



2025/0359(COD)

14.2.2026

AMENDMENTS 171 - 317

Draft report

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

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

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

Amendment 171

Adnan Dibrani, Evin Incir, Christel Schaldemose

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 5 – paragraph 1 – point a

Present text

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

Amendment

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

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

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

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

Or. en

Justification

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

Amendment 172

Assita Kanko

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

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

Or. en

Justification

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

Amendment 173

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

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

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

Or. en

Amendment 174

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

added:

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

Or. en

Amendment 175

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

‘(ha) the placing on the market, the putting into service, or the use of an AI system that can generate or manipulate sexualised or intimate audio, image, or video of individuals and can facilitate non-consensual sharing of intimate or manipulated material as defined in Directive (EU) 2024/1385.’;

Or. en

Amendment 176

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 177

Kateřina Konečná

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

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

Amendment 178
Pernando Barrena Arza

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

Present text

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

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

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

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

Amendment

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

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

Justification

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

Amendment 179

Regina Doherty

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 180

Pernando Barrena Arza

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Or. en

Justification

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

Amendment 181

Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 182

Andreas Schwab

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 1

Present text

Amendment

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:

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

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

high-risk if its proper functioning is necessary and essential to ensure compliance with applicable Union safety requirements.

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

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

Or. en

Amendment 183

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 1 – point a

Present text

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

Amendment

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

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

Or. en

Amendment 184
Piotr Müller, Assita Kanko

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

Present text

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

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

Amendment

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

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

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

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

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

Or. en

Justification

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

Amendment 185
Stefano Cavedagna

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

Text proposed by the Commission

Amendment

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

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

Or. en

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

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

Present text

Amendment

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

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

‘Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk

where the AI system performs profiling of natural persons, except where it is designed to be used solely by the end user for that purpose.’;

Or. en

Justification

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

Amendment 187

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

Proposal for a regulation

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

Regulation EU (2024/1689)

Article 6 – paragraph 3 – subparagraph 3

Present text

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

Amendment

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

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

Or. en

Justification

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

Amendment 188 **Stefano Cavedagna**

Proposal for a regulation

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

Regulation (EU) 2024/1689

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

Text proposed by the Commission

Amendment

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

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

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

Or. en

Justification

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

Amendment 189 **Leila Chaibi, Pernando Barrena Arza**

on behalf of The Left Group

Proposal for a regulation
Article 1 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 190
Mary Khan

Proposal for a regulation
Article 1 – paragraph 1 – point 5 a (new)
Regulation (EU) 2024/1689
Article 6 – paragraph 3 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 191
Tomáš Zdechovský

Proposal for a regulation
Article 1 – paragraph 1 – point 5 a (new)

Present text

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

Amendment

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

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

Or. en

Justification

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

Amendment 192

Lukas Mandl, Sander Smit

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 3

Present text

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

Amendment

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

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

Or. en

Justification

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

Amendment 193

Axel Voss, Arba Kokalari

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 3

Present text

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

Amendment

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

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

Or. en

Justification

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

Amendment 194

Piotr Müller, Assita Kanko

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 6 – paragraph 3 – subparagraph 1

Present text

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

Amendment

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

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

Or. en

Justification

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

Amendment 195
Regina Doherty

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

Present text

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

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

Amendment

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

‘3. An AI system to which Annex III refers shall not be considered as high-risk where it does not pose a significant risk of

harm to the fundamental rights of natural persons, including by ensuring human review.’;

- (a) the AI system is intended to perform a narrow procedural task;
- (b) the AI system is intended to improve the result of a previously completed human activity;
- (c) the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or
- (d) the AI system is intended to perform a preparatory task to an assessment relevant for the purposes of the use cases listed in Annex III.

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

Or. en

Amendment 196

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

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

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

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

Or. en

Amendment 197

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

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

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

Or. en

Justification

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

Amendment 198

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

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689
Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 199

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

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689
Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 200

Kateřina Konečná

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 201
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EU) 2029/1689
Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 202

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

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

deleted

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

Or. en

Amendment 203

Piotr Müller, Assita Kanko

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

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.;

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

Or. en

Amendment 204

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

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

4. A provider who considers that an AI system referred to in Annex III is not 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 **limited to the minimum information necessary to demonstrate that the conditions of Article 6(3) are met.**

Or. en

Justification

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

Amendment 205

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EU) 2024/1689

Article 6 – paragraph 4

Text proposed by the Commission

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

‘4. A provider who considers that an AI system referred to in Annex III is not

Amendment

deleted

high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.’;

Or. en

Amendment 206
Tomáš Zdechovský

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

Text proposed by the Commission

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

Amendment

4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service, **with no registration obligation**. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.;

Or. en

Justification

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

Amendment 207
Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

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

Text proposed by the Commission

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.;

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

Or. en

Amendment 208

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

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EU) 2024/1689

Article 10

Text proposed by the Commission

Amendment

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

deleted

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

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

(b) *paragraph 5 is deleted;*

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

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

Amendment 209

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

Proposal for a regulation

Article 1 – paragraph 1 – point 7

Regulation (EU) 2024/1689

Article 10

Text proposed by the Commission

Amendment

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

(a) paragraph 1 is replaced by the following:

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

(b) paragraph 5 is deleted;

(c) paragraph 6 is replaced by the following:

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

Amendment 210

Markéta Gregorová

Proposal for a regulation

Article 1 – paragraph 1 – point 7 – point b

Regulation (EU) 2024/1689

Article 10 – paragraph 5 – subparagraph 1

Text proposed by the Commission

Amendment

(b) paragraph 5 *is deleted*;

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

‘To the extent that it is strictly necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. The processing of personal data pursuant to this paragraph shall be considered high-risk in the meaning of Article 30 of Regulation (EU) 2016/679. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur:’;

Or. en

Amendment 211

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

Proposal for a regulation

Article 1 – paragraph 1 – point 7 – point c

Regulation (EU) 2024/1689

Article 10 – paragraph 6

Text proposed by the Commission

Amendment

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

deleted

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

Amendment 212

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

Proposal for a regulation

Article 1 – paragraph 1 – point 8

Regulation (EU) 2024/1689

Article 11 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

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

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

Amendment 213
Kateřina Konečná

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 214
Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 1 – paragraph 1 – point 8

Regulation (EU) 2024/1689

Article 11 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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

Or. en

Amendment 215

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

Proposal for a regulation

Article 1 – paragraph 1 – point 8

Regulation (EU) 2024/1689

Article 11 – paragraph 1 – subparagraph 2

Text proposed by the Commission

That technical documentation shall be

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.;

