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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	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). - Presidency compromise text

Delegations will find in the Annex a Presidency compromise text in relation to the above proposal, for examination at the meeting of the Antici Group (Simplification) on 30 January 2026. Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~.

ANNEX

2025/0359 (COD)

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)

(Text with EEA relevance)

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.

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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).

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

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

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

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

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

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

their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other non-legally binding initiatives. **European competence frameworks, for example the Digital Competence Framework for Citizens (DigComp), Digital Competence Framework for Educators (DigCompEdu) and the Digital Competence Framework for Organisations (DigCompO), should be taken into account in the encouragement under this article.** The European Artificial Intelligence Board ('Board') **should support the Commission and Member States in the promotion of AI literacy by adopting recommendations setting out common objectives to be achieved in order to meet their obligation and** will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems. **Moreover, this in no way affects the obligations that providers and deployers have under other provisions such as Article 26(2) to ensure the necessary competence, training and authority of relevant persons.**

(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 **providers of high-risk AI systems to process** ~~the processing of~~ special categories of personal data ~~under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council[6].~~ **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.** ~~Given that discrimination~~ **Nevertheless, biases likely to have those effects** might **also** result from ~~those other AI systems and models~~ **the actions of the deployers of high-risk AI systems. Furthermore, such biases could also arise in the case of other AI systems or models. In each of those further cases, a substantial public interest exists to permit, exceptionally and where strictly necessary, the processing of special category personal data for the purposes of bias detection and correction. I**~~i~~t is therefore ~~appropriate that~~ **necessary to extend the legal basis established under** Regulation (EU) 2024/1689 **so that it also applies to the** ~~in providing for a legal basis for the processing of special categories of personal data also by~~ providers and deployers of other AI systems and AI models~~, as well as deployers of high-risk AI systems. The~~ **That** legal basis ~~is established in~~ **should be subject to the same limitations, 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

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

European Parliament and of the Council[7] and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council[8]**.** ~~provides a legal basis allowsing, where necessary for the **purpose of the** detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.~~**Furthermore, to enable providers of high-risk AI systems to lawfully undertake bias detection and mitigation activities in preparation for compliance with the high-risk requirements, including Article 10(2), points (f) and (g), of Regulation (EU) 2024/1689, the legal basis established by Article 4a should apply from entry into application of this Regulation.**

(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[9] and (EU) 2017/746[10] 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. **Moreover, it should be clarified that a conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I should have to apply only once to be designated under this Regulation.**

(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

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

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

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

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

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

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

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

(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.

(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.

(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 to that Regulation **and excluding AI systems referred to in point (2) of Annex III to that Regulation**. While sectoral authorities continue to remain responsible for the supervision of AI systems related to products covered by that Union harmonisation legislation, Article 75(1) Regulation (EU) 2024/1689 should be modified to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision. This does not include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, the AI Office should be empowered to take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020 of the European Parliament and of the Council[11]. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, ~~the~~ **rules should be laid down regarding the cooperation with** authorities involved in the application of Regulation (EU) 2024/1689 ~~should cooperate actively~~**and assistance of those authorities**

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

to the AI Office in the exercise of those powers, **as well as the assistance of the police or equivalent enforcement authority** ~~in particular where enforcement actions need to be taken in the territory of a Member State~~.

(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[12], 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~~**enforcement** powers ~~listed in Article 14 of Regulation (EU) 2019/1020 should be~~ conferred upon the AI Office. ~~The Commission should~~**It is** therefore ~~be empowered~~**appropriate** to ~~adopt implementing acts to specify those~~ **set out provisions regarding the exercise of the AI Office's** powers **of investigation and enforcement as well in respect of AI systems supervised by the AI Office**, including **as regards judicial authorisation and fundamental rights as well as** 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. **Moreover, the Commission should be empowered to adopt**

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

implementing acts to further specify those powers. The implementing acts should also lay down the modalities of collaboration and consultation with the authorities involved in the application of that Regulation, including on the exchange of information. This should ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689.

