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Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs

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Final Compromise Amendments

on the Draft Report

on the 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)

2025/0359(COD) - CJ40/10/04577

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COMPROMISE AMENDMENT 1

Amendments covered: AM 8 (Rapps), 9 (Rapps), 129 (S&D), 131 (EPP/ECR), 132 (ECR), 134 (RENEW), 136 (EPP), 137 (S&D), 138 (EPP), 139 (ECR), AM 17 (Rapps), 18 (Rapps), 19 (Rapps), 20 (Rapps), 265 (S&D), 266 (The Left), 275 (Greens), 278 (Greens), 135 (EPP), 293 (S&D), JURI 44

If CA 1 is adopted, all amendments related to Articles 4, 9, 10, 57, 58, 60 and 60a will fall.

(4) Article 4 is replaced by the following:

‘ *Article 4*

AI literacy

1. ‘***~~The Commission and Member States shall encourage~~*** Providers and deployers of AI systems ***shall ~~to~~*** take measures to ***support the improvement of ~~ensure a sufficient level of~~*** AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, ***~~level of~~*** education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.’ ***(AM 8, 131, 136, 137). This obligation does not cover any guarantee of a specific level of AI literacy of any individual (131).***

1a. The Commission shall issue guidance on the practical implementation of the obligation on providers and deployers of AI systems under paragraph 1. (AM 129)

1b. The Commission and the Member States shall encourage and support AI literacy in society and among the general population and support, facilitate and complement the efforts of providers and deployers of AI systems, in particular SMEs, for example via the creation of Public Private Partnerships in fulfilling their obligation under paragraph 1.; (AM 9, 132, 134, 138, 139, 135)

Articles 9 and 10 of Regulation 2024/1689, unchanged.

(17) Article 57 is amended as follows:

(a) the following paragraph 3a is inserted:

‘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, ***including startups (AM 17)***.

The AI Office shall ensure that, to the extent ~~the~~ innovative AI systems referred to in paragraph 5 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 established at Union level and involved in the supervision of those aspects to the extent ~~of~~ that they relate to their respective tasks and powers, in accordance with Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU)2018/680.; (AM 18, 265, 266, 275)

(b) paragraph 5 is replaced by the following:

'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 authorit***ies***, 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.'***(AM 19)***;

(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.';

(d) paragraph 13 is replaced by the following:

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

(e) paragraph 14 is replaced by the following:

'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 ***~~may~~*** support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.' ***(AM 278)***;

When discussed within the framework of the Board, the European Data protection Supervisor and the AI office shall, as part of their roles within the Board, also provide their feedback and exchange best practices on matters related to the establishment and operation of AI regulatory sandboxes established under their respective competences.

(18) Article 58, paragraph 1, is replaced by the following:

'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:

(a) eligibility and selection criteria for participation in the AI regulatory sandbox;

(b) procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;

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

(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, ***the involvement and supervision by the competent data protection authorities*** and the coordination and cooperation at national and EU level. ***(AM 20)***';

(19) Article 60 is amended as follows:

(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.';

(20) the following Article 60a is inserted:

'*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, ***national competent authorities such as (AM 293)*** 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.';

COMPROMISE AMENDMENT 2

Amendments covered: Rapp 10, 11, 23, 24, EPP 106, 168, 169**,** S&D 171**,** ECR 172, S&D 173, Left 174, Greens 175, RE 176, 181, EPP 182, 223, 224, 225, RE 241, Left 243, Greens 244, RE 245, S&D 246, EPP 247, 361 RE 396, RE 398, EPP 399, RE 400, Left 402, EPP/ECR 403, EPP 404, RE 406, EPP 407, RE 408, Greens 409, S&D 410, ECR 411, RE 412, EPP 413, EPP 417, RE 418, EPP 423, EPP 420, EPP 426, RE 427, RE 428, EPP 429, EPP 431, 435, 436, 437, 438, ECR 439, EPP 440, JURI 23, 24, 25, 26, 54, 55, 56, 57, 59, CULT 17, 18

If CA 2 is adopted, all amendments related to Articles 1-3, 4a 5, 6, 27, 96 (1), 111, 113 Annex I, Annex VIII, recitals 8b, 9, 23b, 25a will fall.

(Compromise Package)

(31) Article 113 is amended as follows:

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

'(d) Chapter III, Sections 1, 2, and 3, ***with the exception of Article 6(5)***, shall apply ~~***following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates***~~:

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

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

~~***In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:***~~ ***(Rapp 24, RE 396, RE 398, EPP 399, RE 400, Left 402, EPP/ECR 403, EPP 404, RE 406, EPP 407, RE 408, Greens 409, S&D 410, ECR 411, RE 412, EPP 413, EPP 417, RE 418, EPP 423, EPP 420, RE 427, RE 428, EPP 429, EPP 431)***

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

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

(b) in the third paragraph, point (e) is added:

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

Article 111 is amended as follows:

(a)paragraph 2 is replaced by the following:

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

(b)the following paragraph 4 is added:

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

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

‘*Article 4a*

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

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

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

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

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

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

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

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

~~2. Paragraph 1 may apply ***exceptionally*** to providers and deployers of other AI systems and models and deployers of high-risk AI systems ***to the extent the processing is where*** necessary and proportionate ***if the processing occurs*** for the purposes set out therein and provided that ***all*** the conditions ***and safeguards set out under the safeguards*** set out in this paragraph ***are met. This paragraph does not create any obligation to conduct such bias detection and correction with special categories of personal data (AM 11, 168, 169)***~~

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

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

(b) all of the conditions and safeguards set out in paragraph 1 are applied.

This paragraph does not create any obligation to conduct such bias detection and correction.'

(5a) Article 6(1) is amended as follows:

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 whose functioning is necessary to ensure that the product or AI system complies with applicable Union safety requirements***, 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.

(5b) In Article 6, paragraph 1a is added:

1a. For the purposes of this Regulation, functionalities intended solely for user assistance, performance optimisation, service efficiency, automation, convenience, or quality control of non-safety-related aspects shall not be regarded as safety functions under this Regulation, where their failure would not directly create risks to health or safety.

