



**2025/0359(COD)**

14.2.2026

# **AMENDMENTS 25 - 170**

## **Draft report**

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

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

Proposal for a regulation

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



## Amendment 25

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

### Proposal for a regulation

#### Recital 2

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

(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) 2024/1689 seek to achieve.

##### *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 **had led to unexpected compliance complications**. 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) 2024/1689 seek to achieve.

Or. en

## Amendment 26

**Mary Khan**

### Proposal for a regulation

#### Recital 2 a (new)

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

##### *Amendment*

**(2a) Artificial intelligence constitutes a key driver of economic growth, productivity and technological progress and is of strategic importance for the**

*Union's competitiveness and technological sovereignty. The Union should foster an innovation-friendly and investment-conducive framework that enables the development, deployment and uptake of AI technologies, in particular by start-ups and small and medium-sized enterprises, and supports the emergence of a strong European AI ecosystem. Simplification measures under this Regulation should therefore be interpreted and applied in a manner that promotes innovation and avoids unnecessary regulatory burdens, while ensuring a reasonable level of protection.*

Or. en

#### **Amendment 27**

**Virginie Joron, Jaroslav Bžoch, Ernő Schaller-Baross, Pál Szekeres, Klara Dostalova, Jorge Martín Frías, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

#### **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, ***in particular by removing provisions that duplicate other Union legislation***, with a view to the effective application of the relevant rules.

Or. en

#### **Amendment 28**

**Sebastian Tynkkynen**

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

##### **Recital 3**

*Text proposed by the Commission*

(3) Näin ollen asetukseen (EU) 2024/1689 on tarpeen tehdä kohdennettuja muutoksia tiettyjen täytäntöönpanohaasteiden ratkaisemiseksi, jotta kyseessä olevia sääntöjä päästään soveltamaan tuloksellisesti.

*Amendment*

(3) Näin ollen asetukseen (EU) 2024/1689 on tarpeen tehdä kohdennettuja muutoksia tiettyjen täytäntöönpanohaasteiden ratkaisemiseksi, ***sekä hallinnollisen taakan keventämiseksi***, jotta kyseessä olevia sääntöjä päästään soveltamaan tuloksellisesti.

Or. fi

**Amendment 29**

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

**Proposal for a regulation  
Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***(3a) Additionally, the Commission, the AI Office and Member States' competent authorities should ensure that supervision, enforcement and monitoring of sectorial and national laws do not create overlaps, inconsistent interpretations or divergent enforcement in order to enable AI innovation in the private and public sector. To that end, the AI Office should have adequate human and financial resources to support coordination and contribute to consistent interpretation and enforcement across the Union.***

Or. en

**Amendment 30  
Kateřina Konečná**

**Proposal for a regulation  
Recital 4**

**(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they face challenges similar to SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC<sup>4</sup> and Annex to Commission Recommendation 2025/3500/EC<sup>5</sup>.** *deleted*

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<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>).

**Amendment 31**

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

**Proposal for a regulation****Recital 4***Text proposed by the Commission*

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs *tend to* demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they face challenges similar to SMEs in relation to administrative burden, *leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for targeted support*. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that *regulation may have on their activity* once those enterprises outgrow the segment of SMEs and *are faced with* rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC<sup>4</sup> and Annex to Commission Recommendation 2025/3500/EC<sup>5</sup>.

*Amendment*

(4) ***99,7% of all EU companies are small and medium-sized enterprises, the majority of which are micro and small enterprises. Those*** outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – ***can also*** play a vital role in the Union's economy. Compared to SMEs, SMCs ***may*** demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they ***may also*** face challenges similar to SMEs in relation to administrative burden. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that ***may arise*** once those enterprises outgrow the segment of SMEs and ***become subject to*** rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs ***where appropriate while safeguarding the overarching objectives and level of protection afforded under Regulation (EU) 2024/1689***. 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>.

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<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>)

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<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 32**

### **Marion Walsmann, Sabine Verheyen**

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

##### **Recital 4**

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

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

###### *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> .

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<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>) .

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>. ***The planned relief measures should also apply to public enterprises of this size.***

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<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 33** **Stefano Cavedagna**

#### **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 burdens, 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***

##### *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. ***While small mid-caps and SMEs have different operational and financial capacities, the challenges they face in relation to administrative burdens are in some cases similar, making certain adjustments necessary in the implementation of Regulation (EU)***

*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>.*

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<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>)

*2024/1689. In any case, such extension should follow a strict proportionality approach, as these are two different categories of undertakings. This approach prevents any generalised equal treatment and instead requires recognition of the differences between SMEs and small mid-caps in the definition of standards, guidelines or model contractual clauses for the purposes of this Regulation.*

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<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

### *Justification*

*The extension of the specific rules for SMEs to small mid-caps (SMCs) should not be the rule; on the contrary, it is essential that such equalization be exceptional in nature and occur only in relation to specific provisions of the AI Act. Equating SMEs and SMCs inevitably risks creating various disadvantages – in terms of competition and competitiveness – to the detriment of truly smaller companies, especially micro-sized ones.*

**Amendment 34**  
**Sebastian Tynkkynen**

**Proposal for a regulation**  
**Recital 4**

(4) Yrityksillä, jotka ovat kasvaneet niin, että ne jäävät mikroyritysten ja pk-yritysten määritelmän ulkopuolelle – eli pienillä midcap-yrityksillä – on keskeinen rooli unionin taloudessa. Pienten midcap-yritysten kasvu on pk-yrityksiin verrattuna yleensä nopeampaa ja innovointi ja digitalisaatio yleisempää. Niillä on kuitenkin samankaltaisia hallinnolliseen taakkaan liittyviä haasteita kuin pk-yrityksillä, minkä vuoksi niitä on asetuksen (EU) 2024/1689 täytäntöönpanossa kohdeltava oikeasuhteisesti ja tuettava kohdennetusti. Jotta yritysten siirtyminen pk-yrityksestä pieneksi midcap-yritykseksi sujuisi saumattomasti, on tärkeää puuttua johdonmukaisesti niiden toimintaan sääntelystä mahdollisesti kohdistuviin vaikutuksiin, kun nämä yritykset kasvavat ulos pk-yrityssegmentistä ja joutuvat noudattamaan suuriin yrityksiin sovellettavia sääntöjä. Asetuksessa (EU) 2024/1689 säädetään useista pienen mittaluokan tarjoajia koskevista huojennuksista, jotka olisi ulotettava koskemaan pieniä midcap-yrityksiä. Jotta voidaan selkeyttää pk-yritysten ja pienten midcap-yritysten kohtelua asetuksessa (EU) 2024/1689, on tarpeen ottaa käyttöön pk-yritysten ja pienten midcap-yritysten määritelmät, joiden olisi vastattava komission suosituksen 2003/361/EY<sup>4</sup> liitteessä ja komission suosituksen 2025/3500/EY<sup>5</sup> liitteessä esitettyjä määritelmiä.

(4) Yrityksillä, jotka ovat kasvaneet niin, että ne jäävät mikroyritysten ja pk-yritysten määritelmän ulkopuolelle – eli pienillä midcap-yrityksillä – on keskeinen rooli unionin taloudessa. Pienten midcap-yritysten kasvu on pk-yrityksiin verrattuna yleensä nopeampaa ja innovointi ja digitalisaatio yleisempää. Niillä on kuitenkin samankaltaisia **ja merkittäviä** hallinnolliseen taakkaan liittyviä haasteita kuin pk-yrityksillä, minkä vuoksi niitä on asetuksen (EU) 2024/1689 täytäntöönpanossa kohdeltava oikeasuhteisesti ja tuettava kohdennetusti. Jotta yritysten siirtyminen pk-yrityksestä pieneksi midcap-yritykseksi sujuisi saumattomasti, on tärkeää puuttua johdonmukaisesti niiden toimintaan sääntelystä mahdollisesti kohdistuviin vaikutuksiin, kun nämä yritykset kasvavat ulos pk-yrityssegmentistä ja joutuvat noudattamaan suuriin yrityksiin sovellettavia sääntöjä. Asetuksessa (EU) 2024/1689 säädetään useista pienen mittaluokan tarjoajia koskevista huojennuksista, jotka olisi ulotettava koskemaan pieniä midcap-yrityksiä. Jotta voidaan selkeyttää pk-yritysten ja pienten midcap-yritysten kohtelua asetuksessa (EU) 2024/1689, on tarpeen ottaa käyttöön pk-yritysten ja pienten midcap-yritysten määritelmät, joiden olisi vastattava komission suosituksen 2003/361/EY<sup>4</sup> liitteessä ja komission suosituksen 2025/3500/EY<sup>5</sup> liitteessä esitettyjä määritelmiä.

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<sup>4</sup> Komission suositus, annettu 6 päivänä toukokuuta 2003, mikroyritysten sekä pienten ja keskisuurten yritysten määritelmästä (EUVL L 124, 20.5.2003, s. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

<sup>5</sup> Komission suositus (EU) 2025/1099, annettu 21 päivänä toukokuuta 2025, pienten midcap-yritysten määritelmästä

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<sup>4</sup> Komission suositus, annettu 6 päivänä toukokuuta 2003, mikroyritysten sekä pienten ja keskisuurten yritysten määritelmästä (EUVL L 124, 20.5.2003, s. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

<sup>5</sup> Komission suositus (EU) 2025/1099, annettu 21 päivänä toukokuuta 2025, pienten midcap-yritysten määritelmästä

Or. fi

**Amendment 35**  
**Stefano Cavedagna**

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

*Text proposed by the Commission*

*Amendment*

***(4a) SMEs play a key role in AI value chains, particularly as deployers. Small enterprises often carry out fine-tuning, customisation or technical adaptation of general-purpose or open-source AI models on behalf of clients, using data provided by those clients. Under the current framework, such activities may lead to the small enterprise being classified as a ‘provider’, resulting in disproportionate legal and certification burdens. It is therefore appropriate to clarify that a small enterprise carrying out fine-tuning using data supplied by the client should not be considered a ‘provider’, unless the activity results in a substantial modification or a change of intended purpose.***

Or. en

*Justification*

*The legislation classifies small businesses that perform fine-tuning activities locally (on the client's servers) as "providers", placing entirely disproportionate legal responsibilities and certification burdens on them. It is essential to exclude the possibility that, under the AI Act, a small business that performs fine-tuning activities using data provided by the client can be recognized as a "provider", except in cases where the activity results in a substantial modification (Article 3 AI Act, No. 23) or a change in the intended purpose (Article 3 AI Act, No. 12).*

**Amendment 36**

**Mary Khan**

**Proposal for a regulation**

**Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***(4a) In the application and enforcement of Regulation (EU) 2024/1689, the Commission, the AI Office and national competent authorities should take due account of the objective of promoting innovation and technological development. Supporting innovation should form an integral part of their mandates, alongside ensuring compliance with this Regulation.***

Or. en

**Amendment 37**

**Tomáš Zdechovský**

**Proposal for a regulation**

**Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***(4a) To support innovation and scale-up without lowering protection standards, SMEs and SMCs should benefit from simplified compliance pathways, including standardised documentation templates and differentiated application of obligations depending on whether AI systems are deployed in business-to-business or consumer-facing contexts.***

Or. en

**Amendment 38**

**Arba Kokalari, Axel Voss**

**Proposal for a regulation**

**Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 39**  
**Stefano Cavedagna**

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

*Text proposed by the Commission*

*Amendment*

***(4b) Enhancing the role of SMEs as critical players in AI value chains requires the Commission and Member States to address the issue of liability dumping. In contractual practice, larger companies tend to shift compliance obligations beyond their control to smaller suppliers. This shift jeopardises the very viability of SMEs and requires targeted interventions. The contractual clauses developed by the AI Office pursuant to Article 25 of Regulation (EU) 2024/1689 must prevent such unbalanced contractual practices, which weaken the entire digital ecosystem and jeopardize the competitiveness of the entire value chain.***

Or. en

*Justification*

*In contractual practice, larger companies tend to shift compliance obligations under European digital regulations (AI Act, Cyber Resilience Act, NIS2, etc.) onto smaller suppliers. This jeopardizes the legal and economic sustainability of MSMEs, burdening them with burdens that go beyond their position in the value chain and, therefore, their effective control capabilities. The regulatory framework should therefore include minimum*

*guarantees, including through standard European contractual clauses, consistent with the principle that responsibility follows control.*

#### **Amendment 40**

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

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

*Text proposed by the Commission*

*Amendment*

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

*deleted*

*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 41**  
**Kateřina Konečná**

**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**

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*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 42**

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

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

##### **Recital 5**

*Text proposed by the Commission*

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation

*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

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.*** 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 ***and helps raising ethical and social awareness about the benefits and risks of AI.*** While a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, AI literacy ***is*** a strategic priority. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Commission and ***the European Data Protection Board,*** in cooperation with ***other competent authorities and after consulting all relevant stakeholders, to issue guidance on how this obligation should be implemented in practice.*** 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 ***independent from the providers and deployers of AI systems themselves.***

## Amendment 43

Sandro Gozi, Stéphanie Yon-Courtin

### 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

##### *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 this provision ***poses some challenges.*** In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to ***maintain the obligation on*** providers and deployers to ***ensure an adequate*** level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, ***while also requiring the Member States and the Commission, without prejudice to their respective competences, to support, facilitate and complement those efforts by encouraging and assisting providers and deployers in meeting that obligation,*** 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

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.

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 44**  
**Jaroslav Bžoch, Klara Dostalova**

**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

*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.

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 *provide support, if needed, to* providers and deployers 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, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. *This applies without prejudice to obligations that providers and deployers have under other provisions of Regulation (EU) 2024/1689, such as Article 26(2), to ensure the necessary competence, training and authority of relevant persons.* 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 45**  
**Stefano Cavedagna**

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

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

(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 **and general, possibly ambiguous legal obligations are** not suitable for all types of providers and deployers in relation to the promotion of AI literacy, **and different types of activities will require different competencies. Given the legal ambiguities of a general obligation, SMEs are particularly vulnerable to interpreting the relevant compliance burden of AI literacy.** AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. **To ensure the dissemination of AI literacy in the EU**, 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 **support AI literacy by** individually, collectively and in cooperation with relevant stakeholders **providing guidance to help** encourage providers and deployers to **promote** AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, **for example by** offering training opportunities, providing informational resources, **or** allowing exchange of good practices. 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. The Commission and the Member States **should continue** to

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

promote **and further develop** 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

### *Justification*

*While AI literacy is an essential concept for European industry, not just ethically but also to create a global competitive advantage in the European workforce, a general obligation to administer it would not serve it well. The amendment clarifies further the role that the Commission and Member States can have in promoting AI literacy, while avoiding an obligation which would reintroduce legal uncertainty in the text, risk discouraging AI use and adoption in all EU industries (particularly SMEs, which often do not have the legal resources to interpret a general obligation) and can be interpreted too openly by individual EU countries. The amendment requires the Commission and Member States to support AI literacy in citizens of Member States while avoiding ambiguous legal obligations.*

#### **Amendment 46**

**Sandro Gozi, Stéphanie Yon-Courtin**

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

#### **Recital 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***(5a) 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 47**

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

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

*Text proposed by the Commission*

*Amendment*

*(5a) 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 48**  
**Kateřina Konečná**

**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 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.**

*deleted*

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<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. en

#### **Amendment 49**

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

**Proposal for a regulation**

**Recital 6**

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

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<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

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. ***Adverse effects such as*** 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 ***providers of high-risk AI the exceptional*** 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> ***under strict conditions and safeguards. In view of the risks this would entail, providers should be subject to the registration obligation under Article 49(2) of Regulation (EU) 2024/1689.***

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<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>).

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. en

## Amendment 50

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

### Proposal for a regulation

#### Recital 6

*Text proposed by the Commission*

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. ***Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of*** Regulation (EU) 2024/1689

*Amendment*

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. Regulation (EU) 2024/1689 provides a legal basis authorising, ***exceptionally***, the processing of special categories of personal data ***for this***

*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 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.

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<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

**purpose. It should be clarified that** 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 and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

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<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>).

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. en

## **Amendment 51**

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

### **Proposal for a regulation**

#### **Recital 6**

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

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

##### *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 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.

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<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

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 *pursuant to* Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

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<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>).

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. en

### *Justification*

*Simplification and streamlining with GDPR in order to enable companies to process personal data for the purposes of ensuring safety and bias monitoring in line with the high standards and safeguards as set out in European data regulation (first and foremost the GDPR) instead of complicated double-regulation through different kinds of safeguards in the AI Act.*

### **Amendment 52**

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

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

*Text proposed by the Commission*

*Amendment*

***(6a) Recent developments have demonstrated the incompatibility of certain AI practices with the Union's fundamental rights framework. The nudification of women, manipulation of intimate images 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 53**  
**Arba Kokalari, Axel Voss**

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

*Text proposed by the Commission*

*Amendment*

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

Or. en

**Amendment 54**  
**Kim Van Sparrentak, Markéta Gregorová**  
on behalf of the Verts/ALE Group

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

***(6b) The emergence of new so-called deepfake and deepnude technologies, sometimes disguised as ‘face swapping’ tools, however, facilitates criminal practices on an unprecedented scale. Considering the unacceptable threat to health, including mental health, safety and fundamental rights of individuals, the placing on the market, the putting into service, or the use of an AI system to generate or manipulate sexualised or intimate audio, image, or video of individuals and that is likely to facilitate non-consensual sharing of intimate or manipulated material as defined in Directive (EU) 2024/1385 should be prohibited. Directive (EU) 2024/1385 already criminalises the non-consensual sharing of intimate or manipulated material or threatening to engage in such conduct which is likely to cause serious harm or serious psychological harm to the victim or which is likely to cause the victim to seriously fear for their own safety or that of dependents. This prohibition should therefore cover AI systems that can produce, manipulate, alter material to create an intimate visual depiction of an individual or make it appear as though an individual is engaged in sexual activities. This should cover all types of such material regardless of the modality in as far as they can facilitate non-consensual sharing of intimate depictions. This should close current loopholes where the placing on the market, providing or deploying such systems that generate sexualised or intimate content is not yet prohibited under EU law, whereas these systems are likely facilitate crimes at an unprecedented scale. This prohibition should not be understood as a comprehensive ban of generative AI.***

Or. en

## Amendment 55

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

### 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.

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<sup>9</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No

##### *Amendment*

(7) In order to ensure consistency 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, ***duplication*** should be ***avoided***. ***AI systems used for industrial purposes are already highly regulated through the New Legislative Framework (NLF) which ensures a high level of protection for health and safety. Most of these regulations have already been updated to cover Artificial Intelligence systems and components in the concerned products. AI systems or components covered under these legal acts do not pose any additional risks to fundamental rights of natural persons. This Regulation shall therefore not affect industrial AI systems, which are already covered by sectoral legislation under the NLF, such as the Machinery Regulation, the Medical Devices Regulation or the Radio Equipment Directive. Any remaining gaps regarding Artificial Intelligence integrated in products under the NLF shall be closed within the sectoral acts applicable as an additional horizontal Regulation leads to competitive disadvantages through increased legal uncertainty, bureaucracy and high costs, without any added value for health, safety and fundamental rights.***

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<sup>9</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No

1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

<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>).

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. en

#### **Amendment 56**

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

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

#### **Recital 7 a (new)**

*Text proposed by the Commission*

*Amendment*

***(7a) Similarly, AI systems only used for business-to-business and business-internal purposes, that do not interact with end users or consumers, are not posing any threats to fundamental rights and shall therefore be excluded from this Regulation.***

Or. en

#### **Amendment 57**

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

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

#### **Recital 8**

*Text proposed by the Commission*

*Amendment*

***(8) With a view to ensuring the smooth application and consistency of Regulation (EU) 2024/1689, amendments***

***deleted***

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

*Justification*

*This Regulation shall not affect industrial AI systems, which are already covered by sectoral legislation under the New Legislative framework (Section A of Annex I).*

**Amendment 58**

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

**Proposal for a regulation**

**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

*Amendment*

(8) With a view to ensuring the smooth application and consistency of Regulation (EU) 2024/1689, 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

harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and which aim to assess high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I to that Regulation, should apply for the designation as a notified body under that Regulation within **18 months from** [the entry into application of this Regulation]. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689. **Moreover, Regulation (EU) 2024/1689 should be 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.**

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 the entry into application of this Regulation. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689.

Or. en

**Amendment 59**  
**Arba Kokalari, Axel Voss**

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

*Text proposed by the Commission*

*Amendment*

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

*declaration of conformity or parts thereof  
issued under this Regulation.*

Or. en

**Amendment 60**

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

**Proposal for a regulation**

**Recital 9**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

Or. en

**Amendment 61**

**Sandro Gozi, Stéphanie Yon-Courtin**

**Proposal for a regulation**

**Recital 9**

*Text proposed by the Commission*

*Amendment*

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

**deleted**

Or. en

## **Amendment 62**

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

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

*Text proposed by the Commission*

*Amendment*

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

**deleted**

*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.*

Or. en

**Amendment 63**  
**Kateřina Konečná**

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

*Text proposed by the Commission*

*Amendment*

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

*deleted*

Or. en

**Amendment 64**  
**Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller, Laurence Farreng**

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

*Text proposed by the Commission*

*Amendment*

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

*deleted*

Or. en

**Amendment 65**

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

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

*Text proposed by the Commission*

*Amendment*

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

*deleted*

*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.*

Or. en

## Amendment 66

Jaroslav Bžoch, Klara Dostalova

### Proposal for a regulation

#### Recital 9

*Text proposed by the Commission*

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

*Amendment*

(9) To streamline compliance and reduce the associated costs, *the registration of* AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation *should be simplified by streamlining the required content in Section B of Annex VIII to that Regulation. The registration requirements should be simplified and more proportionate as it remains crucial for market surveillance as well as for public accountability to register such AI systems in the EU database. The simplified registration should therefore rely on the documentation already required under Article 6(4), which should be made available to competent authorities through a restricted, non-public section of the EU database, without creating any additional or duplicative documentation obligations. This approach should contribute to reducing the additional requirements laid down in Annex VIII, Section B. In order to ensure consistency and legal certainty, the Commission should facilitate a common approach to the format and content of such assessments, including,*

*where appropriate, through the development of common templates, guidance or references to relevant standards.*

Or. en

**Amendment 67**  
**Sebastian Tynkkynen**

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

*Text proposed by the Commission*

(9) Vaatimusten noudattamisen sujuvoittamiseksi ja siitä aiheutuvien kustannusten vähentämiseksi tekoälyjärjestelmien tarjoajia ei pitäisi vaatia rekisteröimään asetuksen (EU) 2024/1689 6 artiklan 3 kohdassa tarkoitettuja tekoälyjärjestelmiä asetuksen 49 artiklan 2 kohdan nojalla EU:n tietokantaan. Koska tällaisia järjestelmiä ei tietyin edellytyksin pidetä suuririskisinä, jos ne eivät aiheuta merkittävää riskiä ihmisten terveydelle, turvallisuudelle tai perusoikeuksille, rekisteröintivaatimusten asettaminen aiheuttaisi **kohtuuttoman** rasitteen. Tarjoajalla, joka katsoo järjestelmänsä kuuluvan 6 artiklan 3 kohdan soveltamisalaan, on kuitenkin edelleen velvollisuus dokumentoida oma arvionsa ennen kuin kyseinen järjestelmä saatetaan markkinoille tai otetaan käyttöön. Kansalliset toimivaltaiset viranomaiset voivat pyytää tätä arviota tarkasteltavakseen.