(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 carry out pre-market conformity assessments of those systems.

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

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

(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~~ **Against this background**, it is appropriate to **align the implementation timeline and set the date for the application of Sections 1, 2 and 3 of Chapter III to 2 December 2027 for AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and to 2 August 2028 for AI systems classified as high-risk pursuant to Article 6(1) and Annex I** ~~put in place a mechanism that links the entry into application to the availability of measures in support of compliance with Chapter III, which may include harmonised standards, common specifications, and Commission guidelines. This should be confirmed by the Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case~~. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations.

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

(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[13] 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.

(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**.**

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13 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).

(27) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(1) and (2) of Regulation (EU) 2018/1725 and delivered their joint opinion on 20 January 2026,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2024/1689

Regulation (EU) 2024/1689 is amended as follows:

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

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

(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 and Articles 111 and~~ 112 shall apply. Article**s** 57 **to 59** 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.;

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

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

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

(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 to take measures **within their respective roles and responsibilities** to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, level of education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used. **European competence frameworks shall be taken into account in the encouragement under this article.**

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2. The Board shall adopt recommendations to support the Commission and Member States in the promotion of AI literacy required by paragraph 1, including by setting out non-binding common objectives.';

(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~~ **provisions** set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:

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

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

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

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

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

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

2. ~~Paragraph 1 may apply to p~~**P**roviders and deployers of other AI systems and models and deployers of high-risk AI systems ~~where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;~~ **may exceptionally process special categories of personal data to the extent that:**

(a) processing is strictly 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.

(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.';~~

(7) Article 10 is amended as follows:

(a) paragraph 1 is replaced by the following:

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

(b) paragraph 5 is deleted;

(c) paragraph 6 is replaced by the following:

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

(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.’;

(10) ~~in~~ Article 28 the following paragraph~~s 8~~ **are**~~is~~ added:

‘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~~ ensure~~s~~ 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. **To that end, notifying authorities designated under this Regulation and under any other Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments.**

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.

A conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I shall have to apply only once to be designated under this Regulation. A designation under this Regulation shall be applicable for all Union harmonisation legislation listed in Section A of Annex I for which the conformity assessment body is designated.

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.’;

‘9. 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 application of the single application and single assessment procedure referred to in paragraph 8, unless the Member State designates another notifying authority for this Regulation.’;

(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.

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.';

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

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

For the purposes of that conformity assessment, notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I shall have the power to assess the conformity of high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with the requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under the relevant Union harmonisation legislation. Without prejudice to Article 28, such notified bodies which have been notified under the Union harmonisation legislation in Section A of Annex I, shall apply for designation in accordance with Section 4 at the latest [18 months from the entry into application of this Regulation].

Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option to opt out from a third-party conformity

assessment, provided that that manufacturer has applied harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.

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

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

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

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

(16) in Article 56~~(6)~~, **paragraph 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, 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.';

(17) Article 57 is amended as follows:

(a) the following paragraph ~~3a~~ is inserted:

'**3a.** The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1)**, and may exercise the roles and tasks of national competent authorities in accordance with this Chapter**. Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when **compliance with** Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to **SMCs and** SMEs**, including start-ups**.';

(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 authority, ensuring that appropriate safeguards are in place. Such sandboxes may include testing in real world conditions supervised therein. When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan.’;

(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 EDPS 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.’;

(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 and~~ the coordination and cooperation at national and **Union**~~EU~~ level.’;

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

4. The signatories of the voluntary real-world testing agreement~~,~~ shall specify conditions of the testing in real world conditions and establish **governance and accountability arrangements and** 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.';

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

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

(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.~~

(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.';

(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.';

(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**, and that model and that system are developed by the same provider, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations of this Regulation in accordance with the tasks and

responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system**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.