Recital 8b: ***"For the purposes of this Regulation, the fact that an AI system is integrated into, or operates within, a product subject to Union harmonisation legislation on product safety should not, in itself, imply that the AI system performs a safety function. An AI system should be regarded as performing a safety function only where its functioning is necessary to ensure that the product or the AI system complies with applicable Union safety requirements. By***

contrast, functionalities intended solely for user assistance, performance optimisation, service efficiency, automation, convenience, or quality control of non-safety-related aspects should not be regarded as safety functions under this Regulation, where their failure would not directly create risks to health or safety."

In Article 99, paragraph 6a inserted:

6a. In the case of SMCs, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 4 and 5, whichever thereof is lower. This shall not apply to providers of general-purpose AI models with systemic risk.

(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 generates realistic images or videos so as to depict sexually explicit activities or the intimate parts of an identifiable natural person, without that person's consent.

This prohibition does not apply to providers or deployers of AI systems who have put in place effective safety measures to prevent the generation of such depictions and to avoid misuse continuously, after the system has been placed, on the market or put into service despite the intention of the provider or deployer.

This prohibition shall not prevent AI providers from developing any capabilities referred to in the first subparagraph.

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

'2. For AI systems classified as high-risk AI systems in accordance with Article 6(1) related to products covered by the Union harmonisation legislation listed in ***~~Section B of~~*** Annex I, only Article 6(1), Article 60a, Articles 102 to 109, ***Articles 110a-110l*** and Articles 111 and 112 shall apply. Article 57 shall apply only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation (AM 106).;

(31a) In Annex I, Section A is deleted.

(31b) In Annex I, Section B, the following points are added:

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);
2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);
3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);
5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);
6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);
7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);
8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);
9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);
10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);
11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);
12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).
13. Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council Directive 73/361/EEC

Mirroring AI Act requirements to be included in sectoral laws:

Article 110a
Amendment to Regulation (EU) 2023/1230

In Article 8 of Regulation (EU) 2023/1230, the following paragraphs 2 and 3 are added:

'***2***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***48*** to amend the ~~general safety and performance~~ ***essential health and safety*** requirements set out in Annex I***II*** ~~***and requirement related to technical documentation set out in Annex IV***~~ in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

3. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***2*** of this Article or Common Specifications pursuant to Article ~~9~~ ***20*** of this Regulation concerning ~~devices~~ ***machinery and related products*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689.***

Article 110b
Amendment to Regulation (EU) 2025/2509

In Article 5 of Regulation (EU) 2025/2509, the following paragraphs 4 and 5 are added:

4. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***53*** to amend the ~~general safety and performance~~ ***essential safety*** requirements set out in Annex ***II*** ~~***and requirement related to technical documentation set out in Annex IV***~~ in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

5. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***4*** of this Article or Common Specifications pursuant to Article ~~9~~ ***16*** of this Regulation concerning ~~devices~~ ***toys*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***

Article 110c
Amendment to Directive 2013/53/EU

In Article 4 of Directive 2013/53/EU, the following paragraphs 3 and 4 are added:

'***3***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***50*** to amend the ~~general safety and performance~~ ***essential*** requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

4. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***3*** of this Article or Common Specifications pursuant to Article ~~9~~ ***14a*** of this Regulation concerning ~~devices~~ ***products*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or

that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110d
Amendment to Directive 2014/33/EU

In Article 5 of Directive 2014/33/EU, the following paragraphs 3 and 4 are added:

'***3***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***42*** to amend the ~~general safety and performance~~ ***essential health and safety*** requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

4. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***3*** of this Article or Common Specifications pursuant to Article ~~9~~ ***14a*** of this Regulation concerning ~~devices~~ ***lifts and safety components for lifts*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110e
Amendment to Directive 2014/34/EU

In Article 4 of Directive 2014/34/EU, the following paragraphs 2 and 3 are added:

2. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***39*** to amend the ~~general safety and performance~~ ***essential health and safety*** requirements set out in Annex ***II*** in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

3. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***2*** of this Article or Common Specifications pursuant to Article ~~9~~ ***12a*** of this Regulation concerning ~~devices~~ ***products*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110f
Amendment to Directive 2014/53/EU

In Article 3 of Directive 2014/53/EU, the following paragraphs 5 and 6 are added:

5. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***45*** to amend the ~~general safety and performance~~ ***essential*** requirements ~~set out in Annex ***II***~~ in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

6. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***5*** of this Article or Common Specifications pursuant to Article ~~9~~ ***16a*** of this Regulation concerning ~~devices~~ ***radio equipment*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110g
Amendment to Directive 2014/68/EU

In Article 4 of Directive 2014/68/EU, the following paragraphs 4 and 5 are added:

'***4***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***44*** to amend the ~~general safety and performance~~ ***essential safety*** requirements set out in Annex ***I*** in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

5. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***4*** of this Article or Common Specifications pursuant to Article ~~9~~ ***12a*** of this Regulation concerning ~~devices~~ ***products*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110h
Amendment to Regulation (EU) 2016/424

In Article 6 of Regulation (EU) 2016/424, the following paragraphs 2 and 3 are added:

'***2***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***44*** to amend the ~~general safety and performance~~ ***essential*** requirements set out in Annex ***II*** in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***
3. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***2*** of this Article or Common Specifications pursuant to Article ~~9~~ ***12a*** of this Regulation concerning ~~devices~~ ***cableway installations, subsystems and safety components*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110i
Amendment to Regulation (EU) 2016/425

In Article 5 of Regulation (EU) 2016/425, the following paragraphs 2 and 3 are added:

'***2***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***44*** to amend the ~~general safety and performance~~ ***essential health and safety*** requirements set out in Annex ***II*** in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

3. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***2*** of this Article or Common Specifications pursuant to Article ~~9~~ ***14a*** of this Regulation concerning ~~devices~~ ***personal protective equipment*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110j
Amendment to Regulation (EU) 2016/426

In Article 5 of Regulation (EU) 2016/426, the following paragraphs 2 and 3 are added:

'***2***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***41*** to amend the ~~general safety and performance~~ ***essential*** requirements set out in Annex ***I*** in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred***

to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.

