available under the AI Act.

Amendment 352 **Kateřina Konečná**

Proposal for a regulation
Article 1 – paragraph 1 – point 27
Regulation (EU) 2024/1689
Article 95 – paragraph 4

Text proposed by the Commission

Amendment

(27) Article 95, paragraph 4 is replaced by the following: ***deleted***

‘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.’;

Or. en

Amendment 353 **Leila Chaibi, Pernando Barrena Arza** on behalf of The Left Group

Proposal for a regulation
Article 1 – paragraph 1 – point 27
Regulation (EU) 2024/1689
Article 95 – paragraph 4

Text proposed by the Commission

Amendment

(27) Article 95, paragraph 4 is replaced by the following: *deleted*

‘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.’;

Or. en

Amendment 354

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jouvét, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

Article 1 – paragraph 1 – point 27

Regulation (EU) 2024/1689

Article 95 – paragraph 4

Text proposed by the Commission

Amendment

(27) Article 95, paragraph 4 is replaced by the following: *deleted*

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.;

Or. en

Amendment 355

Leila Chaibi, Pernando Barrena Arza
on behalf of The Left Group

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

Amendment

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

‘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.’;

Or. en

Amendment 356
Kateřina Konečná

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

Amendment

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

‘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.’;

Or. en

Amendment 357
Axel Voss, Arba Kokalari

Proposal for a regulation
Article 1 – paragraph 1 – point 28 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 358
Tomáš Zdechovský

Proposal for a regulation
Article 1 – paragraph 1 – point 27 a (new)
Regulation (EU) 2024/1689
Article 96 – paragraph 1 – subparagraph 1 – point a

Present text

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

Amendment

(27a) in Article 96, paragraph 1, subparagraph 1, point (a) is replaced by the following:

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

Or. en

Justification

This amendment reflects concerns of the industry about the lack of guidance on Article 26 (Obligations of deployers of high-risk AI systems).

Amendment 359
Lukas Mandl, Sander Smit

Proposal for a regulation
Article 1 – paragraph 1 – point 27 a (new)
Regulation (EU) 2024/1689
Article 96 – paragraph 1 – subparagraph 1 – point a

Present text

Amendment

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

(27a) in Article 96, paragraph 1, subparagraph 1, point (a) is replaced by the following:

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

Or. en

Justification

This amendment reflects concerns of the industry about the lack of guidance on Article 26 (Obligations of deployers of high-risk AI systems). The guidelines of the Commission on the practical implementation of this Regulation should therefore particularly focus on Article 26, among others.

Amendment 360

Axel Voss, Arba Kokalari

Proposal for a regulation

Article 1 – paragraph 1 – point 28 a (new)

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1 – point a

Present text

Amendment

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

(28a) Article 96, paragraph 1, subparagraph 1, point (a) is replaced by the following:

"(a) the application of the requirements and obligations referred to in Articles 8 to 15 and in Article 25 **and 26**";

Or. en

(Regulation (EU) 2024/1689)

Justification

This amendment reflects concerns of the industry about the lack of guidance on Article 26 (Obligations of deployers of high-risk AI systems). The guidelines of the Commission on the practical implementation of this Regulation should therefore particularly focus on Article 26, among others.

Amendment 361

Axel Voss

Proposal for a regulation

Article 1 – paragraph 1 – point 28 b (new)

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1 – point g (new)

Text proposed by the Commission

Amendment

(28b) in Article 96, paragraph 1, subparagraph 1, the following point is inserted:

‘(g) the application of the requirements and obligations referred to in Article 27, including the possibility for the fundamental rights impact assessment to be represented by the data protection impact assessment pursuant to Article 27(4) of this Regulation, using, where relevant, standardised templates, checklists and best-practice measures.’;

Or. en

Justification

This amendment reflects the difficulty of the industry to comply with requirements laid out in Article 27 on fundamental rights impact assessment for high-risk AI systems. Therefore, it requires the Commission to create guidelines on the practical implementation of this article, including specifically on the interplay between the fundamental rights impact assessments and the data protection impact assessments.