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

Or. en

Amendment 216

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

Proposal for a regulation

Article 1 – paragraph 1 – point 9

Regulation (EU) 2024/1689

Article 17 – paragraph 2

Text proposed by the Commission

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

‘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

Amendment

deleted

protection required to ensure the compliance of their high-risk AI systems with this Regulation.’;

Or. en

Amendment 217
Kateřina Konečn

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

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 218

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

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

Text proposed by the Commission

Amendment

2. The implementation of the aspects

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.;

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

Or. en

Amendment 219

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

Proposal for a regulation

Article 1 – paragraph 1 – point 9

Regulation (EU) 2024/1689

Article 17 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 220

Axel Voss

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 25 – paragraph 1 – subparagraph 1 a (new)

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

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

Or. en

Justification

The AI value chain relies heavily on downstream adaptation (i.e. fine-tuning and integration of existing GPAI models), so EU rules must provide a predictable pathway for AI deployers to innovate without automatically being reclassified as AI providers. An operational threshold for “substantial modification” increases legal certainty and ensures consistent application across Member States, reducing unnecessary compliance risk for EU integrators, in particular SMEs. Using a measurable compute-based benchmark draws a clear line between limited adaptation and capability-changing redevelopment that should trigger provider obligations.

Amendment 221

Axel Voss

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 25 – paragraph 2

Present text

2. Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the

Amendment

(9b) in Article 25, paragraph 2 is replaced by the following:

‘2. Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the

market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation. That initial provider shall closely cooperate with new providers and shall make available the necessary information and provide the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems. ***This paragraph shall not apply in cases where the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system and therefore does not fall under the obligation to hand over the documentation.***

market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation.

That initial provider, as well as providers of general-purpose AI models whose models are integrated into high-risk AI systems, shall closely cooperate with new providers and shall make available the necessary information and provide the reasonably expected technical access and other assistance that are required for the fulfilment of the obligations set out in this Regulation, in particular regarding the compliance with the conformity assessment of high-risk AI systems.

This obligation shall include:

- (a) Technical documentation sufficient to assess compliance with Article 16 requirements;***
- (b) Known limitations and failure modes that could affect high-risk applications;***
- (c) Reasonable technical access for testing and validation purposes.’;***

Or. en

Justification

Clear value-chain collaboration duties are necessary to make the reallocation of “provider” responsibility in Article 25 workable in practice: once a new provider takes over after rebranding, substantial modification or change of intended purpose, they still depend on upstream information to complete conformity assessment and ongoing compliance. Stakeholder evidence highlights persistent “responsibility gaps” in the AI value chain, especially where GPAI models are integrated and modified, because key compliance elements (i.e. documentation, known limitations, failure modes, testability) often sit with upstream actors. Requiring initial providers and GPAI model providers to provide the necessary documentation, reasonable technical access and assistance therefore reduces legal uncertainty and prevents de-facto non-compliance driven by missing information rather than bad faith. This is particularly important for EU SMEs and Start-Ups, for whom predictable cooperation from upstream suppliers is a prerequisite to meet high-risk obligations efficiently and consistently across the Single Market.

Amendment 222

Mary Khan

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 27 – paragraph 4

Present text

4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.

Amendment

(9a) in Article 27, paragraph 4 is replaced by the following:

‘4. If any of the obligations laid down in this Article are already met through a data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, that data protection impact assessment may be used to fulfil, in whole or in part, the requirements of the fundamental rights impact assessment referred to in paragraph 1 of this Article, where its scope and content are equivalent.’;

Or. en

Amendment 223

Tomáš Zdechovský

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 27 – paragraph 4

Present text

4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.

Amendment

(9a) in Article 27, paragraph 4 is replaced by the following:

‘4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall be represented by that data protection impact assessment in case of these obligations.’;

Or. en

Justification

The AI Act stipulates that if obligations laid down in Article 27 on fundamental rights impact assessment (FRIA) are already met through the data protection impact assessment (DPIA) conducted pursuant to the GDPR or the LED, the FRIA shall complement the DPIA. However, it does not specify how it should be complemented. This amendment introduces a clarification that the FRIA shall be represented by the DPIA in cases of the legal obligations in question.

Amendment 224

Lukas Mandl, Sander Smit

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 27 – paragraph 4

Present text

4. If any of the obligations laid down in this Article is already met through the

Amendment

(9a) in Article 27, paragraph 4 is replaced by the following:

‘4. If any of the obligations laid down in this Article is already met through the

data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.

data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall be represented by that data protection impact assessment in case of these obligations.’;

Or. en

Justification

The AI Act stipulates that if obligations laid down in Article 27 on fundamental rights impact assessment (FRIA) are already met through the data protection impact assessment (DPIA) conducted pursuant to the GDPR or the LED, the FRIA shall complement the DPIA. However, it does not specify how it should be complemented. This amendment introduces a clarification that the FRIA shall be represented by the DPIA in cases of the legal obligations in question.

Amendment 225

Axel Voss

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 27 – paragraph 4

Present text

4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall **complement** that data protection impact assessment.

Amendment

(9c) in Article 27, paragraph 4 is replaced by the following:

‘4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall **be represented by** that data protection impact assessment ***in case of these obligations.’;***

Or. en

Justification

The AI Act stipulates that if obligations laid down in Article 27 on fundamental rights impact assessment (FRIA) are already met through the data protection impact assessment (DPIA) conducted pursuant to the GDPR or the LED, the FRIA shall complement the DPIA. However, it does not specify how it should be complemented. This amendment introduces a clarification that the FRIA shall be represented by the DPIA in cases of the legal obligations in question.

Amendment 226

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

Proposal for a regulation

Article 1 – paragraph 1 – point 10

Regulation (EU) 2024/1689

Article 28 – paragraph 8

Text proposed by the Commission

Amendment

(10) in Article 28, the following paragraph 8 is added: **deleted**

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

The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under

the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation, provided that the relevant Union harmonisation legislation provides for such a procedure.

The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation.’;

Or. en

Justification

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

Amendment 227

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

Proposal for a regulation

Article 1 – paragraph 1 – point 10

Regulation (EU) 2024/1689

Article 28 – paragraph 8 – subparagraph 3

Text proposed by the Commission

The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation.;

Amendment

The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and the relevant Union harmonisation legislation. ***Single procedures shall not be used to circumvent or avoid any relevant legal***

requirement under the respective legal acts. When a single application and assessment is submitted, it shall be ensured that all and requirements of the harmonisation legislation and this Regulation are fulfilled.;

Or. en

Amendment 228

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

Proposal for a regulation

Article 1 – paragraph 1 – point 11

Regulation (EU) 2024/1689

Article 29 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Amendment

Notified bodies, which are designated under any of the Union harmonisation legislation listed in Section A of Annex I and which apply for the single assessment referred to in Article 28(8), shall submit the single application for assessment to the notifying authority designated in accordance with that Union harmonisation legislation.

deleted

Or. en

Justification

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

Amendment 229

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 40 – paragraph 2 – subparagraph 1

Present text

Amendment

In accordance with Article 10 of Regulation (EU) (No) 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, as applicable, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general-purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum.