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

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

1a. The authorities involved in the application of this Regulation shall cooperate actively **and afford the AI Office the necessary assistance for**~~in~~ the exercise of t~~hose~~**its** powers**, including, where necessary, in connection with inspections or other enforcement measures carried out in the territory of a Member State. To this end, the competent authorities shall enjoy the powers provided for under this Regulation and Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks under this paragraph, in accordance with the applicable national procedures. Where the AI Office finds that a person opposes or obstructs an inspection ordered pursuant to Article 75a, the national competent authority of the Member State concerned shall afford them the necessary assistance, requesting, where appropriate, the assistance of the police or an equivalent enforcement authority, to enable them to conduct their on-side inspection**~~in particular where enforcement actions need to be taken in the territory of a Member State~~**.;**

~~(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 shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the

Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated under this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (2) shall apply *mutatis mutandis* to the Commission when exercising its powers under this paragraph.

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

The following Article 75a is inserted:

'Article 75a

Investigation and enforcement in respect of AI systems supervised by the AI Office

1. When exercising its tasks of supervision and enforcement outlined in Article 75(1), the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.

2. Where the AI Office has reasonable grounds to suspect non-compliance with this Regulation of an AI system referred to in Article 75 paragraph 1, it shall adopt a decision for opening a proceeding. Upon initiating such proceedings, the AI Office shall notify the operator of the AI system concerned. For the purposes of investigating compliance of operators of the systems falling under the scope of Article 75, paragraph 1, with the obligations laid down in this Regulation, the AI Office may exercise investigatory powers, at its own initiative or following a complaint received under Article 85 of this Regulation even before opening proceedings pursuant to this paragraph.

3. In order to carry out the tasks assigned to it under this Section, the AI Office may, by simple request or by decision, require the operator to provide information that is necessary for the purpose of assessing compliance of the operator with this Regulation. When sending such requests for information to the operator concerned, the AI Office shall state the legal basis and the purpose of the request, specify what information is required and set the period within which the information is to be provided, and the fines provided for in Article 99 for supplying incorrect, incomplete or misleading information. When requesting information by decision, it shall further indicate the right to have the decision reviewed by the Court of Justice of the European Union.

4. In order to carry out the tasks assigned to it under this section, the AI Office may conduct all necessary remote or on-site inspections, announced

or unannounced. The officials of the AI Office authorised to conduct an inspection may enter any of the business premises, land or property located in the Union of the operator concerned. The operator concerned shall submit to on-site inspections ordered by decision of the Commission. The decision shall specify the subject matter and purpose of the investigation, the relevant penalties referred to in paragraph 9, and the right to have the decision reviewed by the Court of Justice of the European Union.

5. If, during proceedings under this Article, the operator concerned offers commitments to ensure compliance with the relevant provisions of this Regulation, the AI Office may by decision make those commitments binding on the operator concerned and declare that there are no further grounds for action. The AI Office may, upon request or on its own initiative, reopen the proceedings:

a) where there has been a material change in any of the facts on which the decision was based;

b) where the operator acts contrary to its commitments; or

c) where the decision was based on incomplete, incorrect or misleading information provided by the operator concerned.

Where the AI Office considers that the commitments offered by the operator concerned are unable to ensure effective compliance with the relevant provisions of this Regulation, it shall reject those commitments in a reasoned decision when concluding the proceedings.

6. The AI Office shall adopt a non-compliance decision where it finds that the operator does not comply with the relevant provisions of this Regulation, ordering, where relevant, the operator concerned to take the necessary measures to ensure compliance with the decision. Before adopting a decision of non-compliance, the AI Office shall communicate its preliminary findings to the operator concerned. In the preliminary findings, the Commission shall explain the measures that it considers taking, or that it considers that the operator concerned should take, in order to effectively address the preliminary findings. In the decision pursuant to the first sentence the AI Office shall order the operator concerned to take the necessary measures to ensure compliance with the decision within a reasonable period specified therein and to provide information on the measures that that operator intends to take to comply with the decision. The operator concerned shall provide the AI Office with a description of the measures it has taken to ensure compliance with the decision upon their implementation. Prior to requesting any measure, the AI Office may engage in a structured dialogue with the operator of the AI system in question. During this dialogue, the operator may propose commitments in accordance with paragraph 5.