Amendment 362

Stefano Cavedagna

Proposal for a regulation

Article 1 – paragraph 1 – point 27 a (new)

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(27a) in Article 96, paragraph 1, subparagraph 1, the following point is

inserted:

‘(fa) the practical application of the AI Act’s research exemptions under Article 2(6) and (8), including information on how they apply in sectoral contexts, such as in pre-clinical research, clinical studies and product development in the field of medicinal products or medical devices.’;

Or. en

Justification

Although the AI Act explicitly excludes from its rules AI models and systems for the sole purpose of scientific R&D, practical and legally binding guidelines are needed to ensure legal certainty and avoid excessive regulatory burdens for companies using artificial intelligence in these activities.

Amendment 363

Lukas Mandl, Sander Smit

Proposal for a regulation

Article 1 – paragraph 1 – point 27 a (new)

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(27a) in Article 96, paragraph 1, subparagraph 1, point (fa) is inserted:

‘(fa) the application of the requirements and obligations referred to in Article 27, including the possibility for the fundamental rights impact assessment to be represented by the data protection impact assessment pursuant to Article 27(4) of this Regulation, using, where relevant, standardised templates, checklists and best-practice measures.’;

Or. en

Justification

This amendment reflects the difficulty of the industry to comply with requirements laid out in Article 27 on fundamental rights impact assessment for high-risk AI systems. Therefore, it

requires the Commission to create guidelines on the practical implementation of this article, including specifically on the interplay between the fundamental rights impact assessments and the data protection impact assessments.

Amendment 364

Tomáš Zdechovský

Proposal for a regulation

Article 1 – paragraph 1 – point 27 a (new)

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(27a) in Article 96, paragraph 1, subparagraph 1, point (fa) is inserted:

‘(fa) the application of the requirements and obligations referred to in Article 27, including the possibility for the fundamental rights impact assessment to be represented by the data protection impact assessment pursuant to Article 27(4) of this Regulation, using, where relevant, standardised templates, checklists and best-practice measures.’;

Or. en

Justification

This amendment reflects the difficulty of the industry to comply with requirements laid out in Article 27 on fundamental rights impact assessment for high-risk AI systems. Therefore, it requires the Commission to create guidelines on the practical implementation of this article, including specifically on the interplay between the fundamental rights impact assessments and the data protection impact assessments.

Amendment 365

Virginie Joron, Jaroslav Bžoch, Klara Dostalova, Jorge Martín Frías, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 28 a (new)

Regulation (EU) 2024/1689

Article 96 – paragraph 2

Present text

Amendment

2. At the request of the Member States or the AI Office, or on its own initiative, the Commission shall update guidelines previously adopted when deemed necessary.

(28a) in Article 96, paragraph 2 is replaced by the following:

2. At the request of the Member States, the Commission shall update guidelines previously adopted when deemed necessary.'

Or. en

Amendment 366

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

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

Amendment

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

deleted

‘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.’;

Or. en

Amendment 367

Leila Chaibi, Pernando Barrena Arza
on behalf of The Left Group

Proposal for a regulation

Article 1 – paragraph 1 – point 29

Text proposed by the Commission

Amendment

(29) Article 99 is amended as follows: *deleted*

(a) paragraph 1 is replaced by the following:

‘1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of SMCs and SMEs, including start-ups, and their economic viability when imposing penalties.’;

(b) paragraph 6 is replaced by the following:

‘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.’;

Or. en

Amendment 368

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jouvet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

Article 1 – paragraph 1 – point 29

Text proposed by the Commission

Amendment

(29) Article 99 is amended as follows: *deleted*

(a) paragraph 1 is replaced by the following:

‘1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of SMCs and SMEs, including start-ups, and their economic viability when imposing penalties.’;

(b) paragraph 6 is replaced by the following:

‘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.’;

Or. en

**Amendment 369
Regina Doherty**

**Proposal for a regulation
Article 1 – paragraph 1 – point 29 – point a
Regulation (EU) 2024/1689
Article 99 – paragraph 1**

Text proposed by the Commission

1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of SMCs and SMEs, including start-ups, and their economic viability when imposing penalties.;

