



**2025/0359(COD)**

13.2.2026

# **AMENDMENTS**

## **9 - 103**

**Draft opinion**

**Emma Rafowicz**

(PE784.261v01-00)

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 – 2025/0359(COD))



## Amendment 9

Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk

### Proposal for a regulation

#### Recital 1 a (new)

*Text proposed by the Commission*

*Amendment*

**(1a)** *In order to preserve Europe’s global competitiveness with regard to AI, implementation of the AI Act should be predictable, proportionate and conducive to rapid and simple uptake by AI enterprises operating across the Union.*

Or. fr

## Amendment 10

Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk

### Proposal for a regulation

#### Recital 2

*Text proposed by the Commission*

*Amendment*

(2) The experience gathered in implementing the ***parts*** of Regulation (EU) 2024/1689 that have already entered into application can inform the implementation of those ***parts*** that are yet to apply. ***In this context, the delayed preparation of standards, which should provide technical solutions for providers of high-risk AI systems to ensure compliance with their obligations under that regulation, and the delayed establishment of the governance and the conformity assessment frameworks at national level result in a compliance burden that is heavier than expected. In addition, consultations of stakeholders have revealed the need for additional measures that facilitate and provide clarification on the implementation and compliance, without reducing the level of protection for health, safety and fundamental rights from AI-related risks that the rules of Regulation (EU)***

(2) The experience gathered in implementing the ***provisions*** of Regulation (EU) 2024/1689 that have already entered into application can inform the implementation of those ***provisions*** that are yet to apply. ***That experience has shown that delays in drawing up harmonised standards, establishment of governance structures and the designation of conformity assessment bodies at national level risk bringing about legal uncertainty and a compliance burden that is heavier than initially intended. That uncertainty could deter investment, slow down innovation or delay access to the market. Targeted additional measures must therefore be taken urgently to facilitate the implementation of and compliance with regulatory requirements, while prioritising simplification and clarity.***

**Amendment 11**  
**Annamária Vicsek**

**Proposal for a regulation**  
**Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(2 a) The effective implementation of Regulation (EU) 2024/1689 requires that any adjustments aimed at facilitating its application do not detract from the clarity and accessibility of the regulatory framework. In accordance with Article 3(3) of the Treaty on European Union (TEU), which provides that the Union shall respect its rich cultural and linguistic diversity and shall ensure that Europe’s cultural heritage is safeguarded and enhanced — in particular in the context of the development of innovative AI systems — due regard should be given, in the application of this Regulation, notably in the fields of education, culture and the media, to the protection of national specificities, cultural expressions and media pluralism.***

Or. en

**Amendment 12**  
**Mario Furore**

**Proposal for a regulation**  
**Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(2 a) While the objective of simplifying the implementation of harmonised rules on artificial intelligence is legitimate, such simplification should not lead to a de***

*facto lowering of safeguards in sectors where AI systems directly affect cultural expression, media pluralism, authors' rights and working conditions in the cultural and creative sectors. In particular, the simplification of implementation rules under this Regulation should be without prejudice to Union law on copyright and related rights.*

Or. en

**Amendment 13**  
**Emma Rafowicz, Sabrina Repp**

**Proposal for a regulation**  
**Recital 3**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 14

Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk

### Proposal for a regulation

#### Recital 3

*Text proposed by the Commission*

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

*Amendment*

(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, ***including reducing administrative burdens and removing provisions that duplicate provisions in other Union texts***, with a view to the effective application of the relevant rules.

Or. fr

## Amendment 15

Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk

### Proposal for a regulation

#### Recital 4

*Text proposed by the Commission*

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – ***the 'small mid-cap enterprises' ('SMCs')*** – play a vital role in the Union's economy. ***Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they face challenges similar to SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises.*** Regulation (EU)

*Amendment*

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition play a vital role in the Union's economy ***and are key drivers of innovation, digitalisation and growth. SMEs often face a sudden, disproportionate increase in their regulatory obligations when they pass the applicable thresholds, which can slow their development and hinder their investments. Ensuring the continuity and proportionality of regulatory treatment is therefore essential to avoid creating obstacles to growth.*** Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to ***SMEs***. In order to ***provide legal predictability and clarity***, definitions should ***be introduced that*** correspond to ***those*** set out in the Annex to

2024/1689 provides for several measures for small-scale providers, which should be extended to *SMCs*. In order to *clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689*, it is *necessary to introduce definitions for SMEs and SMCs, which* should correspond to *the definition* set out in the Annex to Commission Recommendation 2003/361/EC<sup>4</sup> and Annex to Commission Recommendation 2025/3500/EC<sup>5</sup>.

Commission Recommendation  
2003/361/EC and Annex to Commission  
Recommendation 2025/3500/EC.

---

<sup>4</sup> *Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, pp. 36–41, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>)*.