3. When adopting ~~implementing acts pursuant to paragraph 6 of this Article,~~ delegated acts pursuant to paragraph ~~7~~ ***2*** of this Article or Common Specifications pursuant to Article ~~9~~ ***13a*** of this Regulation concerning ~~devices~~ ***appliances or fitting*** that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110k
Amendment to Regulation (EU) 2017/745

In Article 5 of Regulation (EU) 2017/745, the following paragraphs 7 and 8 are added:

'7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the general safety and performance requirements set out in Annex ***I*** in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Article 110l
Amendment to Regulation (EU) 2017/746

In Article 5 of Regulation (EU) 2017/746, the following paragraphs 7 and 8 are added:

'***7***. The Commission is empowered to adopt delegated acts in accordance with Article ~~115~~ ***107*** to amend the ~~general safety and performance~~ ***general safety and performance*** requirements set out in Annex ***I*** in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies. ***For high-risk AI systems referred to in Article 6(1) of Regulation (EU)2024/1689 the relevant requirements set out in Chapter III, Section 2 of (EU) Regulation 2024/1689 shall be deemed to constitute essential health and safety requirements for the purpose of this Regulation.***

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation ***as well as relevant harmonised standards***. ***With regard to high-risk AI systems, the Commission shall not go beyond the requirements laid down in the Regulation (EU) 2024/1689***.

Accompanying Recital 23b:

In order to safeguard the horizontal nature of this Regulation and ensure the proper functioning of the internal market, the relevant requirements laid down in Chapter III, Section 2 of this Regulation should be deemed to constitute essential health and safety requirements for high-risk AI systems covered by Union harmonisation legislation listed in Annex I and should be applied in a consistent and coherent manner across those sectoral frameworks. For this purpose, the Commission should be entitled to adopt delegated acts taking into account the requirements set out in Chapter III, Section 2 of this Regulation as regards their application to AI systems falling within its scope as well as relevant harmonised standards. In doing so, the Commission should not go beyond the requirements laid down in Regulation (EU) 2024/1689 for this purpose and should take into account the specific context of sectorial legislation. Before adopting the acts referred to in the first subparagraph, the Commission should conduct open and transparent consultations with relevant stakeholders, including competent authorities, notified bodies, civil society and industry.

Articles 1 and 3 of Regulation 2024/1689, unchanged.

(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 deployer shall, when conducting*** the fundamental rights impact assessment referred to in paragraph 1 of this Article ***include cross references to the relevant sections of*** ~~shall complement~~ that data protection impact assessment ***or include relevant parts of that data protection impact assessment into the fundamental rights impact assessment***.

28b) in Article 96, paragraph 1, subparagraph 1, the following point is inserted:
(g) the application of the requirements and obligations referred to in Article 27, including the possibility to reference or include relevant sections or parts of the data protection impact assessment into the fundamental rights impact assessment pursuant to Article 27(4) of this Regulation, using, where relevant, standardised templates

~~(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 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.'~~; **Deleted**

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

(32) in Annex VIII, section B***, points 7 and 9 are*** deleted;

Recital 9:
(9) To streamline compliance and reduce the associated costs, ~~providers of AI systems should not be required to register~~ ***the registration of*** AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation~~.~~ ~~Given that~~ ***should be simplified by streamlining the required content in Section B of Annex VIII to that Regulation. While it remains crucial for effective market surveillance and public accountability that such AI systems are registered in the EU database, the registration requirements should be simplified and made more proportionate. This simplification will strike a better balance without undermining the protection laid down by Regulation 2024/1689.*** Such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons~~, imposing registration requirements would constitute a disproportionate compliance burden~~. ~~Nevertheless~~ ***Furthermore***, a provider ~~who considers that an AI system falls under~~ ***applying*** Article 6(3) remains obligated to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.

Recital 25a:
When implementing and enforcing this Regulation, national competent authorities, the AI office and the Commission should take into account the objectives under Article 1(1) of Regulation (EU) 2024/1689 and follow the principles of necessity, proportionality, legal certainty and technological neutrality, while at the same time ensuring that unnecessary administrative and compliance burdens are minimised.

COMPROMISE AMENDMENT 3:

Amendments covered: Rapp 12, Rapp 15, EPP 221, ECR 235, Greens 236, S&D 263, S&D 301, EPP 312, S&D 313, EPP 321, S&D 319, Rapp 22, EPP 325, S&D 329, Greens 328, Rapp 5, S&D 330, S&D 333, S&D 339, RE 340, EPP 341

If CA 3 is adopted, all amendments related to Articles 25, 28, 29, 30, 40-43, 49, 56, 64, 72 and 75 will fall.

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

"2. Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the AI system on the market or put it into service shall no longer be considered to be a provider of that specific AI system for the purposes of this Regulation.

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

This obligation ***shall include:***

(a) Technical documentation ***sufficient to assess compliance with Article 16 requirements;***

(b) Known limitations and failure modes that could affect high-risk applications;

(c) Reasonable technical access for testing and validation purposes.

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.

~~(10) in Article 28, the following paragraphs 8 *and 8a* are added (*Rapp 12*):~~

~~'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. *Notifying authorities designated under this Regulation and under Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments, in particular to avoid an inconsistent or divergent interpretation of Union law. (Rapp 13)* Deleted~~

~~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.~~ ***Deleted***

~~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.'~~; ***Deleted***

~~8a. A notifying authority that has been designated under the Union harmonisation legislation listed in Section A of Annex I is also the notifying authority for the submission of the single application and single assessment procedure referred to in pargraph 8, unless the Member State designates another notifying authority for the purposes of this Regulation. (Rapp 14)~~ Deleted

~~(Rec. 7) In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to the procedure for designating notified bodies under Regulation (EU) 2024/1689, while maintaining the same level of scrutiny, a single application and a single assessment procedure should be available for new conformity assessment bodies and notified bodies which are designated under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, such as under Regulations (EU) 2017/745 20 and (EU) 2017/746 21 of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation. The single application and assessment procedure aims at facilitating, supporting and expediting the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies under that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto.~~ ***~~Such procedure should not affect the application of requirements under this Regulation and the relevant Union harmonisation legislation. (AM 227)~~ Deleted***

(11) in Article 29, paragraph 4 is replaced by the following:

'4. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support and expedite their designation procedure under this Regulation, as appropriate.