Amendment

1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96, ***while not creating unjustified market distortions***. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of SMCs and SMEs, including start-ups, and their economic viability when imposing penalties.;

Or. en

Amendment 370
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1 – point 29 – point a
Regulation (EU) 2024/1689
Article 99 – paragraph 1

Text proposed by the Commission

1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued

Amendment

1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued

by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of **SMCs and** SMEs, including start-ups, and their economic viability when imposing penalties.;

by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall take into account the interests of SMEs, including start-ups, and their economic viability when imposing penalties.;

Or. en

Amendment 371

Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a
Regulation (EU) 2024/1689
Article 111 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 372

Axel Voss

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 99 – paragraph 4 - point d a (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 GPAI model providers, pursuant to Article 25(2), (3) and (4);’;

Or. en

Justification

This last-minute flaw in the technical trilogues creates an enforcement gap in the value-chain rules: cooperation and information-sharing duties under Article 25 risk becoming largely “paper obligations” if they are not backed by an effective sanctioning hook. In practice, downstream providers - often EU SMEs and Start-Ups - depend on timely, accurate technical information and reasonable assistance from upstream actors to meet their own high-risk compliance duties, especially after rebranding or substantial modification. Re-including Article 25(2) - (4) in Article 99(4) ensures that failures to provide substantive cooperation (not only the failure to sign an agreement) can be addressed consistently by competent authorities and the AI Office. This supports a workable allocation of responsibilities along the AI value chain, strengthens enforceability of Article 25, and improves legal certainty for European firms integrating GPAI into regulated AI products and services.

Amendment 373

Kateřina Konečná

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

Amendment

(b) paragraph 6 is replaced by the following: ***deleted***

‘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.’;

Or. en

Amendment 374

Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

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

Amendment

(b) *paragraph 6 is replaced by the following:*

deleted

‘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.’;*

Or. en

Amendment 375

Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller

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

Amendment

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.;*

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 **for***

Amendment 376

Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation

Article 1 – paragraph 1 – point 30

Regulation (EU)2024/1689

Article 111

Text proposed by the Commission

Amendment

(30) Article 111 is amended as follows: *deleted*

(a) paragraph 2 is replaced by the following:

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

(b) the following paragraph 4 is added:

‘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 377
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1 – point 30
Regulation (EU) 2024/1689
Article 111

Text proposed by the Commission

Amendment

(30) *Article 111 is amended as follows:* **deleted**

(a) *paragraph 2 is replaced by the following:*

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

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

‘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 378

Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller, Laurence Farreng

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

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 operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.;

deleted

Or. en

Amendment 379

Stefano Cavedagna

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

Amendment

2. Without prejudice to the application of Article 5 as referred to in Article 113(3),

2. Without prejudice to the application of Article 5 as referred to in Article 113(3),

third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. ***In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.***

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.;

Or. en

Justification

Compared to the public sector's compliance timeframe of August 2030, it appears significantly longer than the deadlines applicable to micro and SMEs, despite the former having significantly greater resources. This disparity seems difficult to justify, especially considering that the use of AI by public authorities often entails higher risks than enterprise applications.

Amendment 380

Leila Chaibi, Pernando Barrena Arza

on behalf of The Left Group

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***

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 ***2 August 2026*** only if, as from that date, those

obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, *the providers and deployers of high-risk AI systems intended to be used by public authorities* shall *take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.*;

systems are subject to significant changes in their designs. In any case, *they shall be brought into compliance with this Regulation by 31 December 2030.*

Or. en

Amendment 381

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a

Regulation (EU) 2024/1689

Article 111 – paragraph 2

Text proposed by the Commission

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

Amendment

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to 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 **2 August 2026**, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August **2028.**;

Or. en

Amendment 382

Axel Voss, Arba Kokalari

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a

Regulation (EU) 2024/1689

Article 111 – paragraph 2

Text proposed by the Commission

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

Amendment

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to 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 **substantial modification** in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.;

Or. en

Justification

To align the paragraph with the 2022 NLF Blue Guide standard term that is also used in the remaining parts of the EU AI Act.