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

Or. fr

## **Amendment 16**

**Lara Magoni, Marco Squarta, Ivaylo Valchev**

### **Proposal for a regulation**

#### **Recital 4**

*Text proposed by the Commission*

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they face challenges similar to SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for

*Amendment*

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they face challenges similar to SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for

targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC<sup>4</sup> and Annex to Commission Recommendation 2025/3500/EC<sup>5</sup>.

---

<sup>4</sup> Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, pp. 36–41, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

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

targeted support, *especially for enterprises operating in the cultural, creative, educational and media sectors, which are particularly affected by AI manipulation*. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC<sup>4</sup> and Annex to Commission Recommendation 2025/3500/EC<sup>5</sup>.

---

<sup>4</sup> Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, pp. 36–41, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

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

Or. en

## **Amendment 17** **Antonín Staněk**

### **Proposal for a regulation** **Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**(4 a) This Regulation follows a risk-based approach centred on the protection**

*of health, safety and fundamental rights of natural persons. In purely industrial or enterprise-level deployments of AI systems where there is no direct interaction with natural persons and no impact on their rights or safety, the application of specific transparency or information obligations should remain proportionate to the risks concerned and should not impose unnecessary administrative burdens.*

Or. en

**Amendment 18**  
**Erik Marquardt**

**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

*Amendment*

**(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require**

**deleted**

*the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.*

Or. en

**Amendment 19**  
**Laurence Farreng**

**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

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

Or. en

#### **Amendment 20**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

(5) Article 4 of Regulation (EU) 2024/1689 **currently** imposes an obligation on **all** providers and deployers of AI systems to **ensure AI literacy** of their staff. **AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the**

*Amendment*

(5) Article 4 of Regulation (EU) 2024/1689 imposes an obligation on providers and deployers of AI systems to **develop the AI culture** of their staff. **While that culture is essential for informed decision-making and responsible deployment of AI systems, feedback from stakeholders indicates that a standard obligation does not sufficiently reflect the diversity of providers, deployers, economic models and risk profiles, and could therefore prove to be ineffective and disproportionate, in particular for smaller enterprises. AI culture should be promoted primarily by non-binding, incentivising accompanying measures, rather than prescriptive obligations. Article 4 should therefore be amended to require the Commission and Member States, within their respective competences, to encourage AI culture by way of recommendations, training and the exchange of information and good practices, without prejudice to broader education and skills initiatives.**

*wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.*

Or. fr

## **Amendment 21**

**Emma Rafowicz, Sabrina Repp**

### **Proposal for a regulation**

#### **Recital 5**

##### *Text proposed by the Commission*

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. *AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective*

##### *Amendment*

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf. *Such literacy tools and measures should consist, in particular, in teaching and learning basic notions and skills about AI systems and their functioning, including the different types of products and uses, their risks and benefits and the severity of the harm they can cause and its probability of occurrence, through active rather than passive learning processes particularly for minors, which should not be limited to reading, for example. Ensuring such AI literacy is crucial to support responsible deployment and use of AI systems within organisations and to enable those persons to understand, in relation to their tasks, the functioning, intended purpose and limitations of the AI systems they operate or use as well as to critically evaluate the potential impact of such systems on their working conditions, professional autonomy, and workplace surveillance. Stakeholder experience shows that*

*competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.*

*measures to ensure AI literacy should be proportionate and adaptable to the type of provider or deployer, the organisational context and the AI systems concerned. However, the need for flexibility as to the form of those measures does not remove the necessity of maintaining a direct obligation on providers and deployers to take such measures. It is therefore appropriate to maintain the obligation laid down in Article 4, while allowing providers and deployers to determine, in a proportionate manner, the most suitable measures to ensure a sufficient level of AI literacy of their staff and other relevant persons acting on their behalf so as to ensure compliance and enforcement of this Regulation.*

Or. en

## **Amendment 22**

**Lara Magoni, Marco Squarta, Ivaylo Valchev**

### **Proposal for a regulation**

#### **Recital 5**

*Text proposed by the Commission*

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of

*Amendment*

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of

providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.

providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences, *which will need to be encouraged and further implemented*, for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.

Or. en

**Amendment 23**  
**Emma Rafowicz, Sabrina Repp**

**Proposal for a regulation**  
**Recital 5 a (new)**

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

Or. en

**Amendment 24**  
**Laurence Farreng**

**Proposal for a regulation**  
**Recital 5 a (new)**

***(5 a) AI systems that alter, manipulate or artificially produce images or videos depicting natural persons engaged in sexually explicit activities, displaying their intimate body parts, or undresses a person without consent cause harm to victims and violate fundamental rights to dignity***

*and privacy. The proliferation of such technologies, marketed as 'nudification' applications, has created an urgent need for explicit regulatory prohibition. While Regulation (EU) 2024/1689 establishes a framework for prohibited AI practices, the effective protection of persons, particularly women and minors who are disproportionately targeted, requires the explicit prohibition of such AI systems. This is without prejudice towards the rights, freedoms and principles recognised by Article 6 TEU and the Charter of Fundamental Rights of the European Union, and the exercise of the rights guaranteed therein to freedom of expression and information and the freedom of the arts and sciences.*

