



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 Jouvét, 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) 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, ***and to ease the administrative burden***, with a view to the effective application of the relevant rules.

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/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵.

deleted

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

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

j).

Or. en

Amendment 31

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

Recital 4

Text proposed by the Commission

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

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

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

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

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

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

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

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/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵.

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

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

provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵. ***The planned relief measures should also apply to public enterprises of this size.***

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

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

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

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***

administrative *burden*, leading to a need for *proportionality* in the implementation of Regulation (EU) 2024/1689 and for *targeted support*. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵.

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) 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.

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

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

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

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

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

Text proposed by the Commission

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

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

⁵ Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the

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 **that are significant and** similar to **those of** SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵.

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

⁵ Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the

definition of small mid-cap enterprises (OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>)

definition of small mid-cap enterprises (OJ L, 2025/1099, 28.5.2025, ELI: <http://data.europa.eu/eli/reco/2025/1099/oj>)

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

deleted

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 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

deleted

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

Or. en

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

Amendment

(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff ***and other persons dealing with the operation and use of AI systems on their behalf.*** 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.***

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 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***

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

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.

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 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-

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.

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 **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

Text proposed by the Commission

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

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 ***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***

(‘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.

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 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 Council⁶. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷ and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council⁸ provides a legal basis allowing, where necessary for the

deleted

detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

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

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

⁸ *Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).*

Or. en

Amendment 49

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 6

Text proposed by the Commission

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of Regulation (EU) 2024/1689 already provides a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council⁶. ***Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷ and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council⁸ provides a legal basis allowing, where necessary for the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation***

Amendment

(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 Council⁶ ***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.***

(EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

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

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

⁸ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

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

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

⁸ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

Or. en

Amendment 50

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

Proposal for a regulation

Recital 6

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. ***Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of Regulation (EU) 2024/1689 already provides a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council⁶. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems.*** The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷ and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council⁸ ***provides a legal basis allowing, where necessary for the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models,*** subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

⁶ 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

(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 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.

⁶ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of

such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>).

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

⁸ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>).

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

⁸ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

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

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 Council⁶. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷ and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council⁸ provides a legal basis allowing, where necessary for the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards *that complement* Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

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

⁷ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union

other than high-risk AI systems for which of Regulation (EU) 2024/1689 already provides a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council⁶. Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷ and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council⁸ provides a legal basis allowing, where necessary for the detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards *pursuant to* Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

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

⁷ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union

institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>).

⁸ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>).

⁸ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <http://data.europa.eu/eli/dir/2016/680/oj>).

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)**

Text proposed by the Commission

Amendment

(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) 2017/745⁹ and (EU) 2017/746¹⁰ of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation. The single application and assessment procedure aims at facilitating, supporting and expediting the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies**

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**

under that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto.

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.

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

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

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

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

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.

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 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*

deleted

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.

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 58

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

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

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

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 harmonisation legislation.**

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 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 Jovet, 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

deleted

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 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 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 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,

deleted

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.

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, 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 66

Jaroslav Bžoch, Klara Dostalova

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***

*(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***

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.

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) 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

Amendment

(9) To streamline compliance and reduce the **significant** associated **administrative** 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

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 fundamental rights of persons, imposing registration requirements would constitute **an unnecessary** 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. 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

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

infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.

(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

(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

Amendment

(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.

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 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.

deleted

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

(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

deleted

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

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.

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 Jovet, 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

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.

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

(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

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 Jouvét, 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

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.

(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

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

the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, the AI Office should be empowered to take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council¹¹. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.

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

modified to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, the AI Office should be empowered to take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council¹¹. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State.

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

Or. en

Amendment 79
Sebastian Tynkkynen

Proposal for a regulation
Recital 15

Text proposed by the Commission

(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council¹², it is appropriate to grant the Commission the powers of a competent market surveillance authority under Regulation (EU) 2024/1689 where an AI system qualifies as a very large online platform or a very large online search engine within the meaning of Regulation (EU) 2022/2065, or where it is embedded in such a platform or search engine. This should contribute to ensuring that the exercise of the Commission's supervision and enforcement powers under Regulation (EU) 2024/1689 and Regulation (EU) 2022/2065, as well as those applicable to general-purpose AI models integrated into such platforms or search engines, are carried out in a coherent manner. In the case of AI systems embedded in or qualifying as a very large online platform or search engine, the first point of entry for the assessment of the AI systems are the risk assessment, mitigating measures and audit obligations prescribed by Articles 34, 35 and 37 of Regulation (EU) 2022/2065, without prejudice to the AI Office's powers to investigate and enforce ex post non-compliance with the rules of this Regulation. In the context of the analysis of this risk assessment, mitigating measures and audits, the Commission services responsible for the enforcement of Regulation (EU) 2022/2065 may seek the opinion of the AI Office on the outcome of a potential earlier or parallel risk assessment carried out under this Regulation and the applicability of prohibitions under this Regulation. In addition, the AI Office and the competent national authorities under (EU) 2024/1689 should coordinate their enforcement efforts