*Amendment*

(9) Vaatimusten noudattamisen sujuvoittamiseksi ja siitä aiheutuvien **merkittävien hallinnollisten** kustannusten vähentämiseksi tekoälyjärjestelmien tarjoajia ei pitäisi vaatia rekisteröimään asetuksen (EU) 2024/1689 6 artiklan 3 kohdassa tarkoitettuja tekoälyjärjestelmiä asetuksen 49 artiklan 2 kohdan nojalla EU:n tietokantaan. Koska tällaisia järjestelmiä ei tietyin edellytyksin pidetä suuririskisinä, jos ne eivät aiheuta merkittävää riskiä ihmisten terveydelle, turvallisuudelle tai perusoikeuksille, rekisteröintivaatimusten asettaminen aiheuttaisi **tarpeettoman** rasitteen. Tarjoajalla, joka katsoo järjestelmänsä kuuluvan 6 artiklan 3 kohdan soveltamisalaan, on kuitenkin edelleen velvollisuus dokumentoida oma arvionsa ennen kuin kyseinen järjestelmä saatetaan markkinoille tai otetaan käyttöön. Kansalliset toimivaltaiset viranomaiset voivat pyytää tätä arviota tarkasteltavakseen.

Or. fi

**Amendment 68**  
**Kristian Vigenin, Brando Benifei, Hannes Heide, Francisco Assis, François Kalfon, Elisabeth Grossmann, Christel Schaldemose, Pierre Jouvét, Marc Angel, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo**

**Proposal for a regulation**  
**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 **subject to sufficient safeguards**. 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 **authorities** 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 **involving all relevant competent authorities, including data protection authorities and the European Data Protection Board**. By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.

Or. en

**Amendment 69**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

*Amendment*

(10) Articles 57, **58 and 60** of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, **and to extend the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation.** In particular, to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world testing plan should be integrated in the sandbox plan agreed by the providers or 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.

(10) Articles 57 **and 58** 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. 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.

Or. en

**Amendment 70**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

*Amendment*

(11) **To foster innovation, it is also appropriate to extend the scope of real-world testing outside AI regulatory sandboxes in Article 60 of Regulation (EU) 2024/1689, currently applicable to high-risk AI systems listed in Annex III to**

**deleted**

*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.*

Or. en

#### **Amendment 71**

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

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

#### **Recital 11**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

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

Or. en

**Amendment 72**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

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

*Amendment*

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

*among themselves.*

Or. en

### **Amendment 73**

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

### **Proposal for a regulation**

#### **Recital 11**

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. en

#### **Amendment 74**

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

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

##### **Recital 12**

*Text proposed by the Commission*

*Amendment*

**(12) Article 63 of Regulation (EU) 2024/1689 offers microenterprises who are providers of high-risk AI systems the possibility to benefit from a simplified way to comply with the obligation to establish a quality management system. With a view to facilitating compliance for more innovators, that possibility should be extended to all SMEs, including start-ups.** *deleted*

Or. en

#### **Amendment 75**

**Kateřina Konečná**

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

##### **Recital 12**

*Text proposed by the Commission*

*Amendment*

**(12) Article 63 of Regulation (EU) 2024/1689 offers microenterprises who are providers of high-risk AI systems the possibility to benefit from a simplified way to comply with the obligation to establish a quality management system. With a view to facilitating compliance for more innovators, that possibility should be extended to all SMEs, including start-ups.** *deleted*

Or. en

#### **Amendment 76**

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

**Proposal for a regulation**  
**Recital 12**

*Text proposed by the Commission*

(12) Article 63 of Regulation (EU) 2024/1689 offers microenterprises who are providers of high-risk AI systems the possibility to benefit from a simplified way to comply with the obligation to establish a quality management system. With a view to facilitating compliance for more innovators, that possibility should be extended to *all SMEs*, including start-ups.

*Amendment*

(12) Article 63 of Regulation (EU) 2024/1689 offers microenterprises who are providers of high-risk AI systems the possibility to benefit from a simplified way to comply with the obligation to establish a quality management system. With a view to facilitating compliance for more innovators, that possibility should be extended to *small companies*, including start-ups, *within the meaning of Recommendation 2003/361/EC*.

Or. en

**Amendment 77**

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

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

*Text proposed by the Commission*

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

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

*Amendment*

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

Or. en

**Amendment 78**  
**Arba Kokalari**

## Proposal for a regulation

### Recital 14

#### *Text proposed by the Commission*

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

#### *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 and excluding AI systems referred to in point (2) of Annex III*** 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

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

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.

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<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>).

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<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 79** **Sebastian Tynkkynen**

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

#### *Text proposed by the Commission*

(15) Kun otetaan huomioon Euroopan parlamentin ja neuvoston asetuksen (EU) 2022/2065<sup>12</sup> mukainen nykyinen valvonta- ja täytäntöönpanojärjestelmä, on aiheellista myöntää komissiolle asetuksen (EU) 2024/1689 nojalla toimivaltaisen markkinavalvontaviranomaisen valtuudet, jos tekoälyjärjestelmä katsotaan asetuksessa (EU) 2022/2065 tarkoitetuksi erittäin suureksi verkkoalustaksi tai erittäin suureksi verkkohakukoneeksi tai jos se on sulautettu tällaiseen alustaan tai hakukoneeseen. Tämän on määrä auttaa varmistamaan, että asetuksen (EU) 2024/1689 ja asetuksen (EU) 2022/2065 mukaisia sekä tällaisiin alustoihin tai hakukoneisiin integroituihin yleiskäyttöisiin tekoälymalleihin sovellettavia komission valvonta- ja täytäntöönpanovaltuuksia käytetään johdonmukaisesti. Kun on kyse tekoälyjärjestelmistä, jotka on sulautettu erittäin suureen verkkoalustaan tai

#### *Amendment*

(15) Kun otetaan huomioon Euroopan parlamentin ja neuvoston asetuksen (EU) 2022/2065<sup>12</sup> mukainen nykyinen valvonta- ja täytäntöönpanojärjestelmä, on aiheellista myöntää komissiolle asetuksen (EU) 2024/1689 nojalla toimivaltaisen markkinavalvontaviranomaisen valtuudet, jos tekoälyjärjestelmä katsotaan asetuksessa (EU) 2022/2065 tarkoitetuksi erittäin suureksi verkkoalustaksi tai erittäin suureksi verkkohakukoneeksi tai jos se on sulautettu tällaiseen alustaan tai hakukoneeseen. Tämän on määrä auttaa varmistamaan, että asetuksen (EU) 2024/1689 ja asetuksen (EU) 2022/2065 mukaisia sekä tällaisiin alustoihin tai hakukoneisiin integroituihin yleiskäyttöisiin tekoälymalleihin sovellettavia komission valvonta- ja täytäntöönpanovaltuuksia käytetään johdonmukaisesti. Kun on kyse tekoälyjärjestelmistä, jotka on sulautettu erittäin suureen verkkoalustaan tai

verkkohakukoneeseen tai jotka katsotaan itsessään sellaiseksi, ensimmäisen lähtökohdan tekoälyjärjestelmien arviointia varten muodostavat asetuksen (EU) 2022/2065 34, 35 ja 37 artiklassa säädetty riskianalyysiin, riskien vähentämiseen ja tarkastuksiin liittyvät velvoitteet, sanotun kuitenkin rajoittamatta tekoälytoimiston valtuuksia tutkia tämän asetuksen vaatimusten täyttymistä jälkikäteisesti ja toteuttaa tarvittavat täytäntöönpanotoimet. Tähän riskianalyysiin, riskien vähentämiseen ja tarkastuksiin liittyen asetuksen (EU) 2022/2065 täytäntöönpanosta vastaavat komission yksiköt voivat pyytää tekoälytoimistolta lausuntoa tämän asetuksen nojalla tehdyn mahdollisen aikaisemman tai rinnakkaisen riskinarvioinnin tuloksista ja tähän asetukseen perustuvien kieltojen sovellettavuudesta. Lisäksi tekoälytoimiston ja asetuksen (EU) 2024/1689 nojalla toimivaltaisten kansallisten viranomaisten olisi koordinoitava täytäntöönpanotoimiaan asetuksen (EU) 2022/2065 valvonnasta ja täytäntöönpanosta vastaavien toimivaltaisten viranomaisten, myös komission, kanssa sen varmistamiseksi, että vilpittömän yhteistyön periaatetta, suhteellisuusperiaatetta ja kaksoisrangaistavuuden kieltävää *ne bis in idem* -periaatetta noudatetaan, mutta siten, että yhden asetuksen nojalla saatuja tietoja käytettäisiin toisen asetuksen noudattamisen valvontaan ja täytäntöönpanotoimiin vain, jos kyseinen yritys suostuu siihen. Näiden viranomaisten olisi pidettävä säännöllisesti yhteyttä ja otettava huomioon toimivaltaansa kuuluvilla aloilla mahdolliset sakot ja uhkasakot, jotka samalle tarjoajalle on määrätty samasta toiminnasta ***muiden unionin tai kansallisten sääntöjen rikkomista koskevassa menettelyssä annetulla lainvoimaisella päätöksellä, jotta voidaan varmistaa, että määrättyjen sakkojen ja seuraamusten kokonaismäärä on oikeasuhteinen ja vastaa asianomaisten***

verkkohakukoneeseen tai jotka katsotaan itsessään sellaiseksi, ensimmäisen lähtökohdan tekoälyjärjestelmien arviointia varten muodostavat asetuksen (EU) 2022/2065 34, 35 ja 37 artiklassa säädetty riskianalyysiin, riskien vähentämiseen ja tarkastuksiin liittyvät velvoitteet, sanotun kuitenkin rajoittamatta tekoälytoimiston valtuuksia tutkia tämän asetuksen vaatimusten täyttymistä jälkikäteisesti ja toteuttaa tarvittavat täytäntöönpanotoimet. Tähän riskianalyysiin, riskien vähentämiseen ja tarkastuksiin liittyen asetuksen (EU) 2022/2065 täytäntöönpanosta vastaavat komission yksiköt voivat pyytää tekoälytoimistolta lausuntoa tämän asetuksen nojalla tehdyn mahdollisen aikaisemman tai rinnakkaisen riskinarvioinnin tuloksista ja tähän asetukseen perustuvien kieltojen sovellettavuudesta. Lisäksi tekoälytoimiston ja asetuksen (EU) 2024/1689 nojalla toimivaltaisten kansallisten viranomaisten olisi koordinoitava täytäntöönpanotoimiaan asetuksen (EU) 2022/2065 valvonnasta ja täytäntöönpanosta vastaavien toimivaltaisten viranomaisten, myös komission, kanssa sen varmistamiseksi, että vilpittömän yhteistyön periaatetta, suhteellisuusperiaatetta ja kaksoisrangaistavuuden kieltävää *ne bis in idem* -periaatetta noudatetaan, mutta siten, että yhden asetuksen nojalla saatuja tietoja käytettäisiin toisen asetuksen noudattamisen valvontaan ja täytäntöönpanotoimiin vain, jos kyseinen yritys suostuu siihen. Näiden viranomaisten olisi pidettävä säännöllisesti yhteyttä ja otettava huomioon toimivaltaansa kuuluvilla aloilla mahdolliset sakot ja uhkasakot, jotka samalle tarjoajalle on määrätty samasta toiminnasta. ***Samasta rikkomuksesta ei tulisi sakottaa useamman lainsäädännön perusteella.***

*rikkomisten vakavuutta.*

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<sup>12</sup> Euroopan parlamentin ja neuvoston asetus (EU) 2022/2065, annettu 19 päivänä lokakuuta 2022, digitaalisten palvelujen sisämarkkinoista ja direktiivin 2000/31/EY muuttamisesta (digipalvelusäädös) (EUVL L 277, 27.10.2022, s. 1, ELI: <http://data.europa.eu/eli/reg/2022/2065/oj>).

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<sup>12</sup> Euroopan parlamentin ja neuvoston asetus (EU) 2022/2065, annettu 19 päivänä lokakuuta 2022, digitaalisten palvelujen sisämarkkinoista ja direktiivin 2000/31/EY muuttamisesta (digipalvelusäädös) (EUVL L 277, 27.10.2022, s. 1, ELI: <http://data.europa.eu/eli/reg/2022/2065/oj>).

Or. fi

**Amendment 80**  
**Sebastian Tynkkynen**

**Proposal for a regulation**  
**Recital 15 a (new)**

*Text proposed by the Commission*

*Amendment*

***(15a) Useaan lainsäädäntöön perustuvien päällekkäisten hallinnollisten velvoitteiden syntymistä on vältettävä kaikin keinoin, jotta yritysten hallinnollista taakkaa voidaan keventää. Tämä vaatii valvonnasta ja täytäntöönpanosta vastaavien viranomaisten tehokkaan yhteydenpidon lisäksi lainsäädännön säännöllistä tarkistamista.***

Or. fi

**Amendment 81**  
**Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jouvet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide**

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

*Text proposed by the Commission*

*Amendment*

(16) To further operationalise the AI Office's supervision and enforcement set

(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.

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

Or. en

#### **Amendment 82**

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

#### **Proposal for a regulation Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) The effective and consistent application of Regulation (EU) 2024/1689 requires strong coordination and supervision at Union level. In light of the rapidly increasing number and capabilities of AI models placed on the Union market, as well as the evolving risk landscape associated with their deployment, the role of the AI Office in ensuring harmonised implementation across Member States becomes increasingly important. Adequate and forward-looking resourcing of the AI Office is therefore essential not only for effective enforcement, but also for safeguarding legal certainty, preventing regulatory fragmentation, and maintaining a high level of protection of fundamental rights, safety and innovation***

### Amendment 83

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

### Proposal for a regulation

#### Recital 19

#### *Text proposed by the Commission*

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

#### *Amendment*

(19) Article 77 and related provisions of Regulation (EU) 2024/1689 constitute an important governance mechanism, as they aim to enable authorities or bodies responsible for enforcing or supervising Union law intended to protect fundamental rights to fulfil their *mandates* under specific conditions and to foster cooperation with market surveillance authorities responsible for the supervision and enforcement of that Regulation. It is necessary to clarify the scope of such cooperation, as well as to clarify which public authorities or bodies benefit from it. With a view to reinforcing the cooperation, it should be clarified that requests to access information and documentation should be made to the competent market surveillance authority, which should respond to such requests *without undue delay*, and that the involved authorities or bodies should have a mutual obligation to cooperate. ***It should be clarified that these provisions are without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, these provisions do not limit any powers that those authorities and bodies have to request information pursuant to other Union or national law. Accordingly, those authorities and bodies retain any power they have to directly request information from operators***

*pursuant to their mandate or other law.*

Or. en

**Amendment 84**  
**Kateřina Konečná**

**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 85**  
**Sabine Verheyen, Bogdan Andrzej Zdrojewski**

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

*Text proposed by the Commission*

*Amendment*

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

**deleted**

**Amendment 86**

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

**Proposal for a regulation**

**Recital 20**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

**Amendment 87**

**Sandro Gozi, Stéphanie Yon-Courtin**

**Proposal for a regulation**

**Recital 20**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

## Amendment 88

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

### Proposal for a regulation

#### Recital 20

*Text proposed by the Commission*

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

*Amendment*

(20) To allow sufficient time for providers of generative AI systems subject to the marking obligations laid down in Article 50(2) **and 50(4)** 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 **12** months.

Or. en

*Justification*

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

## Amendment 89

Kateřina Konečná

### Proposal for a regulation

#### Recital 21

*Text proposed by the Commission*

(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**

*Amendment*

**deleted**

***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.***

Or. en

**Amendment 90**  
**Sandro Gozi, Stéphanie Yon-Courtin**

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

*Text proposed by the Commission*

*Amendment*

***(21) To provide sufficient time for providers of high-risk AI systems and to clarify applicable rules to the AI systems already placed on the market or put into service before the entry into application of***

*deleted*

*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.*

Or. en

**Amendment 91**  
**Jaroslav Bžoch, Klara Dostalova**

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

*Text proposed by the Commission*

*Amendment*

(21) To provide sufficient time for

(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.

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. *The effectiveness of transitional arrangements is closely linked to the timely availability of clear guidelines, including relevant standards, common specifications and codes of practice, in order to reduce the risk of divergent interpretation and uneven application of the rules across Member States.*

Or. en

**Amendment 92**  
**Sandro Gozi, Stéphanie Yon-Courtin**

**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**

**deleted**

*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.*

Or. en

**Amendment 93**  
**Kateřina Konečná**

**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*

*deleted*

*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.*

Or. en

#### **Amendment 94**

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

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

#### **Recital 22**

*Text proposed by the Commission*

(22) Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry

*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***

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. ***Therefore, to provide the necessary time for adaptation and implementation of the corresponding obligations, Sections 1, 2 and 3 of Chapter III as regards AI systems classified as high-risk pursuant to Article 6(1) and (2) and Annexes I and III should start applying as of 2 August 2027.***

obligations.

Or. en

## **Amendment 95**

**Leila Chaibi, Fernando Barrena Arza**  
on behalf of The Left Group

### **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 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

##### *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.

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. *The amended timeline should be strictly limited to obligations that are dependent on the development of technical standards. All other provisions should enter into application in line with the original timeline foreseen by the AI Act, namely by 2 August 2026. This notwithstanding, until the full entry into application of Chapter III, compliance with the remaining obligations — especially for deployers — might need to be interpreted more flexibly given that providers will not be under the obligation to draw up all relevant information and documentation.*

Or. en

**Amendment 96**  
**Jaroslav Bžoch, Klara Dostalova**

**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

*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.***

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. It is appropriate to ***align the implementation timeline and set the date for the application of Sections 1, 2 and 3 of Chapter III to 2 August 2028 for all AI systems classified as high-risk pursuant to Article 6(2) and Annex III to Regulation (EU) 2024/1689 as well as pursuant to Article 6(1) and Annex I to that Regulation. In this context, it is essential to ensure the timely availability of the harmonised standards supporting compliance with Chapter III. The Commission shall take all necessary steps to facilitate the development and adoption of such harmonised standards sufficiently in advance of the application dates. Where harmonised standards are not available in time, the Commission will, in accordance with Articles 40 and 41 of Regulation (EU) 2024/1689, ensure the availability of alternative compliance tools, including common specifications or Commission guidance, in order to provide legal certainty to providers and deployers and to avoid disproportionate compliance costs.***

**Amendment 97**  
**Sebastian Tynkkynen**

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

*Text proposed by the Commission*

(22) Asetuksen (EU) 2024/1689 113 artiklassa vahvistetaan sen voimaantulopäivä ja soveltamisen alkamisajankohta ja erityisesti se, että yleinen soveltaminen alkaa 2. elokuuta 2026. Asetuksen (EU) 2024/1689 III luvun 1, 2 ja 3 jaksossa säädettyjen suuririskisiin tekoälyjärjestelmiin liittyvien velvoitteiden osalta standardien, yhteisten eritelmien ja vaihtoehtoisen ohjeistuksen viivästyminen ja viiveet kansallisten toimivaltaisten viranomaisten perustamisessa johtavat haasteisiin, jotka vaarantavat kyseisten velvoitteiden tosiasiallisen soveltamisen aloittamisen ja uhkaavat lisätä merkittävästi täytäntöönpanokustannuksia tavalla, joka ei oikeuta pitämään niiden soveltamisen alkuperäistä aloittamisajankohtaa, joka on 2. elokuuta 2026, ennallaan. Saatujen kokemusten perusteella on aiheellista luoda mekanismi, joka kytkee soveltamisen aloittamisen III luvun noudattamista tukevien tekijöiden, kuten esimerkiksi yhdenmukaistettujen standardien, yhteisten eritelmien ja komission ohjeistusten, saatavuuteen. Komission olisi vahvistettava tämä saatavuus päätöksellä, minkä jälkeen suuririskisiä tekoälyjärjestelmiä koskevia sääntöjä ja velvoitteita olisi sovellettava kuuden kuukauden kuluttua suuririskisiksi asetuksen (EU) 2024/1689 6 artiklan 2 kohdan ja liitteen III nojalla luokiteltuihin tekoälyjärjestelmiin ja 12 kuukauden kuluttua suuririskisiksi asetuksen (EU) 2024/1689 6 artiklan 1 kohdan ja liitteen I nojalla luokiteltuihin tekoälyjärjestelmiin. Tätä joustoa olisi kuitenkin jatkettava vain

*Amendment*

(22) Asetuksen (EU) 2024/1689 113 artiklassa vahvistetaan sen voimaantulopäivä ja soveltamisen alkamisajankohta ja erityisesti se, että yleinen soveltaminen alkaa 2. elokuuta 2026. Asetuksen (EU) 2024/1689 III luvun 1, 2 ja 3 jaksossa säädettyjen suuririskisiin tekoälyjärjestelmiin liittyvien velvoitteiden osalta standardien, yhteisten eritelmien ja vaihtoehtoisen ohjeistuksen viivästyminen ja viiveet kansallisten toimivaltaisten viranomaisten perustamisessa johtavat haasteisiin, jotka vaarantavat kyseisten velvoitteiden tosiasiallisen soveltamisen aloittamisen ja uhkaavat lisätä merkittävästi täytäntöönpanokustannuksia tavalla, joka ei oikeuta pitämään niiden soveltamisen alkuperäistä aloittamisajankohtaa, joka on 2. elokuuta 2026, ennallaan. Saatujen kokemusten perusteella on aiheellista luoda mekanismi, joka kytkee soveltamisen aloittamisen III luvun noudattamista tukevien tekijöiden, kuten esimerkiksi yhdenmukaistettujen standardien, yhteisten eritelmien ja komission ohjeistusten, saatavuuteen. Komission olisi vahvistettava tämä saatavuus päätöksellä, minkä jälkeen suuririskisiä tekoälyjärjestelmiä koskevia sääntöjä ja velvoitteita olisi sovellettava kuuden kuukauden kuluttua suuririskisiksi asetuksen (EU) 2024/1689 6 artiklan 2 kohdan ja liitteen III nojalla luokiteltuihin tekoälyjärjestelmiin ja 12 kuukauden kuluttua suuririskisiksi asetuksen (EU) 2024/1689 6 artiklan 1 kohdan ja liitteen I nojalla luokiteltuihin tekoälyjärjestelmiin. Tätä joustoa olisi kuitenkin jatkettava vain

2. joulukuuta 2027 saakka suuririskiseksi asetuksen 6 artiklan 2 kohdan ja liitteen III nojalla luokiteltujen tekoälyjärjestelmien osalta ja 2. elokuuta 2028 saakka suuririskiseksi asetuksen 6 artiklan 1 kohdan ja liitteen I nojalla luokiteltujen tekoälyjärjestelmien osalta ja kyseisten sääntöjen soveltamisen olisi joka tapauksessa alettava noihin päivämääriin mennessä. Ero asetuksen 6 artiklan 2 kohdan ja liitteen III nojalla luokiteltuja tekoälyjärjestelmiä ja 6 artiklan 1 kohdan ja liitteen I nojalla luokiteltuja tekoälyjärjestelmiä koskevien sääntöjen soveltamisen aloittamisen välillä vastaa asetuksessa (EU) 2024/1689 säädettyjen alkuperäisten soveltamispäivien välistä eroa ja sen tarkoituksena on antaa riittävästi aikaa mukautumiseen ja vastaavien velvoitteiden täytäntöönpanoon.