(12a) in Article 40, paragraph 2, subparagraph 1 is replaced by the following:

'In accordance with Article 10 of Regulation (EU) (No) 1025/2012, the Commission shall issue, without undue delay, standardisation requests covering all requirements set out in Section 2 of this Chapter and, by 2 July 2027, standardisation requests covering obligations set out in Chapter V, Sections 2 and 3, of this Regulation. The standardisation request shall also ask for deliverables on reporting and documentation processes to improve AI systems' resource performance, such as reducing the high-risk AI system's consumption of energy and of other resources during its lifecycle, and on the energy-efficient development of general purpose AI models. When preparing a standardisation request, the Commission shall consult the Board and relevant stakeholders, including the advisory forum.'

Or. en

Amendment 230

Piotr Müller, Assita Kanko

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41

Text proposed by the Commission

Amendment

(12a) Article 41 is deleted.

(This amendment applies throughout the text.)

Or. en

Justification

Backtracking the Commission's power to adopt common specifications avoids creating a parallel compliance pathway that circumvents the established system of harmonised standards. Maintaining a single, predictable standards framework preserves legal certainty and protects public and private investment in the development of consensus-based technical standards.

Amendment 231

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 – introductory part

Present text

The Commission may adopt, implementing acts establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:

Amendment

(12b) in Article 41, the introductory part is replaced by the following:

'1. The Commission shall adopt, implementing acts by 2 July 2027 establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the e following conditions have been fulfilled: obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:';

Or. en

Amendment 232

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 a (new)

(12c) in Article 41, the following paragraph is inserted:

'1a. When there is no harmonised standard that enable compliance with the essential requirements set out in Section 2 of this Chapter and no reference in the Official Journal of the European Union is expected to be published within a reasonable period, the Commission shall by means of implementing acts adopt common specifications in order to address an urgent concern with regard to noncompliant AI systems, which cannot be adequately mitigated by alternative measures. A situation shall be considered to constitute an urgent concern when the suspension of cooperation with international standardisation organisations impedes the development of relevant harmonised standards by European standardisation organisations. In such a situation the Commission shall adopt common specifications only after prior authorisation of the Council. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2). When preparing those implementing acts, the Commission shall be assisted by an expert group that includes relevant stakeholder representatives.'

Or. en

Amendment 233

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 1 b (new)

(12d) In Article 41, the following paragraph 1b is inserted:

'1b. The Commission shall provide the European Parliament, in a timely manner, with all relevant information concerning the implementing acts referred to in paragraph 1. That shall include, in particular, details on the drafting process of the implementing act, details on the composition of the expert groups supporting the process, details on the timeline and, where the drafting of an implementing act is outsourced, information on the main contractual aspects of such outsourcing, including the name of the entity responsible for the drafting, the total value of the contract and its duration.'

Or. en

Amendment 234

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 41 – paragraph 6

Present text

6. Where a Member State considers that a common specification does not entirely meet the requirements set out in Section 2 or, as applicable, comply with obligations set out in Sections 2 and 3 of Chapter V, it shall inform the Commission thereof with a detailed explanation. The Commission shall assess that information and, if appropriate, amend the implementing act

Amendment

(12e) in Article 41, paragraph 6 is replaced by the following:

'6. Where the European Parliament or a Member State considers that a common specification does not entirely meet the requirements set out in Section 2 or, as applicable, comply with obligations set out in Sections 2 and 3 of Chapter V, it shall inform the Commission thereof with a detailed explanation. The Commission shall assess that information and, if

establishing the common specification concerned.

appropriate, amend the implementing act establishing the common specification concerned.';

Or. en

Amendment 235
Stefano Cavedagna

Proposal for a regulation
Article 1 – paragraph 1 – point 12 a (new)
Regulation (EU) 2024/1689
Article 42 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(12a) In Article 42, the following paragraph is inserted:

'2a. Where an AI system is subject to the requirements of Regulation (EU) 2024/2847 as well as requirements set out in Article 15, and where those high-risk AI systems fulfil the essential cybersecurity requirements set out in Regulation (EU) 2024/2847, they shall be presumed to comply with the cybersecurity requirements set out in Article 15 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued pursuant to Regulation (EU) 2024/2847. Providers of such AI systems shall not be obliged to comply with the requirements set out in Article 15 until Regulation (EU) 2024/2847 becomes applicable.';

Or. en

Justification

While the intent of the draft report is commendable, Regulation (EU) 2024/2847 will only be applicable as of 11 December 2027, while requirements introduced by Article 15 of the AI Act may enter into force earlier. This amendment aims to avoid an interim period where providers will be subject to Article 15, thus requiring them to undergo conformity procedures with both regulations.

Amendment 236

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 42 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(12f) in Article 42, the following paragraph is added:

‘2a. Where an AI system is subject to the requirements of Regulation (EU) 2024/2847 as well as requirements set out in Article 15 of this Regulation, and where those high-risk AI systems fulfil the essential cybersecurity requirements set out in the Regulation (EU) 2024/2847, they shall be deemed to comply with the cybersecurity requirements set out in Article 15 of this Regulation in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under Regulation (EU) 2024/2847.’;

Or. en

Amendment 237

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

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 42 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(12a) in Article 42, the following paragraph 3 is inserted:

'2a. Where an AI system complies with Regulation (EU) 2024/2847, such compliance shall be deemed sufficient to demonstrate compliance with the cybersecurity requirements laid down in Article 15, to the extent that those requirements are covered by the EU declaration of conformity issued under that Regulation.'

Or. en

Amendment 238

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

Proposal for a regulation

Article 1 – paragraph 1 – point 13

Regulation (EU) 2024/1689

Article 43 – paragraph 3

Text proposed by the Commission

Amendment

(13) in Article 43, paragraph 3 is replaced by the following:

deleted

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

For the purposes of that conformity assessment, notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I shall have the power to assess the conformity of high-risk AI systems with the requirements set out in Section 2, provided that the compliance of

those notified bodies with the requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under the relevant Union harmonisation legislation. Without prejudice to Article 28, such notified bodies which have been notified under the Union harmonisation legislation in Section A of Annex I, shall apply for designation in accordance with Section 4 at the latest [18 months from the entry into application of this Regulation].

Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option to opt out from a third-party conformity assessment, provided that that manufacturer has applied harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.

