



2025/0359(COD)

17.2.2026

AMENDMENTS

35 - 213

Draft report
Sergey Lagodinsky
(PE784.179v01-00)

Amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

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

Amendment 35

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Recital 1 a (new)

Text proposed by the Commission

Amendment

(1 a) In order to preserve Europe's global competitiveness in AI, the implementation of the AI Act should be predictable, proportionate and conducive to rapid market uptake and scaling of AI solutions across the Union.

Or. en

Amendment 36

Adrián Vázquez Lázara

Proposal for a regulation

Recital 1 a (new)

Text proposed by the Commission

Amendment

(1 a) Obligations under this Regulation shall be implemented in a proportionate manner, taking into account the nature, scale and complexity of the activities concerned.

Or. en

Justification

This amendment reinforces the principle of proportionality without reducing regulatory standards. It ensures practical and risk-based implementation, particularly important for SMEs and smaller operators, while maintaining the integrity of the Regulation.

Amendment 37

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Recital 2

(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.**

(2) The experience gathered in implementing the **provisions** of Regulation (EU) 2024/1689 that have already entered into application can inform the implementation of those **provisions** that are yet to apply. **That experience has shown that delays in the** preparation of **harmonised** standards, **the** establishment of governance **structures** and the **designation of** conformity assessment **bodies** at national level **risk creating legal uncertainty and** a compliance burden that is heavier than **initially anticipated. Such uncertainty may deter investment, slow innovation and delay market entry. There is therefore a pressing** need for additional **targeted** measures **to** facilitate implementation and compliance, **with a focus on simplification and clarity, while maintaining** the level of protection **pursued by** Regulation (EU) 2024/1689.

Or. en

Amendment 38

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Recital 2

(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

(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.

in some Member States 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.

Or. en

Amendment 39
Adrián Vázquez Lázara

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2 a) This Regulation aims to simplify the implementation of Regulation (EU) 2024/1689 and to reduce unnecessary administrative burden without altering its scope. It does not introduce new legal categories of artificial intelligence systems, nor does it prejudge any future policy choices regarding systems exhibiting higher degrees of autonomy. Any such assessment should take place in the context of a dedicated legislative review.

Or. en

Amendment 40
Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation
Recital 3

Text proposed by the Commission

Amendment

(3) Consequently, targeted

(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.

amendments to Regulation (EU) 2024/1689 are necessary to address *structural* implementation challenges, *reduce unnecessary administrative burdens and improve legal certainty, thereby ensuring* the effective *and innovation-friendly* application of the relevant rules.

Or. en

Amendment 41
Mario Mantovani

Proposal for a regulation
Recital 4

Text proposed by the Commission

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

Amendment

(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. *Though small mid-cap enterprises and SMEs have different operational and financial capabilities, the* challenges *they face* in relation to administrative burden *are in some cases similar*, leading to a need for *a number of adjustments concerning* the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. *In all cases, such an extension must follow a strictly proportionate approach, seeing as SMEs and SMCs are two different categories of*

to Commission Recommendation 2025/3500/EC⁵.

enterprises; this approach precludes any blanket uniform treatment and, on the contrary, requires that the differences between SMEs and small mid-cap enterprises be emphasized in the definition of model standards, guidelines or terms for contracts for the purposes of this Regulation. For the purposes of legal certainty and in order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC⁴ and Annex to Commission Recommendation 2025/3500/EC⁵.

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

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

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

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

Or. it

Justification

Extending SME-specific regulations to SMCs should not be the norm; rather, it is fundamental that such harmonisation be exceptional and implemented solely in relation to specific provisions outlined by the AI Act. Treating SMCs and SMEs in the same way entails the inevitable risk of creating a number of competition- and competitiveness-related imbalances that will harm the undertakings that are genuinely the smallest, especially micro-enterprises.

Amendment 42

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

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.

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) 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 ***and are key drivers of innovation, digitalisation and growth.*** Compared to SMEs, SMCs ***often face a sudden and disproportionate increase in regulatory obligations when they cross applicable thresholds, which may discourage scaling and investment.*** ***Ensuring continuity and proportionality of regulatory treatment is therefore essential to avoid creating disincentives to growth.*** Regulation (EU) 2024/1689 provides for several measures for small-scale providers, ***which should be extended to SMCs. To ensure legal clarity and predictability, definitions of SMEs and SMCs should be introduced*** 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>)

Or. en

Amendment 43

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) AI agents should constitute a new category of artificial intelligence applications that can execute sophisticated real-world operations rapidly and with reduced or complete absence of human oversight. While conventional AI systems deliver outputs like forecasts, generated content, suggestions or judgments, AI agents distinguish themselves through their capacity to carry out concrete actions autonomously. The absence of immediate human validation significantly expands the digital impact and might amplify systemic risks in case of compromise. Given that the exclusion laid down in Article 2(4) of Regulation (EU) 2024/1689 applies only to AI systems used exclusively for military, defence or national security purposes, autonomous AI agents deployed in dual-use or other non-exclusive contexts remain subject to this Regulation. This clarification is of particular relevance where autonomous AI agents deployed in non-exclusive contexts are capable of making or executing decisions that may result in the deprivation of human life without human oversight. To address this potential regulatory gap and provide legal clarity, it would be advisable to amend the definition to expressly include systems that execute autonomous actions under the jurisdiction of Regulation (EU) 2024/1689, thereby ensuring that such systems are subject not only to the applicable regulatory safeguards but also to clear liability consequences.

Or. en

Amendment 44
Mario Mantovani

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) Recital 4a (new):

SMEs have a fundamental role in AI value chains, particularly as deployers. Indeed, small enterprises often fine-tune, personalise and perform technical adaptation operations on general-purpose or open-source AI models on their clients' behalf using data provided by the latter. The current Regulation discourages small enterprises from installing general-purpose AI models on client company servers for the purposes of performing fine-tuning locally, as these enterprises would be considered to be providers within the meaning of the Regulation, making them subject to disproportionate legal responsibilities and certification burdens. It would therefore be appropriate to add a clarification to the definitions of Regulation (EU) 2024/1689 so as to prevent small enterprises performing fine-tuning operations by using client-provided data from being considered as providers unless these operations result in substantial modifications to, or changes in the intended purpose of, the AI systems in question.

Or. it

Justification

The current Regulation considers small enterprises that perform fine-tuning operations locally (i.e. on client servers) to be providers, thereby imposing totally disproportionate legal responsibilities and certification burdens on them. Among other things, this state of affairs prompts enterprises to forego local fine-tuning and instead perform this operation by means of application programming interfaces (APIs) supplied by (generally non-EU-based) large providers of general-purpose models with a view to retaining their status as deployers.

Amendment 45
Adrián Vázquez Lázara

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) 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 46
Mario Mantovani

Proposal for a regulation
Recital 4 b (new)

Text proposed by the Commission

Amendment

(4b) 4b: Enhancing the role of SMEs as critical players in AI value chains requires the Commission and Member States to address the issue of the transfer of liability. In contractual practice, larger companies tend to transfer compliance obligations to smaller suppliers that do not have the control capacity to fulfil these obligations. These transfers undermine the very financial sustainability of SMEs and micro-enterprises and require targeted measures. The terms for contracts developed by the AI Office pursuant to Article 25 of Regulation (EU) 2024/1689 must prevent these imbalanced contractual practices, which weaken the digital ecosystem as a whole and undermine the resilience of the entire

value chain.

Or. it

Justification

In contractual practice, larger companies tend to transfer compliance obligations under EU digital legislation (AI Act, Cyber Resilience Act, NIS2, etc.) to smaller suppliers, undermining SMEs' and micro-enterprises' legal and economic sustainability, burdening them with costs that are not commensurate with their position in the value chain and are therefore beyond their actual control capacity. The regulatory framework should include minimum safeguards consistent with the principle that accountability must follow control.

Amendment 47

Laurence Farreng

Proposal for a regulation

Recital 5

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 48

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

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.**

Amendment

(5) Article 4 of Regulation (EU) 2024/1689 imposes an obligation on providers and deployers of AI systems to ensure AI literacy of their staff. **While AI literacy is an important enabler of informed decision-making and responsible deployment of AI systems, a uniform, horizontal obligation does not sufficiently reflect the diversity of providers, deployers, business models and risk profiles, and may therefore be ineffective**

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.

and disproportionately burdensome, particularly for smaller enterprises. AI literacy should be promoted primarily through supportive, non-binding and incentive-based measures rather than prescriptive obligations. Accordingly, Article 4 should be amended to require the Commission and the Member States, within their respective competences, to encourage AI literacy through guidance, training opportunities, information sharing and the exchange of best practices, including via the European Artificial Intelligence Board and the Apply AI Alliance, without prejudice to broader education and skills initiatives.

Or. en

Amendment 49
Daniel Buda

Proposal for a regulation

Recital 5

Text proposed by the Commission

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

Amendment

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

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.