Or. en

**Amendment 25**  
**Maria Guzenina**

**Proposal for a regulation**  
**Recital 5 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 26**  
**Maria Guzenina**

**Proposal for a regulation**  
**Recital 5 b (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 27**  
**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

**Proposal for a regulation**  
**Recital 6**

*Text proposed by the Commission*

*Amendment*

**(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of Regulation (EU) 2024/1689 already provides a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council<sup>6</sup>. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing**

**(6) Bias detection and correction can help protect natural persons from the adverse effects of AI. In order to safeguard legal certainty and encourage responsible innovation, Regulation (EU) 2024/1689 should therefore provide for a clear legal basis for the processing of special categories of personal data, whenever processing is strictly necessary to detect or reduce bias, subject to appropriate safeguards. That legal basis should be consistently applied to providers and deployers of AI systems and models, in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679, Article 10(2), point (g) of Regulation (EU) 2018/1725 and Article 10, point (a) of Directive (EU) 2016/680, thereby reducing**

of special categories of personal data *also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established* in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 *of the European Parliament and of the Council*<sup>7</sup> and Article 10, point (a) of Directive (EU) 2016/680 *of the European Parliament and of the Council*<sup>8</sup> *provides a legal basis allowing, where necessary for the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.*

legal *uncertainty and simplifying compliance within the internal market.*

---

<sup>6</sup> *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>).*

<sup>7</sup> *Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>).*

<sup>8</sup> *Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the*

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

Or. fr

**Amendment 28**  
**Erik Marquardt**

**Proposal for a regulation**  
**Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

*(6 a) Recent developments have demonstrated the incompatibility of certain AI practices with the Union's fundamental rights framework. The nudification of women, manipulation of intimate images and generation of child sexual abuse material constitute clear breaches of fundamental rights and Union law. However, significant legal uncertainty remains as to whether AI-powered nudity applications fall within the scope of the AI practices prohibited by Article 5 of Regulation (EU) 2024/1689. Article 112 of that Regulation obliges the Commission to assess, on an annual basis, the necessity of amendments to the list of prohibited practices laid down in Article 5 and the list set out in Annex III, and to submit the findings of that assessment to the European Parliament and the Council. The Commission has failed to meet the deadline for the previous assessment period. For this reason, it seems adequate to specify that prohibited practices under Article 5 include the placing on the market, the putting into service or the use of an AI*

*system that can generate or manipulate sexualised audio, images and videos of individuals, thereby facilitating non-consensual sharing of intimate or manipulated material as defined in Directive (EU) 2024/1385.*

Or. en

## Amendment 29

Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk

### Proposal for a regulation

#### Recital 7

*Text proposed by the Commission*

(7) In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to ***the procedure for*** designating notified bodies under Regulation (EU) 2024/1689, ***while maintaining the same level of scrutiny,*** a single application and ***a single*** assessment procedure should be available ***for new*** conformity assessment bodies ***and notified bodies which*** are designated under the Union harmonisation legislation listed in Section A of Annex I ***to Regulation (EU) 2024/1689, such as under Regulations (EU) 2017/745<sup>9</sup> and (EU) 2017/746<sup>10</sup> of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation. The single application and assessment procedure aims at facilitating, supporting and expediting the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies under that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto.***

---

<sup>9</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

*Amendment*

(7) In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to designating notified bodies under Regulation (EU) 2024/1689, a single application and assessment procedure should be available ***whenever*** conformity assessment bodies are ***already*** designated under the Union harmonisation legislation listed in Section A of Annex I ***of*** that regulation. ***That simplification is essential to expedite market access for products containing AI and cutting costs to providers, while maintaining control and compliance levels equivalent to the applicable requirements.***

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

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

Or. fr

**Amendment 30**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 7 a (new)**

*Text proposed by the Commission*

*Amendment*

***(7 a) The interaction between this Regulation and other Union harmonisation legislation, in particular legislation laying down cybersecurity or product safety requirements, should be organised in a manner that avoids unnecessary duplication of conformity assessment procedures and documentation. Where a product or system is subject to this Regulation and to other Union legislation with overlapping requirements, providers should, where appropriate, be able to rely on a coordinated or combined conformity assessment procedure, provided that all applicable requirements are effectively covered and assessed.***

Or. en

## Amendment 31

Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk

### Proposal for a regulation

#### Recital 8

*Text proposed by the Commission*

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

*Amendment*

(8) With a view to ensuring smooth *and consistent* application of Regulation (EU) 2024/1689, *targeted clarifications and technical corrections* should be made *so as to remove all ambiguity, prevent redundant processes and allow* providers *to rely on existing quality management systems implemented* under *other* Union harmonisation legislation. *That approach bolsters legal certainty, reduces the cost of ensuring compliance and encourages quicker deployment of* AI systems without *reducing the level of protection* required by *Union law*.

