EU Digital Omnibus on AI enters force, delaying high-risk AI Act duties to 2027-28

Source copy kept by wheresthe.ai for the story “EU Digital Omnibus on AI enters force, delaying high-risk AI Act duties to 2027-28” (https://wheresthe.ai/d/eu-digital-omnibus-ai-in-force-2026-07/).

Source: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L_202601744

Text saved 18 Oct 2026 (the page as published).

SHA-256 of the saved text: b422957287c9df646b8aa5df43c51719ec76f9a00c52199a01731bcb01c35fcc

---

L_202601744EN.000101.fmx.xml

Official Journal of the European Union

EN

L series

2026/1744

24.7.2026

REGULATION (EU) 2026/1744 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 July 2026

amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 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 Central Bank（1）,

Having regard to the opinion of the European Economic and Social Committee（2）,

Having regard to the opinion of the Committee of the Regions（3）,

Acting in accordance with the ordinary legislative procedure（4）,

Whereas:

(1)

Regulation (EU) 2024/1689 of the European Parliament and of the Council（5）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 AI, 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. The entry into application of its provisions is staggered, with all rules entering into application by 2 August 2027.

(2)

The experience gathered from the implementation of the parts of Regulation (EU) 2024/1689 that already apply can inform the implementation of those parts that are yet to apply. In this context, the delayed preparation of standards, which 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 has resulted in a compliance burden that is heavier than expected. In addition, consultations of stakeholders have revealed the need for additional measures to facilitate and provide

clarification on implementation and compliance, without reducing the level of protection for health, safety and fundamental rights from AI-related risks that the provisions of Regulation (EU) 2024/1689 seek to achieve.

(3)

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.

(4)

In order to enable AI innovation in the private and public sectors, it is important that the Commission and Member States' competent authorities ensure that the supervision, enforcement and monitoring of sectoral and national laws do not create overlaps, inconsistent interpretations or divergent enforcement.

(5)

Regulation (EU) 2024/1689 lays down horizontal rules for AI systems to ensure a consistent and high level of protection of public interests as regards health safety and fundamental rights. For high-risk AI systems referred to in Article 6(1), that Regulation applies in conjunction with the Union harmonisation legislation listed in Section A of Annex I. In certain cases, it is possible for such Union harmonisation legislation to lay down requirements that achieve the same or a higher level of protection of relevant public interests as achieved by the specific requirements or obligations laid down in Regulation (EU) 2024/1689. In that case, it should be possible to limit the application of specific requirements or obligations laid down in Regulation (EU) 2024/1689 in order to facilitate compliance, minimise administrative burden and duplications, while preserving the level of protection ensured by that Regulation. Such limitation should be possible where, and to the extent that, the Union harmonisation legislation listed in Section A of Annex I lays down requirements providing for an equivalent level of protection of health, safety or fundamental rights as the requirement or obligation concerned. The Commission should be empowered to adopt delegated acts to supplement that Regulation by identifying such cases and specifying the products concerned, the requirements or obligations that may be limited, and the conditions and scope of any limitation, ensuring that the level of protection provided by Regulation (EU) 2024/1689 is not reduced.

(6)

Most Union companies are small and medium-sized enterprises, the majority of which are micro and small enterprises. Enterprises outgrowing the micro, small and medium-sized enterprises (SMEs) definition, namely the 'small mid-cap enterprises' (SMCs), play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a faster pace of growth, and a higher 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 to SMCs, it is important to address in a coherent manner the effect that Regulation may have on their activity once those enterprises become SMCs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale operators, which should be extended to SMCs where appropriate while safeguarding the overarching objectives and level of protection afforded under Regulation (EU) 2024/1689. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC (6) and Annex to Commission Recommendation (EU) 2025/1099 (7) , respectively.