(‘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. ro

Amendment 50
Mario Mantovani

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) Small and medium-sized enterprises (SMEs), particularly micro-enterprises, account for 99 % of the EU's business fabric and employ more than 100 million people. However, the regulatory requirements that were designed for major technology players represent a disproportionate burden for SMEs and micro-enterprises given these smaller undertakings' limited human and logistical resources. Data gathered by the Commission show that, for SMEs, the cost of complying with similar regulations (the GDPR and MDR, for example) as a percentage of total turnover is, on average, ten times greater than it is for large companies. In order to ensure that this Regulation genuinely helps SMEs to develop, it is imperative that substantial simplification measures that do more than just implement symbolic cuts are adopted. The 'think small first' principle enshrined by the EU Small Business Act requires assessing regulatory impact specifically as regards SMEs and the adoption of

exemptions, simplifications and targeted aid measures in cases where protection objectives can be met with less burdensome instruments. A proportionate approach fosters more effective voluntary compliance. Past experience with other complex regulations like the GDPR, REACH and NIS2 shows that schemes which differentiate according to undertaking size increase the overall compliance rate and bring down enforcement costs for the authorities. Furthermore, the responsible innovation of SMEs that are active in specialised fields and have limited customer bases has lower systemic risk profiles compared to global platforms that have billions of users, further justifying a differentiated approach, something that the EU has already recognised in many sectors (including data protection, financial services and medical devices).

Or. it

Amendment 51
Laurence Farreng

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission

Amendment

(5 a) AI systems that alter, manipulate or artificially produce images or videos depicting natural persons engaged in sexually explicit activities, displaying their intimate body parts, or undresses a person without consent cause harm to victims and violate fundamental rights to dignity and privacy. The proliferation of such technologies, marketed as 'nudification' applications, has created an urgent need for explicit regulatory prohibition. While Regulation (EU) 2024/1689 establishes a framework for prohibited AI practices, the effective protection of persons, particularly women and minors who are

disproportionately targeted, requires the explicit prohibition of such AI systems. This is without prejudice towards the rights, freedoms and principles recognised by Article 6 TEU and the Charter of Fundamental Rights of the European Union, and the exercise of the rights guaranteed therein to freedom of expression and information and the freedom of the arts and sciences.

Or. en

Amendment 52

Ton Diepeveen, Pascale Piera

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*

Amendment

(6) Bias detection and correction constitute *an important* public interest *objective, as they help* protect natural persons from adverse effects, including discrimination. Discrimination *may arise not only from* high-risk AI systems, *but* also from other AI systems and models. *In order to provide legal certainty and facilitate responsible innovation,* Regulation (EU) 2024/1689 should *therefore* provide *a clear* legal basis for the processing of special categories of personal data *where this is strictly necessary for the detection and mitigation of bias, subject to appropriate safeguards. This legal basis should apply consistently to* providers and deployers of AI systems and models, in compliance with Article 9(2), point (g), of Regulation (EU) 2016/679, Article 10(2), point (g), of Regulation (EU) 2018/1725 and *Article 10, point (a), of Directive (EU) 2016/680, thereby reducing legal uncertainty and facilitating compliance across the internal market.*

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 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:*

Amendment 53
Adrián Vázquez Lázara

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

Amendment

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

Amendment 54
Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation
Recital 7

Text proposed by the Commission

Amendment

(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***

(7) In order to ensure consistency, avoid duplication and minimise administrative burdens ***related*** to the ***designation of*** notified bodies under Regulation (EU) 2024/1689, a single application and assessment procedure should be available ***where*** conformity assessment bodies are ***already*** designated under Union harmonisation legislation

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

listed in Section A of Annex I to *that* Regulation. *Such streamlining is essential to accelerate market access for AI-enabled products and to reduce costs for providers, while maintaining an equivalent level of scrutiny and compliance with applicable requirements.*

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 55

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Recital 8

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

(8) With a view to ensuring the smooth **and consistent** application of Regulation (EU) 2024/1689, **targeted clarifications and technical corrections** should be **introduced to remove ambiguity, avoid duplicative procedures and allow providers to rely on existing quality management systems established under other Union harmonisation legislation. This approach enhances legal certainty, reduces compliance costs and supports faster deployment of AI systems, without lowering the level of protection required under Union law.**

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

Amendment 56
Adrián Vázquez Lázara

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

Amendment

(8 a) 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 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 57
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

deleted

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.

Or. en

Amendment 58

Ton Diepeveen, Juan Carlos Girauta Vidal

Proposal for a regulation

Recital 9

Text proposed by the Commission

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

Amendment

(9) To streamline compliance and reduce the associated costs, providers of AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 ***should not be required to register those systems*** in the EU database. *As* such systems are not considered high-risk under ***the*** conditions ***set out in that provision***, imposing registration ***obligations*** would constitute a disproportionate ***administrative*** burden ***with limited added value***. ***Maintaining documentation obligations while removing registration requirements strikes an appropriate balance between oversight and innovation.***

by national competent authorities.

Or. en

Amendment 59

Adrián Vázquez Lázara

Proposal for a regulation

Recital 9

Text proposed by the Commission

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

Amendment

(9) To streamline compliance and reduce the associated costs, 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. ***Where registration/documentation is required, it should be possible via a single digital interface and in machine-readable format, to avoid duplicate submissions across authorities.***

Or. en

Amendment 60

Daniel Buda

Proposal for a regulation

Recital 10

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

(10) Articles 57, 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 ***common protocols for cooperating and communicating with the competent national authorities with a view to facilitating participation in testing activities and/or access to the test results relating to innovative solutions, AI systems and providers of general-purpose AI systems which are aimed at one or more Member States and which are intended for the testing of AI solutions*** at Union level, ***pursuant to*** 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. ***In addition, further clarifications should be given with regard to AI models that fall within the category of general-purpose AI and with regard to the conditions and circumstances under which such solutions can be accepted for testing outside of the EU-regulated testing environment, as appropriate.***

Or. ro

Amendment 61
Ton Diepeveen

Proposal for a regulation
Recital 10

Text proposed by the Commission

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

Amendment

(10) ***In order to foster innovation and facilitate experimentation,*** Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to further ***streamline*** the governance of AI regulatory sandboxes, ***strengthen coordination at Union level and simplify procedural requirements. Integrating sandbox and real-world testing plans into a single document reduces administrative complexity and accelerates testing, while the possibility for the AI Office to establish Union-level sandboxes enhances cross-border cooperation and efficient use of resources.***

Or. en

Amendment 62
Daniel Buda

Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission

Amendment

(10a) To ensure a balanced, efficient

and proportionate implementation of AI regulatory sandboxes at national level, the implementation deadline of 2 August 2026 established under Article 57(1) of Regulation (EU) 2024/1689 should be extendable.

Or. ro

Amendment 63

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Recital 11

Text proposed by the Commission

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

Amendment

(11) *Extending the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by Union harmonisation legislation listed in Annex I to Regulation (EU) 2024/1689 is essential to foster innovation under real market conditions. Such testing supports faster development cycles and earlier detection of potential risks, while remaining subject to applicable Union and national safeguards. Voluntary agreements between the Commission and Member States should further facilitate testing where sector-specific frameworks apply.*

Or. en

Amendment 64

Mario Mantovani

Proposal for a regulation

Recital 11

Text proposed by the Commission

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

Amendment

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

Or. it

Amendment 65

Ton Diepeveen, Ernő Schaller-Baross, Juan Carlos Girauta Vidal, Pascale Piera

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 *allows* microenterprises to comply with quality management system *obligations in a simplified manner. In order to maximise the innovation potential of the Union's AI ecosystem, this simplification* should be extended to all SMEs, including start-ups, *which face similar capacity constraints and play a central role in AI innovation.*

Or. en

Amendment 66 Ton Diepeveen

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 *and consultation procedures* of the scientific panel. *Reducing* procedural complexity *and allowing direct consultation by* Member States *enhances efficiency, lowers costs and improves access to expertise*, without *undermining the panel's independence or quality.*

Or. en

Amendment 67 Ton Diepeveen

Proposal for a regulation Recital 14

Text proposed by the Commission

(14) In order to strengthen the

Amendment

(14) In order to strengthen the

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

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. ***Clear allocation of responsibilities and avoidance of overlapping supervision are essential to legal certainty and investment confidence.*** While sectoral authorities continue to remain responsible for the supervision of AI systems related to products covered by that Union harmonisation legislation, Article 75(1) Regulation (EU) 2024/1689 should be modified to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, the AI Office should be empowered to take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council¹¹. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 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>).

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 68 **Ton Diepeveen**

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)**

Amendment

(15) Considering the existing supervisory **framework** under Regulation (EU) 2022/2065, **granting** the Commission the powers of a competent market surveillance authority under Regulation (EU) 2024/1689 **for AI systems qualifying as very large online platforms or search engines ensures coherent, proportionate and non-duplicative enforcement. Coordination between authorities should prevent multiple penalties for the same conduct and ensure that overall sanctions remain** proportionate.