Amendment 383

Sabine Verheyen, Bogdan Andrzej Zdrojewski

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

Regulation (EU) 2024/1689

Article 111 – paragraph 4

Text proposed by the Commission

(b) the following paragraph 4 is

Amendment

deleted

added:

‘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.’;

Or. en

Justification

The deletion is justified, as the amendment would harm the creative sector and cultural heritage, and it could create legal inconsistency within Article 50. Moreover, it could undermine European competitiveness, as it would benefit only providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content that were placed on the market before 2 August 2026, which are predominantly non-European providers.

Amendment 384

Leila Chaibi, Pernando Barrena Arza
on behalf of The Left Group

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 *deleted*
added:

‘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.’;

Or. en

Amendment 385

Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller, Laurence Farreng

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.’;

Or. en

Amendment 386

Stefano Cavedagna

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.’;

Or. en

Justification

The Omnibus amendment to Article 111 of the AI Act grants providers a transitional period until February 2, 2027 for content marking obligations, but the Code of Practice defining technical compliance will only be finalized near that date. More critically, deployers subject to Article 50, paragraph 4 obligations receive no transitional period despite depending entirely on providers' technical solutions and Code of Practice specifications to fulfil their transparency obligations toward end users. This asymmetry creates significant legal uncertainty and exposes deployers to liability without adequate means of compliance. This amendment, together with the following amendment to article 113, aims to improve legal certainty by setting a uniform date for both providers and deployers.

Amendment 387

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Juvet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

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.’;

Or. en

Amendment 388

Piotr Müller, Assita Kanko

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.;

Or. en

Justification

This part becomes irrelevant after moving it to Article 113 (point 31, subpoint a).

Amendment 389

Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Laurence Farreng

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.’;

Or. en

Amendment 390

Regina Doherty

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

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 shall take the necessary steps in order to comply with Article 50(2) by 2 February **2028**.;

Or. en

Amendment 391

Christian Doleschal

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

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, shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;

Or. en

Amendment 392

Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

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 shall take the necessary steps in order to comply with Article 50(2) **and 50(4) by 2 August 2027**.;

Or. en

Justification

Adapting to reality. The Commission aims at finalizing the Code of Practice possibly in June 2026, which would make an immediate application for all Systems put on the market as of August 2026 practically impossible.

Amendment 393

Zala Tomašič, Jan Farský, Alexandr Vondra, Ondřej Krutílek

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

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 **video** content, that have been placed on the market before 2 August **2027** shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;

Or. en

Justification

The obligation to ensure machine-readable marking is appropriate for synthetic audio, image and video content, but not for text. Text is continuously edited, reformatted and reused across contexts, which makes reliable machine-readable marking technically infeasible and disproportionate, while providing limited added value for transparency.

Amendment 394

Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

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

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 **August** 2027.;

Or. en

Amendment 395

Tomáš Zdechovský

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

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 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;

Or. en

Justification

Avoiding 2 tier model for simplification

Amendment 396
Sandro Gozi, Stéphanie Yon-Courtin

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].’;

Or. en

Amendment 397
Kateřina Konečná

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].’;

Or. en

Amendment 398
Fabienne Keller

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].’;

Or. en

Amendment 399

Sabine Verheyen, Bogdan Andrzej Zdrojewski

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

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, Section 1, 2, and 3 shall apply from 2 August 2028 for all high-risk AI systems pursuant to Article 6(1) and Annex I and Article 6(2) and Annex III. The Commission shall adopt all remaining pieces of secondary legislation and guidelines without undue delay.

(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;

Or. en

**Amendment 400
Fabienne Keller**

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point c a (new)

Text proposed by the Commission

Amendment

(aa) in Article 113, paragraph 3, the following point (ca) is added:

‘(ca) Chapter III, Sections 1, 2, and 3, shall apply (i) on 2 February 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III,‘

Or. en

**Amendment 401
Mary Khan**

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 1

Text proposed by the Commission

Amendment

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:

deleted

(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.