(7)

The notion of a 'safety component' is crucial for the classification of certain AI systems as high-risk according to Regulation (EU) 2024/1689. Thus, the notion should be targeted to include only the AI systems which could have an adverse impact on the health and safety of persons or property, in line with the risk-based approach of that Regulation. The definition set out in Article 3, point (14) of Regulation (EU) 2024/1689 does not provide the necessary clarity to allow providers of AI systems to determine whether an AI system qualifies as a safety component and, as a result, risks extending the high-risk classification of AI systems beyond what is justified by the risk-based approach of that Regulation. It is therefore necessary to amend that definition. First, it is necessary to provide clarity on the concept of a 'safety function'. The safety function should be an intended purpose of the system, which is determined by the provider of the system. An AI system fulfils a safety function where its intended purpose, as determined by the provider, is to prevent or mitigate risks to the health and safety of persons or property. In particular, this does not include AI systems which are intended to solely fulfil functions related to

user assistance, performance optimisation, service efficiency, automation, convenience, or non-safety related aspects for quality control operations. The mere fact that an AI system is integrated into or operates within a product that is subject to Union harmonisation legislation does not, in itself, mean that it fulfils a safety function.

(8)

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. Development of AI literacy 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 skills to make informed decisions regarding the deployment of AI systems. However, experience shared by stakeholders reveals that a solution imposing stringent obligations to ensure a sufficient level of AI literacy would not be suitable for all types of providers and deployers in relation to the promotion of AI literacy. Moreover, data indicates that imposing such obligations 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 information, Article 4 of Regulation (EU) 2024/1689 should be amended to require providers and deployers to take measures to support the development of AI literacy of their staff and of other persons dealing with the operation and use of AI systems on their behalf. The Commission and Member States should support and facilitate the efforts of providers and deployers of AI systems, including through offering training opportunities, providing informational resources, and allowing exchange of good practices and other initiatives. When complying with this obligation, the Commission and the Member States could take into account the European competence frameworks, for example the Digital Competence Framework for Citizens (DigComp) and the AI Literacy Framework for Primary and Secondary Education. The European Artificial Intelligence Board (the Board) should support the Commission and Member States by adopting recommendations setting out common objectives to be achieved in order to meet their obligation and ensure regular exchange between the Commission and Member States on the topic, while the Apply AI Alliance should allow discussion with the wider community.

(9)

Bias detection and correction constitute a substantial public interest because they protect natural persons from the adverse effects of biases, including discrimination. For that reason, Regulation (EU) 2024/1689 provides a legal basis authorising providers of high-risk AI systems to process special categories of personal data in certain exceptional cases and subject to strict safeguards. This legal basis is linked to the obligation on those providers to establish practices concerning the detection, prevention and correction 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. Nevertheless, biases likely to have those effects could also result from 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. For example, biases in eligibility or risk-scoring tools used to assess applications for various types of public permits or licences can restrict rights or effectively prevent certain groups from accessing public services. Accordingly, a substantial public interest exists to allow, exceptionally and where strictly necessary, the processing of special categories of personal data for the purposes of bias detection and correction to providers and deployers of other AI systems and models and deployers of high-risk AI systems. It is therefore necessary to extend the legal basis, established pursuant to Regulation (EU) 2024/1689, to those providers and deployers. That legal basis should be subject to the same limitations, conditions and safeguards that apply in accordance with the existing Article 10(5) of that Regulation, thereby ensuring compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 of the European Parliament and of the Council (8) , Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council (9) and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council (10) . Furthermore, to enable providers of high-risk AI systems to lawfully undertake bias detection and correction activities in preparation for compliance with the requirements for high-risk AI systems, including Article 10(2), points (f) and (g), of Regulation (EU) 2024/1689, the legal basis established by Article 4a of Regulation (EU) 2024/1689 should apply from the date of entry into application of that Regulation.

(10)

Article 5 of Regulation (EU) 2024/1689 prohibits certain practices of AI systems that are particularly harmful and abusive, contradict certain Union values and violate certain fundamental rights. Article 5 is to be kept under review, as laid down in Article 112(1) of that Regulation. In light of technological and societal developments since the adoption of that Regulation, including the deployment and widespread use of AI systems generating non-consensual intimate images, videos, audio and similar material (‘non-consensual intimate material’) and child

sexual abuse material, it is necessary to amend Article 5 of that Regulation.