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

Or. fr

**Amendment 32**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 8 a (new)**

*Text proposed by the Commission*

*Amendment*

*(8 a) For high-risk AI systems integrated in products covered by Union harmonisation legislation listed in Annex I, the conformity assessment and quality management requirements of this Regulation should build upon and complement the arrangements already required under that legislation. Where sector-specific Union legislation already lays down binding requirements addressing the design, testing or monitoring of AI-enabled products, compliance with those requirements should be duly taken into account in the conformity assessment under this Regulation, in order to avoid unnecessary duplication and limit additional obligations to what is strictly necessary.*

Or. en

**Amendment 33**  
**Laurence Farreng**

**Proposal for a regulation**  
**Recital 9**

*Text proposed by the Commission*

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

*Amendment*

**deleted**

Or. en

**Amendment 34**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

**Proposal for a regulation**  
**Recital 9**

*Text proposed by the Commission*

**(9) To streamline compliance and reduce the associated costs, providers of AI systems should not be required to register AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation. Given that such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing registration requirements would**

*Amendment*

**(9) To simplify compliance and reduce unnecessary costs, providers of AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 should not be required to register such systems in the EU database. Given that such systems are not considered to pose a high risk within the meaning of that provision, imposing a registration requirement would constitute a disproportionate administrative burden that adds little value. Maintaining documentation requirements and**

constitute a disproportionate *compliance* burden. *Nevertheless, a provider who considers that an AI system falls under Article 6(3) remains obligated to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.*

*removing registration requirements strikes a fair balance between oversight and innovation.*

Or. fr

**Amendment 35**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 9 a (new)**

*Text proposed by the Commission*

*Amendment*

**(9 a)** *In order to reduce consent fatigue and ensure compliance with the requirements of valid consent under Union data protection law, any mechanism introducing browser-level consent or similar generalised consent models should not replace the conditions laid down in Regulation (EU) 2016/679. Simplification measures in this area should ensure that consent remains specific, informed and freely given.*

Or. en

**Amendment 36**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 9 b (new)**

*Text proposed by the Commission*

*Amendment*

**(9 b)** *In business-to-business contexts where data access and use rights are determined by contract between parties on an equal footing, additional mandatory data sharing obligations should be limited*

*to situations clearly defined by Union law and should avoid imposing disproportionate implementation burdens.*

Or. en

### **Amendment 37**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

#### **Proposal for a regulation**

##### **Recital 10**

*Text proposed by the Commission*

(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to ***strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In particular, to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world testing plan should be integrated in the sandbox plan agreed by the providers or prospective providers and the competent authority in a single document. In addition, it is appropriate to provide for the possibility of the AI Office to establish an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.***

*Amendment*

(10) ***With a view to encouraging innovation and facilitate experimentation,*** Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to further ***streamline regulatory sandboxes for AI, boost Union-level coordination and simplify procedural requirements. Combining sandbox and real-world testing plans into a single document reduces administrative complexity and speeds up testing.***

Or. fr

### **Amendment 38**

**Proposal for a regulation**

**Recital 10**

*Text proposed by the Commission*

(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In particular, to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world testing plan should be integrated in the sandbox plan agreed by the providers or prospective providers and the competent authority in a single document. In addition, it is appropriate to provide for the possibility of the AI Office to establish an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.

*Amendment*

(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In particular, to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world testing plan should be integrated in the sandbox plan agreed by the providers or prospective providers and the competent authority in a single document. In addition, it is appropriate to provide for the possibility of the AI Office to establish an AI regulatory sandbox at Union level ***without prejudice to the primary role of national competent authorities and existing national regulatory sandboxes*** for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.

Or. en

**Amendment 39**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

**Proposal for a regulation**

**Recital 11**

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

(11) To foster innovation ***under actual market conditions***, it is ***essential*** to extend the scope of real-world ***tests. Those tests make it possible to speed up development cycles and detect potential risks earlier, while remaining*** covered by the ***applicable*** Union ***and*** national ***guarantees***. Voluntary agreements between the Commission and Member States ***should further facilitate tests whenever they deem them useful.***

Or. fr

#### **Amendment 40**

**Gabriela Firea, Emma Rafowicz, Hannes Heide**

#### **Proposal for a regulation**

#### **Recital 11 a (new)**

***(11 a) Extending opportunities for real-world testing can support innovation, but it should not result in vulnerable groups becoming default test populations. Where real-world testing involves AI systems intended for use in education and vocational training, or is carried out in environments where minors are likely to be affected, the real-world testing plan should set out safeguards that are specific***

*to that setting, including clear information for affected persons and meaningful involvement of deployers such as schools and other public-interest organisations responsible for those environments.*

Or. en

**Amendment 41**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 11 a (new)**

*Text proposed by the Commission*

*Amendment*

*(11 a) In sectors already subject to comprehensive technical regulation, including the automotive sector, requirements introduced under this Regulation should be integrated transparently and sufficiently in advance, ensuring that economic operators are not subject to overlapping or duplicative regulatory requirements.*

Or. en

**Amendment 42**  
**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

**Proposal for a regulation**  
**Recital 13**

*Text proposed by the Commission*

*Amendment*

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

(13) Article 69 of Regulation (EU) 2024/1689 should be amended to simplify the fee structure *and consultation procedures* of the scientific panel. *Reducing* procedural complexity *and providing the possibility for* Member States to consult the scientific panel directly *improves effectiveness, reduces costs and makes access to expertise easier,*

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

without *compromising the panel's independence or quality*.