Or. en

Amendment 402

Leila Chaibi, Pernando Barrena Arza
on behalf of The Left Group

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a
Regulation (EU) 2024/1689
Article 113 – paragraph 3 – point d

Text proposed by the Commission

(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

Amendment

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

(i) on 1 December 2026 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(ii) on 1 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.;

Notwithstanding the above, obligations under

Article 6(2) and Annex III, and

(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;

(i) Article 6(2)-(8)

(ii) Article 13 (2)-(3)

(iii) Article 26 and

(iii) Article 27 shall apply from 2 August 2026 to the extent that compliance is possible independently of the remaining provisions under Chapter III, Sections 1, 2 and 3.

Or. en

Amendment 403

Zala Tomašič, Tomáš Zdechovský, Jan Farský, Alexandr Vondra, Ondřej Krutílek

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

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) Subject to a Commission decision confirming the availability of adequate compliance support measures, Chapter III (Sections 1, 2 and 3) shall apply from 2 August 2028 to AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and to AI systems classified as high-risk pursuant to Article 6(1) and Annex I.

(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;

Or. en

Justification

Implementation periods of 6–12 months are unrealistic for high-risk AI providers. Many industrial AI systems are embedded in operational technologies and critical infrastructure, and compliance (risk management, data governance, documentation, QMS, human oversight, robustness, cybersecurity) is a major undertaking. With standards now expected only in 2026/27, industry and authorities need at least 12 months after OJEU listing. Firm, unconditional dates are essential.

Amendment 404

Axel Voss

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

(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.

Amendment

(d) 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.;

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;

Or. en

Justification

Council wording from 23 January 2026 to provide a high level of legal certainty for the EU AI market.

Amendment 405

Jaroslav Bžoch, Klara Dostalova

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

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:*

Chapter III, Sections 1, 2, and 3, shall apply:

Or. en

Amendment 406

Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

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

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:*

Chapter III, Sections 1, 2, and 3, shall apply:

Or. en

Amendment 407

Regina Doherty

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 - paragraph 3 – point d

Text proposed by the Commission

Amendment

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:*

Chapter III, Sections 1, 2, and 3, shall apply *on the 2 August 2028.*

Or. en

Amendment 408

Michael McNamara, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

(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;

Amendment

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

Or. en

Amendment 409

Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

Chapter III, Sections 1, 2, and 3, shall apply ***following the adoption of a decision***

Amendment

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

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;*

apply:

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

Or. en

Amendment 410

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jouvét, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a
Regulation (EU) 2024/1689
Article 113 – paragraph 3 – point d

Text proposed by the Commission

(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*

Amendment

(d) Chapter III, Sections 1, 2, and 3, shall apply *on 2 August 2027 as regards AI systems classified as high-risk pursuant to Article 6(1) and (2) and Annexes I and III;*

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;

Or. en

Amendment 411

Piotr Müller, Assita Kanko

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

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

Amendment

Chapter III, Sections 1, 2, and 3, *with the exception of Article 6(5), Chapter IV, with the exception of Article 50(1), Article 50(3) and Article 50(4), and Chapter V shall apply on 2 August 2028.*

(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;

Or. en

Justification

In order to simplify the provisions covering application date, one, harmonised date in 2028 is introduced instead of complicated and conditional mechanism proposed by the Commission.

Amendment 412

Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – 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***

Or. en

Amendment 413

Christian Doleschal

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – 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*

Or. en

Amendment 414

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – 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*

Or. en

Amendment 415

Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point i

Text proposed by the Commission

Amendment

(i) 6 months after the adoption of that decision as regards AI systems classified as **(i) 12 months after the adoption of that decision as regards AI systems classified as**

high-risk pursuant to Article 6(2) and Annex III, and

high-risk pursuant to Article 6(2) and Annex III, and

Or. en

Amendment 416

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – 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

Or. en

Amendment 417

Christian Doleschal

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – 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

Or. en

Amendment 418

Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – 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*

Or. en

Amendment 419

Tomáš Zdechovský

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

Where harmonised standards or common specifications are not available by the deadlines referred to in Article 113, providers of high-risk AI systems shall be permitted to demonstrate compliance using Commission-endorsed standardised templates and documentation packages.