~~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***

The notified body shall update the documentation referred to in paragraphs 2 and 3 of this Article whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements laid down in Article 31.';

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

‘2. Notifying authorities shall notify the Commission and the other Member States, based on the list of codes, categories, and corresponding types of AI systems referred to in Annex XIV, and using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.

The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex XIV, in the light of technical progress, advances in knowledge or new scientific evidence by adding to the list of codes, categories, and corresponding types of AI systems a new code, a category or a type of AI system, withdrawing an existing code, category or a type of AI system from that list or moving a code or type of AI system from one category to another.’;

Articles 40 and 41 of Regulation 2024/1689, unchanged.

(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.'; (Rapp 15, ECR 235, Greens 236)

(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.~~ ***Deleted***

~~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].~~ ***Deleted***

~~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.~~ ***Deleted***

~~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.';~~ ***Deleted***

Article 62 of Regulation 2024/1689, unchanged.

In Article 64, paragraph 3 is added:

(3) Without prejudice to the budgetary procedure and through existing financial instruments, the AI Office shall be allocated with adequate human, financial and technical resources, and with infrastructure to fulfil their tasks, to effectively perform its duties and exercise its powers in respect of the enforcement of Regulation (EU 2024/1689). In particular, the AI Office shall have a sufficient number of personnel permanently available with in-depth competences and technical expertise. The AI Board shall assess competence and resource requirements. (Rapp 5, S&D 301, Greens 328)

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

'3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan, ***including a template with elements to be included by 2 February 2027***. ***(EPP 312, S&D 313)***';

(25) Article 75 is amended as follows:

(a) the heading of Article 75 is replaced by the following:

'**Market surveillance and control of AI systems and mutual assistance**';

(b) paragraph 1 is replaced by the following:

'1. Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I ***and AI systems referred to in Annex III, point 2 (EPP 321)***, and that model and that system are developed by the same provider ***or by providers belonging to the same group of undertakings***, the AI Office shall **have powers to** ~~be exclusively competent for the~~ supervis**e** ~~ion~~ and enforce ~~ment of that system with~~ the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI

Office shall also **have powers to** ~~be exclusively competent for the~~ supervis**e** ~~ion~~ and enforce ~~ment of~~ the obligations under this Regulation in relation to AI system**s** that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. ***Where the Commission has not initiated proceedings for the same infringement, the competent authority of a Member State in which the main establishment of the provider of very large online platform or of very large online search engine is located, or where their legal representative is established, may have the powers to supervise and enforce the obligations under this Regulation. ~~However~~ Notwithstanding the first subparagraph, the AI Office supervision and enforcement powers, ~~this~~ doe~~s~~ not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of this Regulation. (S&D 319, Rapp 22, 339)***

When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall ***~~be empowered to~~ (S&D 329)*** take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

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

Article 75, paragraph 1a is inserted:

1a. In the implementation and enforcement of this Regulation, the AI Office shall promote innovation, competitiveness and the protection of fundamental rights, taking them into consideration in the exercise of their functions. The AI Office shall coordinate closely with the competent data protection authorities designated pursuant to General Data Protection Regulation in matters involving the processing of personal data falling within the scope of that Regulation ~~in cases where the aforementioned AI systems present clear and evident risks to the fundamental rights to privacy and data protection.~~ (EPP 325, S&D 330, S&D 333, EPP 341)

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

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

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

‘1c. The Commission ~~***may***~~ ***shall, ~~where it deems it necessary and~~ subject to Article 28(8), ~~shall organise and~~ (RE 340)*** ~~carry out~~ ***ensure that*** pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 ***are carried out*** before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission ~~may~~ ***shall*** entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply *mutatis mutandis* to the Commission when exercising its powers under this paragraph.

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

(33) the following Annex XIV is added:

‘Annex XIV

The list of codes, categories and corresponding types of AI systems for the purpose of the notification procedure referred to in Article 30 specifying the scope of the designation as notified bodies

1. Introduction

Conformity assessment of high-risk AI systems under this Regulation may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated in accordance with this Regulation may carry out conformity assessments and only for the activities related to the types of AI systems concerned. The list of codes, categories, and corresponding types of AI systems sets the scope of the designation of conformity assessment bodies notified under Article 30 of this Regulation.

2. List of Codes, categories, and corresponding AI systems

1. <u>AI systems subject to Annex I of the AI Act</u>

AIA Code	
AIP 0101	AI systems subject to Annex I.A.1. of the AI Act.

AIP 0102	AI systems subject to Annex I.A.2. of the AI Act.
AIP 0103	AI systems subject to Annex I.A.3. of the AI Act.
AIP 0104	AI systems subject to Annex I.A.4. of the AI Act.
AIP 0105	AI systems subject to Annex I.A.5. of the AI Act.
AIP 0106	AI systems subject to Annex I.A.6. of the AI Act.
AIP 0107	AI systems subject to Annex I.A.7. of the AI Act.
AIP 0108	AI systems subject to Annex I.A.8. of the AI Act.
AIP 0109	AI systems subject to Annex I.A.9. of the AI Act.
AIP 0110	AI systems subject to Annex I.A.10. of the AI Act.
AIP 0111	AI systems subject to Annex I.A.11. of the AI Act.
AIP 0112	AI systems subject to Annex I.A.12. of the AI Act.