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>).***

Amendment 69
Ton Diepeveen

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 **clearly specify** the powers conferred upon **it, while ensuring that enforcement tools are used proportionately and as a measure of last resort.** Implementing acts **should therefore precisely define** those powers, **ensuring effectiveness without creating unnecessary compliance uncertainty.**

Or. en

Amendment 70
Ton Diepeveen

Proposal for a regulation
Recital 17

Text proposed by the Commission

(17) **Additionally, it is essential to ensure that** effective procedural safeguards **apply to** providers **of AI systems** subject to **monitoring and** supervision by the AI Office. **To that end, the procedural rights provided for in** Article 18 of Regulation

Amendment

(17) Effective procedural safeguards **are essential to ensure fairness, legal certainty and trust for** providers subject to supervision by the AI Office. **The application mutatis mutandis of** Article 18 of Regulation (EU) 2019/1020 **ensures**

(EU) 2019/1020 *should apply mutatis mutandis to providers of AI systems*, without prejudice to more specific *procedural rights provided for* in Regulation (EU) 2024/1689.

that enforcement remains predictable, transparent and business-friendly, without prejudice to more specific *safeguards laid down* in Regulation (EU) 2024/1689.

Or. en

Amendment 71 **Ton Diepeveen**

Proposal for a regulation **Recital 18**

Text proposed by the Commission

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

Amendment

(18) To **facilitate** access to **the** Union market for AI systems **supervised** by the AI Office and subject to third party conformity assessment, the Commission should be enabled to carry out pre-market conformity assessments. **This supports timely market entry and reduces procedural bottlenecks, particularly for innovative AI** systems.

Or. en

Amendment 72 **Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera**

Proposal for a regulation **Recital 19**

Text proposed by the Commission

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

Amendment

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

Regulation. It is necessary to clarify the scope of such cooperation, as well as to clarify which public authorities or bodies benefit from it. With a view to reinforcing the cooperation, it should be clarified that requests to access information and documentation should be made to the competent market surveillance authority, which should respond to such requests, and that the involved authorities or bodies should have a mutual obligation to cooperate.

Regulation. It is necessary to clarify the scope of such cooperation, as well as to clarify which public authorities or bodies benefit from it, ***while avoiding duplicative requests and administrative burden for providers***. 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.

Or. en

Amendment 73
Laurence Farreng

Proposal for a regulation
Recital 20

Text proposed by the Commission

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

Amendment

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Or. en

Amendment 74
Ton Diepeveen, Ernő Schaller-Baross, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation
Recital 20

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 75
Laurence Farreng

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

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service on the Union market without any additional obligations, requirements or the need for additional certification, as long as the design of that high-risk AI system remains unchanged. For the purposes of application of the grace period provided in Article 111(2), the decisive factor is the date on which the first unit of that type and model of high-risk AI system was placed on the market or put into service on the Union market for the first time. Any significant change to the design of that AI system after the date specified in Article 111(2) should trigger the obligation of the provider to comply fully with all relevant provisions of this Regulation applicable to high-risk AI systems, including the conformity assessment requirements.

Or. en

Amendment 76
Laurence Farreng

Proposal for a regulation
Recital 22

Text proposed by the Commission

Amendment

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

deleted

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.

Or. en

Amendment 77

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

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***.

(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, ***guidance*** should be ***prioritised over binding templates, enabling tailored compliance solutions without lowering policy objectives***.

Or. en

Amendment 78
Adrián Vázquez Lázara

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission

Amendment

(23 a) This Regulation shall not alter Regulation (EU) 2024/1689 as regards the scope, classification or compliance timelines applicable to AI systems.

Or. en

Amendment 79
Victor Negrescu

Proposal for a regulation
Recital 26

Text proposed by the Commission

(26) In order to ensure legal certainty as soon as possible, with a view to the imminent general application of Regulation (EU) 2024/1689, this Regulation should enter into force as a matter of urgency,

Amendment

(26) In order to ensure legal certainty as soon as possible, with a view to the imminent general application of Regulation (EU) 2024/1689, this Regulation should enter into force as a matter of urgency; ***in order to promote a widespread and structured culture of AI literacy, Member States and the Commission shall support cooperation between providers, deployers, universities, and educational institutions, including through dedicated programmes for digital skills and AI education. Particular emphasis shall be placed on training for educators, public sector employees, and future professionals, ensuring alignment with Union values and the responsible use of AI systems.***

Or. en

Amendment 80
Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

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

Text proposed by the Commission

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

Amendment

(g) measures to support innovation ***and market uptake of artificial intelligence***, with a particular focus on small mid-cap enterprises (SMCs) and small and medium-sized enterprises (SMEs), including start-ups, ***through proportionate, risk-based and simplified regulatory approaches.***

Amendment 81

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 2 – introductory part

Text proposed by the Commission

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

Amendment

(2) **(2 a)** 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

Amendment 82

Tobiasz Bocheński

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 2 – paragraph 8

Text proposed by the Commission

Amendment

(2 a) 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. 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

Amendment 83

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 3 – point 1

Text proposed by the Commission

Amendment

(2 a) in Article 3, point 1, is replaced by the following:

'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, actions or decisions that can influence physical or virtual environments.

Or. en

Amendment 84

Adrián Vázquez Lázara

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 2 – paragraph 10

Text proposed by the Commission

Amendment

(2 a) in Article 2, paragraph 10a 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 85

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 2 b (new)

Regulation (EU) 2024/1689

Article 2a

Text proposed by the Commission

Amendment

(2 b) the following Article 2a is inserted:

'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 86

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 3 – introductory part

Text proposed by the Commission

(3) in Article 3, the following points (14a) and **(14b)** are inserted:

Amendment

(3) in Article 3, the following points (14a), **(14b)** and **(68a)** are inserted:

Or. en

Amendment 87

Gheorghe Piperea

Proposal for a regulation

Article 1 – paragraph 1 – point 3 – introductory part

Text proposed by the Commission

(3) in Article 3, the following points (14a) and (14b) are inserted:

Amendment

(3) in Article 3, the following points **(1a)**, (14a) and (14b) are inserted:

Or. en

Amendment 88

Gheorghe Piperea

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EU) 2024/1689

Article 3

Text proposed by the Commission

Amendment

(14a a) (1a) “AI Agent” means an autonomous software system that uses artificial intelligence to perceive its environment, reason through problems, and take actions to achieve specific goals with minimal human intervention.

Or. en

Amendment 89

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EU) 2024/1689

Article 3 – point 68

Text proposed by the Commission

Amendment

(14b a) (68a) 'significant change' means any substantial modification to the architecture, intended purpose, underlying model or training dataset that may affect the system's risk profile.

Or. en

Amendment 90

Mario Mantovani

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 3 – point 3

Text proposed by the Commission

Amendment

(3a) Article 3, point (3) is amended as follows:

(a) 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge, excluding those that perform fine-tuning, personalisation and technical adaptation operations on AI systems on behalf of third-party clients by using data provided by the latter, unless these operations result in substantial modifications to, or changes in the intended purpose of, the AI systems in question;

Justification

The current Regulation considers small enterprises that perform fine-tuning operations locally (i.e. on client servers) to be providers, thereby imposing totally disproportionate legal responsibilities and certification burdens on them. Among other things, this state of affairs prompts enterprises to forego local fine-tuning and instead perform this operation by means of application programming interfaces (APIs) supplied by (generally non-EU-based) large providers of general-purpose models with a view to retaining their status as deployers.

Amendment 91**Tobiasz Bocheński, Piotr Müller****Proposal for a regulation****Article 1 – paragraph 1 – point 3 a (new)**

Regulation (EU) 2024/1689

Article 3 – point 1

*Text proposed by the Commission**Amendment*

(3 a) in Article 3, point 1, is amended as follows:

'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

Amendment 92**Tobiasz Bocheński, Piotr Müller****Proposal for a regulation****Article 1 – paragraph 1 – point 3 b (new)**

Regulation (EU) 2024/1689

Article 3 – point 1

*Text proposed by the Commission**Amendment*

(3 b) in Article 3, point 1a, is inserted:

1a. 'autonomy' means the ability of the artificial intelligence system to operate, within constraints, without human guidance or intervention;'

Or. en

Amendment 93

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

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

REgulation (EU) 2024/1689

Article 3 – point 13

Text proposed by the Commission

Amendment

(3 c) in Article 3 point 13 is amended as follows:

'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 94

Laurence Farreng

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 95
Daniel Buda

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

Text proposed by the Commission

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

Amendment

‘The Commission and Member States shall encourage providers and deployers of AI systems to take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, level of education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used. ***The Commission shall support Member States by making available, free of charge, some standardised training modules and practical compliance materials, including templates and checklists, in all the official languages of the Union. The Member States shall aim to ensure effective access to this type of training, especially for SMEs, SMCs and public administrations, including in less developed regions.***’;

Or. ro

Justification

Ensuring access to practical and multilingual training tools strengthens effective implementation, particularly in Member States with developing AI ecosystems. The amendment maintains the simplification objective while enhancing competitiveness and cohesion.

Amendment 96

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EU)2024/1689

Article 4

Text proposed by the Commission

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

Amendment

‘**Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and proportionate to the nature, intended purpose and risk profile of the AI systems.**

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

Or. en

Amendment 97

Tobiasz Bocheński

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 ***AI literacy, in particular among*** providers and deployers of AI systems, ***with a view to ensuring appropriate knowledge and skills among responsible staff. The actions under this Article shall be solely supportive in nature.***;

Or. en

Amendment 98

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

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 ***voluntary and proportionate*** 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. ***Such measures shall take*** into account ***the*** technical knowledge, experience, level of education and training ***of those persons, the size and nature of the organisation,*** and the context ***in which*** the AI systems are used.