Or. en

Justification

This amendment ensures that regulatory delays do not block market access, while maintaining accountability and auditability.

Amendment 420

Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

Proposal for a regulation

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

Regulation 2024/1689
Article 113 – paragraph 3 – point d a (new)

Text proposed by the Commission

Amendment

(aa) *in the third paragraph, point (da) is inserted:*

(da) *The decisions referred to in point (d) shall be adopted no later than 2 August 2027.*

Or. en

Amendment 421

Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2

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

(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;

Or. en

Amendment 422

Jaroslav Bžoch, Virginie Joron, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

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***

(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;

Or. en

Amendment 423
Christian Doleschal

Proposal for a regulation
Article 1 – paragraph 1 – point 31 – point a
Regulation (EU) 2024/1689
Article 113 – paragraph 3 – point d – subparagraph 2

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***

(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;

Or. en

Amendment 424

Mary Khan

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

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:

Amendment

The application of specified obligations for high-risk AI systems shall be anchored in clear and fixed timelines. Where the application of high-risk requirements is deferred pending adoption of harmonised standards or common specifications, such deferrals should be subject to maximum time limits and take into account the readiness of relevant sectoral ecosystems. In particular, for AI systems that are subject to Union harmonisation legislation, the applicable timelines should reflect the complexity of conformity assessment procedures and market preparedness Chapter III, Sections 1, 2, and 3, shall apply:

Or. en

Amendment 425

Jaroslav Bžoch, Virginie Joron, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point i

Text proposed by the Commission

(i) on 2 **December 2027** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

Amendment

(i) on 2 **August 2028** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

Or. en

Amendment 426
Christian Doleschal

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 –point i

Text proposed by the Commission

Amendment

(i) on 2 **December 2027** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(i) on 2 **August 2028** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

Or. en

Amendment 427

Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 –point i

Text proposed by the Commission

Amendment

(i) on 2 **December 2027** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(i) on 2 **June 2028** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

Or. en

Justification

Aligning the timelines with industry realities. More time is needed in order to properly implement the provisions.

Amendment 428

Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point ii

Text proposed by the Commission

Amendment

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

(ii) on 2 **February 2029** as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.;

Or. en

Justification

Aligning the timelines with industry realities. More time is needed in order to properly implement the provisions.

Amendment 429

Christian Doleschal

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point ii

Text proposed by the Commission

Amendment

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

(ii) on 2 August **2029** as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.;

Or. en

Amendment 430

Mary Khan

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

(aa) in the third paragraph, point (d),

the following subparagraph is added:

2a. These application dates shall apply to all high-risk AI systems that are placed on the market or put into service before the extended deadlines apply.

Or. en

Amendment 431

Christian Doleschal

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point b

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point e

Text proposed by the Commission

Amendment

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

deleted

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

Or. en

Amendment 432

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point b

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point e

Text proposed by the Commission

Amendment

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

*(e) Articles 102 to 110 shall apply from [the date of entry into **force** of this **amending** Regulation].;*

Or. en

Amendment 433

Michael McNamara, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ba) in Article 113, paragraph 3, the following point ea is added:

(ea) The Commission shall establish common specifications in support of compliance with Chapter III, in accordance with Article 41 if the conditions laid down in paragraph 1 of that article are fulfilled on the 1 January 2027 in respect of AI systems classified as high-risk pursuant to Article 6(2) and Annex III, or AI systems classified as high-risk pursuant to Article 6(1) and Annex I.

The said common the standards shall be adopted no later than 2 June 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, or and no later than 2 August 2027 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.

Or. en

Amendment 434

Stefano Cavedagna

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ba) In the third paragraph, point (ea) is added:

(ea) Article 50 (2) and (4) shall apply from 2 August 2027.

Or. en

Justification

The Omnibus amendment to Article 111 of the AI Act grants providers a transitional period until February 2, 2027 for content marking obligations, but the Code of Practice defining technical compliance will only be finalized near that date. More critically, deployers subject to Article 50, paragraph 4 obligations receive no transitional period despite depending entirely on providers' technical solutions and Code of Practice specifications to fulfil their transparency obligations toward end users. This asymmetry creates significant legal uncertainty and exposes deployers to liability without adequate means of compliance. This amendment, together with the previous amendment to article 111, aims to improve legal certainty by setting a uniform date for both providers and deployers.