2. AI systems subject to Annex III.1 of the AI Act

AIA Code	
AIB 0201	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0202	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0203	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by Union institutions, bodies, offices or agencies.
AIB 0204	Remote biometric identification systems under Annex III.1.a. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0205	Biometric categorisation AI systems under Annex III.1.b. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0206	Emotion recognition AI systems under Annex III.1.c. of the AI Act intended to be put into service by law enforcement, immigration or asylum authorities.
AIB 0207	Remote biometric identification systems under Annex III.1.a. of the AI Act (general).
AIB 0208	Biometric categorisation AI systems under Annex III.1.b. of the AI Act (general).
AIB 0209	Emotion recognition AI systems under Annex III.1.c. of the AI Act (general).

*3. **AI technology-specific codes***

*a) **Symbolic AI, expert systems and mathematical optimization***

AIA Code	
AIH 0101	Logic- and knowledge-based AI systems that infer from encoded knowledge or symbolic representation, expert systems
AIH 0102	Logic-based AI systems, excluding basic data processing

*b) **Machine learning, excluding GPAI and single modality generative AI***

AIA Code	
AIH 0201	AI systems that process structured data
AIH 0202	AI systems that process signal and audio data
AIH 0203	AI systems that process text data
AIH 0204	AI systems that process image and video
AIH 0205	AI systems that learn from their environment, excluding agentic AI

*c) **AI systems based on GPAI or single modality generative AI***

AIA Code	
AIH 0301	Single modality generative AI systems
AIH 0302	Multimodal generative AI systems, including AI systems based on GPAI models

*d) **Agentic AI***

AIA Code	
AIH 0401	Agentic AI

3. Application for designation

Conformity assessment bodies shall use the lists of codes, categories and corresponding types of AI systems set out in this Annex when specifying the types of AI systems in the application for designation referred to in Article 29 of this Regulation.'.

COMPROMISE AMENDMENT 4

Amendments covered: Rapps 16, ECR 255, EPP 259, S&D 263

If CA 4 is adopted, all amendments related to Articles 50 and 56 will fall.

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

'7. The ***~~AI Office~~ Commission (Rapp 16, ECR 255)*** 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~~ shall (EPP 259)*** 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).';

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

'6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking utmost account of the opinion of the Board ***and other relevant competent authorities (S&D 263)***, 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.';

COMPROMISE AMENDMENT 5

If CA 5 is adopted, all amendments related to Articles 11, 17 will fall.

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

'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.';

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

COMPROMISE AMEMNDMENT 6

***Amendments covered*:** EPP 296, S&D 297, ECR 298, Rapps 21, Greens 304, S&D 343, 344, 346, 347, 348, EPP 357, 358, 359, 360, 372, JURI 49

If adopted all amendments related to Articles 62, 63, 65, 66, 69, 70, 71, 74, 77, 82, 88, 92, 95, 96, 99 will fall.

Articles 62, 65, 66, 71, 74, 82, 92 of Regulation 2024/1689, unchanged.

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

'1**.** SMEs, including start-ups, ***and micro enterprises*** 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 ***micro enterprises,*** SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.' ***(AM 297, 298)***;

(22) Article 69 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The Member States may be required to pay fees for the advice and support provided by the experts at a rate equivalent to the remuneration fees applicable to the Commission pursuant to the implementing act referred to in Article 68(1).';

~~***(b) paragraph 3 is deleted.***~~ ***(AM 21, 304) Deleted***

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

'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.'

(26) Article 77 is amended as follows:

(a) the heading is replaced by the following:

'**Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities**'

(b) paragraph 1 is replaced by the following:

‘1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language ***and machine-readable*** format ***by electronic means*** where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. ***This is without prejudice to the ~~competences,~~ tasks, powers and independence of the relevant national public authorities or bodies under their mandates in accordance with Union and national law (AM 343)***’;

(c) the following paragraph 1a ***~~and~~*** 1b ***and 1c (AM 344)*** are inserted:

‘1a. Subject to the conditions specified in this Article, the market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer, where necessary ***and without undue delay (AM 346)***.’

‘1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with mutual assistance necessary for fulfilling their respective mandates, with a view to ensuring coherent application of this Regulation and Union law protecting fundamental rights and streamlining procedures ***while respecting their respective competences, tasks, powers and independence (AM 347)***. This shall include, in particular, exchange of information where necessary for the effective supervision or enforcement of this Regulation and the respective other Union legislation.’;

1c. Requests for assistance shall contain all the necessary information, including the purpose of and reasons for the request. (AM 348).

(27) Article 95, paragraph 4 is replaced by the following:

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

(28) in Article 96(1), ***point (a) and*** the second subparagraph ***~~is~~ are*** replaced by the following:

(a) the application of the requirements and obligations referred to in Articles 8 to 15 and in ***Articles*** 25 ***and 26 (357, 358, 359, 360);***

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

(29) Article 99 is amended as follows:

(a) paragraph 1 is replaced by the following:

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

(a a) in paragraph 4 , the following point (da) is inserted:

(da) obligations of providers and third parties, including GPAI model providers, pursuant to Article 25(2), (3) and (4) (AM 372);

(b) paragraph 6 is replaced by the following:

‘6. In the case of SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.’;

COMPROMISE AMENDMENT 7

Amendments covered: 1, 2, 29, 9, 13, 18, 20, 29, 31, 46, 47, 52, 55, 57, 59, 68, 73, 77, 78, 81, 83, 132, 134, 138, 139, 135, 265, 266, 267, 275, 267, 268, 269, JURI 1, 7, 8, 10, CULT 7

If CA 7 is adopted, all amendments related to the recitals will fall.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Regulation (EU) 2024/1689 of the European Parliament and of the Council[3] lays down harmonised rules on artificial intelligence (AI) and aims to improve the functioning of the internal market, to promote the uptake of human-centric and trustworthy artificial intelligence, while ensuring a high level of protection of health, safety and fundamental rights, and supporting innovation. Regulation (EU) 2024/1689 entered into force on 1 August 2024. Its provisions enter into application in a staggered manner, with all rules entering into application by 2 August 2027.

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

1 OJ C , , p. .

2 OJ C , , p. .

3 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).

protection for health, safety and fundamental rights from AI-related risks that the rules of Regulation (EU) 2024/1689 seek to achieve.