Where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I and it falls within one of the categories listed in Annex III, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation listed in Section A of Annex I.’;

Or. en

Justification

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

Amendment 239
Christian Doleschal

Proposal for a regulation

Article 1 – paragraph 1 – point 13

Regulation (EU) 2024/1689

Article 43 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 240

Piotr Müller, Assita Kanko

Proposal for a regulation

Article 1 – paragraph 1 – point 13

Regulation (EU) 2024/1689

Article 43 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

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

deleted

and Annex VII shall also apply.

Or. en

Justification

The original version of Article 43 provides sufficient procedural safeguards and does not introduce new burdens, in contrast to the updated Commission proposal.

Amendment 241

Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation

Article 1 – paragraph 1 – point 14

Regulation (EU) 2024/1689

Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 242

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 14

Regulation (EU) 2024/1689

Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 243

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

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 244
Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 245
Michael McNamara, Sandro Gozi, Irena Joveva, Veronika Cifrová Ostrihoňová, Lucia Yar, Raquel García Hermida-Van Der Walle, Fabienne Keller, Laurence Farreng

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 246

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

Proposal for a regulation

Article 1 – paragraph 1 – point 14

Regulation (EU) 2024/1689

Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

Or. en

Amendment 247

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

Proposal for a regulation

Article 1 – paragraph 1 – point 14

Regulation (EU) 2024/1689

Article 49 – paragraph 2

Text proposed by the Commission

Amendment

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

Or. en

Justification

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

Amendment 248

Kateřina Konečná

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

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 249
Christel Schaldemose

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

Text proposed by the Commission

Amendment

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

(14) in Article 49, paragraph 2 is replaced by the following:

'2. Before placing on the market or putting into service an AI system for which the provider has concluded that it is not high-risk according to Article 6(3), that provider or, where applicable, the authorised representative shall register themselves and that system in the EU database referred to in Article 71.'

Or. en

Amendment 250
Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation
Article 1 – paragraph 1 – point 14 a (new)
Regulation (EU) 2024/1689
Article 49 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

(14a) in Article 49, the following paragraph is inserted:

'5a. Only the Commission and market surveillance authorities shall have access to information referred to in Section B, point 5, of Annex VIII.'

Or. en

Amendment 251

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

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

Text proposed by the Commission

Amendment

(15) in Article 50, paragraph 7 is replaced by the following:

deleted

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

Or. en

Justification

Implementing acts are vital for the Single Market, translating duties into uniform requirements to prevent divergent national approaches. Removing them shifts the burden to ad-hoc interpretations, increasing uncertainty and costs for AI operators. Using these acts ensures structured Member State input via comitology, enhancing practicality. Retaining such tools supports competitiveness and simplification by avoiding fragmentation and ensuring predictable, proportionate compliance.

Amendment 252

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

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

Text proposed by the Commission

Amendment

(15) in Article 50, paragraph 7 is replaced by the following:

deleted

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

Or. en

Amendment 253

Adnan Dibrani, Evin Incir, Christel Schaldemose

Proposal for a regulation

Article 1 – paragraph 1 – point 15 – introductory part

Regulation (EU) 2024/1689

Article 50 – paragraph 6 a (new)

Text proposed by the Commission

(15) in Article 50, paragraph 7 is replaced by the following:

Amendment

(15) in Article 50, ***the following new paragraph 6a is inserted and the title and*** paragraph 7 is replaced by the following:

'Article 50

Obligations for providers and deployers of certain AI systems

6a. Providers of AI systems, including general-purpose AI systems, that generate or manipulate image, audio or video content shall implement effective technical and organisational measures to prevent the generation of deep fakes, resembling existing persons and would falsely appear to a person to be authentic or truthful, without the consent of the existing natural person; with the exception of where the content forms part of an evidently artistic, creative, satirical, fictional or analogous work or programme; as well as deepfakes depicting non-consensual nudity or sexually explicit conduct; and of outputs that depict or provide operational guidance, planning, instruction or assistance for the commission of serious criminal offences against life or physical integrity, including homicide, terrorism or other offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years.'

Or. en

Justification

The purpose of this amendment is to add the non-consensual dissemination of manipulated

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

Amendment 254

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

Proposal for a regulation

Article 1 – paragraph 1 – point 15 – introductory part

Regulation (EU) 2024/1689

Article 50 – paragraph 6 a (new)

Text proposed by the Commission

(15) in Article 50, paragraph 7 is replaced by the following:

Amendment

(15) in Article 50, ***the following paragraph 6a is inserted and the title and paragraph 7 is replaced by the following:***

'Article 50

Obligations for providers and deployers of certain AI systems

6a. Providers of AI systems, including general-purpose AI systems, that generate or manipulate image, audio or video content shall implement effective technical and organisational measures to prevent the generation of deep fakes depicting non-consensual nudity or sexually explicit conduct; and of outputs that depict or provide operational guidance, planning, instruction or assistance for the commission of serious criminal offences against life or physical integrity, including homicide, terrorism or other offences punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least four years.'

Or. en

Amendment 255
Piotr Müller, Assita Kanko

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

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

Compliance with Article 50 should be established either on the basis of voluntary standards or through individual methods decided by stakeholders. Employing common specifications or common rules risks undermining the purpose of the voluntary framework and compromise the joint effort. Furthermore the law shall be applied as adopted and proposed mechanism creates an unnecessary opportunity to gold-plating the rules.

Amendment 256
Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Jovet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation
Article 1 – paragraph 1 – point 15

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 257

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

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689
Article 50 – paragraph 7

Text proposed by the Commission

7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or

Amendment

7. The AI Office, ***in close collaboration with the Board***, shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection,

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).;

marking and labelling of artificially generated or manipulated content. The **Board** may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2, in accordance with the procedure laid down in Article 56(6), first subparagraph. If it deems the code is not adequate, the Commission may, **after consulting the Board and upon its approval**, adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).;

Or. en

Amendment 258

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 15

Regulation (EU) 2024/1689

Article 50 – paragraph 7

Text proposed by the Commission

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

Amendment

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

laid down in Article 98(2).;

Or. en

Amendment 259
Tomáš Zdechovský

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

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

This amendment aims to increase legal clarity and bring the text better in line with the proposed changes in Article 56(6). The Commission is required to assess the adequacy of the codes of practice, in order to ensure that stakeholders get maximum guidance.

Amendment 260
Piotr Müller, Assita Kanko

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 50 – paragraph 2

Present text

Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video *or text* content, shall **ensure** that the outputs of the AI system are marked in a machine-readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account the specificities and limitations of various types of content, the costs of implementation and the generally acknowledged state of the art, as may be reflected in relevant technical standards. This obligation shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate or prosecute criminal offences.