(11)

Non-consensual intimate material constitutes sexual violence and abuse against individuals, in particular women. AI systems that generate or manipulate such material pose a severe risk to health safety and fundamental rights, including victims' human dignity, personal autonomy, integrity and private life, with potentially serious lasting psychological and other harms, and enable abuse at scale. The proliferation of such technologies, often described as 'nudification' applications, has created an urgent need for an explicit regulatory prohibition. Child sexual abuse material, including wholly or partially synthetic material, constitutes a grave threat to the safety and fundamental rights of children. AI systems generating or manipulating such material pose a grave risk to human dignity and the rights of the child, and risk normalising, amplifying and perpetuating sexual violence against children. Accordingly, an amendment to Article 5 of Regulation (EU) 2024/1689 is necessary both to protect women, children, other individuals and society from seriously harmful practices, thereby pursuing the objectives of that Regulation, and to bring clarity to providers and deployers as to the scope of their obligations, thereby addressing implementation challenges.

(12)

It is necessary to define clearly the scope of the prohibition, including in particular the extent of providers' and deployers' obligations. This prohibition should not prevent providers from developing the technical capabilities of AI systems to generate or manipulate images, videos, audio or similar material. As concerns providers, the prohibition should be limited to the placing on the market or the putting into service of AI systems that generate or manipulate non-consensual intimate material or child sexual abuse material in two cases. First, it should cover systems intended to generate or manipulate such material. Second, it should cover systems where such generation or manipulation is a reasonably foreseeable and reproducible outcome and there are no reasonable and adequate technical safety measures and other safeguards in place, taking into account reasonably foreseeable misuse, to reliably prevent, and where necessary correct, that outcome and correct observed or reported misuse, including circumvention of such measures. Technical measures and other safeguards to prevent the generation of such material could include data cleaning, refusal training, safe prompt design and output controls, runtime prompt guardrails, content classification and filtering mechanisms, usage restrictions, abuse detection mechanisms, and notice and action mechanisms. Such preventive measures should be reasonable for the specific AI system, and are considered adequate if they align with the state-of-the-art measures and demonstrably prevent or sufficiently reduce in each specific case the likelihood of generating or manipulating such material, taking into account known and reasonably foreseeable misuse, including reasonably foreseeable circumvention of the preventive measures without significant technical modification. For providers retaining effective control over AI systems, for instance through a platform or a web interface, that could include following and reporting methods for misuse cases in full compliance with Union privacy and data protection law. In cases of observed or reported circumvention of the preventive measures or other safeguards, adequate corrective measures should be taken provided that such measures are reasonable, taking into account the specific AI system, including its release and distribution strategy (such as open-source releases). As concerns deployers, the use of an AI system should be prohibited only where the deployer uses an AI system for the purpose of generating or manipulating non-consensual intimate material or child sexual abuse material. This includes cases where a deployer uses or misuses AI systems placed on the market or put into service that lack reasonable and adequate preventive measures or where a deployer circumvents the preventive measures or uses for such purposes lawful AI systems not intended to generate or manipulate such material. The prohibition on use therefore does not cover the use of an AI system for lawful purposes, such as the generation or manipulation of material other than non-consensual intimate material or child sexual abuse material, even in cases where the AI system lacks reasonable and adequate safeguards that should have been put in place by the provider, nor does it cover accidental generation or manipulation of such content. Concerning the prohibition regarding non-consensual intimate material, where an AI system is intended for generation or manipulation of material falling under this prohibition, measures and other safeguards should include appropriate means for the distribution of the AI system aimed at enabling the reliable collection and demonstration of consent of the depicted person to such generation or manipulation, in compliance with Regulation (EU) 2016/679. The prohibition regarding non-consensual intimate material should be limited to realistic depictions of intimate parts, notably the genitals, pubic area, anus, exposed buttocks or exposed female breasts, nipples or areolae, or of sexually explicit activity. This 'realism' refers to the depiction of the person's face, voice or their body in a credible real-life manner, regardless of the realism of the context of that depiction or whether it fully corresponds to the actual voice or appearance of the depicted person.