Or. fr

### **Amendment 43**

**Lara Magoni, Marco Squarta, Ivaylo Valchev**

#### **Proposal for a regulation**

##### **Recital 14**

###### *Text proposed by the Commission*

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

###### *Amendment*

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

measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>11</sup>. Article 14 of Regulation (EU) 2019/1020 should apply *mutatis mutandis*. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.

---

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

measures and decisions ***that are proportionate and clearly defined*** to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>11</sup>. Article 14 of Regulation (EU) 2019/1020 should apply *mutatis mutandis*. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.

---

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

Or. en

#### **Amendment 44** **Maria Guzenina**

#### **Proposal for a regulation** **Recital 14 a (new)**

*Text proposed by the Commission*

*Amendment*

***(14 a) The supervision of AI systems based on general-purpose AI models should ensure a high level of legal certainty and predictability for providers, while enabling effective public oversight and cooperation with national authorities, including authorities responsible for the protection of fundamental rights and non-discrimination.***

Or. en

**Amendment 45**  
**Catherine Griset, Juan Carlos Girauta Vidal**

**Proposal for a regulation**  
**Recital 15**

*Text proposed by the Commission*

*Amendment*

**(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council**

**deleted**

Or. fr

**Amendment 46**  
**Catherine Griset, Juan Carlos Girauta Vidal**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

*Amendment*

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

**(16) It should be clearly specified that the AI Office will be under the supervision of the Council and that the powers it will be granted must be used proportionately and as a last resort.**

Or. fr

**Amendment 47**

Catherine Griset, Juan Carlos Girauta Vidal

**Proposal for a regulation**

**Recital 17**

*Text proposed by the Commission*

(17) ***Additionally, it is essential to ensure that*** effective procedural safeguards ***apply to*** providers ***of AI systems*** subject to ***monitoring and*** supervision by the AI Office. ***To that end, the procedural rights provided for in*** Article 18 of Regulation (EU) 2019/1020 ***should apply*** mutatis mutandis ***to providers of AI systems,*** without prejudice to more specific ***procedural rights*** provided for in Regulation (EU) 2024/1689.

*Amendment*

(17) Effective procedural safeguards ***are essential to protect equity, legal certainty and the confidence of*** providers subject to supervision by the AI Office. ***The application of*** Article 18 of Regulation (EU) 2019/1020 mutatis mutandis ***ensures that the implementation of regulations remains predictable, transparent and business-friendly,*** without prejudice to more specific ***guarantees*** provided for in Regulation (EU) 2024/1689.

Or. fr

**Amendment 48**

Catherine Griset, Juan Carlos Girauta Vidal

**Proposal for a regulation**

**Recital 18**

*Text proposed by the Commission*

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

*Amendment*

(18) To ***facilitate*** access to ***the*** Union market for AI systems which are subject to third party conformity assessment, the Commission ***could*** be enabled to carry out conformity assessments ***before they are placed on the market in order to reduce procedural hurdles, in particular for innovative AI*** systems.

Or. fr

**Amendment 49**

Antonín Staněk

**Proposal for a regulation**

**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19 a) The interaction between this Regulation and Regulation (EU) 2023/2854 [Data Act] should ensure full protection of trade secrets and confidential business information. Mandatory data sharing obligations should not extend beyond what is explicitly required under Union law and should not undermine contractual freedom in business-to-business relationships.***

Or. en

**Amendment 50**  
**Laurence Farreng**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

Or. en

**Amendment 51**  
**Bogdan Andrzej Zdrojewski, Sabine Verheyen, Zoltán Tarr**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

Or. en

**Amendment 52**  
**Lara Magoni, Marco Squarta, Ivaylo Valchev**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

*Amendment*

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

(20) To allow sufficient time for providers of generative AI systems subject to the marking obligations laid down in Article 50(2) of Regulation (EU) 2024/1689 to adapt their practices within a reasonable time without disrupting the market, it is appropriate to introduce a transitional period of 6 months for providers who have already placed their systems on the market before the 2 August 2026. ***Information indicating that content has been generated or manipulated by an AI system must be presented to end users in a clear, unambiguous, and easily understandable manner, with particular emphasis when such content is employed or disseminated for educational, cultural, or creative purposes.***

Or. en

**Amendment 53**  
**Emma Rafowicz, Sandro Ruotolo, Gabriela Firea, Sabrina Repp**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

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

*Amendment*

(20) To allow sufficient ***transparency, information provided to indicate that content has been generated or manipulated by an AI system should be presented in a clear, understandable and age-appropriate manner to end users, in particular when such content is used or disseminated for educational or cultural and creative purposes***