Amendment

(14a) "Article 50, paragraph 2 is replaced by the following:

'2. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image *or* video content, shall **take measures so** that the outputs of the AI system are marked in a machine-readable format and detectable as artificially generated or manipulated. Providers shall ensure their technical solutions are effective, interoperable, robust and reliable as far as this is technically feasible, taking into account the specificities and limitations of various types of content, the costs of implementation and the generally acknowledged state of the art, as may be reflected in relevant technical standards. This **watermarking** obligation **shall be applied in a proportionate manner linked to the identified risk and that does not**

impede, hamper or otherwise distort the display, lawful commercial exploitation or publication of the work, nor interfere with its normal use, and shall not apply to the extent the AI systems perform an assistive function for standard editing or do not substantially alter the input data provided by the deployer or the semantics thereof, or where authorised by law to detect, prevent, investigate or prosecute criminal offences.';

Or. en

Justification

The watermarking provision is amended to remove the obligation in relation to text, as such marking is difficult to justify in practical terms and provides limited added value in real-world use. While watermarking of audio, image and video content may be beneficial to the general public, its implementation should not undermine the legitimate opportunities offered by AI tools to advance creative, professional or commercial work. The revised wording therefore introduces a proportionality requirement based on paragraph 4.

Amendment 261

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

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 56 – paragraph 6 – subparagraph 1

Text proposed by the Commission

Amendment

(16) in Article 56(6), the first subparagraph is replaced by the following:

deleted

‘6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking utmost account of the opinion of the Board, shall assess whether the codes of

practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. The Commission shall publish its assessment of the adequacy of the codes of practice.’;

Or. en

Justification

Implementing acts translate legal duties into uniform requirements, reducing divergent national approaches. Removing them increases legal uncertainty and compliance costs through ad-hoc interpretations. This route ensures structured Member State input, improving practicality over informal guidance. Retaining these tools supports competitiveness and simplification by avoiding fragmentation, enabling predictable compliance instead of "27 ways" of meeting the same AI Act obligation.

Amendment 262

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

Proposal for a regulation

Article 1 – paragraph 1 – point 16 – introductory part

Text proposed by the Commission

(16) in Article 56(6), *the first subparagraph* is replaced by the following:

Amendment

(16) in Article 56, *paragraph 6* is replaced by the following:

Or. en

Amendment 263

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

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation (EU) 2024/1689

Article 56 – paragraph 6 – subparagraph 1

Text proposed by the Commission

6. The Commission and the Board

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.;

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.;

Or. en

Amendment 264

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

Proposal for a regulation

Article 1 – paragraph 1 – point 16

Regulation 2024/1689

Article 56 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 265

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

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a
Regulation (EU) 2024/1689
Article 57 – paragraph 3 a

Text proposed by the Commission

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

Amendment

The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs. ***The AI Office shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities, the European Data Protection Board and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.***;

Or. en

Amendment 266

Leila Chaibi

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a
Regulation (EU) 2024/1689
Article 57 – paragraph 3 a

Text proposed by the Commission

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

Amendment

The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs. ***To the extent the AI systems involve the processing of personal data, the competent data protection authorities shall be associated with the operation of the AI regulatory sandbox established at Union level and involved in the supervision of those aspects to the extent of their respective tasks and powers, in accordance with Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU)2018/680 ;***

Or. en

Amendment 267

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

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a

Regulation (EU) 2024/1689

Article 57 – paragraph 3 a

Text proposed by the Commission

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

Amendment

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

priority access to SMEs.;

shall be operational no later than 1 January 2027.

Or. en

Justification

The Digital Omnibus envisages the establishment of an EU-level AI regulatory sandbox by the AI Office only from 2028. For SMEs and start-ups that will face compliance obligations under the AI Act earlier, this timeline is too late. Regulatory sandboxes are most effective when available at the early stage of regulatory application. Therefore, the Commission should accelerate the establishment of EU-level AI regulatory sandboxes and ensure their availability well before 2028, and in any event no later than the start of the application of AI Act provisions on high-risk systems.

Amendment 268

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a

Regulation (EU) 2024/1689

Article 57 – paragraph 3 a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 269

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

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a

Regulation (EU) 2024/1689
Article 57 – paragraph 3 a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 270

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

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point a
Regulation (EU) 2024/1689
Article 57 – paragraph 3 a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 271 **Kateřina Konečná**

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point b

Regulation (EU) 2024/1689

Article 57 – paragraph 5

Text proposed by the Commission

5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority, ensuring that appropriate safeguards are in place. ***Such sandboxes may include testing in real world conditions supervised therein. When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan.***;

Amendment

5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority, ensuring that appropriate safeguards are in place.;

Or. en

Amendment 272

Leila Chaibi

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point c

Regulation (EU) 2024/1689

Article 57 – paragraph 9 – point e

Text proposed by the Commission

(c) paragraph 9, point (e) is replaced by the following:

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

Amendment

deleted

Or. en

Amendment 273
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1 – point 17 – point c
Regulation (EU) 2024/1689
Article 57 – paragraph 9 – point e

Text proposed by the Commission

Amendment

(c) paragraph 9, point (e) is replaced by the following: **deleted**

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

Or. en

Amendment 274
Brando Benifei, Kristian Vigenin, Christel Schaldemose, Pierre Juvet, Marc Angel, Francisco Assis, Alex Agius Saliba, José Cepeda, Elena Sancho Murillo, François Kalfon, Elisabeth Grossmann, Hannes Heide

Proposal for a regulation
Article 1 – paragraph 1 – point 17 – point c
Regulation (EU) 2024/1690
Article 57 – paragraph 9 – point e

Text proposed by the Commission

Amendment

(c) paragraph 9, point (e) is replaced by the following: **deleted**

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

Or. en

Amendment 275
Markéta Gregorová, Kim Van Sparrentak

on behalf of the Verts/ALE Group

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 57 – paragraph 10 a (new)

Text proposed by the Commission

Amendment

(ca) in Article 57, paragraph 10a is inserted:

'10a. In cases referred to in paragraph 3a, the AI office shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the national data protection authorities, the EDPB and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.';

Or. en

Amendment 276

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

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point d

Regulation (EU) 2024/1689

Article 57 – paragraph 13

Text proposed by the Commission

Amendment

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

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

Amendment 277
Leila Chaibi

Proposal for a regulation
Article 1 – paragraph 1 – point 17 – point e
Regulation (EU) 2024/1689
Article 57 – paragraph 14

Text proposed by the Commission

Amendment

(e) paragraph 14 is replaced by the following:

deleted

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

Amendment 278
Markéta Gregorová, Kim Van Sparrentak
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 1 – point 17 – point e
Regulation (EU) 2024/1689
Article 57 – paragraph 14

Text proposed by the Commission

Amendment

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

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

Amendment 279

Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point e

Regulation (EU) 2024/1689

Article 57 – paragraph 14

Text proposed by the Commission

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

Amendment

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

Amendment 280

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

Proposal for a regulation

Article 1 – paragraph 1 – point 17 – point e

Regulation (EU) 2024/1689

Article 57 – paragraph 14

Text proposed by the Commission

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

Amendment

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

Amendment 281
Stefano Cavedagna

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 57 – paragraph 7

Present text

7. Competent authorities shall provide providers and prospective providers participating in the AI regulatory sandbox with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation.