Amendment

(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council¹², it is appropriate to grant the Commission the powers of a competent market surveillance authority under Regulation (EU) 2024/1689 where an AI system qualifies as a very large online platform or a very large online search engine within the meaning of Regulation (EU) 2022/2065, or where it is embedded in such a platform or search engine. This should contribute to ensuring that the exercise of the Commission's supervision and enforcement powers under Regulation (EU) 2024/1689 and Regulation (EU) 2022/2065, as well as those applicable to general-purpose AI models integrated into such platforms or search engines, are carried out in a coherent manner. In the case of AI systems embedded in or qualifying as a very large online platform or search engine, the first point of entry for the assessment of the AI systems are the risk assessment, mitigating measures and audit obligations prescribed by Articles 34, 35 and 37 of Regulation (EU) 2022/2065, without prejudice to the AI Office's powers to investigate and enforce ex post non-compliance with the rules of this Regulation. In the context of the analysis of this risk assessment, mitigating measures and audits, the Commission services responsible for the enforcement of Regulation (EU) 2022/2065 may seek the opinion of the AI Office on the outcome of a potential earlier or parallel risk assessment carried out under this Regulation and the applicability of prohibitions under this Regulation. In addition, the AI Office and the competent national authorities under (EU) 2024/1689 should coordinate their enforcement efforts

with the authorities competent for the supervision and enforcement of Regulation (EU) 2022/2065, including the Commission, in order to ensure that the principles of loyal cooperation, proportionality and non bis in idem are respected, while information obtained under the respective other Regulation would be used for the purposes of supervision and enforcement of the other only provided the undertaking agrees. In particular, those authorities should exchange views regularly and take into account, in their respective areas of competence, any fines and penalties imposed on the same provider for the same conduct ***through a final decision in proceedings relating to an infringement of other Union or national rules, so as to ensure that the overall fines and penalties imposed are proportionate and correspond to the seriousness of the infringements committed.***

¹² Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1, ELI: <http://data.europa.eu/eli/reg/2022/2065/oj>).

with the authorities competent for the supervision and enforcement of Regulation (EU) 2022/2065, including the Commission, in order to ensure that the principles of loyal cooperation, proportionality and non bis in idem are respected, while information obtained under the respective other Regulation would be used for the purposes of supervision and enforcement of the other only provided the undertaking agrees. In particular, those authorities should exchange views regularly and take into account, in their respective areas of competence, any fines and penalties imposed on the same provider for the same conduct. ***Fines should not be imposed for the same infringement on the basis of more than one piece of legislation.***

¹² Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 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) The creation of overlapping administrative obligations based on multiple pieces of legislation must be avoided at all costs in order to ease the

administrative burden on businesses. This requires effective communication among the authorities responsible for supervision and enforcement, as well as regular revision of the legislation.

Or. fi

Amendment 81

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 16

Text proposed by the Commission

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

Amendment

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

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 within the internal market.*

Or. en

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

Amendment

(19) Article 77 and related provisions of Regulation (EU) 2024/1689 constitute an important governance mechanism, as they aim to enable authorities or bodies responsible for enforcing or supervising Union law intended to protect fundamental rights to fulfil their **mandate** under specific conditions and to foster cooperation with market surveillance authorities responsible

(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

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.

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

(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

Amendment

deleted

2026.

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*

Or. en

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 *deleted*

2026.

Or. en

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

Or. en

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

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*

(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.

2026.

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

Amendment

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

deleted

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 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

deleted

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

(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

Amendment

(21) To provide sufficient time for providers of high-risk AI systems and to clarify applicable rules to the AI systems already placed on the market or put into service before the entry into application of relevant provisions of the Regulation (EU) 2024/1689, it is appropriate to clarify the application of a grace period provided in Article 111(2) of that Regulation. The grace period, for the purpose of Article 111(2), should apply to a type and model of AI systems already placed in the market. This means that if at least one individual unit of the high-risk AI system has been lawfully placed on the market or put into service before the date specified in Article 111(2), other individual units of the same type and model of high-risk AI system are subject to the grace period provided in

Article 111(2) and thus may continue to be placed on the market, made available or put into service on the Union market without any additional obligations, requirements or the need for additional certification, as long as the design of that high-risk AI system remains unchanged. For the purposes of application of the grace period provided in Article 111(2), the 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.

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

(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

Amendment

deleted

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.

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 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

deleted

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 Juvet, 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 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

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.***

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.***

Or. en

Amendment 95

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

Proposal for a regulation

Recital 22

(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)

(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.

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 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

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.***

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.***

Or. en

Amendment 97
Sebastian Tynkkynen

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 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)

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.

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. *Where the guidelines and standards necessary for the effective implementation of the obligations relating to high-risk AI systems are lacking, the implementation of those obligations should be deferred.*

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.

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 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.* *deleted*

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 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 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)

Regulation (EU) 2024/1689

Article 2 – paragraph 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

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.***

(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.

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

Amendment

(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;

(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 payment or free of charge;

Amendment

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

‘(3) ‘provider’ means a natural or legal person, public authority, agency, or other body that develops 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.’;

Or. en

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

Amendment

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

(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

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

Amendment

(2e) in Article 3, point 14 is 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

(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;

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

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

(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;

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 **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

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

‘Article 4

AI literacy

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

Amendment

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

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.

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

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

Amendment

(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

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. ***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.;

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 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. ***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.***;

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

Amendment

The Commission and Member States shall ***support, facilitate and complement the***

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.;

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 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 *the* 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 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

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

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 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 Jovet, 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 Konečná

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

(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

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)*

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:***

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 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 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, 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 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
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

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

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:

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 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 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

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

Amendment

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

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

Amendment

(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

(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

deleted

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

(c) **the special categories of personal**

Amendment

deleted

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;

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

(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;

Amendment

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

(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;

Amendment

(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

(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***;

Amendment

(e) the special categories of personal 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 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.; ***deleted***

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 safeguards set out in this paragraph.;

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 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