(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective, ***simple and uniform*** application of the relevant rules. ***(AM 1)***

(3a) Additionally, the Commission, the AI Office and Member States' competent authorities should ensure that supervision, enforcement and monitoring of sectorial and national laws do not create overlaps, inconsistent interpretations or divergent enforcement in order to enable AI innovation in the private and public sector. (AM 2)

(4) ***99,8% of all EU companies are small and medium-sized enterprises, the majority of which are micro and small enterprises***[4] Those Enterprises outgrowing the micro, small and medium-sized enterprises ('SME') definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, they face challenges similar to SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs ***where appropriate while safeguarding the overarching objectives and level of protection afforded under Regulation (EU) 2024/1689***.[5] In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC[6] and Annex to Commission Recommendation 2025/3500/EC[7].

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

[4] https://single-market-economy.ec.europa.eu/system/files/2023-08/Annual%20Report%20on%20European%20SMEs%202023_FINAL.pdf

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

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

~~*potential sanctions*~~. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require ~~*the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage*~~ providers and deployers ***of AI systems*** to ***support*** ~~*provide a sufficient level*~~ AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf~~*, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives*~~. The European ~~*Artificial Intelligence Board ('Board') will ensure recurrent exchange between the*~~ Commission ~~*and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States, to*~~ ***should*** promote AI literacy and competences for the wider population, ***and in order to support, facilitate and complement the efforts of providers(AM 134), should be tasked to issue guidance on the practical implementation regarding the obligation on providers and deployers of AI systems, and should, together with the Member States, encourage and support AI literacy in society (AM 129). This should include facilitating and complementing the efforts of providers and deployers of AI systems, in particular SMEs, as the implementation of the relevant obligations poses particular challenges for them (AM 46 partly). One possibility to facilitate AI literacy in the Union could be the creation of Public Private Partnerships (PPPs)*** ~~*including learners, students, and citizens at different ages and in particular through education and training systems*~~***(AM 9, 132, 134, 138, 139, 135)***.

(5a) ***AI systems that alter, manipulate or artificially generates realistic images or videos depicting sexually explicit activities or the intimate parts of an identifiable natural person, without that person's consent, cause harm to victims and violate fundamental rights to dignity and privacy. The proliferation of such technologies, often marketed as 'nudification' applications, has created an urgent need for explicit regulatory prohibition. Regulation (EU) 2024/1689 establishes a framework for prohibited AI practices, which is to be kept under review. This is without prejudice towards the rights, freedoms and principles recognised by Article 6 TEU and the Charter of Fundamental Rights of the European Union, and the exercise of the rights guaranteed therein to freedom of expression and information and the freedom of the arts and sciences. This prohibition should not apply to providers or deployers of AI systems who have put in place effective safety measures, such as technical and organisational measures, to prevent the generation of such depictions and to avoid misuse continuously, after the system has been placed on the market or put into service, despite the intention of the provider or deployer. Moreover, this prohibition should not prevent AI providers from developing their technical capabilities to alter, manipulate or artificially generate images or videos. (46, 47, 52)***

(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. ~~Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of~~ ***For that reason,*** Regulation (EU) 2024/1689 already provides a legal basis authorising the ~~processing of~~ ***providers of high-risk AI systems to process*** special categories of personal data ~~under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council. Given that~~ ***in certain exceptional cases and subject to strict safeguards. This legal basis is linked to those***

providers' obligation to establish practices concerning the detection, prevention and mitigation of biases likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination ***prohibited under Union law. Accordingly, a substantial public interest exists to permit, where strictly necessary,*** the processing of special categories of personal data ***for the purposes of bias detection and correction. It is therefore necessary to extend the legal basis established under Regulation (EU) 2024/1689 so that it also applies to the*** also by providers and deployers of other AI systems and AI models ~~as well as deployers of high-risk AI systems. The~~***.*** ***That*** legal basis ~~is established in~~ ***should be subject to the same conditions and safeguards as apply under the existing Article 10(5), thereby ensuring*** compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council**.**

(7) ~~In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to the procedure for designating notified bodies under Regulation (EU) 2024/1689, while maintaining the same level of scrutiny, a single application and a single assessment procedure should be available for new conformity assessment bodies and notified bodies which are designated under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, such as under Regulations (EU) 2017/745[8] and (EU) 2017/746[9] of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation.~~ ~~***These procedures should also take into consideration the New Legislative Framework (NLF) which ensures a high level of protection for health and safety. (AM 55)***~~ ~~The single application and assessment procedure aims at facilitating, supporting and expediting the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies under that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto.~~ ~~***Notifying authorities designated under this Regulation and under Union harmonisation legislation listed in Section A of Annex I should cooperate in their assessments, in particular to avoid an inconsistent or divergent interpretation of Union law and to avoid duplication. (Rapp 13, AM 55).***~~ ***Deleted***

(8) ~~With a view to ensuring the smooth application and consistency of Regulation (EU) 2024/1689, amendments should be made to it. A technical correction to Article 43(3), first subparagraph, of Regulation (EU) 2024/1689 should be added to align the conformity assessment requirements with the requirements of providers of high-risk AI systems in Article 16 of that Regulation. Moreover, it should be clarified that where a provider of a high-risk AI system is subject to the conformity assessment procedure under Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, and the conformity assessment extends to compliance of the quality management system of that Regulation and of such Union harmonisation legislation,~~

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

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

~~the provider should be able to include aspects related to quality management systems under that Regulation as part of the quality management systems under such Union harmonisation legislation, in line with Article 17(3) of Regulation (EU) 2024/1689. Article 43(3), second subparagraph, should be amended to clarify that notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and which aim to assess high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I to that Regulation, should apply for the designation as a notified body under that Regulation within 18 months from [the entry into application of this Regulation]. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689. Moreover, Regulation (EU) 2024/1689 should be amended to clarify that where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and falls within one of the use-cases listed in Annex III to that Regulation, the provider should follow the relevant conformity assessment procedure as required under that relevant harmonisation legislation.~~ ***Deleted***