Or. en

**Amendment 54**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 20 a (new)**

*Text proposed by the Commission*

*Amendment*

***(20 a) In order to reduce consent fatigue and ensure compliance with the requirements of valid consent under Union data protection law, any mechanism introducing browser-level consent or similar generalised consent models should not replace the conditions laid down in Regulation (EU) 2016/679. Simplification measures in this area should ensure that consent remains specific, informed and freely given.***

Or. en

**Amendment 55**  
**Laurence Farreng**

**Proposal for a regulation**  
**Recital 21**

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

**deleted**

Or. en

Amendment 56

Laurence Farreng

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

*Amendment*

**(22) Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, notably that the general date of application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. Building on experience, it is appropriate to put in place a mechanism that links the entry into application to the availability of measures in support of compliance with Chapter III, which may include harmonised standards, common specifications, and Commission guidelines. This should be confirmed by the Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those**

**deleted**

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

Or. en

**Amendment 57**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

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

*Amendment*

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

Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations.

Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations. *In order to ensure legal certainty and a practicable implementation, the Commission should ensure that the availability of harmonised standards, common specifications, guidance and other supporting tools is taken into account when determining the effective entry into application of obligations for high-risk AI systems, in accordance with Article 113, while safeguarding the overall level of protection provided by this Regulation.*

Or. en

**Amendment 58**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 22 a (new)**

***(22 a) In order to ensure legal certainty and a realistic implementation of the transparency and provenance obligations laid down in Article 50(2) and (4), the application of those obligations should take due account of the availability of harmonised standards, common specifications, relevant technical guidance and codes of practice developed at Union level. The Commission should ensure that providers are granted an appropriate period of time to adapt their systems once such supporting measures are available, in particular where those obligations require technical solutions enabling the detection or marking of artificially generated or manipulated content. Particular attention should be paid to small and medium-sized enterprises and small mid-cap enterprises.***

Or. en

**Amendment 59**  
**Antonín Staněk**

**Proposal for a regulation**  
**Recital 24 a (new)**

*Text proposed by the Commission*

*Amendment*

***(24 a) In order to ensure legal certainty and avoid fragmentation within the internal market, the application of this Regulation in conjunction with Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 should be interpreted and applied in a consistent manner across Member States. The Commission, in cooperation with the European Data Protection Board, should issue binding or coordinated guidance clarifying the interaction between this Regulation and Union data protection law, in particular regarding the qualification of personal data and the***

*lawful bases for processing in the context of AI development and deployment.*

Or. en

**Amendment 60**  
**Annamária Vicsek**

**Proposal for a regulation**  
**Recital 26 a (new)**

*Text proposed by the Commission*

*Amendment*

*(26 a) It is increasingly necessary and timely to address the responsibility, as well as the ethical and moral issues arising from the development of AI, in particular the operation and work of superintelligence, humanoid robots and androids capable of independent functioning.*

Or. en

**Amendment 61**  
**Annamária Vicsek**

**Proposal for a regulation**  
**Recital 26 b (new)**

*Text proposed by the Commission*

*Amendment*

*(26 b) Large language models are becoming increasingly important across industries due to their role in automation and efficiency improvement. EU funding support should be requested for smaller AI models to encourage diversity, improve energy efficiency, and strengthen technological sovereignty beyond these large models.*

Or. en

**Amendment 62**  
**Catherine Griset, Juan Carlos Girauta Vidal**

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

*Text proposed by the Commission*

(g) measures to support innovation, with a particular focus on ***small mid-cap enterprises (SMCs) and*** small and medium-sized enterprises (SMEs), including start-ups.;

*Amendment*

(g) measures to support innovation ***and market take-up of AI***, with a particular focus on small and medium-sized enterprises (SMEs), including start-ups, ***through regulatory approaches that are proportionate, risk-based and simplified.***;

Or. fr

**Amendment 63**  
**Laurence Farreng**

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

*Text proposed by the Commission*

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

***‘Article 4***

***AI literacy***

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

*Amendment*

***deleted***

Or. en

**Amendment 64**  
**Erik Marquardt**

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

*Text proposed by the Commission*

*Amendment*

*Article 4*

*deleted*

Or. en

**Amendment 65**  
**Emma Rafowicz, Sandro Ruotolo, Gabriela Firea, Sabrina Repp**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 5**  
Regulation (EU) 2024/1689  
Article 4

*Text proposed by the Commission*

*Amendment*

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

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

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

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

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

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

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

Or. en

**Amendment 66**  
**Erik Marquardt**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 5**  
Regulation (EU) 2024/1689  
Article 4a, paragraph 2a new

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 67**  
**Laurence Farreng**

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 68**  
**Erik Marquardt**

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

*Text proposed by the Commission*

*Amendment*

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

*'(ha) "The placing on the market, the putting into service, or the use of an AI system that can generate or manipulate sexualised or intimate audio, image, or video of individuals and can facilitate non-consensual sharing of intimate or manipulated material as defined in Directive 2024/1385." 5<sup>1a</sup>.*