Amendment 435
Andreas Schwab

Proposal for a regulation
Article 1 – paragraph 1 – point 31 a (new)
Regulation (EU) 2024/1689
ANNEX I

Text proposed by the Commission

Amendment

(31a) Annex I is amended as follows:

(1) Section A is deleted;

(2) In Section B, the following points are added:

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);

2. 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);

3. 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);

4. *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);*

5. *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);*

6. *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);*

7. *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);*

8. *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);*

9. *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);*

10. *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);

11. 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);

12. 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).

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 Directive 73/361/EEC

Or. en

Amendment 436
Aura Salla

Proposal for a regulation
Article 1 – paragraph 1 – point 31 a (new)
Regulation (EU) 2024/1689
ANNEX I

Text proposed by the Commission

Amendment

(31a) Annex I is amended as follows:

(1) Section A is deleted;

(2) in Section B, the following points are added:

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);

2. ***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);***
3. ***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);***
4. ***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);***
5. ***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);***
6. ***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);***
7. ***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);***
8. ***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);***
9. ***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);

10. 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);

11. 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);

12. 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).

Or. en

Justification

This amendment ensures legal clarity and avoids unnecessary duplication between the AI Act and existing product safety legislation.

Amendment 437

Axel Voss, Arba Kokalari

Proposal for a regulation

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

Regulation (EU) 2024/1689

ANNEX I

Present text

Amendment

(31a) ANNEX I is replaced by the following:

ANNEX I

"ANNEX I

List of Union harmonisation legislation

Section A. List of Union harmonisation legislation based on the New Legislative Framework

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);

2. 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);

3. 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);

4. 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);

5. 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);

6. 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);

7. 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);

8. 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);

9. Regulation (EU) 2016/425 of the European Parliament and of the Council of

List of Union harmonisation legislation

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);

9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);10.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);11.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);12.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).**Section B. List of other Union harmonisation legislation**13.Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);14.Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);15.Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);16.Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);17.Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016,

p. 44);18.Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);19.Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);20.Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the

market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.

2. 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);

3. 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);

4. 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);

5. 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);

6. 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);

7. 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);

8. 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);

9. 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);

10. 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);

11. 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);

12. 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).

13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);

14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);

15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L

60, 2.3.2013, p. 1);

16. *Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);*

17. *Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44);*

18. *Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);*

19. *Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);*

20. *Regulation (EU) 2018/1139 of the European Parliament and of the Council*

of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned."

Or. en

Justification

Following the Commission's own "Health Omnibus" logic (COM(2025) 1023 final), it is consistent for the AI Omnibus to move not only MDR/IVDR but all Annex I, Section A acts to Section B and to reflect this streamlining in Article 2(2). This avoids duplicate and potentially conflicting horizontal AI obligations on top of mature sectoral regimes, reducing compliance fragmentation and forum-shopping risks for the same product or service. Sector-specific legislation is better placed to calibrate AI requirements to safety and supervision realities, using existing competent authorities and established conformity-assessment pathways. A targeted "sector-first" approach still preserves AI Act safeguards where needed, but boosts EU AI uptake by making compliance clearer, proportionate and implementable for EU SMEs and Start-Ups.

Amendment 438
Henrik Dahl

Proposal for a regulation
Article 1 – paragraph 1 – point 31 a (new)
Regulation (EU) 2024/1689
ANNEX I

ANNEX I

(31a) ANNEX I is replaced by the following:

List of Union harmonisation legislation

"ANNEX I

Section **B** List of Union harmonisation legislation

Section **A**. List of Union harmonisation legislation **based on the New Legislative Framework**

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);

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);

2. 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);

2. 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);

3. 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);

3. 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);

4. 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);

4. 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);

5. 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);

5. 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);

6. Directive 2014/53/EU of the European

6. 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);

7. Directive 2014/68/EU of the

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);

7. 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);

8. 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);

9. 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);

10. 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);

11. 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);

12. 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).