Upon request of the provider or prospective provider of the AI system, the competent authority shall provide a written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Providers may use such documentation to demonstrate their compliance with this Regulation through the conformity assessment process or relevant market surveillance activities. In this regard, the exit reports and the written proof provided by the national competent authority shall be taken positively into account by market surveillance authorities and notified bodies, with a view to accelerating conformity assessment procedures to a reasonable extent.

Amendment

(ba) in Article 57, paragraph 7 is replaced by the following:

'7. Competent authorities shall provide providers and prospective providers participating in the AI regulatory sandbox with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation. Upon request of the provider or prospective provider of the AI system, the competent authority shall provide a written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. AI systems that have participated in an AI regulatory sandbox are presumed to be conforming to the requirements set in this Regulation, limited to the activities detailed in the exit reports and the written proof provided by the national competent authority.'

Or. en

Justification

The current wording of Article 57, paragraph 7, does not guarantee benefits proportionate to the organizational, technical and procedural effort required of companies to participate in sandboxes. A presumption of conformity based on the activities successfully carried out in the sandbox would make the value of participation more immediately tangible, especially SMEs and startups.

Amendment 282

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

Proposal for a regulation

Article 1 – paragraph 1 – point 18

Regulation (EU) 2024/1689

Article 58 – paragraph 1 – introductory part

Text proposed by the Commission

1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

Amendment

1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts, ***on the basis of a prior opinion from the Board***, specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

Or. en

Amendment 283

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

Proposal for a regulation

Article 1 – paragraph 1 – point 18

Regulation (EU) 2014/1689

Article 58 – paragraph 1 – point d

Text proposed by the Commission

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

Amendment

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

Amendment 284

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

Proposal for a regulation

Article 1 – paragraph 1 – point 18 a (new)

Regulation (EU) 2014/1689

Article 58 – paragraph 2 – point d

Present text

Amendment

(d) that access to the AI regulatory sandboxes is free of charge for SMEs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;

(18a) in Article 58, paragraph 2, point (d) is replaced by the following:

'(d) that access to the AI regulatory sandboxes is free of charge for SMEs and SMCs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;'

Amendment 285

Stefano Cavedagna

Proposal for a regulation

Article 1 – paragraph 1 – point 18 a (new)

Regulation (EU) 2024/1689

Article 58 – paragraph 2 – point i a (new)

Text proposed by the Commission

Amendment

(18a) in Article 58, paragraph 2, the following point is inserted:

'(ia) that AI systems which have participated in an AI regulatory sandbox benefit from a presumption of conformity with the requirements of this Regulation relating to the activities carried out in the sandbox.'

Justification

The amendment empowers the Commission to develop implementing acts detailing the functioning of AI sandboxes ensuring a presumption of conformity for participants, thus making them more attractive for AI providers, especially SMEs and startups.

Amendment 286
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1 – point 19
 Regulation (EU) 2024/1689
 Article 60

Text proposed by the Commission

Amendment

(19) Article 60 is amended as follows: *deleted*

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.’;

(b) paragraph 2 is replaced by the following:

‘2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.’;

Amendment 287
Leila Chaibi

Proposal for a regulation
Article 1 – paragraph 1 – point 19
Regulation (EU) 2024/1689
Article 60

Text proposed by the Commission

Amendment

(19) Article 60 is amended as follows: **deleted**

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.’;

(b) paragraph 2 is replaced by the following:

‘2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.’;

Amendment 288

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

Proposal for a regulation

Article 1 – paragraph 1 – point 19

Regulation (EU) 2024/1689

Article 60

Text proposed by the Commission

Amendment

(19) Article 60 is amended as follows: *deleted*

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.’;

(b) paragraph 2 is replaced by the following:

‘2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.’;

Or. en

Amendment 289

Leila Chaibi

Proposal for a regulation
Article 1 – paragraph 1 – point 20
Regulation (EU) 2024/1689
Article 60 a

Text proposed by the Commission

Amendment

(20) the following Article 60a is inserted: **deleted**

‘Article 60a

Testing of high-risk AI systems covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions outside AI regulatory sandboxes

1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I, in accordance with this Article and a voluntary real-world testing agreement, without prejudice to the prohibitions under Article 5.

2. The voluntary real-world testing agreement referred to in paragraph 1 shall be concluded in writing between interested Member States and the Commission. It shall set the requirements for the testing of those AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions.

3. Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world

testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.

4. The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish detailed elements of the real-world testing plan for AI systems covered by Union harmonisation legislation listed in Section B of Annex I.

5. Article 60(2), (5) and (9) shall apply.’;

Or. en

Amendment 290
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1 – point 20
Regulation (EU) 2024/1689
Article 60 a

Text proposed by the Commission

Amendment

(20) the following Article 60a is inserted: *deleted*

‘Article 60a

Testing of high-risk AI systems covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions outside AI regulatory sandboxes

1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I, in accordance with this Article and a voluntary real-world testing agreement, without prejudice to the prohibitions under Article 5.

2. The voluntary real-world testing

agreement referred to in paragraph 1 shall be concluded in writing between interested Member States and the Commission. It shall set the requirements for the testing of those AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions.

3. Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.

4. The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish detailed elements of the real-world testing plan for AI systems covered by Union harmonisation legislation listed in Section B of Annex I.

5. Article 60(2), (5) and (9) shall apply.’;

Or. en

Amendment 291

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

Proposal for a regulation

Article 1 – paragraph 1 – point 20

Regulation (EU) 2024/1689

Article 60 a

(20) the following Article 60a is inserted: **deleted**

‘Article 60a

Testing of high-risk AI systems covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions outside AI regulatory sandboxes

- 1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I, in accordance with this Article and a voluntary real-world testing agreement, without prejudice to the prohibitions under Article 5.***
- 2. The voluntary real-world testing agreement referred to in paragraph 1 shall be concluded in writing between interested Member States and the Commission. It shall set the requirements for the testing of those AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions.***
- 3. Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.***

4. ***The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish detailed elements of the real-world testing plan for AI systems covered by Union harmonisation legislation listed in Section B of Annex I.***

5. ***Article 60(2), (5) and (9) shall apply.’;***

Or. en

Amendment 292

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

Proposal for a regulation

Article 1 – paragraph 1 – point 20

Regulation (EU) 2024/1689

Article 60 a – paragraph 3

Text proposed by the Commission

3. Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.