Conversely, it excludes cartoonish or physically impossible depictions of a person's body. The prohibition of non-consensual intimate material does not affect the generation or manipulation of other forms of nude material, such as material that does not depict identifiable natural persons, realistic partially nude depictions where intimate parts are not revealed and sexually explicit activities are not depicted, or non-realistic artistic nude works that do not realistically depict identifiable natural persons engaged in sexually explicit activity or depict their intimate parts. It also does not cover generative AI applications where intimate parts are not exposed or, if exposed, this is subject to the freely given, specific, informed, unambiguous and explicit consent of the depicted person (for example, try-on applications and medical applications, such as medical anatomical simulations and mammograms); this prohibition does not preclude the exceptional use of AI systems generating or manipulating nude depictions of the intimate parts of an identifiable person, in accordance with fundamental rights law, including data protection law, and applicable medical law, for the purpose of medical diagnosis and treatment by medical professionals where the person concerned is incapable of consent (for instance in an emergency situation). Finally, the prohibition on 'manipulating' non-consensual intimate material excludes cases where pre-existing intimate material is manipulated in a way that does not increase the exposure of any depicted intimate parts or alter the nature of any depicted sexually explicit activities, for instance the mere enhancement of an existing image depicting intimate parts or video depicting sexually explicit activities, such as changing the background, adding a text heading or enhancing the contrast or the brightness. Conversely, any manipulation of material, including material that already depicts intimate parts or sexually explicit activity, that increases the level of exposure of any depicted intimate parts or alters the nature of any depicted sexually explicit activities, falls under the scope of this prohibition.

(13)

The prohibition on child sexual abuse material should not prevent the placing on the market, putting into service or use of an AI system where a 'without right' defence applies under national law, as referred to in Article 5(1) of Directive 2011/93/EU of the European Parliament and of the Council (11) . This includes activities carried out under domestic legal powers, such as the legitimate generation, or manipulation of child sexual abuse material by the authorities in order to conduct criminal proceedings or to prevent, detect or investigate crime, as well as the legitimate use of the AI system in the context of red-teaming and evaluation activities for the purpose of assessing the system's compliance with the prohibition laid down in this Regulation.

(14)

These prohibitions constitute justified interferences with the freedom of expression and information and the freedom to conduct a business. They pursue objectives of general interest and protect the rights and freedoms of others, including those set out in Article 1, Article 3(1) and Articles 4, 7, 8, 21, 23 and 24 of the Charter of Fundamental Rights of the European Union (the Charter). They are closely tailored. In the case of intimate material, they are limited to realistic depictions of identifiable natural persons and to cases where the AI system is used to increase the level of nudity or explicitness; and exclude generation or manipulation with the person's consent. Moreover, they are limited to requiring providers to implement 'reasonable and adequate' measures and safeguards in the case of systems not intended to generate or manipulate the prohibited material. They are also aligned with existing Union law, including Directive 2011/93/EU and Directive (EU) 2024/1385 of the European Parliament and of the Council (12) . The interferences respect the essence of Articles 11 and 16 of the Charter, are prescribed by law, and are proportionate.

(15)

The conduct covered by these prohibitions may also violate other law, including criminal law. The prohibitions do not preclude prosecution under such law. However, insofar as an infringement of the prohibitions may result in the imposition of penalties of a criminal nature, which may be laid down pursuant to Article 99(1) of Regulation (EU) 2024/1689, and to the extent that the same conduct is sanctioned under criminal law, including criminal law falling within the scope of Directives 2011/93/EU and (EU) 2024/1385, Member States are required to ensure respect for the ne bis in idem principle in accordance with the Charter.

(16)

The prohibitions are without prejudice to remedies available under national laws for individuals to protect their fundamental rights, including rights to their image, privacy and human dignity.

(17)

In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to the procedure

for the designation of notified bodies pursuant to Regulation (EU) 2024/1689, while maintaining the same level of scrutiny, a single application and a unified assessment procedure should be available for new conformity assessment bodies and notified bodies which are designated pursuant to the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, such as Regulations (EU) 2017/745 (13) and (EU) 2017/746 (14) of the European Parliament and of the Council, where such an application and procedure is established pursuant to that Union harmonisation legislation. The single application and unified assessment procedure aims to facilitate, support and expedite the designation procedure in accordance with Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies in accordance with that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto. The unified assessment procedure should be carried out with respect to the tasks and responsibilities of the authorities involved. Moreover, it should be clarified that a conformity assessment body that is designated pursuant to more than one piece of Union harmonisation legislation listed in Section A of Annex I should have to apply only once to be designated pursuant to this Regulation.