Or. en

Amendment 99

Ton Diepeveen, Juan Carlos Girauta Vidal

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

Text proposed by the Commission

Amendment

Compliance with this article may be demonstrated through existing data protection impact assessments, internal governance procedures or equivalent documentation prepared pursuant to Union data protection law, without requiring duplication.

Or. en

Amendment 100
José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

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

Text proposed by the Commission

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 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:

1. To the extent **strictly** necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate **provisions on** 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 101
Tobiasz Bocheński

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

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 102
Tobiasz Bocheński

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

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 103

Tobiasz Bocheński

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4

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 104

Daniel Buda

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU)2024/1689

Article 4

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, ***in accordance with the provisions of Article 9 of Regulation (EU) 2016/679;***

Or. ro

Amendment 105

Tobiasz Bocheński

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

Article 4

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 106
Daniel Buda

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

Text proposed by the Commission

Amendment

(fa) before processing begins, a data protection impact assessment is carried out and internal responsibilities for access, retention and erasure are recorded in a data governance register.

Or. ro

Justification

The amendment strengthens legal certainty and safeguards while preserving the objective of bias detection and correction. It aligns the provision with established data protection practices.

Amendment 107
Ton Diepeveen, Pascale Piera

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

2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary, proportionate **and demonstrably linked to bias detection or mitigation**, 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 108

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 5

Regulation (EU) 2024/1689

– Article 4a – paragraph 2

Text proposed by the Commission

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

Amendment

2. Paragraph 1 may **also** apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where **strictly** necessary and proportionate **for bias detection and correction, subject to** the safeguards set out in this **Article and applicable Union data protection law**.

Or. en

Justification

Keeps COM legal basis generous and adds proportionality language

Amendment 109

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 5 – paragraph 1 – point h

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

(ha) the placing on the market, the putting into service or the use of an AI system that generates, manipulates or alter imagine, audio or video content depicting a natural person's freely given, specific, informed and unambiguous consent, or in a manner that materially facilitates sexual exploitation or sexual abuse;

(hb) the placing on the market, putting into service or use of AI systems that generate or manipulate image, audio or video content where such systems enable or are used for the creation of deep fakes depicting non-consensual nudity or sexually explicit conduct;

(hc) the placing on the market, putting into service or use of AI systems that are intended to be used for the profiling of natural persons for the purpose of influencing political views, electoral behaviour or participation in democratic processes, where such systems rely on the analysis or inference of personal characteristics, behavioural patterns or vulnerabilities;

(hd) the placing on the market, putting into service or use of AI systems that are specifically designed or substantially modified for the purpose of generating, amplifying or coordinating large-scale deceptive or misleading content with the intent or reasonably foreseeable effect of distorting public discourse or democratic processes;

(he) the placing on the market, putting into service or use of AI systems in the field of employment that assess, score or monitor natural persons based on inferred personality traits, behavioural characteristics or biometric data, where such systems produce or are likely to produce significant adverse effects on working conditions, access to employment

or dismissal;

Or. en

Amendment 110

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 1

Text proposed by the Commission

Amendment

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

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

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

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

A lack of harmonised standards or part thereof, the references of which have been published in the Official Journal of the European Union, leading to third-party conformity assessment according to the applicable Union harmonisation

legislation in Annex I, can in itself not lead to a product or AI system being classified as high-risk.'

Or. en

Amendment 111
Laurence Farreng

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 112
Tobiasz Bocheński, Piotr Müller

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

Text proposed by the Commission

Amendment

(5 b) In Article 6, paragraph 3, introductory part is amended as follows:

' 3. By derogation from paragraph 2, an AI system referred to in Annex III shall not be considered to be high-risk where it does not pose a significant risk of harm to

the health, safety or fundamental rights of natural persons, including by not materially influencing the outcome of decision making or by ensuring meaningful human intervention or review. The first subparagraph shall apply where any of the following conditions is fulfilled:'

Or. en

Amendment 113
Gheorghe Piperea

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EU) 2024/1689
Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 114
Laurence Farreng

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EU) 2024/1689
Article 6 – paragraph 4

Text proposed by the Commission

Amendment

(6) in Article 6(4), paragraph 4 is **deleted**

replaced by the following:

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

Or. en

Amendment 115

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 6 – introductory part

Text proposed by the Commission

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

Amendment

(6) in Article 9(2), paragraph b is replaced by the following:

(b) the estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse, including cybersecurity specific threat modelling;

Or. en

Amendment 116

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market

Amendment

deleted

or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.;

Or. en

Amendment 117

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

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

Amendment

4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment ***to the extent strictly necessary to demonstrate that the conditions laid down in Article 6(3) are fulfilled.***;

Or. en

Amendment 118

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

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

Amendment

4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. ***That documentation shall be kept proportionate and concise***

provider shall provide the documentation of the assessment.;

*and shall be provided to national competent authorities **only upon reasoned request**;*

Or. en

Amendment 119
Mario Mantovani

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

Text proposed by the Commission

Amendment

(6a) In Article 6, paragraph 5a is inserted:

5a. By way of derogation from the previous paragraphs, a high-risk AI system that is developed for internal use and is employed accordingly by a micro-enterprise to optimise its company processes shall not be subject to the obligations set out in Chapter III, Sections 2 and 3, provided that:

(a) the system is neither put on the market nor made available to third parties;

(b) the system does not process the personal data of external subjects;

(c) the system does not fall under the categories set out in Annex III, points 1,2,6 and 8;

(d) the system is only used by members of staff operating devices owned/controlled by the enterprise;

(e) the system does not implement any of the prohibited practices set out in Article 5.

The micro-enterprises making use of this derogation shall maintain simplified documentation in accordance with the template set out in Annex IV (a) and shall make it available to the competent

authorities upon request.

Or. it

Justification

Micro-enterprises (companies with fewer than 10 employees and an annual turnover that does not exceed EUR 2 million, see Commission Recommendation 2003/361/EC of 6 May 2003) often use AI tools for simple international automation processes (stock management, sales projections, shift optimisation). Making these undertakings subject to the same obligations as multinational corporations or SMCs is disproportionate and discourages digital uptake. The internal use exemption, combined with proportionate guarantees, drastically reduces red tape while maintaining essential protections.

Amendment 120

Ton Diepeveen, Ernő Schaller-Baross, Juan Carlos Girauta Vidal

Proposal for a regulation

Article 1 – paragraph 1 – point 6 a (new)

Regulation (EU) 2024/1689

Article 9

Present text

Providers of high-risk AI systems shall establish, implement, **document** and maintain a risk management system **throughout the entire lifecycle** of the AI system.

Amendment

(6 a) Article 9 is amended as follows:

"Providers of high-risk AI systems shall establish, implement and maintain a risk management system **that is proportionate to the nature, scale, complexity and intended purpose** of the AI system. **Documentation requirements shall be limited to essential elements necessary to demonstrate compliance and shall, where appropriate, be satisfied through existing internal processes, international standards or industry best practices, without requiring duplication.**"

Or. en

(Regulation (EU) 2024/1689)

Amendment 121

Ton Diepeveen, Ernő Schaller-Baross, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

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Article 1 – paragraph 1 – point 7 – point a
Regulation (EU) 2024/1689
Article 10, paragraph 1

Text proposed by the Commission

Amendment

1 a. (a a) in Article 10, paragraph 1a, is inserted:

'1a. Compliance may be demonstrated by reference to recognised international standards, sector-specific standards or established industry best practices.'

Or. en

Amendment 122
Mario Mantovani

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

Text proposed by the Commission

Amendment

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

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

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

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

Or. it

Justification

For the purposes of legal certainty, the wording should be amended to dispel any doubts as to whether the information contained in the form is sufficient: the notified bodies must not impose additional formalities or disclosure requests on small enterprises.

Amendment 123
Gheorghe Piperea

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

Text proposed by the Commission

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

Amendment

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

purposes of the conformity assessment.;

purposes of the conformity assessment.;
where national authorities and notified bodies deem the simplified technical documentation insufficient, they may request further documentation.

Or. en

Amendment 124

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 8

Regulation (EU) 2024/1689

Article 11 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 125

Ton Diepeveen, Ernő Schaller-Baross, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 8

Regulation (EU) 2024/1689

Article 11 – paragraph 1

Text proposed by the Commission

Amendment

(8 a) in Article 11, paragraph 1 a is inserted:

'Technical documentation may be updated progressively and shall not require re-submission in its entirety where only limited changes are made.'

Or. en

Amendment 126

Mario Mantovani

Proposal for a regulation

Article 1 – paragraph 1 – point 8 a (new)

Regulation (EU) 2024/1689

Article 11 – paragraph 3 (new)

Text proposed by the Commission

Amendment

(8a) Article 11 – paragraph 3 (new):

3. The Commission shall, within 3 months of the entry into force of this Regulation, adopt binding standardised templates and single European forms for the technical documentation referred to in Annex IV and shall differentiate them according to:

(a) enterprise size (micro-enterprises, SMEs, large enterprises);

(b) area of application;

(c) risk level.