Amendment

3. Member States, ***that are party to the voluntary real-world testing agreement***, the Commission, ***the relevant*** market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.

Or. en

Amendment 293

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

Proposal for a regulation

Article 1 – paragraph 1 – point 20

Regulation (EU) 2024/1689

Article 60 a – paragraph 3

Text proposed by the Commission

3. Member States, the Commission, market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.

Amendment

3. Member States, the Commission, ***national competent authorities such as*** market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the voluntary real-world testing agreement and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex.

Or. en

Amendment 294

Stefano Cavedagna

Proposal for a regulation

Article 1 – paragraph 1 – point 20 a (new)

Regulation (EU) 2024/1689

Article 62

Text proposed by the Commission

Amendment

(20a) Article 62 is amended as follows:

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

"(d) facilitate the participation of SMEs

and other relevant stakeholders in the standardization development process, including through appropriate dedicated financial support mechanisms to reimburse the costs of participation of SME experts in European bodies.";

(b) in paragraph 3, point (da) is added:

"(da) establish and maintain a public repository of certified open-source AI components, including for the purposes of the obligations under Article 16, the use of these components is presumed to comply with the requirements set out in Section 2."

Or. en

Justification

Compliance with the Regulation will depend on the appropriate tools made available to small businesses for regulatory compliance. In this regard, it is essential to strengthen support for SMEs in the process of developing authorized standards. Currently, participation in technical discussions at European standardization organizations (CEN, CENELEC, ETSI) is only affordable for large companies. Without reimbursement for SME experts, standards will be tailored exclusively to the needs of large corporations, making compliance impractical for small operators. Furthermore, it will be crucial to relieve SMEs of overly complex audits of open-source components developed by third parties. In this regard, the establishment of a "Safe Harbor" linked to an EU-certified repository managed by the AI Office is the only way to enable the safe use of open-source without exposing small businesses to unacceptable compliance risks.

Amendment 295 **Kateřina Konečná**

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

Text proposed by the Commission

Amendment

(21) Article 63(1) is replaced by the following:

deleted

'1. SMEs, including start-ups, may comply with certain elements of the

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

Or. en

Amendment 296

Axel Voss

Proposal for a regulation

Article 1 – paragraph 1 – point 21

Regulation (EU) 2024/1689

Article 63 – paragraph 1

Text proposed by the Commission

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

Amendment

1. **SMCs and** SMEs, including start-ups, may comply with certain elements of the **legal obligations defined under Article 9, 10, 11, 12, 17, 43** in a simplified manner. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of **SMCs and** SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems. ***In order to benefit from those reduced requirements (such as simplified risk assessments, reduced logging obligations, generalized technical documentation, accelerated conformity assessments, training with sensitive/pseudonymized data), the AI system or underlying AI model must be trained with EU Compute.***

Justification

Targeted simplification for SMCs/SMEs can unlock compliance capacity, but it should be linked to objective conditions that reduce dependency and strengthen Europe's ability to verify and enforce high-risk requirements. The "EU compute" criterion is not about company nationality; it is about ensuring that training and key operational controls sit under EU jurisdiction and technical control (i.e. hardware, access, logs, keys and data governance), making audits, incident response and supervision realistically executable. This creates a concrete demand-side incentive for trusted European infrastructure, so that the AI Act/Omnibus does not unintentionally channel more high-risk development onto non-EU stacks while Europe remains mainly a data supplier. The criterion must therefore be defined as effective EU control over compute and operations, to avoid paper compliance and false "sovereignty" labelling.

Amendment 297

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

Proposal for a regulation

Article 1 – paragraph 1 – point 21

Regulation (EU) 2024/1689

Article 63 – paragraph 1

Text proposed by the Commission

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

Amendment

1. **Micro and small enterprises**, including start-ups, **within the meaning of Recommendation 2003/361/EC**, may comply with certain elements of the quality management system required by Article 17 in a simplified manner, **provided that they do not have partner enterprises or linked enterprises within the meaning of that Recommendation**. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of **micro and small enterprises**, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.;

Amendment 298
Stefano Cavedagna

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

Text proposed by the Commission

1. SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of 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 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. en

Justification

A strictly proportional approach requires differentiation based on company size. Microenterprises, in fact, should be able to enjoy a further degree of simplification compared to small and medium-sized enterprises, avoiding competitive disadvantages and adapting compliance to the economic operator's capabilities.

Amendment 299
Svenja Hahn, Nikola Minchev, Cynthia Ní Mhurchú, Moritz Körner, Sophie Wilmès, Jan-Christoph Oetjen, Ana Vasconcelos, Hilde Vautmans

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 300

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

Proposal for a regulation

Article 1 – paragraph 1 – point 21

Regulation (EU) 2024/1689

Article 63 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 301

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

Proposal for a regulation

Article 1 – paragraph 1 – point 21 a (new)

Regulation (EU) 2024/1689

Article 64 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

(21a) in Article 64, the following paragraph 2a is inserted:

‘2a. The Commission and Member States shall ensure that the AI Office is provided with adequate technical, financial, and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation. In particular, the AI Office shall have a sufficient number of personnel permanently available whose competences and expertise shall include an in-depth understanding of AI technologies, data and data computing, personal data protection, cybersecurity, fundamental rights, health and safety risks and knowledge of existing standards and legal requirements. The AI Board shall assess and, if necessary, update competence and resource requirements referred to in this paragraph on an annual basis.’;

Or. en

Amendment 302

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

Proposal for a regulation

Article 1 – paragraph 1 – point 21 a (new)

Regulation (EU) 2024/1689

Article 65 – paragraph 5

Present text

Amendment

5. The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority. The rules of procedure shall, in particular, lay down procedures for the selection process, the duration of the mandate of, and specifications of the tasks of, the Chair, detailed arrangements for voting, and the organisation of the Board's activities and those of its sub-groups.

(21a) Article 65(5) is replaced by the following;

'5. The designated representatives of the Member States shall adopt the Board's rules of procedure by a two-thirds majority. The rules of procedure shall, in particular, lay down procedures for the selection process, the duration of the mandate of, and specifications of the tasks of, the Chair, and the organisation of the Board's activities and those of its sub-groups.