(8a) Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847 complement each other so that the safety and cybersecurity of products with digital elements is ensured. It is necessary to ensure the alignment of Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847, to allow for their smooth implementation. Where high-risk AI systems fulfil the essential cybersecurity requirements set out in Regulation (EU) 2024/2847, they should be deemed to comply with the cybersecurity requirements set out in Article 15 of Regulation (EU) 2024/1689 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued pursuant to Regulation (EU) 2024/2847. (AM 15, 59, 235, 236, 237)

(8b) See compromise package related to Article 6(1)

(9) ***See compromise package***

(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In particular, to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world testing plan should be integrated in the sandbox plan agreed by the providers or prospective providers and the competent authority in a single document. In addition, it is appropriate to provide for the possibility of the AI Office to establish an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. ***When discussed within the framework of the Board, the European Data Protection Supervisor and the AI Office, as part of their roles within the board, should provide feedback and exchange best practices on matters related to the establishment and operation of AI regulatory sandboxes that were established under their respective competences (AM 278).*** By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be ~~better~~ streamlined and resources optimally utilised. ***In order to foster innovation and facilitate the uptake of AI, SMEs, including startups, and SMCs should be provided with priority access to the AI regulatory sandboxes established by the AI Office.***

Where AI regulatory sandboxes, including the controlled environment to foster innovation ~~to be provided in the AI regulatory sandboxes~~, involve innovative AI systems that ~~the~~ processing ~~of~~ personal data, the relevant national supervisory authorities should be involved in accordance with their tasks and powers. (AM 18, 20, 265, 266, 267, 275)

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

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

(12a) In order to allow the AI Office to effectively exercise its duties under Regulation (EU) 2024/1689 and in light of the new powers conferred on it by this Regulation, adequate human, financial and technical resources should be provided, without prejudice to the budgetary procedure and existing financial instruments. In particular, the AI Office should have a sufficient number of personnel whose expertise include an in-depth understanding of AI technologies..

(13) Article 69 of Regulation (EU) 2024/1689 should be amended to simplify the fee structure of the scientific panel. If Member States call upon the panel's expertise, the fees they may be required to pay the experts should be equivalent to the remuneration the Commission is obliged to pay in similar circumstances. ~~Furthermore, to reduce the procedural complexity, Member States should be able to consult the experts of the scientific panel directly, without involvement of the Commission.~~

(14) In order to strengthen the governance system for AI systems based on general-purpose AI models, it is necessary to clarify the role of the AI Office in monitoring and supervising compliance of such AI systems with Regulation (EU) 2024/1689, while excluding AI systems related to products covered by the Union harmonisation legislation listed in Annex I ***and AI systems referred to in Annex III, point 2*** to that Regulation. While sectoral authorities continue to remain responsible for the supervision of AI systems related to products covered by that Union harmonisation legislation, Article 75(1) Regulation (EU) 2024/1689 should be modified to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market

surveillance authorities under Regulation (EU) 2024/1689, the AI Office should ~~***be empowered to***~~ take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council[10]. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of Regulation (EU) 2024/1689 should cooperate actively in the exercise of those powers, in particular where enforcement actions need to be taken in the territory of a Member State ***(AM78).***

(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[11], it is appropriate to grant the Commission the powers of a competent market surveillance authority under Regulation (EU) 2024/1689 where an AI system qualifies as a very large online platform or a very large online search engine within the meaning of Regulation (EU) 2022/2065, or where it is embedded in such a platform or search engine. This should contribute to ensuring that the exercise of the Commission's supervision and enforcement powers under Regulation (EU) 2024/1689 and Regulation (EU) 2022/2065, as well as those applicable to general-purpose AI models integrated into such platforms or search engines, are carried out in a coherent manner. In the case of AI systems embedded in or qualifying as a very large online platform or search engine, the first point of entry for the assessment of the AI systems are the risk assessment, mitigating measures and audit obligations prescribed by Articles 34, 35 and 37 of Regulation (EU) 2022/2065, without prejudice to the AI Office's powers to investigate and enforce *ex post* non-compliance with the rules of this Regulation. In the context of the analysis of this risk assessment, mitigating measures and audits, the Commission services responsible for the enforcement of Regulation (EU) 2022/2065 may seek the opinion of the AI Office on the outcome of a potential earlier or parallel risk assessment carried out under this Regulation and the applicability of prohibitions under this Regulation. In addition, the AI Office and the competent national authorities under (EU) 2024/1689 should coordinate their enforcement efforts with the authorities competent for the supervision and enforcement of Regulation (EU) 2022/2065, including the Commission, in order to ensure that the principles of loyal cooperation, proportionality and non bis in idem are respected, while information obtained under the respective other Regulation would be used for the purposes of supervision and enforcement of the other only provided the undertaking agrees. In particular, those authorities should exchange views regularly and take into account, in their respective areas of competence, any fines and penalties imposed on the same provider for the same conduct through a final decision in proceedings relating to an infringement of other Union or national rules, so as to ensure that the overall fines and penalties imposed are proportionate and correspond to the seriousness of the infringements committed.

(16) To further operationalise the AI Office's supervision and enforcement set out in Article 75(1) of Regulation (EU) 2024/1689, it is necessary to further define ~~the~~ which of the powers listed in Article 14 of Regulation (EU) 2019/1020 should be conferred upon the

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

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

AI Office. The Commission should therefore be empowered to adopt implementing acts to specify those powers, including the ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings referred to in Article 99, and applicable procedures. This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689. ***(AM 81)***

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

(18) To enable access to Union market for AI systems which are under the supervision by the AI Office pursuant to Article 75 of Regulation (EU) 2024/1689 and subject to third party conformity assessment, the Commission should ~~be enabled to~~ ***ensure that*** pre-market conformity assessments ***are carried out for*** those systems. ***Furthermore, the AI Office should maintain organised records of communications with providers and deployers of general-purpose AI models with systemic risk, Such records should be documented in a consistent manner.***