2. joulukuuta 2027 saakka suuririskiseksi asetuksen 6 artiklan 2 kohdan ja liitteen III nojalla luokiteltujen tekoälyjärjestelmien osalta ja 2. elokuuta 2028 saakka suuririskiseksi asetuksen 6 artiklan 1 kohdan ja liitteen I nojalla luokiteltujen tekoälyjärjestelmien osalta ja kyseisten sääntöjen soveltamisen olisi joka tapauksessa alettava noihin päivämääriin mennessä. Ero asetuksen 6 artiklan 2 kohdan ja liitteen III nojalla luokiteltuja tekoälyjärjestelmiä ja 6 artiklan 1 kohdan ja liitteen I nojalla luokiteltuja tekoälyjärjestelmiä koskevien sääntöjen soveltamisen aloittamisen välillä vastaa asetuksessa (EU) 2024/1689 säädettyjen alkuperäisten soveltamispäivien välistä eroa ja sen tarkoituksena on antaa riittävästi aikaa mukautumiseen ja vastaavien velvoitteiden täytäntöönpanoon. ***Mikäli suuririskisiin tekoälyjärjestelmiin liittyvien velvoitteiden tehokkaan täytäntöönpanon kannalta välttämättömät ohjeistukset ja standardit ovat puutteellisia, olisi velvoitteiden täytäntöönpanoa lykättävä.***

Or. fi

## Amendment 98

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

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

*Text proposed by the Commission*

*Amendment*

***(22a) To ensure a sufficient degree of legal clarity in the event of continued delays in the availability of harmonised standards, it is necessary to mitigate potential legal uncertainty resulting from their absence. To that end, the Commission should be required to adopt common specifications by 2 December 2027. This deadline aligns with the deferred application date of Sections 1, 2,***

*and 3 of Chapter III of Regulation (EU) 2024/1689 for AI systems classified as high-risk under Article 6(1) and Annex I of that Regulation, which has also been postponed to 2 December 2027. Additionally, the Commission should be required to issue standardisation requests covering the obligations set forth in Chapter V, Sections 2 and 3, of that Regulation by 2 December 2027, as it has not proceeded without undue delay.*

Or. en

### **Amendment 99**

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

### **Proposal for a regulation**

#### **Recital 23**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

*the same time, recognising the need to offer clarity how providers of high-risk AI systems are required to comply, the Commission should be required to publish guidance.*

Or. en

#### **Amendment 100**

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

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

**Article 1 – paragraph 1 – point 1**  
Regulation (EU) 2024/1689  
Article 1 – paragraph 2 – point g

*Text proposed by the Commission*

*Amendment*

**(1) in Article 1(2), point (g) is replaced by the following:** *deleted*

**‘(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.’;**

Or. en

#### **Amendment 101**

**Kateřina Konečná**

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

**Article 1 – paragraph 1 – point 1**  
Regulation (EU) 2024/1689  
Article 1 – paragraph 2 – point g

*Text proposed by the Commission*

*Amendment*

**(1) in Article 1(2), point (g) is replaced by the following:** *deleted*

**‘(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.*’;

Or. en

## **Amendment 102**

**Marion Walsmann, Sabine Verheyen**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 1 – paragraph 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, with a particular focus on small mid-cap enterprises (SMCs) and small and medium-sized enterprises (SMEs), including **public enterprises of that size and** start-ups.;

Or. en

## **Amendment 103**

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

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 1 – paragraph 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, with a particular focus on small and medium-sized enterprises (SMEs), including start-ups, **within the meaning of Recommendation 2003/361/EC**;

Or. en

## **Amendment 104**

**Markéta Gregorová, Kim Van Sparrentak**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 2**

Regulation (EU) 2024/1689

Article 2 – paragraph 2

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 105**

**Aura Salla**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 2**

Regulation (EU) 2024/1689

Article 2 – paragraph 2

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

*Justification*

*Reduce unnecessary burden and provide more legal certainty for AI uptake*

**Amendment 106**

**Axel Voss, Arba Kokalari**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 2**

Regulation (EU) 2024/1689

Article 2 – paragraph 2

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

*Justification*

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

**Amendment 107**

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

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

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

**‘2a. This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models. Such activities shall be conducted in accordance with applicable Union law. That exception shall cover AI systems and AI models, including their outputs, where they are developed, tested or used for the purposes of research and development activities, including commercial research and development. Research and development shall cover all stages of scientific and applied research, including industrial research and experimental development.’;**

Or. en

*Justification*

*The AI Act’s R&D exemption should align with EU-led/funded and cross-border public-private research, including OpenEuroLLM. Tying it to “no market placement/putting into service” can make it unusable for industrial R&D, where systems must be deployed or even placed on the market for testing and joint development. Clarify that AI systems/models used for R&D, including commercial R&D, are covered.*

#### **Amendment 108**

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

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

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

**(2a) In Article 2, paragraph 3, the following subparagraphs are added:**

**‘This Regulation does not apply to AI**

***systems that are regulated by Annex I, Section A.***

***This Regulation does not apply to AI systems used for business-to-business and business-internal purposes, that do not interact with end-users or consumers.’;***

Or. en

### *Justification*

*Industrial AI systems are already highly regulated through the New Legislative Framework which ensures a high level of protection for health and safety. Most of these regulations have already been updated to cover Artificial Intelligence systems and components in the concerned products. AI systems or components covered under these legal acts do not pose any additional risks to fundamental rights of natural persons. This Regulation shall therefore not affect industrial AI systems, which are already covered by sectoral legislation under the New Legislative framework, such as the Machinery Regulation, the Medical Devices Regulation or the Radio Equipment Directive. Any remaining gaps regarding Artificial Intelligence integrated in products under the NLF shall be closed within the sectoral acts applicable as an additional horizontal Regulation leads to competitive disadvantages through increased legal uncertainty, bureaucracy and high costs, without any added value for health, safety and fundamental rights. Similarly, AI systems only used for business-to-business and business-internal purposes, that do not interact with end users or consumers, are not posing any threats to fundamental rights and shall therefore be excluded from this Regulation.*

### **Amendment 109**

**Virginie Joron, Klara Dostalova, Jorge Martín Frías, Elisabeth Dieringer, Matthieu Valet, Ernő Schaller-Baross, Pál Szekeres, Alexandre Varaut, Pascale Piera**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(2a) The following article is inserted:***

***‘Article 2a***

***Safeguards for innovation and competitiveness***

***1. The Commission and Member States shall ensure that the implementation of this Regulation does not create unnecessary barriers to investment, scaling-up or cross-border***

*deployment of artificial intelligence systems within the Union.*

*2. Any future delegated or implementing acts adopted pursuant to this Regulation shall be subject to an innovation and competitiveness impact assessment, with particular emphasis on their effects on start-ups, SMEs, SMCs and private investment in artificial intelligence technologies.’;*

Or. en

**Amendment 110**  
**Piotr Müller, Assita Kanko**

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

*Text proposed by the Commission*

*Amendment*

*(2a) The following Article 2a is inserted:*

*‘Article 2a*

*Proportionality and Technological Neutrality*

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

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

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

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

*achieve the objectives of this Regulation.;*

Or. en

## **Amendment 111**

**Axel Voss, Arba Kokalari**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 2 – paragraph 6

*Present text*

*Amendment*

6. This Regulation does not apply to AI systems or AI models, including their output, specifically developed and put into service for the *sole* purpose of scientific research and development.

**(2a) in Article 2, paragraph 6 is replaced by the following:**

‘6. This Regulation does not apply to AI systems or AI models, including their output, specifically developed and put into service for the purpose of scientific research and development. ***The open-sourcing of research artifacts, such as code or models, by researchers shall not constitute a placing on the market.***’

Or. en

*(Regulation (EU) 2024/1689)*

*Justification*

*It should be clarified that the AI Act’s research exemption covers the full R&D cycle (including iterative training, fine-tuning, validation, benchmarking and safety testing) to avoid chilling innovation activities that are not yet intended for deployment. It should also include R&D conducted with a view to future commercialisation, as long as the AI system/model is not placed on the market or put into service and remains in controlled research settings. Without this clarification, legal uncertainty risks pulling routine engineering work and academic industry collaboration into obligations designed for market deployment, creating disproportionate burdens especially for SMEs and start-ups. A clear exemption also incentivises robust pre-release evaluation and safety work, improving quality and trust while keeping the Act’s core duties focused on real-world use and actual risk.*

## **Amendment 112**

**Axel Voss, Arba Kokalari**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 2 b (new)**  
Regulation (EU) 2024/1689  
Article 2 – paragraph 8

*Present text*

8. This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law.  
***Testing in real world conditions shall not be covered by that exclusion.***

*Amendment*

***(2b) in Article 2, paragraph 8 is replaced by the following:***

‘8. This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law.’

Or. en

*Justification*

*It should be clarified that the AI Act’s research exemption covers the full R&D cycle (including iterative training, fine-tuning, validation, benchmarking and safety testing) to avoid chilling innovation activities that are not yet intended for deployment. It should also include R&D conducted with a view to future commercialisation, as long as the AI system/model is not placed on the market or put into service and remains in controlled research settings. Without this clarification, legal uncertainty risks pulling routine engineering work and academic industry collaboration into obligations designed for market deployment, creating disproportionate burdens especially for SMEs and start-ups. A clear exemption also incentivises robust pre-release evaluation and safety work, improving quality and trust while keeping the Act’s core duties focused on real-world use and actual risk.*

**Amendment 113**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 2 b (new)**  
Regulation (EU) 2024/1689  
Article 2 – paragraph 8

*Present text*

*Amendment*

***(2b) in Article 2, paragraph 8 is amended as follows:***

8. This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. ***Testing in real world conditions shall not be covered by that exclusion.***

‘8. This Regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law.

***This exception shall be further extended to AI systems and AI models, together with their outputs, that are developed, tested or used for research and development purposes, including commercial research and development, covering all stages of scientific and applied research, from industrial research to experimental development. Such activities shall be conducted in accordance with applicable Union law.’;***

Or. en

(Regulation 2024/1689)

**Amendment 114**  
**Arba Kokalari, Axel Voss**

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 115**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 2 c (new)**  
Regulation (EU) 2024/1689  
Article 3 – paragraph 1 – point 1

*Present text*

(1) ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that **may exhibit** adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;

*Amendment*

**(2c) Article 3, point 1 is amended as follows:**

"(1) ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that **exhibits** adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;

"

Or. en

*(Regulation 2024/1689)*

**Amendment 116**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 2 a (new)**  
Regulation (EU) 2024/1689  
Article 3 – paragraph 1 – point 3

*Present text*

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

*Amendment*

**(3) in Article 3, point 3 is replaced by the following:**

payment or free of charge;

***‘(3) ‘provider’ means a natural or legal person, public authority, agency, or other body that develops a general-purpose AI-system or AI model, or that has a general-purpose AI-system or AI model developed, and places such a system or model on the market or puts the AI-system into service under its own name or trademark, whether in return for payment or free of charge, excluding those who perform fine-tuning, customization, or technical adaptation of AI-systems on behalf of third-party clients, using data provided by the client, unless this activity results in a substantial modification or change in the intended purpose’;***

Or. en

#### *Justification*

*The legislation classifies small businesses that perform fine-tuning activities locally (on the client's servers) as "providers," placing entirely disproportionate legal responsibilities and certification burdens on them. It is essential to exclude the possibility that, under the AI Act, a small business that performs fine-tuning activities using data provided by the client can be recognized as a "provider," except in cases where the activity results in a substantial modification (Article 3 AI Act, No. 23) or a change in the intended purpose (Article 3 AI Act, No. 12).*

#### **Amendment 117**

**Piotr Müller, Assita Kanko**

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

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

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 3 a (new)

*Text proposed by the Commission*

*Amendment*

***(2d) in Article 3, the following point is added:***

***‘(3a) ‘autonomy’ means the ability of the artificial intelligence system to operate, within constraints, without human guidance or intervention.’;***

## Amendment 118

Axel Voss

### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 9

#### *Present text*

(9) ‘placing on the market’ means the first making available of an AI system or a general-purpose AI model on the Union market;

#### *Amendment*

**(2a) In Article 3, point 9 is replaced by the following:**

**‘(9) ‘placing on the market’ means the first making available of an AI system or a general-purpose AI model on the Union market *but does not include cases of making it available to other entities within the same cooperate group*’;**

Or. en

#### *Justification*

*To ensure that purely internal intra-group sharing of an AI system or GPAI model is not treated as “placing on the market”, which would otherwise prematurely trigger provider-related obligations designed for external distribution. It aligns the concept of “placing on the market” with its core function in EU product law: regulating first external availability on the Union market, not internal group deployment and testing. Without this carve-out, entities could be deemed providers merely by making models available within the same corporate group, creating disproportionate compliance friction for normal internal roll-outs and shared service structures.*

## Amendment 119

Piotr Müller, Assita Kanko

### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 14

*Present text*

*Amendment*

(14) ‘safety component’ means a component of a product or of an AI system which fulfils a safety function for that product or AI system, **or** the failure or malfunctioning of which endangers the health and safety of persons or property;

**(2e) in Article 3, point 14 is amended as follows:**

**(14)** ‘safety component’ means a component of a product or of an AI system which fulfils a safety function for that product or AI system, **and** the failure or malfunctioning of which endangers the health and safety of persons or property’;

Or. en

## **Amendment 120**

**Marion Walsmann, Sabine Verheyen**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 3**

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 14 a

*Text proposed by the Commission*

*Amendment*

(14a) micro, small and medium-sized enterprise (‘SME’) means a micro, small or medium-sized enterprise as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC;

(14a) micro, small and medium-sized enterprise (‘SME’) means a micro, small or medium-sized enterprise as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC **as well as public enterprises of that size;**

Or. en

## **Amendment 121**

**Kateřina Konečná**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 3**

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 14 b

*Text proposed by the Commission*

*Amendment*

**(14b) small mid-cap enterprise (‘SMC’) means a small mid-cap enterprise as**

**deleted**

*defined in point (2) of the Annex to  
Commission Recommendation (EU)  
2025/1099;*

Or. en

**Amendment 122**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 3**

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 14 b

*Text proposed by the Commission*

*Amendment*

**(14b) small mid-cap enterprise ('SMC')**  
**means a small mid-cap enterprise as**  
**defined in point (2) of the Annex to**  
**Commission Recommendation (EU)**  
**2025/1099;**

**deleted**

Or. en

**Amendment 123**

**Marion Walsmann, Sabine Verheyen**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 3**

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 14 b

*Text proposed by the Commission*

*Amendment*

**(14b) small mid-cap enterprise ('SMC')**  
**means a small mid-cap enterprise as**  
**defined in point (2) of the Annex to**  
**Commission Recommendation (EU)**  
**2025/1099;**

**(14b) small mid-cap enterprise ('SMC')**  
**means a small mid-cap enterprise as**  
**defined in point (2) of the Annex to**  
**Commission Recommendation (EU)**  
**2025/1099 as well as public enterprises of**  
**that size;**

Or. en

## **Amendment 124**

**Axel Voss**

### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 3 a (new)**

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 68 a (new)

*Text proposed by the Commission*

*Amendment*

**(3a) in Article 3, the following point is added:**

**‘(68a) ‘open-source AI model’ means an AI model that is released under a free and open-source licence that allows for the access, usage, modification, and distribution of the model, and whose parameters, including the weights, the information on the model architecture, and the information on model usage, are made publicly available’;**

Or. en

### *Justification*

*Introducing a single, explicit Open Source definition in Article 3 creates legal certainty for AI providers, deployers and national competent authorities across the entire acquis. The EU currently uses multiple, partly diverging Open Source definitions (within the AI Act and in parallel instruments: the PLD and CRA), which risks inconsistent interpretation, compliance fragmentation and litigation. A harmonised definition ensures that obligations and exemptions linked to open-source are applied predictably, avoiding both over- and under-inclusion of genuine open-source components. This also supports Europe’s innovation and cybersecurity objectives by giving open-source communities and SMEs clear, stable conditions for collaboration and responsible distribution.*

## **Amendment 125**

**Axel Voss**

### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 3 b (new)**

Regulation (EU) 2024/1689

Article 3 – paragraph 1 – point 68 b (new)

*Text proposed by the Commission*

*Amendment*

**(3b) in Article 3, the following point is**

*added:*

*'(68b) 'open-source AI system' means an AI system released under a free and open-source licence that allows for the access, usage, modification, and distribution of the system, and whose information on system usage is made publicly available';*

Or. en

### *Justification*

*Introducing a single, explicit Open Source definition in Article 3 creates legal certainty for AI providers, deployers and national competent authorities across the entire acquis. The EU currently uses multiple, partly diverging Open Source definitions (within the AI Act and in parallel instruments: the PLD and CRA), which risks inconsistent interpretation, compliance fragmentation and litigation. A harmonised definition ensures that obligations and exemptions linked to open-source are applied predictably, avoiding both over- and under-inclusion of genuine open-source components. This also supports Europe's innovation and cybersecurity objectives by giving open-source communities and SMEs clear, stable conditions for collaboration and responsible distribution.*

## **Amendment 126** **Kateřina Konečná**

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

*Text proposed by the Commission*

*Amendment*

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

**'Article 4**

**AI literacy**

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

*the persons or groups of persons on whom the AI systems are to be used.’;*

Or. en

**Amendment 127**

**Leila Chaibi, Pernando Barrena Arza**

on behalf of The Left Group

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 4**

Regulation (EU) 2024/1689

Article 4

*Text proposed by the Commission*

*Amendment*

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

*deleted*

**‘Article 4**

**AI literacy**

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

Or. en

**Amendment 128**

**Markéta Gregorová, Kim Van Sparrentak**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 4**

Regulation (EU) 2024/1689

Article 4

*Text proposed by the Commission*

*Amendment*

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

*deleted*

*‘Article 4*

*AI literacy*

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

Or. en

#### **Amendment 129**

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

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

**Article 1 – paragraph 1 – point 4**

Regulation (EU) 2024/1689

Article 4 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

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

(4) *In Article 4, the following paragraph is added:*

*‘Article 4*

*1a. The European Commission and the European Data Protection Board, in collaboration with all relevant competent authorities, shall issue guidance on the practical implementation of the obligation on providers and deployers of AI systems to ensure a sufficient level of AI literacy of their staff and other relevant persons.*

*AI literacy*

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

Or. en

**Amendment 130**  
**Angelika Winzig, Sophia Kircher**

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

*Text proposed by the Commission*

*Amendment*

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

(4) Article 4 is ***deleted.***

‘Article 4

AI literacy

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

Or. en

## *Justification*

*Article 4 should be deleted to prevent legal uncertainty and disproportionate administrative burdens. A general mandate for AI literacy is redundant, as enterprises already have a strong economic incentive to ensure their workforce is adequately trained to use digital tools effectively. Furthermore, the Regulation remains coherent without this provision, as specific competence requirements for high-risk AI systems are already legally anchored under the human oversight obligations in Article 26. Extending such mandates to all AI systems, regardless of their risk profile, contradicts the principle of proportionality and hampers the competitiveness of the European industry. Rather than imposing rigid regulatory requirements on the private sector, AI literacy should be addressed through Member State-led educational initiatives and existing EU funding instruments.*

### **Amendment 131**

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

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

#### **Article 1 – paragraph 1 – point 4**

Regulation (EU) 2024/1689

Article 4

#### *Text proposed by the Commission*

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

#### *Amendment*

The Commission and Member States shall 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. ***The role of providers and deployers under this Article shall be supportive in nature, aimed at promoting appropriate knowledge and skills for the operation and use of AI systems, and shall not be construed as an obligation to guarantee a specific level of AI literacy of any individual.***

Or. en

## *Justification*

*This clarification reflects that Article 4 is an encouragement provision rather than an*

*obligation of result, increases legal certainty by confirming that providers and deployers only have a supportive role in promoting appropriate knowledge and skills, and prevents over-compliance or inconsistent enforcement driven by unrealistic expectations to guarantee individual AI literacy outcomes.*

## **Amendment 132**

**Piotr Müller, Assita Kanko**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 4**

Regulation (EU) 2024/1689

Article 4

#### *Text proposed by the Commission*

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

#### *Amendment*

The Commission and *the* Member States ***shall encourage AI literacy among the general population and*** shall encourage providers and deployers of AI to ensure a sufficient level of AI literacy ***among relevant*** staff.;

Or. en

## **Amendment 133**

**Jaroslav Bžoch, Klara Dostalova**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 4**

Regulation (EU) 2024/1689

Article 4

#### *Text proposed by the Commission*

The Commission and Member States shall encourage providers and deployers of AI systems to take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their

#### *Amendment*

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.;

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. ***This paragraph is without prejudice to the obligations of providers and deployers laid down elsewhere in this Regulation, including those under Article 26(2) concerning the competence, training and authority of relevant persons.***;

Or. en

**Amendment 134**  
**Sandro Gozi, Stéphanie Yon-Courtin**

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

*Text proposed by the Commission*

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

*Amendment*

The Commission and Member States shall ***support, facilitate and complement the efforts of*** providers and deployers of AI systems ***who remain responsible for taking*** 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 ***in which*** the AI systems are to be used , and considering the persons or groups of persons on whom the AI systems are to be used.;