Section B. List of other Union

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);

8. 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);

9. 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);

10. 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);

11. 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);

12. 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).

13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);

14. Regulation (EU) No 168/2013 of the European Parliament and of the

harmonisation legislation

13.Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);

14.Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);

15.Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);

16.Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);

17.Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44);

Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);

15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);

16. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);

17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44);

18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);

19. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No

18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);

19. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No

672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);

20. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned."

"

109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);

20.Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.

Annex

Or. en

(Regulation (EU) 2024/1689)

Justification

Product safety is already regulated under technology-neutral Union harmonisation legislation in Annex I. The inclusion of AI does not in itself render a product unsafe. Parallel application of the AI Act and Section A would create duplication and unnecessary costs. Section A should therefore be merged into Section B. The Commission has already proposed this for Medical Devices and IVDs; the same logic should apply to the remaining acts.

Amendment 439

Piotr Müller, Assita Kanko

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

(31a) In Annex I, Section A, Point 1 is deleted.

Or. en

(Regulation 2024/1689)

Justification

Machinery Regulation already sufficiently covers the issue of AI. There is no need to duplicate multiple processes, with little benefit to the safety.

Amendment 440

Tomáš Zdechovský

Proposal for a regulation

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

Regulation (EU) 2024/1689

ANNEX I – Section A – point 1

Text proposed by the Commission

Amendment

(31a) In Annex I, Section A, Point 1 is deleted.

Or. en

Justification

Directive 2006/42/EC was repealed by Regulation 2023/1230. Avoidance of duplication. In line with this AM, Recital 46 should be updated as well.

Amendment 441

Tomáš Zdechovský

Proposal for a regulation

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

Regulation (EU) 2024/1689

ANNEX I – Section B – point 1 (new)

Text proposed by the Commission

Amendment

(31a) In Annex I, Section B, the following point is added:

1a. 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

Or. en

Amendment 442

Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Regulation (EU) 2024/1689
ANNEX VIII – Section B

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 443

Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jouvet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Regulation (EU) 2024/1689
ANNEX VIII – Section B

Text proposed by the Commission

Amendment

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

deleted

Amendment 444

Marion Walsmann, Hildegard Bentele, Christine Schneider, Stefan Köhler, Sven Simon, Andreas Schwab

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Regulation (EU) 2024/1689

ANNEX VIII – Section B

Text proposed by the Commission

Amendment

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

Or. en

Justification

Maintaining registration for non-high-risk Annex III systems ensures oversight and provides authorities with comparable data. This helps prioritize market surveillance and identify emerging use cases. Since providers must assess risk anyway to claim exemptions, the added administrative burden is limited and proportionate, while the transparency and supervisory benefits are tangible.

Amendment 445

Leila Chaibi, Pernando Barrena Arza
on behalf of The Left Group

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Regulation (EU) 2024/1689

Annex VIII – Section B

Text proposed by the Commission

Amendment

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

Or. en

Amendment 446
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 1 – paragraph 1 – point 32
Regulation (EU) 2024/1689
Annex VIII – Section B

Text proposed by the Commission

Amendment

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

Or. en

Amendment 447
Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation
Article 1 – paragraph 1 – point 32
Regulation (EU) 2024/1689
ANNEX VIII – Section B

Text proposed by the Commission

Amendment

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

Or. en

Amendment 448
Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle

Proposal for a regulation
Article 1 – paragraph 1 – point 32
Regulation (EU) 2024/1689
ANNEX VIII – Section B

Text proposed by the Commission

Amendment

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

Or. en

Amendment 449

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 32 a (new)

Regulation (EU) 2024/1689

Annex VIII – Section B

Text proposed by the Commission

Amendment

(32a) in Annex VIII, Section B points 6 to 8 are deleted.

Or. en

Amendment 450

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 32 a (new)

Regulation (EU) 2024/1689

Annex VIII – Section B – point 5

Present text

Amendment

(32a) In Annex VIII, Section B, point 5 is amended as follows:

5. A description of the intended purpose of the AI system.

5. Documentation of the assessment created in accordance with Article 6(4).

Or. en