---

*<sup>1a</sup> Directive (EU) 2024/1385 of the European Parliament and of the Council of 14 May 2024 on combating violence against women and domestic violence, OJ L, 2024/1385, 24.5.2024, ELI: <http://data.europa.eu/eli/dir/2024/1385/oj>.*

Or. en

**Amendment 69**

**Laurence Farreng**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 6**

Regulation (EU) 2024/1689

Article 6 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 70**

**Erik Marquardt**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 6**

Regulation (EU) 2024/1689

Article 6 paragraph 4

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

## Amendment 71

Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk

### Proposal for a regulation

#### Article premier – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. fr

## Amendment 72

Annamária Vicsek

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 10

Regulation (EU) 2024/1689

Article 28 – paragraph 8

#### *Text proposed by the Commission*

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

#### *Amendment*

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

single application and single assessment procedure.

single application and single assessment procedure. ***The notifying authority is a national accreditation body designated, this paragraph shall apply only insofar as it is compatible with the roles, tasks and procedural autonomy of national accreditation bodies under that Regulation, and shall not require the establishment of procedures exceeding or altering the accreditation and designation framework laid down therein.***

Or. en

**Amendment 73**  
**Annamária Vicsek**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 10 a (new)**  
Proposal for a regulation  
Article 28 – paragraph 8a (new)

*Text proposed by the Commission*

*Amendment*

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

***Where, for high-risk AI systems, the notifying authority designated pursuant to this Regulation is a national accreditation body within the meaning of Regulation, the designation of conformity assessment bodies under this Regulation shall be based exclusively on accreditation. In such cases, the national accreditation body shall not be required, nor entitled, to carry out any assessment, verification or designation procedure other than those provided for under the applicable accreditation rules. Consequently, the national accreditation body acting as notifying authority shall not be obliged to apply, including through a single or integrated procedure, designation procedures deriving from other Union harmonisation legislation, in particular those listed in Section A of Annex I, where such procedures are not based on***

*accreditation under national law.*

Or. en

**Amendment 74**  
**Antonín Staněk**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 13 a (new)**  
Regulation (EU) 2024/1689  
Article 43 – paragraph 3a (new)

*Text proposed by the Commission*

*Amendment*

*(13 a) In Article 43, the following paragraph 3a is added:*

*3a. Where a high-risk AI system is part of a product or system which is subject to Union harmonisation legislation listed in Annex I and to other Union legislation laying down cybersecurity, safety or resilience requirements, the provider may, where appropriate, carry out a coordinated or combined conformity assessment procedure covering the requirements of this Regulation and of the other applicable Union legislation, provided that: (a) all relevant requirements are assessed in an equivalent, transparent and comprehensive manner; and (b) any notified body or conformity assessment body involved is designated for the relevant legal acts concerned. The Commission shall issue guidance on the practical arrangements for such coordinated or combined conformity assessment procedures.*

Or. en

**Amendment 75**  
**Laurence Farreng**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 14**

Regulation (EU) 2024/1689

Article 49 – paragraph 2

*Text proposed by the Commission*

*Amendment*

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

**deleted**

Or. en

**Amendment 76**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

**Proposal for a regulation**

**Article premier – paragraph 1 – point 15**

Regulation (EU) 2024/1689

Article 50 – paragraph 7

*Text proposed by the Commission*

*Amendment*

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

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

Or. fr

**Amendment 77**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

## Proposal for a regulation

### Article premier – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 56 – paragraph 6 – first subparagraph

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. fr

## Amendment 78

Emma Rafowicz, Sandro Ruotolo, Gabriela Firea, Sabrina Repp

## Proposal for a regulation

### Article 1 – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 5 paragraph 6

#### *Text proposed by the Commission*

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

#### *Amendment*

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

the codes of practice.;

of the codes of practice.;

Or. en

### *Justification*

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

### **Amendment 79**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

#### **Proposal for a regulation**

**Article premier – paragraph 1 – point 17 – point a**

Regulation (EU) 2024/1689

Article 57 – paragraph 3a

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. fr

### **Amendment 80**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

#### **Proposal for a regulation**

**Article premier – paragraph 1 – point 17 – point d**

Regulation (EU) 2024/1689

Article 57 – paragraph 13

*Text proposed by the Commission*

*Amendment*

**(d) paragraph 13 is replaced by the following:**

**deleted**

**'13. The AI regulatory sandboxes shall be designed and implemented in such a way that they facilitate cross-border cooperation between national competent authorities.;**'

Or. fr

### **Amendment 81**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

#### **Proposal for a regulation**

**Article premier – paragraph 1 – point 17 – point e**

Regulation (EU) 2024/1689

Article 57 – paragraph 14

*Text proposed by the Commission*

*Amendment*

14. National competent authorities shall coordinate their activities and cooperate within the framework of the **Board**. **They shall** support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.;