Or. en

**Amendment 135**  
**Axel Voss**

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

*Text proposed by the Commission*

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

*Amendment*

The Commission and Member States shall **create *Public-Private Partnerships (PPPs)*** **to support** providers and deployers of AI systems **in taking** measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, level of education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.;

Or. en

*Justification*

*Many EU SMEs and Start-Ups struggle to operationalise the AI Act’s context-specific AI literacy duty, which depends on roles, training levels and the use-case and is therefore hard to standardise internally without guidance. Public-Private Partnerships might help: they could turn existing corporate “good practice” programmes into reusable templates and sector toolkits, allowing SMEs and start-ups to comply faster and more consistently. This approach complements the EU’s existing SME-support infrastructure (e.g. European Digital Innovation Hubs). A structured PPP approach also helps avoiding fragmented national interpretations of “sufficient” literacy by disseminating shared benchmarks and materials, while keeping flexibility for different risk contexts and user groups.*

**Amendment 136**  
**Dóra Dávid**

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

*Text proposed by the Commission*

**‘The Commission and Member States shall encourage** providers and deployers of AI systems **to take** measures to ensure **a**

*Amendment*

Providers and deployers of AI systems **shall** take measures to ensure **the** AI literacy of their staff and other persons

*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.;

dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.;

Or. en

**Amendment 137**  
**Christel Schaldemose**

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

*Text proposed by the Commission*

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

*Amendment*

Providers and deployers of AI systems *shall* take measures to ensure, *to their best extent*, 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, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.;

Or. en

**Amendment 138**  
**Dóra Dávid**

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

*Text proposed by the Commission*

*Amendment*

***1a. The Commission and the Member States shall support the AI literacy in society and support SME providers and SME deployers of AI systems in fulfilling their obligation under paragraph 1, through a common reference framework for AI literacy, taking into account different roles, risk profiles, and use cases of AI systems.;***

Or. en

**Amendment 139**  
**Stefano Cavedagna**

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

*Text proposed by the Commission*

*Amendment*

***1a. The Commission and the Member States shall support AI literacy in society and support the providers and deployers of AI systems in promoting AI literacy of their staff and users.;***

Or. en

*Justification*

*While AI literacy is an essential concept for European industry, not just ethically but also to create a global competitive advantage in the European workforce, a general obligation to administer it would not serve it well. The amendment clarifies further the role that the Commission and Member States can have in promoting AI literacy, while avoiding an obligation which would reintroduce legal uncertainty in the text, risk discouraging AI use and adoption in all EU industries (particularly SMEs, which often do not have the legal resources to interpret a general obligation) and can be interpreted too openly by individual EU countries. The amendment requires the Commission and Member States to support AI literacy in citizens of Member States while avoiding ambiguous legal obligations.*

## Amendment 140

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

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4 a

*Text proposed by the Commission*

*Amendment*

**(5) *the following Article 4a is inserted in Chapter I:*** ***deleted***

***‘Article 4a***

***Processing of special categories of personal data for bias detection and mitigation***

***1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:***

***(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;***

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

***(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable***

*safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;*

*(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;*

*(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;*

*(f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.*

*2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.’;*

Or. en

**Amendment 141**  
**Kateřina Konečn**

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

*Text proposed by the Commission*

*Amendment*

*(5) the following Article 4a is inserted in Chapter I:* *deleted*

***‘Article 4a***

***Processing of special categories of personal data for bias detection and mitigation***

***1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:***

***(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;***

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

***(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;***

***(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;***

***(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period,***

*whichever comes first;*

*(f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.*

*2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.’;*

Or. en

#### **Amendment 142**

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

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

#### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a

*Text proposed by the Commission*

*Amendment*

*(5) the following Article 4a is inserted in Chapter I: deleted*

*‘Article 4a*

*Processing of special categories of personal data for bias detection and mitigation*

*1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the*

***fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:***

***(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;***

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

***(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;***

***(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;***

***(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;***

***(f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.***

***2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of***

***high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.’;***

Or. en

**Amendment 143**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a

*Text proposed by the Commission*

*Amendment*

**(5) *the following Article 4a is inserted in Chapter I:*** ***deleted***

***‘Article 4a***

***Processing of special categories of personal data for bias detection and mitigation***

***1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:***

***(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;***

***(b) the special categories of personal data are subject to technical limitations***

*on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;*

*(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;*

*(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;*

*(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;*

*(f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.*

*2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.’;*

Or. en

#### **Amendment 144**

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

## Proposal for a regulation

### Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – introductory part

*Text proposed by the Commission*

1. To the extent necessary **to ensure bias** detection and correction in relation to high-risk AI systems **in accordance with Article 10 (2), points (f) and (g), of this Regulation**, providers of such systems may **exceptionally** process special categories of personal data, subject to **appropriate** safeguards for the fundamental rights and freedoms of natural persons. **In addition to the safeguards** set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and **Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:**

*Amendment*

1. To the extent **that it is** necessary **for the purposes of ensuring safety and bias monitoring**, detection and correction in relation to **the** high-risk AI systems, **the** providers of such systems may process special categories of personal data **referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725**, subject to **the** safeguards for the fundamental rights and freedoms of natural persons **as** set out in **those** Regulations.

Or. en

*Justification*

*Simplification and streamlining with GDPR in order to enable companies to process personal data for for the purposes of ensuring safety and bias monitoring in line with the high standards and safeguards as set out in European data regulation (first and foremost the GDPR) instead of complicated double-regulation through different kinds of safeguards in the AI Act.*

## Amendment 145

Ana Vasconcelos, Svenja Hahn, Sophie Wilmès

## Proposal for a regulation

### Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – introductory part

*Text proposed by the Commission*

1. To the extent necessary to ensure bias detection **and** correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may

*Amendment*

1. To the extent necessary to ensure bias detection, correction, **and monitoring systems post deployment** in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this

exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Or. en

## **Amendment 146**

**Jaroslav Bžoch, Klara Dostalova**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – introductory part

#### *Text proposed by the Commission*

1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

#### *Amendment*

1. To the extent **strictly** necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally **be allowed to** process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Or. en

## **Amendment 147**

**Lukas Mandl, Sander Smit**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 5**

*Text proposed by the Commission*

1. ***To the extent necessary*** to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may ***exceptionally*** process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

*Amendment*

1. ***In order*** to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Or. en

*Justification*

*Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. These adverse effects typically harm natural persons on the basis of characteristics defined by their special categories of personal data. To fulfill the purpose, the use of special categories of personal data should therefore be a possible standard practice, not a purely exceptional measure, as long as appropriate safeguards are in place.*

**Amendment 148**  
**Tomáš Zdechovský**

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

*Text proposed by the Commission*

1. ***To the extent necessary*** to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may ***exceptionally*** process special categories of personal data, subject to appropriate

*Amendment*

1. ***In order*** to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may process special categories of personal data, subject to appropriate safeguards for the

safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Or. en

### *Justification*

*Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. These adverse effects typically harm natural persons on the basis of characteristics defined by their special categories of personal data. To fulfill the purpose, the use of special categories of personal data should therefore be a possible standard practice, not a purely exceptional measure, as long as appropriate safeguards are in place.*

## **Amendment 149**

**Axel Voss**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – introductory part

#### *Text proposed by the Commission*

1. ***To the extent necessary*** to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may ***exceptionally*** process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

#### *Amendment*

1. ***In order*** to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Or. en

## *Justification*

*Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. These adverse effects typically harm natural persons on the basis of characteristics defined by their special categories of personal data. To fulfill the purpose, the use of special categories of personal data should therefore be a possible standard practice, not a purely exceptional measure, as long as appropriate safeguards are in place.*

### **Amendment 150**

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

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

##### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – introductory part

#### *Text proposed by the Commission*

1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may **exceptionally** process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

#### *Amendment*

1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

Or. en

### **Amendment 151**

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

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

##### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point a

*Text proposed by the Commission*

*Amendment*

**(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;** *deleted*

Or. en

*Justification*

*Deletion following amendment on Article 4a (1).*

### **Amendment 152**

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

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

##### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point a

*Text proposed by the Commission*

*Amendment*

**(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;**

**(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data *with comparable effectiveness*;**

Or. en

### **Amendment 153**

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

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

##### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point b

*Text proposed by the Commission*

*Amendment*

**(b) the special categories of personal data are subject to technical limitations on the re-use of the personal data, and** *deleted*

***state-of-the-art security and privacy-preserving measures, including pseudonymisation;***

Or. en

*Justification*

*Deletion following amendment on Article 4a (1).*

**Amendment 154**

**Ana Vasconcelos, Svenja Hahn**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point b

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 155**

**Christel Schaldemose**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point b

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 156**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point c

*Text proposed by the Commission*

*Amendment*

**(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;** **deleted**

Or. en

*Justification*

*Deletion following amendment on Article 4a (1).*

**Amendment 157**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point d

*Text proposed by the Commission*

*Amendment*

**(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;** **deleted**

Or. en

*Justification*

*Deletion following amendment on Article 4a (1).*

**Amendment 158**

**Lukas Mandl, Sander Smit**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point d

*Text proposed by the Commission*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

*Amendment*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties, ***except in accordance with Regulation (EU) 2016/679 Article 26, where there may be two or more joint controllers, and Article 28, where processing of data is carried out on behalf of a controller;***

Or. en

*Justification*

*This amendment explains the interplay and alignment with applicable rules under the GDPR, whereby data is processed between joint controllers or where the controller or processor are two different entities.*

**Amendment 159**

**Axel Voss**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point d

*Text proposed by the Commission*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

*Amendment*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties, ***except in accordance with Regulation (EU) 2016/679 Article 26, where there may be two or more joint controllers, and Article***

**28, where processing of data is carried out on behalf of a controller;**

Or. en

*Justification*

*This amendment explains the interplay and alignment with applicable rules under the GDPR, whereby data is processed between joint controllers or where the controller or processor are two different entities.*

**Amendment 160**  
**Tomáš Zdechovský**

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

*Text proposed by the Commission*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

*Amendment*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties, ***except in accordance with Regulation (EU) 2016/679 Article 26, where there may be two or more joint controllers, and Article 28, where processing of data is carried out on behalf of a controller;***

Or. en

*Justification*

*This amendment explains the interplay and alignment with applicable rules under the GDPR, whereby data is processed between joint controllers or where the controller or processor are two different entities.*

**Amendment 161**  
**Zala Tomašič, Tomáš Zdechovský, Jan Farský, Alexandr Vondra, Ondřej Krutílek**

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

*Text proposed by the Commission*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

*Amendment*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties ***except where strictly necessary for the purposes of bias detection and correction and subject to equivalent safeguards, including confidentiality obligations, access controls and a prohibition of further use;***

Or. en

**Amendment 162**

**Ana Vasconcelos, Svenja Hahn**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point d

*Text proposed by the Commission*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

*Amendment*

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties, ***except where authorized by article 26 or 28 of Regulation (EU) 2016/679 of the European Parliament and of the Council (GDPR);***

Or. en

**Amendment 163**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point e

*Text proposed by the Commission*

*Amendment*

**(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;** **deleted**

Or. en

*Justification*

*Deletion following amendment on Article 4a (1).*

#### **Amendment 164**

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

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

#### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point e

*Text proposed by the Commission*

*Amendment*

(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;

(e) the special categories of personal data are deleted once the bias has been corrected **and the effectiveness of the correction has been verified through monitoring**, or the personal data has reached the end of its retention period, whichever comes first;

Or. en

#### **Amendment 165**

**Ana Vasconcelos, Svenja Hahn**

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

#### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point e

*Text proposed by the Commission*

*Amendment*

(e) the special categories of personal

(e) the special categories of personal

data are deleted once *the bias has been corrected or* the personal data has reached the end of its retention period, *whichever comes first*;

data are deleted once the personal data has reached the end of its retention period;

Or. en

#### **Amendment 166**

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

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

##### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 1 – point f

*Text proposed by the Commission*

*Amendment*

**(f) *the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.*** **deleted**

Or. en

*Justification*

*Deletion following amendment on Article 4a (1).*

#### **Amendment 167**

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

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

##### **Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 2

*Text proposed by the Commission*

*Amendment*

**2. *Paragraph 1 may apply to*** **deleted**

*providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;*

Or. en

*Justification*

*Deletion following amendment on Article 4a (1).*

**Amendment 168**

**Axel Voss**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 2

*Text proposed by the Commission*

2. *Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;*

*Amendment*

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

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

*(b) all of the conditions and safeguards set out in paragraph 1 are applied. This paragraph does not create any obligation to conduct such bias detection and correction.*

*Justification*

*In line with Council version from 23 January 2026 to increase the paragraph's legal clarity.*

**Amendment 169****Dóra Dávid****Proposal for a regulation****Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 2

*Text proposed by the Commission*

2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems ***where necessary and proportionate if*** the processing ***occurs*** for the purposes set out therein and provided that the conditions ***set out under the*** safeguards set out in ***this*** paragraph.;

*Amendment*

2. Paragraph 1 may apply ***exceptionally*** to providers and deployers of other AI systems and models and deployers of high-risk AI systems ***to the extent*** the processing ***is strictly necessary*** for the purposes set out therein and provided that the conditions ***and*** safeguards set out in ***that*** paragraph ***are met. The Commission shall issue practical guidance on the application of this article for SMEs.;***

Or. en

**Amendment 170****Mary Khan****Proposal for a regulation****Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4 a – paragraph 2

*Text proposed by the Commission*

2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where ***necessary and proportionate*** if the processing occurs for the purposes set out therein and provided that the conditions set out under the

*Amendment*

2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems ***only*** where ***the risk of adverse effects resulting from such bias is sufficiently serious to justify the processing of special categories of***

safeguards set out in this paragraph.;

*personal data*, if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;

Or. en



**2025/0359(COD)**

14.2.2026

# **AMENDMENTS 171 - 317**

## **Draft report**

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

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

Proposal for a regulation

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



## Amendment 171

Adnan Dibrani, Evin Incir, Christel Schaldemose

### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 5 – paragraph 1 – point a

*Present text*

*Amendment*

(a) the placing on the market, the putting into service or the use of an AI system that deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with the objective, or the effect of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision, thereby causing them to take a decision that they would not have otherwise taken in a manner that causes or is reasonably likely to cause that person, another person or group of persons significant harm;

***(5a) in Article 5, paragraph 1, subparagraph 1, point (a) is replaced by the following:***

***'(a) the placing on the market, the putting into service or the use of an AI system that:***

***(i) deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with the objective, or the effect of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision, thereby causing them to take a decision that they would not have otherwise taken in a manner that causes or is reasonably likely to cause that person, another person or group of persons significant harm;***

***(ii) generates or manipulates image, audio or video content constituting a 'deep fake', that resembles existing persons and would falsely appear to a person to be authentic or truthful, without the consent of the existing natural person; with the exception of where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme, by which the transparency obligations set out in article 50 in this regulation applies;'***

Or. en

### *Justification*

*The purpose of this amendment is to add the non-consensual dissemination of manipulated and AI-generated deepfakes, exploiting their identity, voice or face, to the list of prohibited practices under the AI Act. Exploiting a person's identity, without their consent, to create and spread content falsely depicting the individual in question using AI, should be considered a form of identity theft, and individuals should be safeguarded against such malicious practices online.*

#### **Amendment 172**

**Assita Kanko**

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

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

***‘(ba) the placing on the market or the putting into service of an AI system that enables the depiction of sexually explicit activities, or the intimate parts of a natural person without his or her consent;’;***

Or. en

### *Justification*

*Nudify apps are a real and growing problem. They should be added to the list of prohibited AI practices to better enable authorities and platforms to ban them and to better protect citizens against their unwanted use.*

#### **Amendment 173**

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

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

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

Regulation (EU) 2024/1689

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

***(5a) in Article 5, paragraph 1, subparagraph 1, the following points are added:***

***‘(ha) the placing on the market, the putting into service or the use of an AI system that generates, manipulates or alters image, audio or video content depicting a natural person as nude or engaged in sexually explicit conduct without that person’s freely given, specific, informed and unambiguous consent, or in a manner that materially facilitates sexual exploitation or sexual abuse;***

***(hb) the placing on the market, the putting into service or the use of an AI system that depicts or provides operational guidance, planning, instruction or assistance for the commission of serious criminal offences against life or physical integrity, including homicide, terrorism or other offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years.’;***

Or. en

**Amendment 174**

**Leila Chaibi, Pernando Barrena Arza, Emma Fourreau, Hanna Gedin**  
on behalf of The Left Group

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

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

***‘(ha) The placing on the market, the making available on the market, the***

*putting into service or the use of an artificial intelligence system with the intention of generating or manipulating sexualised audio, images or videos of identifiable individuals without their consent, where such conduct facilitates the non-consensual dissemination of intimate or manipulated material and causes or is likely to cause serious harm; such conduct is to be understood in accordance with the definitions and prohibitions set out in Article 5 of Directive (EU) 2024/1385.’;*

Or. en

#### **Amendment 175**

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

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

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

*‘(ha) the placing on the market, the putting into service, or the use of an AI system that 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 (EU) 2024/1385.’;*

Or. en

#### **Amendment 176**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

***‘(ha) the placing on the market, the putting into service or the use of an AI system that alters, manipulates or artificially 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 177**

**Kateřina Konečná**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

***‘(ha) the placing on the market, putting into service, or use of an AI system or functionality that enables the generation, manipulation of nudified or sexualised audio, images and videos of individuals.’;***

Or. en

## Amendment 178

Pernando Barrena Arza

### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 5 – paragraph 1 – subparagraph 1 – point h

#### *Present text*

(h) the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement, unless and in so far as such use is strictly necessary for one of the following objectives:

(i) the targeted search for specific victims of abduction, trafficking in human beings or sexual exploitation of human beings, as well as the search for missing persons;

(ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or a genuine and present or genuine and foreseeable threat of a terrorist attack;

(iii) the localisation or identification of a person suspected of having committed a criminal offence, for the purpose of conducting a criminal investigation or prosecution or executing a criminal penalty for offences referred to in Annex II and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years.

#### *Amendment*

***(5a) in Article 5, paragraph 1, subparagraph 1, point h is replaced by the following:***

***‘(h) the use of ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement.’;***

Or. en

#### *Justification*

*Enacting a full-fledged ban of real-time biometric identification.*

## **Amendment 179**

**Regina Doherty**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

**‘(ha) the use of AI systems to generate child sexual abuse material.’;**

Or. en

## **Amendment 180**

**Pernando Barrena Arza**

### **Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(5b) In Article 5, paragraphs 2 to 7 are deleted.**

Or. en

*Justification*

*Linked to the ban of RBI. The safeguards for the use of real-time biometric identification included in paragraphs 2 to 7 are not needed if the practice is banned altogether.*

## **Amendment 181**

**Sandro Gozi, Stéphanie Yon-Courtin**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

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

***‘(ha) the placing on the market, the putting into service or the use of an AI system that alters, manipulates or artificially 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 182**  
**Andreas Schwab**

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

*Present text*

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

(a) the AI system is intended to be used as a safety component of a product, or the

*Amendment*

**(5a) In Article 6, paragraph 1 is replaced by the following:**

***1. An AI system shall be considered to be high-risk where it is intended to be used as a critical safety component of a product covered by the Union harmonisation legislation listed in Annex I. A safety component of a product shall be considered critical where its proper functioning is necessary and essential to ensure that the product complies with applicable Union safety requirements. Where the AI system is itself placed on the market as a product, it shall be considered high-risk if its proper functioning is necessary and essential to ensure compliance with applicable Union safety requirements.***

AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

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

Or. en

### **Amendment 183**

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

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

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

Regulation (EU) 2024/1689

Article 6 – paragraph 1 – point a

#### *Present text*

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

#### *Amendment*

***(5a) in Article 6, paragraph 1, point a is amended as follows:***

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

Or. en

### **Amendment 184**

**Piotr Müller, Assita Kanko**

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

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

Regulation (EU) 2024/1689

Article 6 – paragraph 1

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

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

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

**(5a) Article 6, paragraph 1 is replaced by the following:**

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

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

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

***A lack of harmonised standards or part thereof, the references of which have been published in the Official Journal of the European Union, leading to third-party conformity assessment according to the applicable Union harmonisation legislation in Annex I, can in itself not lead to a product or AI system being classified as high-risk.***’;

Or. en

*Justification*

*Introduced changes are necessary to prevent accidental inclusion into the scope of high-risk AI systems, devices such as home appliances.*

**Amendment 185**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 5 a (new)**  
Regulation (EU) 2024/1689  
Article 6 – paragraph 2 – point a (new)

*Text proposed by the Commission*

*Amendment*

**(5a) in Article 6, paragraph 2, the following point is inserted:**

**‘(a) By derogation from paragraph 1, AI systems or models intended primarily for cybersecurity purposes shall not be considered safety components.’;**

Or. en

**Amendment 186**  
**Virginie Joron, Jaroslav Bžoch, Ernő Schaller-Baross, Pál Szekeres, Klara Dostalova, Jorge Martín Frías, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 5 a (new)**  
Regulation (EU) 2024/1689  
Article 6 – paragraph 3 – subparagraph 3

*Present text*

*Amendment*

Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons.

**(5a) in Article 6, paragraph 3, subparagraph 3 is replaced by the following:**

**‘Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons, except where it is designed to be used solely by the end user for that purpose.’;**

Or. en

## *Justification*

*Article 6, paragraph 1 of the AI Act introduces a definition of high-risk AI systems embedded in products covered by Union harmonisation legislation listed in Annex I of the Act, as safety components. However, cybersecurity AI systems that are embedded in such products should not be considered safety components, as they offer protection from cyber threats rather than operating on the intrinsic safety of the product. The same principle is already adopted by Recital 55, which states that “components intended to be used solely for cybersecurity purposes should not qualify as safety components”. This new point 2a aligns the paragraph to the rest of the Act.*

### **Amendment 187**

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

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

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

Regulation EU (2024/1689)

Article 6 – paragraph 3 – subparagraph 3

#### *Present text*

Notwithstanding the first subparagraph, an AI system referred to in Annex III shall ***always*** be considered to be high-risk where the AI system performs profiling of natural persons.