Or. it

Justification

At present, each notified body requires documents in different formats, leading to duplication of work. SMEs commit between 100 and 300 hours every year to preparing ad-hoc documentation. Binding templates based on the European Single Procurement Document (ESPD) will reduce the length of this procedure by 75 % and ensure uniform assessment.

Amendment 127

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 8 a (new)

Regulation (EU) 2024/1689

Article 11 – paragraph 1

Text proposed by the Commission

Amendment

(8 a) in Article 11, paragraph 1a is inserted:

'The Commission's simplified form shall be:

digital-by-default, machine-readable, interoperable (so the same info can be reused for other reporting/authority requests), and enable pre-filling /re-use of previously submitted information.'

Or. en

Amendment 128

Gheorghe Piperea

Proposal for a regulation

Article 1 – paragraph 1 – point 9

Regulation (EU) 2024/1689

Article 17 – paragraph 2

Text proposed by the Commission

Amendment

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

'2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation, in particular, if the provider

is an SMC or an SME, including a start-up. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.;'

Or. en

Amendment 129
Mario Mantovani

Proposal for a regulation
Article 1 – paragraph 1 – point 9 a (new)
Regulation (EU) 2024/1689
Article 17 – paragraph 4 (new)

Text proposed by the Commission

Amendment

(9a) In Article 17, paragraph 4 is inserted:

4. By way of derogation from paragraph 1, micro-enterprises established within the Union that supply high-risk AI systems may fulfil their obligations concerning quality management systems by means of a simplified compliance procedure. This procedure complies with the proportionality principle and is based on the following elements:

(a) a self-declaration of compliance demonstrating the adoption of risk management measures that are proportionate to the size of the enterprise;

(b) the use of the digital self-assessment instruments and standardised templates provided free of charge by the AI Office.

The Commission shall adopt delegated acts to define the technical specifications of the simplified compliance procedure and the criteria for the gradual transition towards the comprehensive quality management system in case the size thresholds for micro-enterprises are exceeded.

Justification

This simplified procedure ensures accountability at limited costs that even individual entrepreneurs can afford. This model draws inspiration from the simplified scheme for SMEs provided for by Regulation (EU) 2017/745 on medical devices.

Amendment 130

Daniel Buda

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 17 – paragraph 2

Text proposed by the Commission

Amendment

(9a) In Article 17(2a) the following text is added:

'If the provider is an SMC or an SME, including start-ups, the national authorities shall provide appropriate guidance and advice, so that the necessary technical documentation and quality management system requirements are tailored to the organisational size and capacity of these categories of providers;'

Or. ro

Amendment 131

Mario Mantovani

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 25 – paragraph 6 (new)

Text proposed by the Commission

Amendment

(9b) In Article 25, paragraph 6 is inserted:

6. Micro-enterprises that supply AI components, foundation models or open-source software shall not be liable for

damages arising from substantial modifications, integrations or misuses concerning the system by third parties further down the value chain. The original provider's liability ends when the system is integrated into a complex architecture which the micro-enterprise does not effectively control and over which it does not perform technical supervision.

Or. it

Justification

This amendment aims to clarify where to draw the line as regards liability for modular architecture with a view to preventing small original developers from being scapegoated for integration errors committed by others.

Amendment 132 **Mario Mantovani**

Proposal for a regulation
Article 1 – paragraph 1 – point 9 c (new)
Regulation (EU) 2024/1689
Article 25 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Amendment

(9c) in Article 25(4), the second sentence is replaced by the following:

The AI Office may develop and recommend voluntary model terms for contracts between providers of high-risk AI systems and third parties that supply tools, services, components or processes that are used for or integrated into high-risk AI systems. When developing those voluntary model terms, the AI Office shall, with a view to preventing the transfer of obligations along the AI value chain, take into account any contractual requirements applicable in certain sectors or commercial cases, as well as the interests of SMEs. The voluntary model terms shall be published and be available free of charge in an easily usable

electronic format.

Or. it

Justification

In contractual practice, larger companies tend to transfer compliance obligations under EU digital legislation (AI Act, Cyber Resilience Act, NIS2, etc.) to smaller suppliers, undermining SMEs' and micro-enterprises' legal and economic sustainability, burdening them with costs that are not commensurate with their position in the value chain and are therefore beyond their actual control capacity. The regulatory framework should include minimum safeguards consistent with the principle that accountability must follow control.

Amendment 133
Mario Mantovani

Proposal for a regulation
Article 1 – paragraph 1 – point 10 a (new)
Regulation (EU) 2024/1689
Article 28 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(10a) in Article 28, paragraph 2a is inserted:

2a. Without prejudice to compensation for damages arising from wilful misconduct or gross negligence, the total civil liability of an SME established in the Union for damages caused by AI systems shall be limited as follows:

(i) turnover-based limit: total compensation for a single event or a series of related events may not exceed 1% of the total annual turnover for the previous financial year, if this amount exceeds EUR 50 000.

(ii) absolute ceiling: in any case, total liability may not exceed EUR 500 000 for high-risk systems, reduced to EUR 150 000 for limited-risk systems. For micro-enterprises, the absolute ceiling may not exceed EUR 150 000.

(iii) subsidiary intervention: the Commission shall ensure that, to prevent the supplier's business continuity from

being affected, where damage exceeds those ceilings, the injured party's right to compensation is guaranteed through dedicated digital innovation guarantee funds.

Or. it

Justification

The purpose of the amendment is to prevent a single algorithmic error that is not malicious and not based on gross negligence from causing the financial default of a start-up, while safeguarding consumer protection through collective compensation funds.

Amendment 134

Ton Diepeveen, Ernő Schaller-Baross, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 11

Regulation (EU) 2024/1689

Article 29 – paragraph 4

Text proposed by the Commission

Amendment

4 a. (11 a) in Article 29, paragraph 4 a is added:

'Notifying authorities shall avoid requesting information or documentation already submitted under other Union legislation.'

Or. en

Amendment 135

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 30 – paragraph 2

Text proposed by the Commission

Amendment

(12 a) in Article 30, paragraph 2a is added:

'Amendments to Annex XIV shall not impose retroactive obligations on conformity assessment bodies already designated.'

Or. en

Amendment 136

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(12 a) Article 41 is deleted.

Or. en

Amendment 137

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 13

Regulation (EU) 2024/1689

Article 43 – paragraph 3

Text proposed by the Commission

Amendment

For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.

deleted

Or. en

Amendment 138

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 13

Regulation (EU) 2024/1689

Article 43 – paragraph 3

Text proposed by the Commission

For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.

Amendment

For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply. ***Providers shall not be required to undergo multiple conformity assessment procedures for the same requirements.***

Or. en

Amendment 139

Mario Mantovani

Proposal for a regulation

Article 1 – paragraph 1 – point 13 a (new)

Regulation (EU) 2024/1689

Article 43 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

(13a) in Article 43, Article 5a is inserted as follows:

5a. By way of derogation from paragraph 3, SMEs providing high-risk AI systems may opt for an accelerated internal control procedure that replaces the procedures set out in Annex VI with the following approaches:

(a) self-assessment with the assistance of

an interactive digital tool provided by the AI Office;

(b) registration in the EU database by means of an automated procedure;

(c) automatically generated simplified EU declaration of conformity;

(d) a quality management system that complies with Article 17(2);

SMEs using this accelerated procedure shall be subject to random ex-post checks based on automatic risk scoring, taking into account the sector in which they operate, the technical complexity of the system and the supplier's compliance history.

This derogation does not apply to the systems referred to in Annex III, points 1, 2, 6 and 8.

Within six months of the entry into force of this Regulation, the AI Office shall adopt operational guidelines for the accelerated procedure, including interactive checklists and standardised forms.

Or. it

Justification

Assessment by certified bodies costs companies between EUR 15 000 and EUR 50 000 per year and takes between 6 and 12 months. If the system uses components that are already compliant, doubling up on assessment is inefficient. Enhanced self-certification with ex-post checks reduces time and costs by 70 % while maintaining security through targeted enforcement.

Amendment 140 **Mario Mantovani**

Proposal for a regulation
Article 1 – paragraph 1 – point 13 b (new)
Regulation (EU) 2024/1689
Article 43 – paragraph 6 (new)

Text proposed by the Commission

Amendment

(13b) in Article 43, paragraph 6 is inserted:

6. To prevent duplicate administrative burdens and disproportionate costs for businesses, the Commission shall adopt delegated acts in order to establish a system of automatic recognition of compliance requirements. This system shall ensure that:

(a) suppliers of AI systems already subject to certification or type approval under Union legislation benefit from a presumption of conformity for requirements that overlap with those laid down in the AI Act;

(b) assessment of compliance for the purposes of this Regulation is limited to specific elements of AI not covered by existing sectoral certifications;

(c) notified bodies accept test results and technical documentation already approved under other internationally recognised certification standards, including relevant ISO standards.

The AI office shall publish and regularly update a table showing the correspondence between the requirements of this Regulation and the main sectoral regulations and international standards, laying down accelerated procedures for obtaining CE marking for SMEs that already hold equivalent certifications.