All decisions of the Board shall be taken by a two-thirds majority of its members.';

Or. en

Amendment 303

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

Proposal for a regulation

Article 1 – paragraph 1 – point 21 a (new)

Regulation (EU) 2024/1689

Article 66 – paragraph 1 – point k

Present text

Amendment

(k) assist the AI Office in supporting national competent authorities in the establishment and development of AI regulatory sandboxes, and facilitate cooperation and information-sharing among AI regulatory sandboxes;

(21a) in Article 66, point (k) is replaced by the following:

'(k) assist the national competent authorities in the establishment and development of AI regulatory sandboxes, and facilitate cooperation and information-sharing among AI regulatory sandboxes;';

Or. en

Amendment 304

Markéta Gregorová, Kim Van Sparrentak

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 1 – paragraph 1 – point 22 – point b

Regulation (EU) 2024/1689

Article 69 – paragraph 3

Text proposed by the Commission

Amendment

(b) paragraph 3 is deleted.

deleted

Or. en

Amendment 305

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

Proposal for a regulation

Article 1 – paragraph 1 – point 22 – point b

Regulation (EU) 2024/1689

Article 69 – paragraph 3

Text proposed by the Commission

Amendment

(b) paragraph 3 is deleted.

deleted

Or. en

Amendment 306

Kateřina Konečná

Proposal for a regulation

Article 1 – paragraph 1 – point 23

Regulation (EU) 2024/1689

Article 70 – paragraph 8

Text proposed by the Commission

Amendment

(23) in Article 70, paragraph 8 is replaced by the following:

deleted

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

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

Or. en

Amendment 307

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

Proposal for a regulation

Article 1 – paragraph 1 – point 23

Regulation (EU) 2024/1689

Article 70 – paragraph 8

Text proposed by the Commission

Amendment

(23) in Article 70, paragraph 8 is replaced by the following:

deleted

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

Or. en

Amendment 308

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

Proposal for a regulation
Article 1 – paragraph 1 – point 23
Regulation (EU) 2024/1689
Article 70 – paragraph 8

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 309
Jaroslav Bžoch, Klara Dostalova

Proposal for a regulation
Article 1 – paragraph 1 – point 23 a (new)
Regulation (EU) 2024/1689
Article 71 – paragraph 4

Present text

4. With the exception of the section referred to in Article 49(4) and Article 60(4), point (c), the information contained in the EU database registered in accordance with Article 49 shall be accessible and publicly available in a user-friendly manner. The information should be easily navigable and machine-readable.

Amendment

(23a) in Article 71, paragraph 4 is replaced by the following:

‘4. With the exception of the section referred to in Article 49(4) and (5) and Article 60(4), point (c), the information contained in the EU database registered in accordance with Article 49 shall be accessible and publicly available in a user-friendly manner. The information should be easily navigable and machine-

The information registered in accordance with Article 60 shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for also making the information accessible the public.

readable. The information registered in accordance with Article 60 shall be accessible only to market surveillance authorities and the Commission, unless the prospective provider or provider has given consent for also making the information accessible the public.’;

Or. en

Amendment 310

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

Proposal for a regulation

Article 1 – paragraph 1 – point 24

Regulation (EU) 2024/1689

Article 72 – paragraph 3

Text proposed by the Commission

Amendment

(24) in Article 72, paragraph 3 is replaced by the following:

deleted

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

Or. en

Justification

Implementing acts ensure uniform requirements and prevent divergent national approaches. Removing them increases legal uncertainty and costs through ad-hoc interpretations. This route provides structured Member State input, improving practicality over informal guidance. Retaining these tools supports competitiveness and simplification by avoiding fragmentation, enabling predictable compliance instead of “27 ways” of meeting the same AI Act obligation.

Amendment 311

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

Proposal for a regulation

Article 1 – paragraph 1 – point 24

Regulation (EU) 2024/1689

Article 72 – paragraph 3

Text proposed by the Commission

Amendment

(24) in Article 72, paragraph 3 is replaced by the following:

deleted

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

Or. en

Amendment 312

Tomáš Zdechovský

Proposal for a regulation

Article 1 – paragraph 1 – point 24

Regulation (EU) 2024/1689

Article 72 – paragraph 3

Text proposed by the Commission

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, **including a template and the list of elements to be included in the plan.**;

Or. en

Justification

The original text of the AI Act requires the Commission to establish a template and the list of

elements to be included in the post-market monitoring plan. This should remain in the guidance prepared by the Commission, to ensure stakeholders have adequate tools to comply with the given obligations.

Amendment 313

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

Proposal for a regulation

Article 1 – paragraph 1 – point 24

Regulation (EU) 2024/1689

Article 72 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan, ***including a template with elements to be included by 2 February 2027.***';

Or. en

Amendment 314

Piotr Müller, Assita Kanko

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Or. en

Justification

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

Amendment 315 **Regina Doherty**

Proposal for a regulation
Article 1 – paragraph 1 – point 24 a (new)
Regulation (EU) 2024/1689
Article 74 a (new)

Text proposed by the Commission

Amendment

(24a) The following article is inserted:

‘Article 74a

Market surveillance authorities shall have the promotion of innovation, competitiveness, and economic growth as central objectives informing their work and integrated into their activities. Market surveillance authorities shall report annually on how they met these objectives.’;

Or. en

Amendment 316 **Stefano Cavedagna**

Proposal for a regulation
Article 1 – paragraph 1 – point 24 a (new)
Regulation (EU) 2024/1689
Article 74 – paragraph 14 a (new)

Text proposed by the Commission

Amendment

(24a) in Article 74, the following paragraph 14a is inserted:

‘14a. In exercising their powers under this Article and Regulation (EU) 2019/1020, market surveillance

authorities shall take into account the impact of their enforcement actions and regulatory initiatives on competitiveness and innovation, ensuring that measures taken are proportionate.’;

Or. en

Justification

The objective of the Omnibus package is to ensure that regulation does not stifle innovation. It seems appropriate that future initiatives by Market Surveillance Authorities are first weighed against their impact on competitiveness and innovation, as provided by the EU Better Regulation principles.

Amendment 317

Piotr Müller, Assita Kanko

Proposal for a regulation

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

Regulation (EU) 2024/1689

Article 74 a (new)

Text proposed by the Commission

Amendment

(24b) The following article is inserted:

‘Article 74a

Enforcement considerations

In carrying out their tasks, national competent authorities and the Commission shall take due account of the objectives of promoting innovation, technological development and the competitiveness of the Union economy. They shall exercise their powers in a proportionate and technologically neutral manner, facilitating, where appropriate, the development, testing and deployment of artificial intelligence systems, the dissemination of best practices, and cooperation between industry, academia and public bodies. Starting from 1 January 2029, national competent authorities and the Commission shall each publish a biannual report, including transparent metrics, demonstrating how

these objectives were integrated into their activities. ';

Or. en