#### *Amendment*

#### ***(5b) in Article 6, paragraph 3, third subparagraph is amended as follows:***

***‘Notwithstanding the first subparagraph, an AI system referred to in Annex III shall be considered to be high-risk where the AI system performs profiling of natural persons ***within the meaning of Article 4, point (4) of Regulation (EU) 2016/679, and where such profiling is posing risks to the health, safety or fundamental rights of those persons and where such profiling is materially influencing the outcome of decision-making.***’;***

Or. en

## *Justification*

*Clarification to make sure that no- or low-risk AI systems are not falsely misclassified as high-risk.*

**Amendment 188**  
**Stefano Cavedagna**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 2 – point da (new)

*Text proposed by the Commission*

*Amendment*

***(5a) in Article 6, paragraph 3, second subparagraph the following points are inserted:***

***‘(da) the AI system is intended to be used solely for cybersecurity purposes;***

***(db) in other cases, where the provider can demonstrate through appropriate technical documentation that the AI system does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons.’;***

Or. en

*Justification*

*AI systems intended solely for cybersecurity purposes should not be classified as high-risk, as they serve to protect against cyber threats rather than posing risks to health, safety, or fundamental rights. This principle is consistent with Recital 55, which states that "components intended to be used solely for cybersecurity purposes should not qualify as safety components". The new letter (f) clarifies that conditions (a)-(e) are not exhaustive. Providers should be able to demonstrate that their AI system does not pose a significant risk of harm to health, safety or fundamental rights through appropriate technical documentation, even when the system does not fit the specific scenarios in letters (a)-(e). This ensures that genuinely low-risk AI systems are not classified as high-risk merely because they fall outside predefined categories, while maintaining the principle that classification must be anchored to actual risk rather than a closed list of use cases.*

**Amendment 189**

**Leila Chaibi, Pernando Barrena Arza**

on behalf of The Left Group

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

**(5a) in Article 6, paragraph 3 is deleted;**

Or. en

## **Amendment 190**

**Mary Khan**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

**(6) in Article 6, paragraph 3, subparagraph 2a is inserted:**

***‘The conditions listed in points (a) to (d) constitute a non-exhaustive list. Providers may demonstrate, on the basis of objective and verifiable evidence, that an AI system does not pose a significant risk of harm and therefore shall not be considered to be high-risk. AI systems benefiting from this paragraph shall remain subject to other applicable obligations under this Regulation, including those laid down in Article 50.’;***

Or. en

## **Amendment 191**

**Tomáš Zdechovský**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 3

*Present text*

*Amendment*

**(5a) in Article 6, paragraph 3, subparagraph 3 is replaced by the**

Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons.

*following:*

***‘Notwithstanding the first subparagraph, an AI system referred to in Annex III shall be considered to be high-risk where the AI system performs profiling of natural persons, where such profiling is liable to materially influence the outcome of decision making.’;***

Or. en

*Justification*

*The purpose of this amendment is to introduce a clarification that, in order to be considered high-risk, profiling needs to be liable to materially influence the outcome of decision making, in line with the logic in the first subparagraph of paragraph 3 of Article 6 of this Regulation.*

## **Amendment 192**

**Lukas Mandl, Sander Smit**

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 3

*Present text*

Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons.

*Amendment*

***(5a) in Article 6, paragraph 3, subparagraph 3 is replaced by the following:***

***‘Notwithstanding the first subparagraph, an AI system referred to in Annex III shall be considered to be high-risk where the AI system performs profiling of natural persons, where such profiling is liable to materially influence the outcome of decision making.’;***

Or. en

*Justification*

*The purpose of this amendment is to introduce a clarification that, in order to be considered high-risk, profiling needs to be liable to materially influence the outcome of decision making, in line with the logic in the first subparagraph of paragraph 3 of Article 6 of this Regulation.*

**Amendment 193**  
**Axel Voss, Arba Kokalari**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 5 a (new)**  
Regulation (EU) 2024/1689  
Article 6 – paragraph 3 – subparagraph 3

*Present text*

Notwithstanding the first subparagraph, an AI system referred to in Annex III shall **always** be considered to be high-risk where the AI system performs profiling of natural persons.

*Amendment*

**(5a) in Article 6, paragraph 3, subparagraph 3 is replaced by the following:**

‘Notwithstanding the first subparagraph, an AI system referred to in Annex III shall be considered to be high-risk where the AI system performs profiling of natural persons, **where such profiling is liable to materially influence the outcome of decision making.**’;

Or. en

*Justification*

*The purpose of this amendment is to introduce a clarification that, in order to be considered high-risk, profiling needs to be liable to materially influence the outcome of decision making, in line with the logic in the first subparagraph of paragraph 3 of Article 6 of this Regulation.*

**Amendment 194**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 5 b (new)**  
Regulation (EU) 2024/1689  
Article 6 – paragraph 3 – subparagraph 1

*Present text*

By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does

*Amendment*

**(5b) in Article 6, paragraph 3, subparagraph 1 is replaced by the following:**

‘By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does

not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making.

not pose a significant risk of harm to the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making *or by ensuring meaningful human intervention or review.*’;

Or. en

### *Justification*

*Amendment ensures that meaningful human oversight is recognised in the context of mitigating AI risk.*

## **Amendment 195** **Regina Doherty**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 5 a (new)**  
Regulation (EU) 2024/1689  
Article 6 – paragraph 3

### *Present text*

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

The first subparagraph shall apply where any of the following conditions is fulfilled:

- (a) the AI system is intended to perform a narrow procedural task;
- (b) the AI system is intended to improve the result of a previously completed human activity;
- (c) the AI system is intended to detect

### *Amendment*

***(5a) in Article 6, paragraph 3 is replaced by the following:***

***‘3. An AI system to which Annex III refers shall not be considered as high-risk where it does not pose a significant risk of harm to the fundamental rights of natural persons, including by ensuring human review.’;***

decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or

(d) the AI system is intended to perform a preparatory task to an assessment relevant for the purposes of the use cases listed in Annex III.

Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons.

Or. en

#### **Amendment 196**

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

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

#### **Article 1 – paragraph 1 – point 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 197**

**Marion Walsmann, Hildegard Bentele, Christine Schneider, Stefan Köhler, Sven Simon,**

**Andreas Schwab**

**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

*Justification*

*Keeping the registration duty for non-high-risk Annex III systems ensures consistent oversight and provides authorities with comparable data. It helps prioritize market surveillance and identify emerging use cases. Since providers must perform risk assessments anyway to claim exemptions, the added administrative burden is limited and proportionate, while the benefits for transparency and supervision are tangible.*

**Amendment 198**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 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 199**

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

#### **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 200**

**Kateřina Konečná**

#### **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 201**  
**Sandro Gozi, Stéphanie Yon-Courtin**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 6**  
Regulation (EU) 2029/1689  
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 202**  
**Leila Chaibi, Pernando Barrena Arza**  
on behalf of The Left Group

**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 203**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – 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 the documentation of the assessment ***to the extent strictly necessary to demonstrate that the conditions laid down in Article 6(3) are fulfilled.***;

Or. en

**Amendment 204**  
**Zala Tomašič, Tomáš Zdechovský, Jan Farský, Alexandr Vondra, Ondřej Krutílek**

**Proposal for a regulation**  
**Article 1 – 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

*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 the documentation of the assessment.;

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 ***limited to the minimum information necessary to demonstrate that the conditions of Article 6(3) are met.***

Or. en

#### *Justification*

*This amendment keeps the Commission’s “document and provide on request” approach and ensures authorities only request what is necessary to verify the Article 6(3) self-assessment. It simplifies registration requirements for all high-risk AI systems, increases legal certainty, reduces unnecessary administrative burden, and promotes consistent supervision across Member States without weakening oversight.*

#### **Amendment 205**

**Jaroslav Bžoch, Klara Dostalova**

#### **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 206**

**Tomáš Zdechovský**

**Proposal for a regulation**  
**Article 1 – 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, **with no registration obligation**. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.;

Or. en

*Justification*

*This amendment supports the idea of the Commission's proposal with more clarity. It emphasises that there is no registration obligation, in order to achieve reduction of bureaucracy.*

**Amendment 207**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 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 **reasonable** request of national competent authorities, the provider shall provide the documentation of the assessment.;

Or. en

## **Amendment 208**

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

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 7**

Regulation (EU) 2024/1689

Article 10

*Text proposed by the Commission*

*Amendment*

(7) *Article 10 is amended as follows:* *deleted*

(a) *paragraph 1 is replaced by the following:*

*‘1. High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2, 3 and 4 of this Article and in Article 4a(1) whenever such data sets are used.’;*

(b) *paragraph 5 is deleted;*

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

*‘6. For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2, 3 and 4 of this Article and Article 4a(1) shall apply only to the testing data sets.’;*

Or. en

## **Amendment 209**

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

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 7**

Regulation (EU) 2024/1689

Article 10

*Text proposed by the Commission*

*Amendment*

(7) *Article 10 is amended as follows:* **deleted**

(a) *paragraph 1 is replaced by the following:*

***‘1. High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2, 3 and 4 of this Article and in Article 4a(1) whenever such data sets are used.’;***

(b) *paragraph 5 is deleted;*

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

***‘6. For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2, 3 and 4 of this Article and Article 4a(1) shall apply only to the testing data sets.’;***

Or. en

## **Amendment 210**

**Markéta Gregorová**

### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 7 – point b**

Regulation (EU) 2024/1689

Article 10 – paragraph 5 – subparagraph 1

*Text proposed by the Commission*

*Amendment*

(b) *paragraph 5 is deleted;*

(b) ***in Article 10, paragraph 5, subparagraph 1 is amended as follows:***

***‘To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate***

*safeguards for the fundamental rights and freedoms of natural persons. The processing of personal data pursuant to this paragraph shall be considered high-risk in the meaning of Article 30 of Regulation (EU) 2016/679. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:’;*

Or. en

#### **Amendment 211**

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

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

**Article 1 – paragraph 1 – point 7 – point c**  
Regulation (EU) 2024/1689  
Article 10 – paragraph 6

*Text proposed by the Commission*

*Amendment*

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

*deleted*

*‘6. For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2, 3 and 4 of this Article and Article 4a(1) shall apply only to the testing data sets.’;*

Or. en

#### **Amendment 212**

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

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

**Article 1 – paragraph 1 – point 8**  
Regulation (EU) 2024/1689  
Article 11 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

**(8) in Article 11(1), the second subparagraph is replaced by the following:** *deleted*

***‘That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMCs and SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMCs and SMEs, including start-ups. Where an SMC or SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.’;***

Or. en

**Amendment 213**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 8**  
Regulation (EU) 2024/1689  
Article 11 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

**(8) in Article 11(1), the second subparagraph is replaced by the following:** *deleted*

*‘That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMCs and SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMCs and SMEs, including start-ups. Where an SMC or SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.’;*

Or. en

#### **Amendment 214**

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

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

#### **Article 1 – paragraph 1 – point 8**

Regulation (EU) 2024/1689

Article 11 – paragraph 1 – subparagraph 2

#### *Text proposed by the Commission*

That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall

#### *Amendment*

That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall

contain, at a minimum, the elements set out in Annex IV. ***SMCs and SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMCs and SMEs, including start-ups. Where an SMC or SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.;***

contain, at a minimum, the elements set out in Annex IV.

Or. en

#### **Amendment 215**

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

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

#### **Article 1 – paragraph 1 – point 8**

Regulation (EU) 2024/1689

Article 11 – paragraph 1 – subparagraph 2

#### *Text proposed by the Commission*

That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. ***SMCs and SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMCs and SMEs, including start-ups. Where an SMC or***

#### *Amendment*

That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. ***SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMEs, including start-ups. Where an SME, including a start-up, opts***

SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.;

to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.’;

Or. en

#### **Amendment 216**

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

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

##### **Article 1 – paragraph 1 – point 9**

Regulation (EU) 2024/1689

Article 17 – paragraph 2

*Text proposed by the Commission*

*Amendment*

**(9) in Article 17, paragraph 2 is replaced by the following:**

*deleted*

**‘2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider’s organisation, in particular, if the provider is an SMC or an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.’;**

Or. en

#### **Amendment 217**

**Kateřina Konečná**

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

##### **Article 1 – paragraph 1 – point 9**

Regulation (EU) 2024/1689

Article 17 – paragraph 2

*Text proposed by the Commission*

*Amendment*

**(9) in Article 17, paragraph 2 is replaced by the following:** *deleted*

**‘2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider’s organisation, in particular, if the provider is an SMC or an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.’;**

Or. en

#### **Amendment 218**

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

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

#### **Article 1 – paragraph 1 – point 9**

Regulation (EU) 2024/1689

Article 17 – paragraph 2

*Text proposed by the Commission*

*Amendment*

2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider’s organisation, in particular, if the provider is **an SMC or** an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.;

2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider’s organisation, in particular, if the provider is an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.’;

Or. en

#### **Amendment 219**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 9**  
Regulation (EU) 2024/1689  
Article 17 – paragraph 2

*Text proposed by the Commission*

2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation, in particular, if the provider is **an SMC or** an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.;

*Amendment*

2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation, in particular, if the provider is an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.;

Or. en

**Amendment 220**  
**Axel Voss**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 9 a (new)**  
Regulation (EU) 2024/1689  
Article 25 – paragraph 1– subparagraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

**(9a) in Article 25, paragraph 1, subparagraph 1a is inserted:**

***‘Entities that purchase and fine-tune a GPAI model or having it fine-tuned to subsequently use it in a high-risk AI system shall only become a provider if the training compute used for the modification is greater than a third of the training compute of the original model. The question whether that entity becomes a provider shall be without prejudice to applicable copyright laws.’;***

Or. en

## Justification

*The AI value chain relies heavily on downstream adaptation (i.e. fine-tuning and integration of existing GPAI models), so EU rules must provide a predictable pathway for AI deployers to innovate without automatically being reclassified as AI providers. An operational threshold for “substantial modification” increases legal certainty and ensures consistent application across Member States, reducing unnecessary compliance risk for EU integrators, in particular SMEs. Using a measurable compute-based benchmark draws a clear line between limited adaptation and capability-changing redevelopment that should trigger provider obligations.*

### Amendment 221

Axel Voss

#### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 25 – paragraph 2

#### *Present text*

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

#### *Amendment*

***(9b) in Article 25, paragraph 2 is replaced by the following:***

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

***That initial provider, as well as providers of general-purpose AI models whose***

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

*This obligation shall include:*

- (a) Technical documentation sufficient to assess compliance with Article 16 requirements;*
- (b) Known limitations and failure modes that could affect high-risk applications;*
- (c) Reasonable technical access for testing and validation purposes.’;*

Or. en

#### *Justification*

*Clear value-chain collaboration duties are necessary to make the reallocation of “provider” responsibility in Article 25 workable in practice: once a new provider takes over after rebranding, substantial modification or change of intended purpose, they still depend on upstream information to complete conformity assessment and ongoing compliance. Stakeholder evidence highlights persistent “responsibility gaps” in the AI value chain, especially where GPAI models are integrated and modified, because key compliance elements (i.e. documentation, known limitations, failure modes, testability) often sit with upstream actors. Requiring initial providers and GPAI model providers to provide the necessary documentation, reasonable technical access and assistance therefore reduces legal uncertainty and prevents de-facto non-compliance driven by missing information rather than bad faith. This is particularly important for EU SMEs and Start-Ups, for whom predictable cooperation from upstream suppliers is a prerequisite to meet high-risk obligations efficiently and consistently across the Single Market.*

#### **Amendment 222**

**Mary Khan**

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

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

*Present text*

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

*Amendment*

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

**‘4. If any of the obligations laid down in this Article are already met through a data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, that data protection impact assessment may be used to fulfil, in whole or in part, the requirements of the fundamental rights impact assessment referred to in paragraph 1 of this Article, where its scope and content are equivalent.’;**

Or. en

**Amendment 223**  
**Tomáš Zdechovský**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 9 a (new)**  
Regulation (EU) 2024/1689  
Article 27 – paragraph 4

*Present text*

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

*Amendment*

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

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

Or. en

### *Justification*

*The AI Act stipulates that if obligations laid down in Article 27 on fundamental rights impact assessment (FRIA) are already met through the data protection impact assessment (DPIA) conducted pursuant to the GDPR or the LED, the FRIA shall complement the DPIA. However, it does not specify how it should be complemented. This amendment introduces a clarification that the FRIA shall be represented by the DPIA in cases of the legal obligations in question.*

#### **Amendment 224**

**Lukas Mandl, Sander Smit**

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

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

Regulation (EU) 2024/1689

Article 27 – paragraph 4

#### *Present text*

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

#### *Amendment*

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

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

Or. en

### *Justification*

*The AI Act stipulates that if obligations laid down in Article 27 on fundamental rights impact assessment (FRIA) are already met through the data protection impact assessment (DPIA) conducted pursuant to the GDPR or the LED, the FRIA shall complement the DPIA. However, it does not specify how it should be complemented. This amendment introduces a clarification that the FRIA shall be represented by the DPIA in cases of the legal obligations in question.*

#### **Amendment 225**

**Axel Voss**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 9 c (new)**  
Regulation (EU) 2024/1689  
Article 27 – paragraph 4

*Present text*

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

*Amendment*

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

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

Or. en

*Justification*

*The AI Act stipulates that if obligations laid down in Article 27 on fundamental rights impact assessment (FRIA) are already met through the data protection impact assessment (DPIA) conducted pursuant to the GDPR or the LED, the FRIA shall complement the DPIA. However, it does not specify how it should be complemented. This amendment introduces a clarification that the FRIA shall be represented by the DPIA in cases of the legal obligations in question.*

**Amendment 226**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 10**  
Regulation (EU) 2024/1689  
Article 28 – paragraph 8

*Text proposed by the Commission*

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

**‘8. Notifying authorities designated**

*Amendment*

**deleted**

***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.***

***The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation, provided that the relevant Union harmonisation legislation provides for such a procedure.***

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

Or. en

#### *Justification*

*This Regulation shall not affect industrial AI systems, which are already covered by sectoral legislation under the New Legislative framework (Section A of Annex I).*

## Amendment 227

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

### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 28 – paragraph 8 – subparagraph 3

#### *Text proposed by the Commission*

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

#### *Amendment*

The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation. ***Single procedures shall not be used to circumvent or avoid any relevant legal requirement under the respective legal acts. When a single application and assessment is submitted, it shall be ensured that all and requirements of the harmonisation legislation and this Regulation are fulfilled.***

Or. en

## Amendment 228

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

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 11

Regulation (EU) 2024/1689

Article 29 – paragraph 4 – subparagraph 2

#### *Text proposed by the Commission*

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

#### *Amendment*

***deleted***

*the single application for assessment to the notifying authority designated in accordance with that Union harmonisation legislation.*

Or. en

*Justification*

*This Regulation shall not affect industrial AI systems, which are already covered by sectoral legislation under the New Legislative framework (Section A of Annex I).*

**Amendment 229**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 40 – paragraph 2 – subparagraph 1

*Present text*

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

*Amendment*

***(12a) in Article 40, paragraph 2, subparagraph 1 is replaced by the following:***

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

*forum.';*

Or. en

**Amendment 230**

**Piotr Müller, Assita Kanko**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 41

*Text proposed by the Commission*

*Amendment*

**(12a) Article 41 is deleted.**

*(This amendment applies throughout the text.)*

Or. en

*Justification*

*Backtracking the Commission's power to adopt common specifications avoids creating a parallel compliance pathway that circumvents the established system of harmonised standards. Maintaining a single, predictable standards framework preserves legal certainty and protects public and private investment in the development of consensus-based technical standards.*

**Amendment 231**

**Markéta Gregorová, Kim Van Sparrentak**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 – introductory part

*Present text*

*Amendment*

**(12b) in Article 41, the introductory part is replaced by the following:**

The Commission may adopt, implementing acts establishing common specifications

**'1. The Commission shall adopt, implementing acts by 2 July 2027**

for the requirements set out in Section 2 of this Chapter or, as applicable, for the obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:

*establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the e following conditions have been fulfilled: obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:';*

Or. en

## **Amendment 232**

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

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

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

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

*procedure referred to in Article 98(2).  
When preparing those implementing acts,  
the Commission shall be assisted by an  
expert group that includes relevant  
stakeholder representatives.';*

Or. en

#### **Amendment 233**

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

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

**Article 1 – paragraph 1 – point 12 d (new)**  
Regulation (EU) 2024/1689  
Article 41 – paragraph 1 b (new)

*Text proposed by the Commission*

*Amendment*

*(12d) In Article 41, the following  
paragraph 1b is inserted:*

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

Or. en

#### **Amendment 234**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 12 e (new)**  
Regulation (EU) 2024/1689  
Article 41 – paragraph 6

*Present text*

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

*Amendment*

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

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

Or. en

**Amendment 235**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 12 a (new)**  
Regulation (EU) 2024/1689  
Article 42 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

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

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

*thereof issued pursuant to Regulation (EU) 2024/2847. Providers of such AI systems shall not be obliged to comply with the requirements set out in Article 15 until Regulation (EU) 2024/2847 becomes applicable.';*

Or. en

#### *Justification*

*While the intent of the draft report is commendable, Regulation (EU) 2024/2847 will only be applicable as of 11 December 2027, while requirements introduced by Article 15 of the AI Act may enter into force earlier. This amendment aims to avoid an interim period where providers will be subject to Article 15, thus requiring them to undergo conformity procedures with both regulations.*

#### **Amendment 236**

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

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

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

Regulation (EU) 2024/1689

Article 42 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(12f) in Article 42, the following paragraph is added:***

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

Or. en

**Amendment 237**

**Virginie Joron, Jaroslav Bžoch, Ernő Schaller-Baross, Pál Szekeres, Klara Dostalova, Jorge Martín Frías, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 42 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(12a) in Article 42, the following paragraph 3 is inserted:***

***'2a. Where an AI system complies with Regulation (EU) 2024/2847, such compliance shall be deemed sufficient to demonstrate compliance with the cybersecurity requirements laid down in Article 15, to the extent that those requirements are covered by the EU declaration of conformity issued under that Regulation.'***

Or. en

**Amendment 238**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 13**

Regulation (EU) 2024/1689

Article 43 – paragraph 3

*Text proposed by the Commission*

*Amendment*

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

***deleted***

***'For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union***

***harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.***

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

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

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

*required under the relevant Union harmonisation legislation listed in Section A of Annex I.’;*

Or. en

*Justification*

*This Regulation shall not affect industrial AI systems, which are already covered by sectoral legislation under the New Legislative framework (Section A of Annex I).*

**Amendment 239**  
**Christian Doleschal**

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

*Text proposed by the Commission*

*Amendment*

*For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.*

*deleted*

Or. en

**Amendment 240**  
**Piotr Müller, Assita Kanko**

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

*Text proposed by the Commission*

*Amendment*

***For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.***

***deleted***

Or. en

*Justification*

*The original version of Article 43 provides sufficient procedural safeguards and does not introduce new burdens, in contrast to the updated Commission proposal.*

**Amendment 241**

**Sandro Gozi, Stéphanie Yon-Courtin**

**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 242**

**Jaroslav Bžoch, Klara Dostalova**

**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 243**

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

**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 244**

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

**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 245**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 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 246**  
**Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jouvét, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 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 247**  
**Marion Walsmann, Hildegard Bentele, Christine Schneider, Stefan Köhler, Sven Simon, Andreas Schwab**