Or. it

Justification

SMEs in the medical and automotive sectors already invest between EUR 50 000 and EUR 200 000 per year in sector-specific certifications (MDR/ISO 26262) that cover 60-80 % of the requirements of the AI Act. Requiring a new assessment disregards previous investments and creates a significant economic barrier. Automatic recognition enhances existing compliance in line with the model already successfully applied in the new legislative framework (NLF) for CE marking.

**Amendment 141
Gheorghe Piperea**

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EU) 2024/1689
Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

Or. en

Amendment 142
José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EU) 2024/1689
Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

Or. en

Amendment 143
Laurence Farreng

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EU) 2024/1689
Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

Or. en

Amendment 144

Proposal for a regulation

Article 1 – paragraph 1 – point 14 a (new)

Regulation (EU) 2024/1689

Article 50 – paragraphs 6

Text proposed by the Commission

Amendment

(14 a) in Article 50, the following new paragraphs are added:

'6a. Providers of AI systems, that generate or manipulate image, audio or video content shall implement effective technical and organisational measures to prevent the generation of deep fakes depicting non-consensual nudity or sexually explicit conduct;

6b. Providers of AI systems that are capable of profiling natural persons for the purpose of influencing political views, electoral behaviour or participation in democratic processes shall implement effective, proportionate and state-of-the-art technical and organisational measures to prevent the use of such systems for the analysis or inference of personal characteristics, behavioural patterns or vulnerabilities in a manner that could distort democratic processes or undermine the free formation of political opinions;

6c. Providers of AI systems intended to be used in the field of employment to assess, score or monitor natural persons shall implement effective, proportionate and state-of-the-art technical and organisational measures to prevent the assessment or scoring of workers or job applicants based on inferred personality traits, behavioural characteristics or biometric data in a manner that could produce significant adverse effects on working conditions, access to employment or dismissal;'

Or. en

Amendment 145

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 14 b (new)

Regulation (EU) 2024/1689

Article 50 – paragraph 4

Text proposed by the Commission

Amendment

(14 b) in Article 50, paragraph 4 is replaced with the following:

4. Deployers of an AI system that generates or manipulates image, audio or video content constituting a deep fake, shall disclose that the content has been artificially generated or manipulated. This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offence. Where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme, the transparency obligations set out in this paragraph are limited to disclosure of the existence of such generated or manipulated content in an appropriate manner that does not hamper the display or enjoyment of the work.

Deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall implement effective, proportionate and state-of-the-art technical and organisational measures to prevent such a publication.

This obligation shall not apply where the use is authorised by law to detect, prevent, investigate or prosecute criminal offences or where the AI-generated content has undergone a process of human review or editorial control and where a natural or legal person holds editorial responsibility for the publication of the content.

Or. en

Amendment 146
Adrián Vázquez Lázara

Proposal for a regulation
Article 1 – paragraph 1 – point 15
Regulation (EU) 2024/1689
Article 50 paragraph 7

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 147
Tobiasz Bocheński, Piotr Müller

Proposal for a regulation
Article 1 – paragraph 1 – point 15
Regulation (EU) 2024/1689
Article 50 – paragraph 7

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

7. The **Commission** shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, in accordance with the procedure laid down in Article 56(6), first subparagraph.

Or. en

Amendment 148

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

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

7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission, ***in consultation with relevant competent authorities and EU bodies***, may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, in accordance with the procedure laid down in Article 56(6), first subparagraph. ***If the Commission, in consultation with***

implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).;

relevant competent authorities and EU bodies, deems the code is not adequate, *it* may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).;

Or. en

Amendment 149

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

Text proposed by the Commission

Amendment

7 a. (15a) in Article 50, the following paragraph is added:

'Adherence to codes of practice shall be presumed to contribute to compliance, unless demonstrated otherwise.'

Or. en

Amendment 150

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 15 a (new)

Regulation (EU) 2024/1689

Article 50 – paragraph 2

Text proposed by the Commission

Amendment

(15 a) in Article 50, paragraph 2 is replaced by the following:

'2. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image or video content, shall take measures so that the outputs of the AI system are marked in a machine-

readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account the specificities and limitations of various types of content, the costs of implementation and the generally acknowledged state of the art, as may be reflected in relevant technical standards. This watermarking obligation shall be applied in a proportionate manner linked to the identified risk and that does not impede, hamper or otherwise distort the display, lawful commercial exploitation or publication of the work, nor interfere with its normal use, and shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate or prosecute criminal offences.'

Or. en

Amendment 151
Mario Mantovani

Proposal for a regulation
Article 1 – paragraph 1 – point 15 a (new)
Regulation (EU) 2024/1689
Article 56 – paragraph 2 – point e (new)

Text proposed by the Commission

Amendment

(15a) in Article 56(2), point (e) is inserted:

(e) the establishment and management of a single digital interface that serves as the exclusive access point for SMEs established in the Union. The Portal must allow for the centralised fulfilment of notification obligations, the storage of technical documentation and interaction

with national supervisory authorities, ensuring the once-only principle for data submission.

The Portal shall provide, at no additional cost:

- (a) automated registration;*
- (b) interactive assessment;*
- (c) document management;*
- (d) continued surveillance;*
- (e) AI-powered helpdesk;*
- (f) integrated payments;*
- (g) interoperability.*

Or. it

Justification

The amendment specifies the role of the AI Office as a provider of technical simplification infrastructure, reducing the bureaucratic burden on EU businesses. The current fragmentation forces SMEs to navigate 27 separate national systems and EU portals (NANDO, the AI database, etc.), at an estimated cost of some 200 hours of administrative work per year. A unified 'e-Estonia' style platform reduces the time spent on compliance by 85 %, transforming the obligation into a competitive advantage.

Amendment 152

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 15 a (new)

Regulation (EU) 2024/1689

Article 50 – paragraph 7

Text proposed by the Commission

Amendment

(15 a) in Article 50, paragraph 7a is added:

'7a. The AI Office, in cooperation with the European Union Agency for Cybersecurity (ENISA), shall develop non-binding technical guidance on emerging AI-specific cybersecurity threats, risks including from autonomous operational capabilities, secure-by-design AI development practices in accordance

Amendment 153

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation (EU)2024/1689

Article 56 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Amendment 154

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 56 – paragraph 6

Text proposed by the Commission

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

Amendment

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

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

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

Or. en

Amendment 155 **Gheorghe Piperea**

Proposal for a regulation **Article 1 – paragraph 1 – point 16** Regulation (EU) 2024/1689 Article 56 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 156 **Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera**

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point b a (new)

Regulation (EU) 2024/1689

Article 57 – paragraph 5

Text proposed by the Commission

Amendment

(b a) in Article 57 the following paragraph is added:

'5a. Participation in an AI regulatory sandbox shall not in itself trigger additional compliance obligations outside the sandbox.'

Or. en

Amendment 157

Gheorghe Piperea

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point c

Regulation (EU) 2024/1689

Article 57, paragraph 9 – point (e)

Text proposed by the Commission

Amendment

(e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.;

(e) facilitating and accelerating access to the Union market for ***safe and highly controlled*** AI systems, in particular when provided by SMCs and SMEs, including start-ups.;

Or. en

Amendment 158

Daniel Buda

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point e

Regulation (EU) 2024/1689

Article 57 – paragraph 5

Text proposed by the Commission

Amendment

14. National competent authorities shall

14. National competent authorities, ***the***

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

European Commission, the European Data Protection Supervisor and the AI Office shall coordinate their activities and cooperate within the framework of the Board. They shall support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.

Or. ro

Amendment 159

Daniel Buda

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point e a (new)

Regulation (EU)2024/1689

Article 57 – paragraph 5

Text proposed by the Commission

Amendment

(ea) in Article 57 the following text is added:

'(14a) The Commission and the AI Office shall ensure transparent and non-discriminatory criteria for accessing the EU-level sandbox and shall support the participation of SMEs and the public administrations of Member States with developing administrative capacity and innovation ecosystems, including by providing technical assistance and procedural guidance.'

Or. ro

Amendment 160

Daniel Buda

Proposal for a regulation

Article 1 – paragraph 1 – point 18

Regulation (EU)2024/1689

Article 58, paragraph 1, point d

Text proposed by the Commission

Amendment

(c) the terms and conditions applicable to the participants;

(c) the terms and conditions applicable to the participants, *in particular those concerning SMEs and SMCs*;

Or. ro

Amendment 161
Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 1 – point 18
Regulations (EU) 2024/1689
Article 58, paragraph 1, point d

Text proposed by the Commission

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

Amendment

(d) the *involvement of European Digital Innovation Hubs, which may act as entry points to AI* regulatory sandboxes for SMEs and public sector deployers, facilitating dissemination of best practices and cross-border access, in coordination with the AI Office.

Or. en

Amendment 162
Mario Mantovani

Proposal for a regulation
Article 1 – paragraph 1 – point 20
Regulation (EU) 2024/1689
Article 62 – paragraph 1 – point d and paragraph 3 – point e (new)

Text proposed by the Commission

Amendment

Article 62 is amended as follows:

(a) point (d) of paragraph 1 is amended as follows:

(d) facilitate the participation of SMEs and other relevant stakeholders in the standardisation development process, including through appropriate dedicated financial support mechanisms to reimburse the cost of SME experts

participating in European bodies;
(b) in paragraph 3, the following point (e) is added:

(e) establish and maintain a public repository of certified open-source AI components; also for the purposes of the obligations referred to in Article 16, the use of these components shall be presumed to be consistent with the requirements laid down in Section 2.