14. National competent authorities shall coordinate their activities and cooperate within the framework of the **Council**. **They may** support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.;

Or. fr

### **Amendment 82**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

#### **Proposal for a regulation**

**Article premier – paragraph 1 – point 18**

Regulation (EU) 2024/1689

Article 58 – paragraph 1

*Text proposed by the Commission*

*Amendment*

1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development,

1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts, **after receiving a prior opinion from the Council**, specifying the detailed arrangements for the

implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

Or. fr

### **Amendment 83**

**Gabriela Firea, Emma Rafowicz, Hannes Heide**

#### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 23**

Regulation (EU) 2024/1689

Article 70 – paragraph 8

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. en

### **Amendment 84**

**Gabriela Firea, Emma Rafowicz, Hannes Heide**

#### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 24**

Regulation (EU) 2024/1689

Article 72 – paragraph 3

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 85**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

**Proposal for a regulation**

**Article premier – paragraph 1 – point 25 – point b**

Regulation (EU) 2024/1689

Article 75 – paragraph 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***

*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 listed in Annex III, point 2, and the model and system are developed by the same provider, the AI Office may issue non-binding recommendations to market authorities in order to monitor that system and assess enforcement of the obligations under this Regulation.***

*large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.*

Or. fr

#### **Amendment 86**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

#### **Proposal for a regulation**

**Article premier – paragraph 1 – point 25 – point b**

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – second subparagraph

*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. fr

#### **Amendment 87**

**Catherine Griset, Juan Carlos Girauta Vidal, Antonín Staněk**

#### **Proposal for a regulation**

**Article premier – paragraph 1 – point 25 – point c**

Regulation (EU) 2024/1689

Article 75 – paragraphs 1a to 1c

*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. fr

## **Amendment 88**

**Gabriela Firea, Emma Rafowicz, 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*

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

#### *Amendment*

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

Or. en

## **Amendment 89**

**Gabriela Firea, Emma Rafowicz, Hannes Heide**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 28**

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – second subparagraph

#### *Text proposed by the Commission*

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

#### *Amendment*

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

**Amendment 90**  
**Mario Furore**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 28**  
Regulation (EU) 2024/1689  
Article 96 (1) – paragraph 1 – second subparagraph

*Text proposed by the Commission*

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

*Amendment*

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

**Amendment 91**  
**Laurence Farreng**

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

*Text proposed by the Commission*

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

*Amendment*

*deleted*

*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.;*

*'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 92** **Erik Marquardt**

**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**

*Amendment*

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

*steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.;*

Or. en

### **Amendment 93**

**Emma Rafowicz, Sandro Ruotolo, Gabriela Firea, Sabrina Repp**

#### **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*

*We firmly reject the proposed six-month postponement. AI systems currently deployed already present tangible risks, and any delay in enforcement would undermine the Regulation, distort competition, and unnecessarily prolong potential harm. Developers and providers have had sufficient time to adapt, and applying the rules as planned is crucial to ensure protection, legal clarity, and fair market conditions, in line with the original objectives of the AI Act.*

### **Amendment 94**

**Bogdan Andrzej Zdrojewski, Sabine Verheyen, Zoltán Tarr**

#### **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 deletion is justified, as the amendment would harm the creative sector and cultural heritage. Moreover, it would create legal inconsistency within Article 50.*

**Amendment 95  
Laurence Farreng**

**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.;*

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

Or. en

#### **Amendment 96**

**Bogdan Andrzej Zdrojewski, Sabine Verheyen, Zoltán Tarr**

#### **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:*

*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.*

*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 97**  
**Erik Marquardt**

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

*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 98**  
**Erik Marquardt**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 – point a**  
Regulation (EU) 2024/1689  
Article 113 paragraph 3 – point (i)

*Text proposed by the Commission*

*Amendment*

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

*deleted*

**Amendment 99**  
**Erik Marquardt**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 – point a**  
Regulation (EU) 2024/1689  
Article 113 paragraph 3 – 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 100**  
**Erik Marquardt**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 – point a**  
Regulation (EU) 2024/1689  
Article 113 paragraph 3 – second paragraph

*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 101

Erik Marquardt

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 paragraph 3 – 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 **July** 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

Or. en

## Amendment 102

Bogdan Andrzej Zdrojewski, Sabine Verheyen, Zoltán Tarr

### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 113 point, paragraph 3, point da(new)

*Text proposed by the Commission*

*Amendment*

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

**Chapter III, Sections 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.**

Or. en

### *Justification*

*This amendment ensures the necessary legal certainty for economic operators, while maintaining sufficient time for implementation. Secondary legislation and guidelines are essential for businesses to prepare and meet their obligations under the EU's AI Act and moreover is of utmost importance for the Act's effective implementation. As such, all remaining pieces of secondary legislation and guidelines should be adopted and published well before the suggested date of application (2 August 2028).*

**Amendment 103**  
**Laurence Farreng**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 32**

*Text proposed by the Commission*

*Amendment*

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

**deleted**

Or. en