(19) Article 77 and related provisions of Regulation (EU) 2024/1689 constitute an important governance mechanism, as they aim to enable authorities or bodies responsible for enforcing or supervising Union law intended to protect fundamental rights to fulfil their mandate under specific conditions and to foster cooperation with market surveillance authorities responsible for the supervision and enforcement of that Regulation. It is necessary to clarify the scope of such cooperation, as well as to clarify which public authorities or bodies benefit from it. With a view to reinforcing the cooperation, it should be clarified that requests to access information and documentation should be made to the competent market surveillance authority, which should respond to such requests ***without undue delay***, and that the involved authorities or bodies should have a mutual obligation to cooperate. ***It should be clarified that these provisions are without prejudice to the tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, those provisions do not limit any powers that those authorities and bodies have to request information pursuant to other Union or national law. Accordingly, those authorities and bodies retain any power they have to directly request information from operators pursuant to their mandate or other law. (AM 83, 343)***

(20) To allow sufficient time for providers of generative AI systems subject to the marking obligations laid down in Article 50(2) of Regulation (EU) 2024/1689 to adapt their practices within a reasonable time without disrupting the market, it is appropriate to introduce a transitional period of **3** months for providers who have already placed their systems on the market before the 2 August 2026.

(21) To provide sufficient time for providers of high-risk AI systems and to clarify applicable rules to the AI systems already placed on the market or put into service before the entry into application of relevant provisions of the Regulation (EU) 2024/1689, it is appropriate to clarify the application of a grace period provided in Article 111(2) of that Regulation. The grace period, for the purpose of Article 111(2), should apply to a type and model of AI systems already placed in the market. This

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

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

(22a) In order to ensure legal certainty and to avoid further application delays, the Commission should ensure that measures in support of compliance with regard to Chapter III, Sections 1, 2, and 3 are in place in due time to ensure timely and effective implementation of the necessary provisions. (AM7)

(23) In light of the objective to reduce implementation challenges for citizens, businesses and public administrations, it is essential that harmonised conditions for the implementation of certain rules are adopted only where strictly necessary. For that purpose, it is appropriate to remove certain empowerments bestowed on the Commission to adopt such harmonised conditions by means of implementing acts in cases where those conditions are not met. Regulation (EU) 2024/1689 should therefore

be amended to remove the empowerments conferred on the Commission in Article 50(7), Article 56(6), and Article 72(3) thereof to adopt implementing acts. ~~***The removal of the empowerment to adopt a harmonised template for a post-market monitoring plan in Article 72(3) of Regulation (EU) 2024/1689 has as an additional benefit that it will offer more flexibility for providers of high-risk AI systems to put in place a system for post-market monitoring that is tailored to their organisation.***~~ At the same time, recognising the need to offer clarity how providers of high-risk AI systems are required to comply ***with their monitoring obligations***, the Commission should be required to publish guidance ***on the postmarket monitoring plan, including a template with elements to be included therein, by 2 February 2027***.

(23a) The parallel application of sectoral Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 of the European Parliament and of the Council and the requirements laid down in that Regulation for high-risk artificial intelligence systems may lead to overlaps of requirements and unnecessary administrative burden for economic operators. Such overlaps could create legal uncertainty, increase compliance costs and potentially lead to competitive disadvantages, without providing additional benefits for the protection of health, safety or fundamental rights. In order to ensure a more coherent and proportionate regulatory framework and to simplify the application of requirements for artificial intelligence systems embedded in products regulated under Union harmonisation legislation, the references to the Union harmonisation legislation currently listed in Section A of Annex I to Regulation (EU) 2024/1689 should therefore be moved to Section B of that Annex. This approach clarifies that artificial intelligence systems integrated into products covered by those sectoral acts are subject to the requirements of this Regulation where relevant, while allowing the conformity assessment procedures and product safety requirements under the respective sectoral legislation to remain the primary framework. Any remaining gaps relating to artificial intelligence systems integrated into such products should be addressed within the relevant sectoral legislation.

(23b) See compromise package

(24) Conformity assessment of high-risk AI systems under Regulation (EU) 2024/1689 may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated under that Regulation may carry out conformity assessments and only for the activities related to the categories and types of AI systems concerned. To enable the specification of the scope of the designation of conformity assessment bodies notified under Article 30 of Regulation (EU) 2024/1689, it is necessary to draw up a list of codes, categories, and corresponding types of AI systems. The list of codes should take into account whether the AI system is a component of a product or itself a product covered by the Union harmonisation legislation listed in Annex I (referred to as 'AIP codes', for AI systems covered by product legislation) or a system referred in Annex III of Regulation (EU) 2024/1689, which currently concerns only biometric AI systems referred to in point (1) of Annex III (referred to as 'AIB codes', for biometric AI systems). Both AIP codes and AIB codes are vertical codes. The AIP codes are reference codes to provide a link to the Union harmonisation legislation listed in Section A of Annex I of Regulation (EU) 2024/1689. The AIB codes are new codes specific to Regulation (EU) 2024/1689 to identify biometric AI systems referred in paragraph 1 of Annex III of that Regulation. The list of codes should also take into account specific types and underlying technologies of AI systems (referred to as 'AIH codes', for horizontal AI system codes). The AIH codes are new AI

technology-specific codes and can be applied in conjunction with AIP or AIB vertical codes. The AIH codes cover AI systems' underlying types and technologies. The list of codes, including three categories, should provide for a multi-dimensional typology of AI systems which ensures that conformity assessment bodies designated as notified bodies are fully competent for the AI systems they are required to assess.

(25) Regulation (EU) 2018/1139 of the European Parliament and the Council[12] lays down common rules in the field of civil aviation. Article 108 of Regulation (EU) 2024/1689 sets out amendments to Regulation (EU) 2018/1139 to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of the civil aviation sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 when adopting any relevant delegated or implementing acts on the basis of that act. A technical correction extending specific articles of Regulation (EU) 2018/1139 is necessary to ensure that those mandatory requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 are fully covered when adopting relevant delegated or implementing acts on the basis of Regulation (EU) 2018/1139.

(25a) ***See compromise package***

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

HAVE ADOPTED THIS REGULATION:

[12] Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91(OJ L 212, 22.8.2018, pp. 1–122, ELI: http://data.europa.eu/eli/reg/2018/1139/oj).