Or. it

Justification

Compliance with the regulation will depend on the appropriate tools being made available to small businesses for regulatory compliance. In this regard, it is essential to step up support for SMEs in the process of setting authorised standards. As it stands, participation in technical committees is sustainable only for large companies. What is more, it will be essential to relieve SMEs from overly complex audits on open-source components developed by third parties. In this regard, a 'safe harbour' linked to an EU repository must be established.

Amendment 163 **Mario Mantovani**

Proposal for a regulation **Article 1 – paragraph 1 – point 21** Regulation (EU) 2024/1689 Article 63 – paragraph 1

Text proposed by the Commission

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

Amendment

1. SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner. ***For micro-enterprises, this simplification should cover all the elements of the quality management system referred to in Article 17.*** For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of SMEs, without affecting the level of protection or the need for compliance with the requirements in

respect of high-risk AI systems.;

Or. it

Justification

While I understand the extension of Section 63 of the AI Act (currently reserved for micro-enterprises) to all SMEs, I believe that a strictly proportional approach requires further differentiation on the basis of the size of the undertaking. Micro-enterprises should benefit from further simplification compared with SMEs, preventing competitive disadvantages and adapting compliance to what the economic operator can actually manage.

Amendment 164

Ton Diepeveen, Juan Carlos Girauta Vidal

Proposal for a regulation

Article 1 – paragraph 1 – point 21

Regulation (EU) 2024/1689

Article 63 – paragraph 1

Text proposed by the Commission

Amendment

1 a. (21 a) in Article 63, the following paragraph is added:

'1a. SMEs shall not be required to establish standalone systems where existing quality management processes achieve equivalent objectives.'

Or. en

Amendment 165

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 23

Regulation (EU) 2024/1689

Article 70 – paragraph 8

Text proposed by the Commission

Amendment

8. National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMCs and SMEs, including start-ups, taking into account the guidance

8. National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMCs and SMEs, including start-ups, taking into account the guidance

and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union law, the national competent authorities under that Union law shall be consulted, as appropriate.;

and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union law, the national competent authorities under that Union law shall be consulted, as appropriate. ***Such guidance shall be non-binding and shall not introduce new obligations;***

Or. en

Amendment 166 **Gheorghe Piperea**

Proposal for a regulation
Article 1 – paragraph 1 – point 24
Regulation (EU) 2024/1689
Article 72 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt ***an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan***

Or. en

Amendment 167 **Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera**

Proposal for a regulation
Article 1 – paragraph 1 – point 24
Regulation (EU) 2024/1689
Article 72 – paragraph 3

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 168

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 24 a (new)

Regulation (EU) 2024/1689

Article 74 – paragraph 13

Text proposed by the Commission

Amendment

(24 a) Article 74, paragraph 13 is deleted.

Or. en

Amendment 169

Daniel Buda

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU)2024/1689

Article 75, paragraph 1, subparagraph 1

Text proposed by the Commission

Amendment

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this

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

Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. ***The competent national authorities may refer signs of non-compliance or systemic risks that have arisen in their country to the AI Office and the AI Office shall, within a reasonable time, inform the referring authority about follow-up measures. The AI Office shall, in exercising its duties, work with the competent national authorities and with the relevant authorities under Regulation (EU) 2022/2065, in accordance with the principles of proportionality and ne bis in idem.***

Or. ro

Justification

While centralised supervision by the AI Office enhances consistency, national competent authorities must retain an effective right to notify potential non-compliance or systemic risks identified on their territory. The amendment strengthens cooperative enforcement without creating duplication of competences or additional administrative burden.

Amendment 170

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in

Amendment

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in

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

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

Or. en

Amendment 171

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75, paragraph 1, subparagraph 1

Text proposed by the Commission

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

Amendment

Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I ***and AI systems referred to in Annex III, point 2*** and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large

(EU) 2022/2065.

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

Or. en

Amendment 172

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

deleted

Or. en

Amendment 173

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3

Text proposed by the Commission

Amendment

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

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

State.;

State. *The exercise of those powers shall be proportionate, risk-based and guided by the objective of ensuring compliance while minimising disruption to lawful business activities.*;

Or. en

Amendment 174

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point b

Regulation (EU) 2024/1689

Article 75 – paragraph 1 – subparagraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 175

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation (EU) 2024/1689

Article 75

Text proposed by the Commission

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

‘1a. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other administrative sanctions, in accordance

Amendment

deleted

with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision tasks under this Article.

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

1c.

The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply mutatis mutandis to the Commission when exercising its powers under this paragraph.

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

Or. en

Amendment 176

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 25 – point c

Regulation(EU)2024/1689

Article 75 – paragraph 1a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 177

Mario Mantovani

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 77 – paragraph 1 a and paragraph 1 b (new)

Text proposed by the Commission

Amendment

(ca) in Article 77, paragraphs 1a and 1b are inserted:

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

necessary. In that event, the request must take into account the size and capacity of the deployer.

1b. With a view to ensuring coherent application of this Regulation and Union law protecting fundamental rights and streamlining procedures, the market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with the mutual assistance that they need to fulfil their respective mandates. This shall include, in particular, exchange of information where necessary for the effective supervision or enforcement of this Regulation and the respective other Union legislation.;

Or. it

Justification

While I welcome the stronger cooperation provided for in Article 77, it is essential that requests for information by the competent authorities remain targeted and proportionate to the size and capacity of the enterprises from which the information is requested.

Amendment 178

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point b

Regulation(EU)2024/1689

Article 77 – paragraph 1

Text proposed by the Commission

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

Amendment

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

documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction.;

authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction.;

Or. en

Amendment 179

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 26 – point b

Regulation (EU) 2024/1689

Article 77 paragraph 1

Text proposed by the Commission

1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction.;

Amendment

1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. ***Requests shall be specific, reasoned and limited to what is necessary.***;

Or. en

Amendment 180

Tobiasz Bocheński

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(26 a) the following Article 79a is inserted:

'Promotion of Innovation and Competitiveness

In the exercise of their responsibilities, Member States and the Commission shall place particular emphasis on fostering innovation, driving technological advancement and reinforcing the competitiveness of the Union economy. They shall act in a proportionate manner, contributing to a stable and business-enabling regulatory framework and, where appropriate, promoting the development of artificial intelligence systems, the sharing of best practices, and strong collaboration with relevant stakeholders.'

Or. en

Amendment 181

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 92 paragraph 3

Text proposed by the Commission

Amendment

(26 b) In Article 92 paragraph 3 is amended as follow:

'3. For the purposes of paragraph 1, the Commission may request access to the general-purpose AI model concerned through APIs or further appropriate technical means and tools.'

Or. en

Amendment 182

Victor Negrescu

Proposal for a regulation

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Article 1 – paragraph 1 – point 28
Regulations (EU) 2024/1689
Article 96 paragraph 1 subparagraph 2

Text proposed by the Commission

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

Amendment

In providing technical assistance under this Regulation, the Commission, ***through the AI Office***, shall ***cooperate, with the European Cybersecurity Competence Centre (ECCC) and its Network of National Coordination Centres to support Member States in strengthening cybersecurity resilience and secure development of AI systems.***

Developing guidance and support measures under this Regulation, ***the Commission, through the AI Office***, shall ***promote approaches contributing to tackling socio-economic and regional inequalities in the development and deployment of artificial intelligence, including accessibility and inclusion for vulnerable groups.***

Or. en

Amendment 183

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

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

Text proposed by the Commission

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

Amendment

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

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

issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall ***apply a system whereby a financial penalty is proportionate to the turnover of the legal person, or to the economic benefit derived or expected from the infringement.***;

Or. en

Amendment 184 **Gheorghe Piperea**

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 185 **Ton Diepeveen, Juan Carlos Girauta Vidal**

Proposal for a regulation

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

Text proposed by the Commission

Amendment

1 a. in Article 99, the following paragraph is inserted:

1a. 'Non-monetary measures shall be prioritised for first-time or minor infringements.'

Or. en

Amendment 186
Mario Mantovani

Proposal for a regulation
Article 1 – paragraph 1 – point 29 – point b a (new)
Regulation (EU) 2024/1689
Article 99 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

(ba) Article 99 – paragraph 7a

(1) During the first 24 months following the applicability of the obligations referred to in Chapter III for each category of high-risk AI systems, the competent national authorities, exercising the powers referred to in Article 99 and applying the principle of proportionality referred to in Article 101, shall take particular account, as significantly mitigating circumstances in determining the amount of administrative fines, of:

(a) the size and financial resources of the undertaking;

(b) documented efforts towards compliance, including:

(i) participation in AI Office training programmes;

(ii) prior consultation with certified bodies or competent authorities;

(iii) partial implementation of the

applicable requirements;

(c) the absence of actual damage to natural persons or the absence of breaches of fundamental rights;

(d) proactive reporting of compliance difficulties to the competent authority;

(e) active cooperation with the authority during inspections.