7. A decision of non-compliance may be accompanied by the imposition of penalties pursuant to Article 99, which shall apply mutatis mutandis to the

AI Office in the execution of its supervision and enforcement tasks outlined in Article 75, paragraph 1, of this Regulation.

8. Where the AI Office determines that there are no grounds to adopt a decision of non-compliance, it shall close the proceeding by a decision. The decision shall apply with immediate effect.

9. The AI Office may impose periodic penalty payments to compel the persons referred to in paragraph 4 to submit to an investigation, to comply with an information request ordered by a decision adopted under paragraph 3, to submit to an on-site inspection ordered by a decision pursuant to paragraph 4, or to provide correct or complete answers or explanations in response to such an investigation, request or inspection.

10. The Commission shall adopt an implementing act to further define the enforcement powers and the procedures for the exercise of the monitoring and supervision tasks of the AI Office under this Section, including its ability to impose penalties, such as fines or other administrative sanctions as well as concerning the procedural rights outlined in Article 18 of Regulation (EU) 2019/1020. The implementing act shall also lay down the modalities of collaboration and consultation with the authorities involved in the application of this Regulation, including on the exchange of information where necessary for the effective supervision or enforcement of this Regulation.'

The following Article 75b is inserted:

'Article 75b

Judicial authorisation and fundamental rights

1. If an on-site inspection provided for in Article 75a(4) requires authorisation by a judicial authority in accordance with national law, the AI Office shall apply for such an authorisation. The AI Office may also apply for such authorisation as a precautionary measure.

2. Where an authorisation as referred to in paragraph 1 is applied for, the national judicial authority shall promptly verify that the coercive measures envisaged are neither arbitrary nor excessive having regard to the subject matter of the investigation or inspection and the documents provided by the AI Office with the decision. In its verification of the proportionality of coercive measures, the national judicial authority may ask the AI Office for detailed explanations, in particular relating to the grounds the AI Office has for suspecting that an infringement of this Regulation has taken place and the seriousness of the suspected infringement and, where relevant, the nature of the involvement of the person subject to the coercive measures. However, the national judicial authority shall not review the necessity of the investigation or inspection nor demand information from the case file of the Commission. In accordance with the Treaties, the legality of the Commission's decision is subject to review only by the Court of Justice of the European Union.

3. The powers conferred on the AI Office under Articles 75 and 75a shall not be used to require the disclosure of information or documents that are subject to legal professional privilege or journalistic material privilege, or whose disclosure would otherwise violate the Charter of Fundamental Rights.'

(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 format 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.**';

(c) the following paragraph 1a and 1b are inserted:

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

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

(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), the second subparagraph is replaced by the following:

'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.';

(b) paragraph 6 is replaced by the following:

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

(30) 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 February 2027.';

(31) Article 113 is amended as follows:

(a) in the third paragraph, point (**cd**) is ~~added~~**replaced by the following**:

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

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

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

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

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

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

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

'~~3.~~**(e)** Articles 102 to 110 shall apply from [the date of entry into ~~application~~**force** of this **amending** Regulation].';

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

(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	

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

d) <u>Agentic AI</u>

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.'.

Article 2

Amendments to Regulation (EU) 2018/1139

Regulation (EU) 2018/1139 is amended as follows:

(1) in Article 27, the following paragraph is added:

'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council[14], the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';

(2) in Article 31, the following paragraph is added:

'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';

(3) in Article 32, the following paragraph is added:

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14 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).

‘3. When adopting delegated acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.’;

(4) in Article 36, the following paragraph is added:

‘3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.’;

(5) in Article 39 the following paragraph is added:

‘3. When adopting delegated acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.’;

(6) in Article 50, the following paragraph is added:

‘3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.’;

(7) in Article 53, the following paragraph is added:

‘3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.’.

Article 3

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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