**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

## *Justification*

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

### **Amendment 248** **Kateřina Konečná**

**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 249** **Christel Schaldemose**

**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;*

*(14) in Article 49, paragraph 2 is replaced by the following:*

*'2. Before placing on the market or putting into service an AI system for which the provider has concluded that it is not high-risk according to Article 6(3), that provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 71.'*

Or. en

**Amendment 250**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 14 a (new)**

Regulation (EU) 2024/1689

Article 49 – paragraph 5 a (new)

*Text proposed by the Commission*

*Amendment*

***(14a) in Article 49, the following paragraph is inserted:***

***'5a. Only the Commission and market surveillance authorities shall have access to information referred to in Section B, point 5, of Annex VIII.'***

Or. en

**Amendment 251**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 50 – paragraph 7

*Text proposed by the Commission*

*Amendment*

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

***deleted***

***'7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, in accordance with the procedure laid down in Article 56(6), first subparagraph. If it***

*deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).’;*

Or. en

*Justification*

*Implementing acts are vital for the Single Market, translating duties into uniform requirements to prevent divergent national approaches. Removing them shifts the burden to ad-hoc interpretations, increasing uncertainty and costs for AI operators. Using these acts ensures structured Member State input via comitology, enhancing practicality. Retaining such tools supports competitiveness and simplification by avoiding fragmentation and ensuring predictable, proportionate compliance.*

**Amendment 252**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 50 – paragraph 7

*Text proposed by the Commission*

*Amendment*

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

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

*accordance with the examination procedure laid down in Article 98(2).';*

Or. en

### **Amendment 253**

**Adnan Dibrani, Evin Incir, Christel Schaldemose**

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

**Article 1 – paragraph 1 – point 15 – introductory part**

Regulation (EU) 2024/1689

Article 50 – paragraph 6 a (new)

#### *Text proposed by the Commission*

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

#### *Amendment*

(15) in Article 50, ***the following new paragraph 6a is inserted and the title and paragraph 7 is replaced by the following:***

#### ***'Article 50***

***Obligations for providers and deployers of certain AI systems***

***6a. Providers of AI systems, including general-purpose AI systems, that generate or manipulate image, audio or video content shall implement effective technical and organisational measures to prevent the generation of deep fakes, resembling existing persons and would falsely appear to a person to be authentic or truthful, without the consent of the existing natural person; with the exception of where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme; as well as deepfakes depicting non-consensual nudity or sexually explicit conduct; and of outputs that depict or provide operational guidance, planning, instruction or assistance for the commission of serious criminal offences against life or physical integrity, including homicide, terrorism or other offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years.'***

*Justification*

*The purpose of this amendment is to add the non-consensual dissemination of manipulated and AI-generated deepfakes, exploiting their identity, voice or face, to the list of prohibited practices under the AI Act. Exploiting a person's identity, without their consent, to create and spread content falsely depicting the individual in question using AI, should be considered a form of identity theft, and individuals should be safeguarded against such malicious practices online.*

**Amendment 254**

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

**Proposal for a regulation****Article 1 – paragraph 1 – point 15 – introductory part**

Regulation (EU) 2024/1689

Article 50 – paragraph 6 a (new)

*Text proposed by the Commission*

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

*Amendment*

(15) in Article 50, ***the following paragraph 6a is inserted and the title and paragraph 7 is replaced by the following:***

***'Article 50******Obligations for providers and deployers of certain AI systems***

***6a. Providers of AI systems, including general-purpose AI systems, that generate or manipulate image, audio or video content shall implement effective technical and organisational measures to prevent the generation of deep fakes depicting non-consensual nudity or sexually explicit conduct; and of outputs that depict or provide operational guidance, planning, instruction or assistance for the commission of serious criminal offences against life or physical integrity, including homicide, terrorism or other offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years.'***

**Amendment 255**

**Piotr Müller, Assita Kanko**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 50 – paragraph 7

*Text proposed by the Commission*

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

*Amendment*

7. The **Commission** 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.;

Or. en

*Justification*

*Compliance with Article 50 should be established either on the basis of voluntary standards or through individual methods decided by stakeholders. Employing common specifications or common rules risks undermining the purpose of the voluntary framework and compromise the joint effort. Furthermore the law shall be applied as adopted and proposed mechanism creates an unnecessary opportunity to gold-plating the rules.*

**Amendment 256**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 15**  
Regulation (EU) 2024/1689  
Article 50 – paragraph 7

*Text proposed by the Commission*

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

*Amendment*

7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission, *in consultation with relevant competent authorities and EU bodies*, 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 *the Commission, in consultation with all relevant national competent authorities and Union bodies*, deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).';

Or. en

**Amendment 257**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 15**  
Regulation (EU) 2024/1689  
Article 50 – paragraph 7

*Text proposed by the Commission*

7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and

*Amendment*

7. The AI Office, *in close collaboration with the Board*, shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the

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).;

obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The **Board** 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 Board and upon 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. en

## **Amendment 258**

**Jaroslav Bžoch, Klara Dostalova**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 15**

Regulation (EU) 2024/1689

Article 50 – paragraph 7

#### *Text proposed by the Commission*

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

#### *Amendment*

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

laid down in Article 98(2).;

Or. en

**Amendment 259**  
**Tomáš Zdechovský**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 15**  
Regulation (EU) 2024/1689  
Article 50 – paragraph 7

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

*Justification*

*This amendment aims to increase legal clarity and bring the text better in line with the proposed changes in Article 56(6). The Commission is required to assess the adequacy of the codes of practice, in order to ensure that stakeholders get maximum guidance.*

**Amendment 260**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 14 a (new)**

*Present text*

Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video *or text* content, shall **ensure** that the outputs of the AI system are marked in a machine-readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account the specificities and limitations of various types of content, the costs of implementation and the generally acknowledged state of the art, as may be reflected in relevant technical standards. This obligation shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate or prosecute criminal offences.

*Amendment*

***(14a) "Article 50, paragraph 2 is replaced by the following:***

***'2. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image *or* video content, shall **take measures so** that the outputs of the AI system are marked in a machine-readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account the specificities and limitations of various types of content, the costs of implementation and the generally acknowledged state of the art, as may be reflected in relevant technical standards. This **watermarking** obligation **shall be applied in a proportionate manner linked to the identified risk and that does not impede, hamper or otherwise distort the display, lawful commercial exploitation or publication of the work, nor interfere with*****

*its normal use, and* shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate or prosecute criminal offences.’;

Or. en

### *Justification*

*The watermarking provision is amended to remove the obligation in relation to text, as such marking is difficult to justify in practical terms and provides limited added value in real-world use. While watermarking of audio, image and video content may be beneficial to the general public, its implementation should not undermine the legitimate opportunities offered by AI tools to advance creative, professional or commercial work. The revised wording therefore introduces a proportionality requirement based on paragraph 4.*

### **Amendment 261**

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

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 16**

Regulation (EU) 2024/1689

Article 56 – paragraph 6 – subparagraph 1

*Text proposed by the Commission*

*Amendment*

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

***deleted***

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

*publish its assessment of the adequacy of the codes of practice.’;*

Or. en

*Justification*

*Implementing acts translate legal duties into uniform requirements, reducing divergent national approaches. Removing them increases legal uncertainty and compliance costs through ad-hoc interpretations. This route ensures structured Member State input, improving practicality over informal guidance. Retaining these tools supports competitiveness and simplification by avoiding fragmentation, enabling predictable compliance instead of "27 ways" of meeting the same AI Act obligation.*

**Amendment 262**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 16 – introductory part**

*Text proposed by the Commission*

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

*Amendment*

(16) in Article 56, **paragraph 6** is replaced by the following:

Or. en

**Amendment 263**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 16**

Regulation (EU) 2024/1689

Article 56 – paragraph 6 – subparagraph 1

*Text proposed by the Commission*

6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking

*Amendment*

6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking

utmost account of the opinion of the Board, 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.;

utmost account of the opinion of the Board **and other relevant competent authorities and Union bodies**, shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. The Commission shall publish its assessment of the adequacy of the codes of practice.;

Or. en

#### **Amendment 264**

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

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

##### **Article 1 – paragraph 1 – point 16**

Regulation 2024/1689

Article 56 – paragraph 6

#### *Text proposed by the Commission*

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

#### *Amendment*

6. The 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 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 **Board** shall publish its assessment of the adequacy of the codes of practice.;

Or. en

#### **Amendment 265**

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

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

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

*Text proposed by the Commission*

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

*Amendment*

The AI Office 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. ***The AI Office shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities, the European Data Protection Board and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.***;

Or. en

**Amendment 266**  
**Leila Chaibi**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 17 – point a**  
Regulation (EU) 2024/1689  
Article 57 – paragraph 3 a

*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

*Amendment*

The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular

when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs.;

when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs. ***To the extent the AI systems involve the processing of personal data, the competent data protection authorities shall be associated with the operation of the AI regulatory sandbox established at Union level and involved in the supervision of those aspects to the extent of their respective tasks and powers, in accordance with Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU)2018/680 ;***

Or. en

#### **Amendment 267**

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

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

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

Regulation (EU) 2024/1689

Article 57 – paragraph 3 a

#### *Text proposed by the Commission*

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

#### *Amendment*

The AI Office 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 ***and SMCs. It shall be operational no later than 1 January 2027.***

Or. en

#### *Justification*

*The Digital Omnibus envisages the establishment of an EU-level AI regulatory sandbox by the AI Office only from 2028. For SMEs and start-ups that will face compliance obligations under the AI Act earlier, this timeline is too late. Regulatory sandboxes are most effective*

when available at the early stage of regulatory application. Therefore, the Commission should accelerate the establishment of EU-level AI regulatory sandboxes and ensure their availability well before 2028, and in any event no later than the start of the application of AI Act provisions on high-risk systems.

#### **Amendment 268**

**Jaroslav Bžoch, Klara Dostalova**

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

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

Regulation (EU) 2024/1689

Article 57 – paragraph 3 a

#### *Text proposed by the Commission*

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

#### *Amendment*

The AI Office 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 **SMCs and SMEs, including startups**;

Or. en

#### **Amendment 269**

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

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

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

Regulation (EU) 2024/1689

Article 57 – paragraph 3 a

#### *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

#### *Amendment*

**When necessary, the Board** 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

Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs.;

legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs *and SMCs*.;

Or. en

#### **Amendment 270**

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

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

**Article 1 – paragraph 1 – point 17 – point a**  
Regulation (EU) 2024/1689  
Article 57 – paragraph 3 a

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. en

#### **Amendment 271**

**Kateřina Konečná**

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

**Article 1 – paragraph 1 – point 17 – point b**  
Regulation (EU) 2024/1689  
Article 57 – paragraph 5

#### *Text proposed by the Commission*

5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of

#### *Amendment*

5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of

innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority, ensuring that appropriate safeguards are in place. ***Such sandboxes may include testing in real world conditions supervised therein. When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan.***;

innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority, ensuring that appropriate safeguards are in place.;

Or. en

**Amendment 272**  
**Leila Chaibi**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 17 – point c**  
Regulation (EU) 2024/1689  
Article 57 – paragraph 9 – point e

*Text proposed by the Commission*

*Amendment*

***(c) paragraph 9, point (e) is replaced by the following:*** ***deleted***

***‘(e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.’;***

Or. en

**Amendment 273**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 17 – point c**  
Regulation (EU) 2024/1689  
Article 57 – paragraph 9 – point e

*Text proposed by the Commission*

*Amendment*

***(c) paragraph 9, point (e) is replaced*** ***deleted***

*by the following:*

***‘(e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.’;***

Or. en

#### **Amendment 274**

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

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

**Article 1 – paragraph 1 – point 17 – point c**

Regulation (EU) 2024/1690

Article 57 – paragraph 9 – point e

*Text proposed by the Commission*

*Amendment*

***(c) paragraph 9, point (e) is replaced by the following:***

*deleted*

***‘(e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.’;***

Or. en

#### **Amendment 275**

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

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

**Article 1 – paragraph 1 – point 17 – point c a (new)**

Regulation (EU) 2024/1689

Article 57 – paragraph 10 a (new)

*Text proposed by the Commission*

*Amendment*

***(ca) in Article 57, paragraph 10a is inserted:***

***‘10a. In cases referred to in paragraph 3a, the AI office shall ensure that, to the extent the innovative AI systems involve***

*the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities, the EDPB and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.';*

Or. en

**Amendment 276**

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

**Proposal for a regulation**

**Article 1 – 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. en

**Amendment 277**

**Leila Chaibi**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 57 – paragraph 14

*Text proposed by the Commission*

*Amendment*

*(e) paragraph 14 is replaced by the following:*

*deleted*

***‘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.’;***

Or. en

#### **Amendment 278**

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

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

**Article 1 – paragraph 1 – point 17 – point e**  
Regulation (EU) 2024/1689  
Article 57 – paragraph 14

*Text proposed by the Commission*

*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, ***the European Data Protection Supervisor, and the AI Office*** shall coordinate their activities and cooperate within the framework of the Board. They shall support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.;

Or. en

#### **Amendment 279**

**Jaroslav Bžoch, Klara Dostalova**

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

**Article 1 – paragraph 1 – point 17 – point e**  
Regulation (EU) 2024/1689  
Article 57 – paragraph 14

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 280**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 57 – paragraph 14

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 281**

**Stefano Cavedagna**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 17 – point b a (new)**

Regulation (EU) 2024/1689

Article 57 – paragraph 7

*Present text*

7. Competent authorities shall provide

PE784.275v01-00

*Amendment*

**(ba) in Article 57, paragraph 7 is replaced by the following:**

**'7. Competent authorities shall**

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providers and prospective providers participating in the AI regulatory sandbox with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation.

Upon request of the provider or prospective provider of the AI system, the competent authority shall provide a written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Providers may use such documentation to demonstrate their compliance with this Regulation through the conformity assessment process or relevant market surveillance activities. In this regard, the exit reports and the written proof provided by the national competent authority shall be taken positively into account by market surveillance authorities and notified bodies, with a view to accelerating conformity assessment procedures to a reasonable extent.

*provide providers and prospective providers participating in the AI regulatory sandbox with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation. Upon request of the provider or prospective provider of the AI system, the competent authority shall provide a written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. AI systems that have participated in an AI regulatory sandbox are presumed to be conforming to the requirements set in this Regulation, limited to the activities detailed in the exit reports and the written proof provided by the national competent authority.';*

Or. en

#### *Justification*

*The current wording of Article 57, paragraph 7, does not guarantee benefits proportionate to the organizational, technical and procedural effort required of companies to participate in sandboxes. A presumption of conformity based on the activities successfully carried out in the sandbox would make the value of participation more immediately tangible, especially SMEs and startups.*

#### **Amendment 282**

**Virginie Joron, Jaroslav Bžoch, Ernő Schaller-Baross, Pál Szekeres, Klara Dostalova, Jorge Martín Frías, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

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

#### **Article 1 – paragraph 1 – point 18**

Regulation (EU) 2024/1689

Article 58 – paragraph 1 – introductory part

*Text proposed by the Commission*

1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

*Amendment*

1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts, ***on the basis of a prior opinion from the Board***, specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

Or. en

**Amendment 283**

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

**Proposal for a regulation**

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

Regulation (EU) 2014/1689

Article 58 – paragraph 1 – point d

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 284**

**Virginie Joron, Jaroslav Bžoch, Ernő Schaller-Baross, Pál Szekeres, Klara Dostalova, Jorge Martín Frías, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 18 a (new)**

*Present text*

(d) that access to the AI regulatory sandboxes is free of charge for SMEs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;

*Amendment*

***(18a) in Article 58, paragraph 2, point (d) is replaced by the following:***

***'(d) that access to the AI regulatory sandboxes is free of charge for SMEs and SMCs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;'***

Or. en

**Amendment 285**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 18 a (new)**  
Regulation (EU) 2024/1689  
Article 58 – paragraph 2 – point i a (new)

*Text proposed by the Commission*

*Amendment*

***(18a) in Article 58, paragraph 2, the following point is inserted:***

***'(ia) that AI systems which have participated in an AI regulatory sandbox benefit from a presumption of conformity with the requirements of this Regulation relating to the activities carried out in the sandbox.'***

Or. en

*Justification*

*The amendment empowers the Commission to develop implementing acts detailing the functioning of AI sandboxes ensuring a presumption of conformity for participants, thus making them more attractive for AI providers, especially SMEs and startups.*

**Amendment 286**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 19**  
Regulation (EU) 2024/1689  
Article 60

*Text proposed by the Commission*

*Amendment*

**(19) Article 60 is amended as follows: deleted**

**(a) in paragraph 1, the first subparagraph is replaced by the following:**

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

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

***‘2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.’;***

Or. en

**Amendment 287**  
**Leila Chaibi**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 19**

*Text proposed by the Commission*

*Amendment*

**(19) Article 60 is amended as follows: *deleted***

**(a) in paragraph 1, the first subparagraph is replaced by the following:**

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

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

***‘2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.’;***

Or. en

## **Amendment 288**

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

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 19**

Regulation (EU) 2024/1689

Article 60

*Text proposed by the Commission*

*Amendment*

**(19) Article 60 is amended as follows:** *deleted*

**(a) in paragraph 1, the first subparagraph is replaced by the following:**

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

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

***‘2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.’;***

Or. en

**Amendment 289**

**Leila Chaibi**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 20**

Regulation (EU) 2024/1689

Article 60 a

*Text proposed by the Commission*

*Amendment*

**(20) the following Article 60a is inserted:** *deleted*

***‘Article 60a***

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

- 1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I, in accordance with this Article and a voluntary real-world testing agreement, without prejudice to the prohibitions under Article 5.***
- 2. The voluntary real-world testing agreement referred to in paragraph 1 shall be concluded in writing between interested Member States and the Commission. It shall set the requirements for the testing of those AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions.***
- 3. Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.***
- 4. The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish detailed elements of the real-world testing plan for AI systems covered by Union harmonisation***

*legislation listed in Section B of Annex I.*

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

Or. en

**Amendment 290**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 20**  
Regulation (EU) 2024/1689  
Article 60 a

*Text proposed by the Commission*

*Amendment*

*(20) the following Article 60a is inserted:* *deleted*

*‘Article 60a*

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

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

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

*3. Member States, the Commission, market surveillance authorities and public*

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

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

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

Or. en

#### **Amendment 291**

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

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

#### **Article 1 – paragraph 1 – point 20**

Regulation (EU) 2024/1689

Article 60 a

*Text proposed by the Commission*

*Amendment*

*(20) the following Article 60a is inserted:*

*deleted*

*‘Article 60a*

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

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

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

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

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

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

Or. en

## Amendment 292

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

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 20

Regulation (EU) 2024/1689

Article 60 a – paragraph 3

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. en

## Amendment 293

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

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 20

Regulation (EU) 2024/1689

Article 60 a – paragraph 3

#### *Text proposed by the Commission*

3. Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and

#### *Amendment*

3. Member States, the Commission, ***national competent authorities such as*** market surveillance authorities and public authorities responsible for the management

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

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

Or. en

**Amendment 294**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 20 a (new)**  
Regulation (EU) 2024/1689  
Article 62

*Text proposed by the Commission*

*Amendment*

**(20a) Article 62 is amended as follows:**

**(a) in paragraph 1, point (d) is amended as follows:**

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

**(b) in paragraph 3, point (da) is added:**

**"(da) establish and maintain a public repository of certified open-source AI components, including for the purposes of the obligations under Article 16, the use of these components is presumed to comply with the requirements set out in Section 2."**

*Justification*

*Compliance with the Regulation will depend on the appropriate tools made available to small businesses for regulatory compliance. In this regard, it is essential to strengthen support for SMEs in the process of developing authorized standards. Currently, participation in technical discussions at European standardization organizations (CEN, CENELEC, ETSI) is only affordable for large companies. Without reimbursement for SME experts, standards will be tailored exclusively to the needs of large corporations, making compliance impractical for small operators. Furthermore, it will be crucial to relieve SMEs of overly complex audits of open-source components developed by third parties. In this regard, the establishment of a "Safe Harbor" linked to an EU-certified repository managed by the AI Office is the only way to enable the safe use of open-source without exposing small businesses to unacceptable compliance risks.*

**Amendment 295**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 21**  
 Regulation (EU) 2024/1689  
 Article 63 – paragraph 1

*Text proposed by the Commission*

*Amendment*

**(21) Article 63(1) is replaced by the following:**

**deleted**

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

**Amendment 296**  
**Axel Voss**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 21**  
Regulation (EU) 2024/1689  
Article 63 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

1. **SMCs and** SMEs, including start-ups, may comply with certain elements of the **legal obligations defined under** Article 9, 10, 11, 12, 17, 43 in a simplified manner. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of **SMCs and** SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems. ***In order to benefit from those reduced requirements (such as simplified risk assessments, reduced logging obligations, generalized technical documentation, accelerated conformity assessments, training with sensitive/pseudonymized data), the AI system or underlying AI model must be trained with EU Compute.***

Or. en

*Justification*

*Targeted simplification for SMCs/SMEs can unlock compliance capacity, but it should be linked to objective conditions that reduce dependency and strengthen Europe’s ability to verify and enforce high-risk requirements. The “EU compute” criterion is not about company nationality; it is about ensuring that training and key operational controls sit under EU jurisdiction and technical control (i.e. hardware, access, logs, keys and data governance), making audits, incident response and supervision realistically executable. This creates a concrete demand-side incentive for trusted European infrastructure, so that the AI Act/Omnibus does not unintentionally channel more high-risk development onto non-EU stacks while Europe remains mainly a data supplier. The criterion must therefore be defined as effective EU control over compute and operations, to avoid paper compliance and false “sovereignty” labelling.*

**Amendment 297**

**Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel,**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 21**

Regulation (EU) 2024/1689

Article 63 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

1. **Micro and small enterprises**, including start-ups, **within the meaning of Recommendation 2003/361/EC**, may comply with certain elements of the quality management system required by Article 17 in a simplified manner, **provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation**. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of **micro and small enterprises**, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.;

Or. en

**Amendment 298**

Stefano Cavedagna

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 21**

Regulation (EU) 2024/1689

Article 63 – paragraph 1

*Text proposed by the Commission*

1. SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of

*Amendment*

1. SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner. **For micro-enterprises, this simplification should cover all elements of the quality management system referred to in Article 17**. For that purpose, the Commission shall

SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.;

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

Or. en

### *Justification*

*A strictly proportional approach requires differentiation based on company size. Microenterprises, in fact, should be able to enjoy a further degree of simplification compared to small and medium-sized enterprises, avoiding competitive disadvantages and adapting compliance to the economic operator's capabilities.*

### **Amendment 299**

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

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 21**

Regulation (EU) 2024/1689

Article 63 – paragraph 1

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. en

### **Amendment 300**

**Virginie Joron, Jaroslav Bžoch, Ernő Schaller-Baross, Pál Szekeres, Klara Dostalova,**

**Jorge Martín Frías, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 21**

Regulation (EU) 2024/1689

Article 63 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 301**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 64 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

**(21a) in Article 64, the following paragraph 2a is inserted:**

***‘2a. The Commission and Member States shall ensure that the AI Office is provided with adequate technical, financial, and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the AI Office shall have a sufficient number of personnel***

*permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. The AI Board shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.';*

Or. en

### **Amendment 302**

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

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

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

Regulation (EU) 2024/1689

Article 65 – paragraph 5

#### *Present text*

5. The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority. The rules of procedure shall, in particular, lay down procedures for the selection process, the duration of the mandate of, and specifications of the tasks of, the Chair, detailed arrangements for voting, and the organisation of the Board's activities and those of its sub-groups.