(2) With regard to micro-enterprises, when at least three of the circumstances set out in the first paragraph apply, the administrative fine may be replaced by:

(a) an assisted compliance plan, drawn up with the free support of the competent authorities, with staggered deadlines;

(b) a certified staff training requirement;

(c) a follow-up audit after six months.

The following are excluded from the application of this paragraph 2:

(i) violations of practices prohibited under Article 5;

(ii) intentional concealment of information or falsification of documents;

(iii) repeat offences after a third formal notification;

(iv) actual harm to persons or established breaches of fundamental rights.

The Commission shall assess the effectiveness of the scheme within 18 months. If the rate of non-compliance among SMEs exceeds 40 %, it may propose to Parliament and the Council an extension of the grace period to 36 months by means of an accelerated legislative procedure.

Or. it

Justification

Immediately imposing significant penalties on SMEs that are dealing with complex rules for the first time is counterproductive: it leads to business closures and fails to improve safety. A grace period with educational enforcement fosters voluntary compliance. Our GDPR

experience shows us that countries with gradual approaches (Germany and the Netherlands) achieved 85% compliance, compared with 60 % in countries with immediate enforcement.

Amendment 187
Mario Mantovani

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

Text proposed by the Commission

Amendment

(29a) Article 99a

1. By way of derogation from the general provisions on civil liability, micro-enterprises established in the Union shall be subject to a fault-based liability regime for damage caused by high-risk AI systems, provided that they demonstrate that they have complied with the due diligence obligations set out in the simplified compliance procedure referred to in this Regulation.

2. The total civil liability of micro-enterprises for damage not arising from wilful misconduct or gross negligence shall be limited and proportionate to the turnover and financial capacity of the undertaking. The Commission shall adopt delegated acts to lay down the criteria for calculating such limitations and the arrangements for coordination with existing guarantee funds with a view to providing compensation for victims without undermining the business continuity of the undertaking.

Or. it

Justification

Strict liability rules are unsustainable for entities without extensive insurance coverage. The amendment introduces a criterion of due diligence based on the size of the undertaking.

Amendment 188

Laurence Farreng

Proposal for a regulation

Article 1 – paragraph 1 – point 30

Regulation (EU) 2024/1689

Article 111

Text proposed by the Commission

Amendment

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

(a) paragraph 2 is replaced by the following:

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

‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.’

Or. en

Amendment 189

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a

Regulation(EU)2024/1689

Article 111 – paragraph 2

Text proposed by the Commission

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

Amendment

2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to **providers and deployers** of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before **2 August 2026**, only if, as from that date, those systems are subject to significant changes in their designs. In any case, **they** shall comply with this Regulation by **2 August 2028.**;

Or. en

Amendment 190

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a

Regulation (EU) 2024/1689

Article 111 – paragraph 2

Text proposed by the Commission

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

Amendment

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

public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.;

intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.;

Or. en

Justification

Operators is an outdated terminology since the AI Act uses providers and deployers. This amendment aims to correct the terminology.

Amendment 191

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point a

Regulation (EU) 2024/1689

Article 111

Text proposed by the Commission

Amendment

2 a. in Article 111, the following paragraph is inserted:

'2a. Routine software updates or maintenance shall not be considered a significant change.'

Or. en

Amendment 192

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

Regulation(EU)2024/1689

Article 111 – paragraph 4

Text proposed by the Commission

Amendment

(b) the following paragraph 4 is added:

deleted

'4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text

content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;

Or. en

Amendment 193

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 30 – point b

Regulation (EU) 2024/1689

Article 111 – paragraph 4

Text proposed by the Commission

Amendment

4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 February 2027.;

deleted

Or. en

Amendment 194

Mario Mantovani

Proposal for a regulation

Article 1 – paragraph 1 – point 30 a (new)

Regulation (EU) 2024/1689

Article 111 – paragraph 2

Text proposed by the Commission

Amendment

(30a) in Article 111, paragraph 2 is replaced by the following:

Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, aside from those systems referred to in paragraph 1 of this Article, that have been placed on the market or put into

service before the date of application of Chapter III and the corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs.

Or. it

Justification

The deadline for compliance in the public sector, set for August 2030, is significantly longer than the deadlines applicable to SMEs and micro-enterprises, despite the fact that the public sector has significantly more resources at its disposal. This disparity appears difficult to justify, particularly considering that use of AI by public authorities often involves higher risks than its use by corporate applications.

Amendment 195
Laurence Farreng

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

Text proposed by the Commission

Amendment

(31) Article 113 is amended as follows: **deleted**

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

‘(d)

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

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

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

In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:

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

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

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

Or. en

Amendment 196

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation(EU)2024/1689

Article 113(3) – point d

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 197

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 198

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113 – paragraph 3 – point d

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 199

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113(3) – point d

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 200
Adrián Vázquez Lázara

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

Text proposed by the Commission

Amendment

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

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

Or. en

Justification

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

Amendment 201
Tobiasz Bocheński, Piotr Müller

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

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 202
José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 203

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113

Text proposed by the Commission

Amendment

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

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

Or. en

Justification

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

Amendment 204

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation(EU)2024/1689

Article 113(3) – point d

Text proposed by the Commission

Amendment

In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, **deleted**

Sections 1, 2, and 3, shall apply:

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

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

Or. en

Amendment 205

Adrián Vázquez Lázara

Proposal for a regulation

Article 1 – paragraph 1 – point 31 – point a

Regulation (EU) 2024/1689

Article 113

Text proposed by the Commission

Amendment

In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:

deleted

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

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

Or. en

Justification

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

Amendment 206

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

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

Text proposed by the Commission

Amendment

In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:

deleted

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

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

Or. en

Amendment 207

José Cepeda, Elena Sancho Murillo, Leire Pajín

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(b a) The following text is added:

'The Commission may be empowered in accordance with Article 97 to adopt delegated acts, in duly justified exceptional circumstances, postponing the application of specific obligations for a maximum period of six months. Such delegated acts shall be subject to prior consultation of the European Parliament and the Council and shall not compromise the effective protection of fundamental rights.'

Or. en

Amendment 208

Mario Mantovani

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 1 – paragraph 3 – point d – subparagraph 3 (new)

Text proposed by the Commission

Amendment

(31a) in Article 113(3), point (d), the following subparagraph 3 is added:

By way of derogation from the deadlines referred to in the preceding points, micro-enterprises established in the Union shall benefit from an additional transition period of 24 months for the application of the provisions of Chapter II, Sections 1, 2 and 3. During this additional period:

(a) the placing on the market of high-risk AI systems by those undertakings shall continue to be permitted, provided that the supplier demonstrates that it has taken proportionate risk self-assessment measures based on harmonised standards or recognised good practices;

(b) national supervisory authorities shall adopt a non-sanctioning monitoring regime, giving priority to technical assistance and guided correction of non-compliance, without prejudice to provisions on public safety and the protection of fundamental rights;

(c) the Commission shall, within 36 months of the date of entry into force, submit a report on the compliance capacity of micro-enterprises, assessing the need for further support measures or an adjustment of the requirements in accordance with the principle of proportionality;

Or. it

Justification

Micro-enterprises and smaller enterprises (often made up of one to three individuals) do not have dedicated compliance resources. Often, the owner accumulates technical, commercial and administrative roles. The standard timelines are unrealistic. The extension requested is in

line with the precedent set with GDPR: many Member States granted up to 36 months in an effort to provide soft enforcement for SMEs. A 2024 study by the Commission notes that micro-enterprises need 3.5 times longer than large certified companies. A gradual, assisted approach reduces business failures.

Amendment 209

José Cepeda, Elena Sancho Murillo, Leire Pajín, Victor Negrescu

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 210

Laurence Farreng

Proposal for a regulation

Article 1 – paragraph 1 – point 32

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 211

Tobiasz Bocheński, Piotr Müller

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(32 a) in the Annex I, in section A, item 1 is deleted;

Or. en

Amendment 212
Angelika Niebler

Proposal for a regulation

Article 1 a (new)

Regulation (EU) 2024/1689

Annex 1: List of Union Harmonisation Legislation

Present text

Amendment

Article 1 a (new)

The Machinery Regulation (EU) 2023/1230 is moved from Annex I Section A to Section B

Annex I

"Annex I

Section A. List of Union harmonisation legislation based on the New Legislative Framework as amended as follows:

(2) Section B, the following points are added from section A:

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

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

Or. en

(32024R1689)

Justification

Particularly in the area of self-learning machines and software, the AI Act contains a number of safety requirements that are already included in the Machinery Regulation. To avoid double regulation, the Machinery Regulation contained in Annex I Section A is to be moved to Section B.

Amendment 213

Ton Diepeveen, Juan Carlos Girauta Vidal, Pascale Piera

Proposal for a regulation

Article 3 a (new)

Text proposed by the Commission

Amendment

Article3a

***Article 3a Innovation and investment
safeguard clause***

1. The Commission and Member States shall ensure that the implementation of this Regulation does not create unnecessary barriers to investment, scaling 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 regard to their effects on start-ups, SMEs and private investment in AI.

Or. en