#### *Amendment*

*(21a) Article 65(5) is replaced by the following;*

*'5. The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority. The rules of procedure shall, in particular, lay down procedures for the selection process, the duration of the mandate of, and specifications of the tasks of, the Chair, and the organisation of the Board's activities and those of its sub-groups.*

*All decisions of the Board shall be taken by a two-thirds majority of its members.';*

Or. en

### **Amendment 303**

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

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 21 a (new)**  
Regulation (EU) 2024/1689  
Article 66 – paragraph 1 – point k

*Present text*

*Amendment*

(k) assist the AI Office in supporting national competent authorities in the establishment and development of AI regulatory sandboxes, and facilitate cooperation and information-sharing among AI regulatory sandboxes;

***(21a) in Article 66, point (k) is replaced by the following:***

***‘(k) assist the national competent authorities in the establishment and development of AI regulatory sandboxes, and facilitate cooperation and information-sharing among AI regulatory sandboxes;’***

Or. en

**Amendment 304**  
**Markéta Gregorová, Kim Van Sparrentak**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 22 – point b**  
Regulation (EU) 2024/1689  
Article 69 – paragraph 3

*Text proposed by the Commission*

*Amendment*

***(b) paragraph 3 is deleted.***

***deleted***

Or. en

**Amendment 305**  
**Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 22 – point b**  
Regulation (EU) 2024/1689  
Article 69 – paragraph 3

*Text proposed by the Commission*

*Amendment*

***(b) paragraph 3 is deleted.***

***deleted***

**Amendment 306**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 23**  
Regulation (EU) 2024/1689  
Article 70 – paragraph 8

*Text proposed by the Commission*

*Amendment*

**(23) in Article 70, paragraph 8 is replaced by the following:** *deleted*

**‘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 307**  
**Leila Chaibi, Pernando Barrena Arza**  
on behalf of The Left Group

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 23**  
Regulation (EU) 2024/1689  
Article 70 – paragraph 8

*Text proposed by the Commission*

*Amendment*

**(23) in Article 70, paragraph 8 is replaced by the following:** *deleted*

**‘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.’;*

Or. en

### **Amendment 308**

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

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

#### **Article 1 – paragraph 1 – point 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, taking into account the guidance and advice of the **AI Board** and the **European Data Protection Board**, 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 **and relevant Union bodies if several authorities are concerned**, shall be consulted, as appropriate.;

Or. en

### **Amendment 309**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 23 a (new)**  
Regulation (EU) 2024/1689  
Article 71 – paragraph 4

*Present text*

4. With the exception of the section referred to in Article 49(4) and Article 60(4), point (c), the information contained in the EU database registered in accordance with Article 49 shall be accessible and publicly available in a user-friendly manner. The information should be easily navigable and machine-readable. The information registered in accordance with Article 60 shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for also making the information accessible the public.

*Amendment*

**(23a) in Article 71, paragraph 4 is replaced by the following:**

**‘4. With the exception of the section referred to in Article 49(4) and (5) and Article 60(4), point (c), the information contained in the EU database registered in accordance with Article 49 shall be accessible and publicly available in a user-friendly manner. The information should be easily navigable and machine-readable. The information registered in accordance with Article 60 shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for also making the information accessible the public.’;**

Or. en

**Amendment 310**  
**Marion Walsmann, Hildegard Bentele, Christine Schneider, Stefan Köhler, Sven Simon, Andreas Schwab**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 24**  
Regulation (EU) 2024/1689  
Article 72 – paragraph 3

*Text proposed by the Commission*

**(24) in Article 72, paragraph 3 is replaced by the following:**

**‘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**

*Amendment*

**deleted**

*guidance on the post-market monitoring plan.’;*

Or. en

*Justification*

*Implementing acts ensure uniform requirements and prevent divergent national approaches. Removing them increases legal uncertainty and costs through ad-hoc interpretations. This route provides structured Member State input, improving practicality over informal guidance. Retaining these tools supports competitiveness and simplification by avoiding fragmentation, enabling predictable compliance instead of “27 ways” of meeting the same AI Act obligation.*

**Amendment 311**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 72 – paragraph 3

*Text proposed by the Commission*

*Amendment*

*(24) in Article 72, paragraph 3 is replaced by the following:* *deleted*

*‘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.’;*

Or. en

**Amendment 312**

**Tomáš Zdechovský**

**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 a template and the list of elements to be included in the plan.***;

Or. en

*Justification*

*The original text of the AI Act requires the Commission to establish a template and the list of elements to be included in the post-market monitoring plan. This should remain in the guidance prepared by the Commission, to ensure stakeholders have adequate tools to comply with the given obligations.*

**Amendment 313**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 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 a template with elements to be included by 2 February 2027.***';

Or. en

**Amendment 314**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 24 a (new)**

*Text proposed by the Commission*

*Amendment*

**(24a) in Article 74, paragraph 13 is deleted.**

Or. en

*Justification*

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

**Amendment 315**  
**Regina Doherty**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 24 a (new)**  
Regulation (EU) 2024/1689  
Article 74 a (new)

*Text proposed by the Commission*

*Amendment*

**(24a) The following article is inserted:**  
**‘Article 74a**

***Market surveillance authorities shall have the promotion of innovation, competitiveness, and economic growth as central objectives informing their work and integrated into their activities. Market surveillance authorities shall report annually on how they met these objectives.’;***

Or. en

**Amendment 316**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 24 a (new)**  
Regulation (EU) 2024/1689  
Article 74 – paragraph 14 a (new)

*Text proposed by the Commission*

*Amendment*

**(24a) in Article 74, the following paragraph 14a is inserted:**

**‘14a. In exercising their powers under this Article and Regulation (EU) 2019/1020, market surveillance authorities shall take into account the impact of their enforcement actions and regulatory initiatives on competitiveness and innovation, ensuring that measures taken are proportionate.’;**

Or. en

*Justification*

*The objective of the Omnibus package is to ensure that regulation does not stifle innovation. It seems appropriate that future initiatives by Market Surveillance Authorities are first weighed against their impact on competitiveness and innovation, as provided by the EU Better Regulation principles.*

**Amendment 317**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 24 b (new)**  
Regulation (EU) 2024/1689  
Article 74 a (new)

*Text proposed by the Commission*

*Amendment*

**(24b) The following article is inserted:**

**‘Article 74a**

**Enforcement considerations**

**In carrying out their tasks, national competent authorities and the Commission shall take due account of the**

*objectives of promoting innovation, technological development and the competitiveness of the Union economy. They shall exercise their powers in a proportionate and technologically neutral manner, facilitating, where appropriate, the development, testing and deployment of artificial intelligence systems, the dissemination of best practices, and cooperation between industry, academia and public bodies. Starting from 1 January 2029, national competent authorities and the Commission shall each publish a biannual report, including transparent metrics, demonstrating how these objectives were integrated into their activities.’;*

Or. en



**2025/0359(COD)**

14.2.2026

# **AMENDMENTS 318 - 450**

## **Draft report**

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

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

Proposal for a regulation

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



## Amendment 318

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

### Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1

*Text proposed by the Commission*

*Amendment*

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

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

***When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.***

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

*particular where enforcement actions need to be taken in the territory of a Member State.’;*

Or. en

#### **Amendment 319**

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

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 1

#### *Text proposed by the Commission*

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

#### *Amendment*

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. ***However, this does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74 paragraph (9) of this Regulation.***

Or. en

**Amendment 320**  
**Regina Doherty**

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 321**  
**Arba Kokalari**

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

*Text proposed by the Commission*

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

*Amendment*

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I **and AI systems referred to in Annex III, point 2**, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.

Or. en

**Amendment 322**  
**Stefano Cavedagna**

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

*Text proposed by the Commission*

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and that model and that system are developed by the same provider, the AI Office shall ***be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks***

*Amendment*

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and that model and that system are developed by the same provider ***or by providers belonging to the same group of undertakings***, the AI Office shall be exclusively competent for the supervision and enforcement of the obligations under

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

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

Or. en

### *Justification*

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

### **Amendment 323**

**Piotr Müller, Assita Kanko**

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 1

#### *Text proposed by the Commission*

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and ***that*** model and ***that*** system are developed by the same provider, the AI Office shall ***be exclusively competent for the supervision and enforcement*** of that system with ***the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or***

#### *Amendment*

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and ***the*** model and ***the*** system are developed by the same provider, the AI Office shall ***have powers to monitor and supervise compliance*** of that ***AI*** system with obligations under this Regulation. ***To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and*** Regulation (EU) 2019/1020.

*that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.*

Or. en

#### *Justification*

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

#### **Amendment 324**

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

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 1

#### *Text proposed by the Commission*

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

#### *Amendment*

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I ***and AI systems referred to in Annex III, point 2***, and that model and that system are developed by the same provider, the AI Office ***may issue non-binding recommendations to market authorities to ensure the monitoring of that system and to assess compliance*** with the obligations ***laid down in*** this Regulation.

Or. en

**Amendment 325**

**Arba Kokalari**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***(ba) the following paragraph 1a is inserted:***

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

Or. en

**Amendment 326**

**Piotr Müller, Assita Kanko**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

***When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.***

***deleted***

Or. en

*Justification*

*As per other changes to point 25.*

**Amendment 327**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

*When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.*

*deleted*

Or. en

**Amendment 328**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and

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*.

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

Or. en

#### **Amendment 329**

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

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 2

#### *Text proposed by the Commission*

When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall ***be empowered to*** take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply *mutatis mutandis*.

#### *Amendment*

When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply *mutatis mutandis*.

Or. en

### Amendment 330

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

#### Proposal for a regulation

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

### Amendment 331

**Piotr Müller, Assita Kanko**

#### Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

*Justification*

*As per other changes to point 25.*

**Amendment 332**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 333**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

***‘The AI Office shall coordinate closely with the competent national data protection authorities when the aforementioned AI systems present risks to the fundamental rights to privacy and data protection, in compliance with Article 8 of the Charter of Fundamental Rights of the EU and in line with Article***

*2(7) of this Regulation.’;*

Or. en

**Amendment 334**  
**Stefano Cavedagna**

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

*Text proposed by the Commission*

*Amendment*

***(ba) the following paragraph 1a is inserted:***

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

Or. en

## *Justification*

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

### **Amendment 335**

**Piotr Müller, Assita Kanko**

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

*Text proposed by the Commission*

*Amendment*

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

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

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

*specific procedural rights provided for in this Regulation.*

*1c. The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply mutatis mutandis to the Commission when exercising its powers under this paragraph.*

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

Or. en

#### *Justification*

*Concentrating regulatory, enforcement and conformity assessment functions in the Commission risks undermining institutional impartiality, legal certainty and the system of mutual trust on which the internal market is based. EU product safety legislation relies on a functional separation between rule-making, technical standard setting, independent conformity assessment and market surveillance. Blurring these roles creates a perception of the Commission both defining and judging compliance with its own rules and weakens the independence of notified bodies.*

## Amendment 336

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

### Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

*Text proposed by the Commission*

*Amendment*

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

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

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

***1c. The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated***

*under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply mutatis mutandis to the Commission when exercising its powers under this paragraph.*

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

Or. en

#### **Amendment 337**

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

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

*Text proposed by the Commission*

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

*Amendment*

1a. The Commission shall *organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union* in accordance with this Regulation. *The Commission may entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall*

*apply mutatis mutandis to the Commission when exercising its powers under this paragraph. In organising and carrying out such tests and assessments, the Commission shall ensure proportionate, SME- and SMC-friendly procedures, including simplified documentation and reduced administrative burden, without lowering the level of protection provided by this Regulation.*

Or. en

### *Justification*

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

### **Amendment 338**

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

### **Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a

#### *Text proposed by the Commission*

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

#### *Amendment*

1a. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including its **duty** to impose penalties, such as fines or other administrative sanctions **whenever the law is not respected**, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision tasks under this

Article.

Or. en

### **Amendment 339**

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

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 a a (new)

*Text proposed by the Commission*

*Amendment*

***1aa. Where the Commission has not initiated proceedings for the same infringement, the Member State in which the main establishment of the provider of very large online platform or of very large online search engine is located or where their legal representative resides or is established, shall have powers to supervise and enforce the obligations under this Regulation, with respect to those providers.***

Or. en

### **Amendment 340**

**Michael McNamara, Svenja Hahn**

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

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

Regulation (EU) 2024/1689

Article 75 – paragraph 1 c

*Text proposed by the Commission*

*Amendment*

The Commission ***shall organise and*** carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are

The Commission ***may, where it deems it necessary and subject to Article 28(8),*** carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party

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.

conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. *Where it does not deem it necessary to carry out the pre-market conformity assessment itself,* the Commission *shall* entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply mutatis mutandis to the Commission when exercising its powers under this paragraph.

Or. en

**Amendment 341**  
**Regina Doherty**

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

*Text proposed by the Commission*

*Amendment*

*(25a) The following article is inserted:*

*‘Article 75a*

*The AI Office shall have the promotion of innovation, competitiveness, and economic growth as central objectives informing its work and integrated into its activities. The AI Office shall report annually on how it met these objectives.’;*

Or. en

**Amendment 342**  
**Leila Chaibi, Pernando Barrena Arza**  
on behalf of The Left Group

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 26**  
Regulation (EU) 2024/1689  
Article 77

*Text proposed by the Commission*

*Amendment*

**(26) Article 77 is amended as follows:** *deleted*

**(a) the heading is replaced by the following:**

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

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

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

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

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

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

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

Or. en

### **Amendment 343**

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

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 26 – point b**

Regulation (EU) 2024/1689

Article 77 – paragraph 1

#### *Text proposed by the Commission*

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

#### *Amendment*

1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and ***machine-readable*** format ***by electronic means*** where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. ***This is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, this article does not limit any powers that those authorities and bodies have to request information pursuant to other Union or national law. Accordingly, those authorities and bodies retain any power***

*they have to directly request information from operators pursuant to their mandate or other law.;*

Or. en

#### **Amendment 344**

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

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

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

#### **Amendment 345**

**Stefano Cavedagna**

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

**Article 1 – paragraph 1 – point 26 – point c**

Regulation (EU) 2024/1689

Article 77 – paragraph 1 a

*Text proposed by the Commission*

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

*Amendment*

1a. Subject to the conditions specified in this Article, the market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer, where necessary. *In this case, the request must take into account the size and capabilities of the deployer.*

Or. en

## *Justification*

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

### **Amendment 346**

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

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

**Article 1 – paragraph 1 – point 26 – point c**

Regulation (EU) 2024/1689

Article 77 – paragraph 1 a

#### *Text proposed by the Commission*

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

#### *Amendment*

1a. The market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer ***without delay and no later than one month after receiving the request***.

Or. en

### **Amendment 347**

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

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

**Article 1 – paragraph 1 – point 26 – point c**

Regulation (EU) 2024/1689

Article 77 – paragraph 1 b

#### *Text proposed by the Commission*

1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and

#### *Amendment*

1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and

provide each other with mutual assistance necessary for fulfilling their respective mandates, with a view to ensuring coherent application of this Regulation and Union law protecting fundamental rights and streamlining procedures. This shall include, in particular, exchange of information *where necessary* for the effective supervision or enforcement of this Regulation and the respective other Union legislation.;

provide each other with mutual assistance necessary for fulfilling their respective mandates, with a view to ensuring coherent application of this Regulation and Union law protecting fundamental rights and streamlining procedures ***while respecting their respective competences, tasks, powers and independence***. This shall include, in particular, exchange of information for the effective supervision or enforcement of this Regulation and the respective other Union legislation.;

Or. en

#### **Amendment 348**

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

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

**Article 1 – paragraph 1 – point 26 – point c**

Regulation (EU) 2024/1689

Article 77 – paragraph 1 c (new)

*Text proposed by the Commission*

*Amendment*

***1c. Requests for assistance shall contain all the necessary information, including the purpose of and reasons for the request. The market surveillance authority shall not refuse to comply with the request unless: a) the requesting authority is not competent for the subject-matter of the request or for the measures it is requested to execute; or b) compliance with the request would infringe this Regulation or Union or Member State law to which the market surveillance authority receiving the request is subject.***

Or. en

#### **Amendment 349**

**Piotr Müller, Assita Kanko**

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

*Text proposed by the Commission*

*Amendment*

**(26a) The following article is inserted:**

**‘Article 80a**

**Record-keeping and transparency of supervisory communications**

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

Or. en

*Justification*

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

**Amendment 350**  
**Henrik Dahl**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 26 a (new)**  
Regulation (EU) 2024/1689  
Article 82

*Text proposed by the Commission*

*Amendment*

**(26a) Article 82 is deleted.**

Or. en

*Justification*

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

### **Amendment 351**

**Piotr Müller, Assita Kanko**

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

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

Regulation (EU) 2024/1689

Article 92 – paragraph 3

*Present text*

*Amendment*

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

3. For the purposes of paragraph 1, the Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools, ***including source code.***

‘3. For the purposes of paragraph 1, the Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools.’;

Or. en

*Justification*

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

**Amendment 352**  
**Kateřina Konečná**

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

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

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 354**  
**Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel,**

**Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 27**

Regulation (EU) 2024/1689

Article 95 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 355**

**Leila Chaibi, Pernando Barrena Arza**

on behalf of The Left Group

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 356**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 28**  
Regulation (EU) 2024/1689  
Article 96 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 357**  
**Axel Voss, Arba Kokalari**

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 358**  
**Tomáš Zdechovský**

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

*Present text*

*Amendment*

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

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

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

Or. en

*Justification*

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

### **Amendment 359**

**Lukas Mandl, Sander Smit**

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

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

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1 – point a

*Present text*

*Amendment*

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

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

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

Or. en

*Justification*

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

### **Amendment 360**

**Axel Voss, Arba Kokalari**

## Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 1 – point a

*Present text*

*Amendment*

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

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

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

Or. en

*(Regulation (EU) 2024/1689)*

*Justification*

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

## Amendment 361

Axel Voss

## Proposal for a regulation

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

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

*Justification*

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

**Amendment 362**  
**Stefano Cavedagna**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

*Justification*

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

**Amendment 363**  
**Lukas Mandl, Sander Smit**

**Proposal for a regulation**

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

*Justification*

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

#### **Amendment 364**

**Tomáš Zdechovský**

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

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

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

*checklists and best-practice measures.’;*

Or. en

*Justification*

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

**Amendment 365**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 96 – paragraph 2

*Present text*

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

*Amendment*

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

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

Or. en

**Amendment 366**

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

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 96 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

#### **Amendment 367**

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

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

#### **Article 1 – paragraph 1 – point 29**

Regulation (EU) 2024/1689

Article 99

*Text proposed by the Commission*

*Amendment*

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

**(a) paragraph 1 is replaced by the following:**

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

*penalties.’;*

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

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

Or. en

#### **Amendment 368**

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

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

#### **Article 1 – paragraph 1 – point 29**

Regulation (EU) 2024/1689

Article 99

*Text proposed by the Commission*

*Amendment*

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

*(a) paragraph 1 is replaced by the following:*

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

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

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

Or. en

**Amendment 369**  
**Regina Doherty**

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 370**  
**Kateřina Konečná**

**Proposal for a regulation**

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 371**

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

**Proposal for a regulation**

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

*Text proposed by the Commission*

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to *operators* of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have

*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

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.***;

Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, ***they shall be brought into compliance by with this Regulation by 31 December 2030.***’;

Or. en

**Amendment 372**  
**Axel Voss**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

Article 99 – paragraph 4 - point d a (new)

*Text proposed by the Commission*

*Amendment*

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

***‘(da) obligations of providers and third parties, including GPAI model providers, pursuant to Article 25(2), (3) and (4);’;***

Or. en

*Justification*

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

**Amendment 373**  
**Kateřina Konečná**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 29 – point b**  
Regulation (EU) 2024/1689  
Article 99 – paragraph 6

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 374**  
**Markéta Gregorová, Kim Van Sparrentak**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 29 – point b**  
Regulation (EU) 2024/1689  
Article 99 – paragraph 6

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

## Amendment 375

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

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 29 – point b

Regulation (EU) 2024/1689

Article 99 – paragraph 6

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 376

Sandro Gozi, Stéphanie Yon-Courtin

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 30

Regulation (EU)2024/1689

Article 111

*Text proposed by the Commission*

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

**deleted**

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

**‘2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant**

*Amendment*

*changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.’;*

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

*‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’;*

Or. en

**Amendment 377**  
**Kateřina Konečná**

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

*Text proposed by the Commission*

*Amendment*

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

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

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

*systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.’;*

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

*‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’;*

Or. en

#### **Amendment 378**

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

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

**Article 1 – paragraph 1 – point 30 – point a**

Regulation (EU) 2024/1689

Article 111 – paragraph 2

*Text proposed by the Commission*

*Amendment*

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

**deleted**

by 2 August 2030.;

Or. en

**Amendment 379**  
**Stefano Cavedagna**

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

*Text proposed by the Commission*

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

*Amendment*

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs.;

Or. en

*Justification*

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

**Amendment 380**  
**Leila Chaibi, Pernando Barrena Arza**  
on behalf of The Left Group

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

*Text proposed by the Commission*

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

*Amendment*

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to **providers and deployers** of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before **2 August 2026** only if, as from that date, those systems are subject to significant changes in their designs. In any case, **they shall be brought into compliance with this Regulation by 31 December 2030.**

Or. en

**Amendment 381**

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

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

*Text proposed by the Commission*

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into

*Amendment*

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into

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

service before **2 August 2026**, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August **2028**.;

Or. en

## Amendment 382

Axel Voss, Arba Kokalari

### Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a

Regulation (EU) 2024/1689

Article 111 – paragraph 2

#### *Text proposed by the Commission*

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

#### *Amendment*

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

Or. en

#### *Justification*

*To align the paragraph with the 2022 NLF Blue Guide standard term that is also used in the*

*remaining parts of the EU AI Act.*

### **Amendment 383**

**Sabine Verheyen, Bogdan Andrzej Zdrojewski**

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

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

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

### **Amendment 384**

**Leila Chaibi, Pernando Barrena Arza**

on behalf of The Left Group

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

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

***‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’;***

Or. en

#### **Amendment 385**

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

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

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

***‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’;***

Or. en

#### **Amendment 386**

**Stefano Cavedagna**

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

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

**‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’;**

Or. en

#### *Justification*

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

#### **Amendment 387**

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

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

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

**‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’;**

Or. en

**Amendment 388**  
**Piotr Müller, Assita Kanko**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 30 – point b**  
Regulation (EU) 2024/1689  
Article 111 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

**4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;**

Or. en

*Justification*

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

**Amendment 389**  
**Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Laurence Farréng**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 30 – point b**  
Regulation (EU) 2024/1689  
Article 111 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

**‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’;**

## Amendment 390

Regina Doherty

### Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

Regulation (EU) 2024/1689

Article 111 – paragraph 4

#### *Text proposed by the Commission*

4. Providers of AI systems, ***including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026*** shall take the necessary steps in order to comply with Article 50(2) by 2 February ***2027***;

#### *Amendment*

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

## Amendment 391

Christian Doleschal

### Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

Regulation (EU) 2024/1689

Article 111 – paragraph 4

#### *Text proposed by the Commission*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, ***that have been placed on the market before 2 August 2026*** shall take the necessary steps in order to comply with Article 50(2) by 2 February **2027**;

#### *Amendment*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, shall take the necessary steps in order to comply with Article 50(2) by 2 February **2027**;

## Amendment 392

Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès,

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, ***that have been placed on the market before 2 August 2026*** shall take the necessary steps in order to comply with Article 50(2) ***by 2 February 2027.***;

*Amendment*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content shall take the necessary steps in order to comply with Article 50(2) ***and 50(4) by 2 August 2027.***;

Or. en

*Justification*

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

**Amendment 393**

**Zala Tomašič, Jan Farský, Alexandr Vondra, Ondřej Krutílek**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or ***text*** content, that have been placed on the market before 2 August ***2026*** shall take the necessary steps in order to comply with Article 50(2) ***by 2 February 2027.***;

*Amendment*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or ***video*** content, that have been placed on the market before 2 August ***2027*** shall take the necessary steps in order to comply with Article 50(2) ***by 2 February 2027.***;

Or. en

*Justification*

*The obligation to ensure machine-readable marking is appropriate for synthetic audio, image*

*and video content, but not for text. Text is continuously edited, reformatted and reused across contexts, which makes reliable machine-readable marking technically infeasible and disproportionate, while providing limited added value for transparency.*

#### **Amendment 394**

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

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

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 **February** 2027.;

*Amendment*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 **August** 2027.;

Or. en

#### **Amendment 395**

**Tomáš Zdechovský**

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

**Article 1 – paragraph 1 – point 30 – point b**

Regulation (EU) 2024/1689

Article 111 – paragraph 4

*Text proposed by the Commission*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market **before 2 August 2026** shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;

*Amendment*

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;

Or. en

*Avoiding 2 tier model for simplification*

**Amendment 396**

**Sandro Gozi, Stéphanie Yon-Courtin**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31**

Regulation (EU) 2024/1689

Article 113

*Text proposed by the Commission*

*Amendment*

**(31) Article 113 is amended as follows: *deleted***

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

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

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

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

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

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

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

**(b) in the third paragraph, point (e) is**

*added:*

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

Or. en

**Amendment 397**  
**Kateřina Konečná**

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

*Text proposed by the Commission*

*Amendment*

**(31) Article 113 is amended as follows:** *deleted*

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

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

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

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

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

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

*(ii) on 2 August 2028 as regards AI*

*systems classified as high-risk pursuant to Article 6(1) and Annex I.’;*

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

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

Or. en

**Amendment 398**  
**Fabienne Keller**

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

*Text proposed by the Commission*

*Amendment*

*(31) Article 113 is amended as follows: deleted*

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

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

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

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

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

*(i) on 2 December 2027 as regards AI*

*systems classified as high-risk pursuant to Article 6(2) and Annex III, and*

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

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

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

Or. en

### **Amendment 399**

**Sabine Verheyen, Bogdan Andrzej Zdrojewski**

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

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

*Text proposed by the Commission*

*Amendment*

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

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

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

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

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

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

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

Or. en

**Amendment 400**  
**Fabienne Keller**

**Proposal for a regulation**

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

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 401**  
**Mary Khan**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 1

*Text proposed by the Commission*

*Amendment*

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

*deleted*

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

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

Or. en

#### **Amendment 402**

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

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

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

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

*Text proposed by the Commission*

*Amendment*

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

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

**(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**

**(i) on 1 December 2026 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.**

**(ii) on 1 December 2027 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**

***Notwithstanding the above, obligations under***

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

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

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

**(iii)** Article 26 and

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

Or. en

### **Amendment 403**

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

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

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

*Text proposed by the Commission*

*Amendment*

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

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

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

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

*In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III,*

**Sections 1, 2, and 3, shall apply:**

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

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

Or. en

### *Justification*

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

### **Amendment 404**

**Axel Voss**

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

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

#### *Text proposed by the Commission*

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

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

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

***In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below***

#### *Amendment*

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

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

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

*are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:*

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

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

Or. en

*Justification*

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

**Amendment 405**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 406**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

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

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 407**

**Regina Doherty**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 - paragraph 3 – point d

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

**Amendment 408**

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

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

*Text proposed by the Commission*

*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***

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

*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;*

Or. en

#### **Amendment 409**

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

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

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

*Text proposed by the Commission*

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

*Amendment*

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

*(i) on 2 July 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, 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.*

*(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.’;*

*In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:*

*(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and*

*(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;*

Or. en

**Amendment 410**

**Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

*Text proposed by the Commission*

*Amendment*

*(d) Chapter III, Sections 1, 2, and 3, shall apply following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates:*

*(d) Chapter III, Sections 1, 2, and 3, shall apply on 2 August 2027 as regards AI systems classified as high-risk pursuant to Article 6(1) and (2) and Annexes I and III;*

*(i) 6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and*

*(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article*

**6(1) and Annex I.**

***In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:***

***(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and***

***(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;***

Or. en

## **Amendment 411**

**Piotr Müller, Assita Kanko**

### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

**Regulation (EU) 2024/1689**

**Article 113 – paragraph 3 – point d**

*Text proposed by the Commission*

*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:***

***(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,***

Chapter III, Sections 1, 2, and 3, ***with the exception of Article 6(5), Chapter IV, with the exception of Article 50(1), Article 50(3) and Article 50(4), and Chapter V shall apply on 2 August 2028.***

**Sections 1, 2, and 3, shall apply:**

**(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and**

**(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;**

Or. en

*Justification*

*In order to simplify the provisions covering application date, one, harmonised date in 2028 is introduced instead of complicated and conditional mechanism proposed by the Commission.*

**Amendment 412**

**Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point i

*Text proposed by the Commission*

*Amendment*

**(i) 6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and** **deleted**

Or. en

**Amendment 413**

**Christian Doleschal**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point i

*Text proposed by the Commission*

*Amendment*

**(i) 6 months after the adoption of that decision as regards AI systems classified** **deleted**

*as high-risk pursuant to Article 6(2) and Annex III, and*

Or. en

**Amendment 414**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point i

*Text proposed by the Commission*

*Amendment*

(i) *6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and* *deleted*

Or. en

**Amendment 415**

**Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point i

*Text proposed by the Commission*

*Amendment*

(i) *6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and* (i) *12 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and*

Or. en

**Amendment 416**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point ii

*Text proposed by the Commission*

*Amendment*

**(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.** *deleted*

Or. en

**Amendment 417**

**Christian Doleschal**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point ii

*Text proposed by the Commission*

*Amendment*

**(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.** *deleted*

Or. en

**Amendment 418**

**Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – point ii

*Text proposed by the Commission*

*Amendment*

**(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.** *deleted*

**Amendment 419**  
**Tomáš Zdechovský**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 – point a**  
Regulation (EU) 2024/1689  
Article 113 – paragraph 3 – point d – subparagraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***Where harmonised standards or common specifications are not available by the deadlines referred to in Article 113, providers of high-risk AI systems shall be permitted to demonstrate compliance using Commission-endorsed standardised templates and documentation packages.***

Or. en

*Justification*

*This amendment ensures that regulatory delays do not block market access, while maintaining accountability and auditability.*

**Amendment 420**  
**Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 – point a a (new)**  
Regulation 2024/1689  
Article 113 – paragraph 3 – point d a (new)

*Text proposed by the Commission*

*Amendment*

***(aa) in the third paragraph, point (da) is inserted:***  
***(da) The decisions referred to in point (d) shall be adopted no later than 2 August 2027.***

Or. en

**Amendment 421**

**Virginie Joron, Ernő Schaller-Baross, Pál Szekeres, Elisabeth Dieringer, Matthieu Valet, Alexandre Varaut, Pascale Piera**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2

*Text proposed by the Commission*

*Amendment*

***In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:*** ***deleted***

***(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and***

***(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;***

Or. en

**Amendment 422**

**Jaroslav Bžoch, Virginie Joron, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2

*Text proposed by the Commission*

*Amendment*

***In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:*** ***deleted***

***(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to***

*Article 6(2) and Annex III, and*

*(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;*

Or. en

**Amendment 423**  
**Christian Doleschal**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2

*Text proposed by the Commission*

*Amendment*

*In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:*

*deleted*

*(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and*

*(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;*

Or. en

**Amendment 424**  
**Mary Khan**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – introductory part

*Text proposed by the Commission*

*Amendment*

*In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below*

*The application of specified obligations for high-risk AI systems shall be anchored in clear and fixed timelines.*

*are earlier than those that follow the adoption of that decision*, Chapter III, Sections 1, 2, and 3, shall apply:

Where the *application of high-risk requirements is deferred pending adoption of harmonised standards or common specifications, such deferrals should be subject to maximum time limits and take into account the readiness of relevant sectoral ecosystems. In particular, for AI systems that are subject to Union harmonisation legislation, the applicable timelines should reflect the complexity of conformity assessment procedures and market preparedness* Chapter III, Sections 1, 2, and 3, shall apply:

Or. en

#### **Amendment 425**

**Jaroslav Bžoch, Virginie Joron, Klara Dostalova**

#### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point i

*Text proposed by the Commission*

*Amendment*

(i) on 2 **December 2027** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(i) on 2 **August 2028** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

Or. en

#### **Amendment 426**

**Christian Doleschal**

#### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point i

*Text proposed by the Commission*

*Amendment*

(i) on 2 **December 2027** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(i) on 2 **August 2028** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

**Amendment 427**

**Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point i

*Text proposed by the Commission*

*Amendment*

(i) on 2 **December 2027** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(i) on 2 **June 2028** as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

Or. en

*Justification*

*Aligning the timelines with industry realities. More time is needed in order to properly implement the provisions.*

**Amendment 428**

**Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point ii

*Text proposed by the Commission*

*Amendment*

(ii) on 2 **August 2028** as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;

(ii) on 2 **February 2029** as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I;

Or. en

*Justification*

*Aligning the timelines with industry realities. More time is needed in order to properly implement the provisions.*

**Amendment 429**  
**Christian Doleschal**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 – point ii

*Text proposed by the Commission*

(ii) on 2 August **2028** as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.;

*Amendment*

(ii) on 2 August **2029** as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.;

Or. en

**Amendment 430**  
**Mary Khan**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point a a (new)**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d – subparagraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(aa) in the third paragraph, point (d), the following subparagraph is added:***

***2a. These application dates shall apply to all high-risk AI systems that are placed on the market or put into service before the extended deadlines apply.***

Or. en

**Amendment 431**  
**Christian Doleschal**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point b**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point e

*Text proposed by the Commission*

*Amendment*

**(b)** *in the third paragraph, point (e) is added:* **deleted**

**(e)** *Articles 102 to 110 shall apply from [the date of entry into application of this Regulation].’;*

Or. en

### **Amendment 432**

**Jaroslav Bžoch, Klara Dostalova**

#### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point b**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point e

*Text proposed by the Commission*

*Amendment*

**(e)** Articles 102 to 110 shall apply from [the date of entry into **application** of this Regulation].;

**(e)** Articles 102 to 110 shall apply from [the date of entry into **force** of this **amending** Regulation].;

Or. en

### **Amendment 433**

**Michael McNamara, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller**

#### **Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 – point b a (new)**

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point e a (new)

*Text proposed by the Commission*

*Amendment*

**(ba)** *in Article 113, paragraph 3, the following point ea is added:*

**(ea)** *The Commission shall establish common specifications in support of compliance with Chapter III, in accordance with Article 41 if the conditions laid down in paragraph 1 of*

*that article are fulfilled on the 1 January 2027 in respect of AI systems classified as high-risk pursuant to Article 6(2) and Annex III, or AI systems classified as high-risk pursuant to Article 6(1) and Annex I.*

*The said common the standards shall be adopted no later than 2 June 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, or and no later than 2 August 2027 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.*

Or. en

**Amendment 434**  
**Stefano Cavedagna**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 – point b a (new)**  
Regulation (EU) 2024/1689  
Article 113 – paragraph 3 – point e a (new)

*Text proposed by the Commission*

*Amendment*

*(ba) In the third paragraph, point (ea) is added:*

*(ea) Article 50 (2) and (4) shall apply from 2 August 2027.*

Or. en

*Justification*

*The Omnibus amendment to Article 111 of the AI Act grants providers a transitional period until February 2, 2027 for content marking obligations, but the Code of Practice defining technical compliance will only be finalized near that date. More critically, deployers subject to Article 50, paragraph 4 obligations receive no transitional period despite depending entirely on providers' technical solutions and Code of Practice specifications to fulfil their transparency obligations toward end users. This asymmetry creates significant legal uncertainty and exposes deployers to liability without adequate means of compliance. This amendment, together with the previous amendment to article 111, aims to improve legal certainty by setting a uniform date for both providers and deployers.*

**Amendment 435**  
**Andreas Schwab**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 a (new)**  
Regulation (EU) 2024/1689  
ANNEX I

*Text proposed by the Commission*

*Amendment*

**(31a) Annex I is amended as follows:**

**(1) Section A is deleted;**

**(2) In Section B, the following points are added:**

**1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);**

**2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);**

**3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);**

**4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);**

**5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);**

**6. Directive 2014/53/EU of the European Parliament and of the Council**

*of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);*

*7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);*

*8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);*

*9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);*

*10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);*

*11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);*

*12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).*

*13. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council*

**Amendment 436**

**Aura Salla**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 a (new)**

Regulation (EU) 2024/1689

ANNEX I

*Text proposed by the Commission*

*Amendment*

**(31a) Annex I is amended as follows:**

**(1) Section A is deleted;**

**(2) in Section B, the following points are added:**

**1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);**

**2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);**

**3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);**

**4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);**

**5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and**

*protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);*

**6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);**

**7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);**

**8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);**

**9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);**

**10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);**

**11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);**

**12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision**

*Justification*

*This amendment ensures legal clarity and avoids unnecessary duplication between the AI Act and existing product safety legislation.*

**Amendment 437**

**Axel Voss, Arba Kokalari**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 a (new)**

Regulation (EU) 2024/1689

ANNEX I

*Present text*

*Amendment*

ANNEX I

List of Union harmonisation legislation

***Section A. List of Union harmonisation legislation based on the New Legislative Framework***1.Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);2.Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);3.Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);4.Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);5.Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the

***(31a) ANNEX I is replaced by the following:***

"ANNEX I

List of Union harmonisation legislation

***1.*** Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);

Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);6.Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);7.Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);8.Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);9.Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);10.Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);11.Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);12.Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).**Section B. List of other Union harmonisation legislation**13.Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation

security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);14.Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);15.Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);16.Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);17.Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44);18.Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);19.Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No

19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1); 20. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.

***2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);***

***3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);***

***4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);***

***5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and***

*protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);*

**6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);**

**7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);**

**8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);**

**9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);**

**10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);**

**11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);**

**12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision**

***2010/227/EU (OJ L 117, 5.5.2017, p. 176).***

***13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);***

***14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);***

***15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);***

***16. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);***

***17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44);***

***18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);***

***19. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants***

***and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);***

***20. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned."***

Or. en

### *Justification*

*Following the Commission's own "Health Omnibus" logic (COM(2025) 1023 final), it is consistent for the AI Omnibus to move not only MDR/IVDR but all Annex I, Section A acts to Section B and to reflect this streamlining in Article 2(2). This avoids duplicate and potentially conflicting horizontal AI obligations on top of mature sectoral regimes, reducing compliance*

*fragmentation and forum-shopping risks for the same product or service. Sector-specific legislation is better placed to calibrate AI requirements to safety and supervision realities, using existing competent authorities and established conformity-assessment pathways. A targeted “sector-first” approach still preserves AI Act safeguards where needed, but boosts EU AI uptake by making compliance clearer, proportionate and implementable for EU SMEs and Start-Ups.*

**Amendment 438**  
**Henrik Dahl**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 a (new)**  
Regulation (EU) 2024/1689  
ANNEX I

*Present text*

*Amendment*

ANNEX I

**(31a) ANNEX I is replaced by the following:**

"ANNEX I

***List of Union harmonisation legislation***

Section **B** List of Union harmonisation legislation

Section **A**. List of Union harmonisation legislation ***based on the New Legislative Framework***

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);

2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);

2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);

3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);

4. Directive 2014/33/EU of the European

5. Directive 2014/34/EU of the

Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);

5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);

8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);

9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);

10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending

European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);

8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);

9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);

10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical

Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

12.Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

***Section B. List of other Union harmonisation legislation***

13.Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);

14.Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);

15.Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);

16.Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);

17.Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the

devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);

14. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52);

15. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1);

16. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);

17. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44);

18. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);

19. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval

rail system within the European Union (OJ L 138, 26.5.2016, p. 44);

18.Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);

19.Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and

requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);

20. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned."

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the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);

20.Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in Article 2(1), points (a) and (b) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.

***Annex***

Or. en

*(Regulation (EU) 2024/1689)*

*Justification*

*Product safety is already regulated under technology-neutral Union harmonisation legislation in Annex I. The inclusion of AI does not in itself render a product unsafe. Parallel application of the AI Act and Section A would create duplication and unnecessary costs.*

*Section A should therefore be merged into Section B. The Commission has already proposed this for Medical Devices and IVDs; the same logic should apply to the remaining acts.*

**Amendment 439**

**Piotr Müller, Assita Kanko**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 a (new)**

Regulation (EU) 2024/1689

ANNEX I – Section A

*Text proposed by the Commission*

*Amendment*

**(31a) In Annex I, Section A, Point 1 is deleted.**

Or. en

*(Regulation 2024/1689)*

*Justification*

*Machinery Regulation already sufficiently covers the issue of AI. There is no need to duplicate multiple processes, with little benefit to the safety.*

**Amendment 440**

**Tomáš Zdechovský**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 31 a (new)**

Regulation (EU) 2024/1689

ANNEX I – Section A – point 1

*Text proposed by the Commission*

*Amendment*

**(31a) In Annex I, Section A, Point 1 is deleted.**

Or. en

*Justification*

*Directive 2006/42/EC was repealed by Regulation 2023/1230. Avoidance of duplication. In line with this AM, Recital 46 should be updated as well.*

**Amendment 441**  
**Tomáš Zdechovský**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 31 a (new)**  
Regulation (EU) 2024/1689  
ANNEX I – Section B – point 1 (new)

*Text proposed by the Commission*

*Amendment*

***(31a) In Annex I, Section B, the following point is added:***

***1a. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC***

Or. en

**Amendment 442**  
**Markéta Gregorová, Kim Van Sparrentak**  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 32**  
Regulation (EU) 2024/1689  
ANNEX VIII – Section B

*Text proposed by the Commission*

*Amendment*

***(32) in Annex VIII, section B is deleted;*** ***deleted***

Or. en

**Amendment 443**  
**Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide**

**Proposal for a regulation**  
**Article 1 – paragraph 1 – point 32**

*Text proposed by the Commission*

*Amendment*

**(32) in Annex VIII, section B is deleted;** *deleted*

Or. en

**Amendment 444**

**Marion Walsmann, Hildegard Bentele, Christine Schneider, Stefan Köhler, Sven Simon, Andreas Schwab**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 32**

Regulation (EU) 2024/1689  
ANNEX VIII – Section B

*Text proposed by the Commission*

*Amendment*

**(32) in Annex VIII, section B is deleted;** *deleted*

Or. en

*Justification*

*Maintaining registration for non-high-risk Annex III systems ensures oversight and provides authorities with comparable data. This helps prioritize market surveillance and identify emerging use cases. Since providers must assess risk anyway to claim exemptions, the added administrative burden is limited and proportionate, while the transparency and supervisory benefits are tangible.*

**Amendment 445**

**Leila Chaibi, Pernando Barrena Arza**  
on behalf of The Left Group

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 32**

Regulation (EU) 2024/1689  
Annex VIII – Section B

*Text proposed by the Commission*

*Amendment*

**(32) in Annex VIII, section B is deleted;** *deleted*

*deleted;*

Or. en

**Amendment 446**

**Sandro Gozi, Stéphanie Yon-Courtin**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 32**

Regulation (EU) 2024/1689

Annex VIII – Section B

*Text proposed by the Commission*

*Amendment*

**(32) in Annex VIII, section B is  
deleted;**

**deleted**

Or. en

**Amendment 447**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 32**

Regulation (EU) 2024/1689

ANNEX VIII – Section B

*Text proposed by the Commission*

*Amendment*

**(32) in Annex VIII, section B is  
deleted;**

**deleted**

Or. en

**Amendment 448**

**Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 32**

Regulation (EU) 2024/1689

ANNEX VIII – Section B

*Text proposed by the Commission*

*Amendment*

**(32) in Annex VIII, section B is deleted;**

**deleted**

Or. en

**Amendment 449**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 32 a (new)**

Regulation (EU) 2024/1689

Annex VIII – Section B

*Text proposed by the Commission*

*Amendment*

**(32a) in Annex VIII, Section B points 6 to 8 are deleted.**

Or. en

**Amendment 450**

**Jaroslav Bžoch, Klara Dostalova**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 32 a (new)**

Regulation (EU) 2024/1689

Annex VIII – Section B – point 5

*Present text*

*Amendment*

**5. A description of the intended purpose of the AI system.**

**(32a) In Annex VIII, Section B, point 5 is amended as follows:**

**5. Documentation of the assessment created in accordance with Article 6(4).**

Or. en