(18)

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 made 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 the 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 pursuant to that Regulation as part of the quality management systems pursuant to such Union harmonisation legislation, in accordance with Article 17(3) of Regulation (EU) 2024/1689. Article 43(3), second subparagraph, of that Regulation should be amended to clarify that notified bodies which have been notified pursuant to 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 have the power to assess the conformity of high-risk AI systems under certain conditions for 18 months from 27 July 2026. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689, thus conformity assessment bodies that wish to be designated and notified pursuant to that Regulation can submit an application at any time during and after these 18 months. 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.

(19)

Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847 of the European Parliament and of the Council (15) complement each other so that the safety and cybersecurity of products with digital elements is ensured. Article 12 of Regulation (EU) 2024/2847 states that where high-risk AI systems and processes put in place by manufacturers 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. In order to improve the visibility of the interplay of Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847, the rule of Article 12 of Regulation (EU) 2024/2847 should also be reflected in Regulation (EU) 2024/1689. The interplay between the two instruments should not be affected.

(20)

In accordance with Article 6(1) of Regulation (EU) 2024/1689, AI systems are classified as high-risk where an AI system that is a component of a product covered by Union harmonisation legislation listed in Section A of Annex I to that Regulation is a safety component and that product requires a third-party conformity assessment. The requirement that such product must require a third-party conformity assessment, however, does not affect the choice of the manufacturer regarding the conformity assessment procedure for such product. Where Union harmonisation legislation listed in Section A of Annex I allows to choose a conformity assessment procedure based on harmonised standards amongst conformity assessment procedures, this possibility remains applicable also to products in which a high-risk AI system is embedded. Article 6(1) of Regulation (EU) 2024/1689 should not

be understood to require products in which a high-risk AI system is embedded to automatically undergo a third-party conformity assessment involving a notified body. Where this possibility is provided for in Union harmonisation legislation, the provider of the product in which the high-risk AI system is embedded could continue to rely on harmonised standards to comply with the requirements of the Union harmonisation legislation and Regulation (EU) 2024/1689 as a conformity assessment procedure.

(21)

In order to enhance competitiveness and innovation, it is essential to support economic operators that are required to comply simultaneously with the requirements or obligations set out in Chapter III, Sections 2 and 3 of Regulation (EU) 2024/1689, and with the relevant requirements and obligations laid down in the Union harmonisation legislation listed in Annex I to that Regulation. To support and simplify the regulatory compliance pathways of such economic operators, the Commission should request that, without undue delay, the European standardisation organisations develop standardisation deliverables, including, where appropriate, harmonised standards. Those standardisation deliverables should be based on the harmonised standards published in the Official Journal of the European Union that give the presumption of conformity with the requirements or obligations of Regulation (EU) 2024/1689, as well as any relevant harmonised standards published in the Official Journal of the European Union that give the presumption of conformity with the relevant requirements or obligations set out in the Union harmonisation legislation listed in Annex I to that Regulation. Such standardisation deliverables should help reduce legal uncertainty, avoid unnecessary duplication of conformity assessment activities, testing, documentation and reporting obligations, and lower compliance costs, in particular for small and medium-sized enterprises and start-ups. Timely development of such deliverables is essential in order to provide economic operators with practical and reliable technical solutions, strengthen legal certainty and facilitate the placing on the market, putting into service and use of AI systems in accordance with this Regulation and the Union harmonisation legislation listed in Annex I to that Regulation.

(22)

To streamline compliance and reduce associated costs, the registration of AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation should be simplified by streamlining the content required under 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 would strike a better balance without undermining the protection laid down by Regulation (EU) 2024/1689. Such AI systems are not considered to be high risk under certain conditions where they do not pose a significant risk of harm to the health, safety or fundamental rights of persons. Furthermore, a provider applying Article 6(3) of Regulation (EU) 2024/1689 remains obligated to document its assessment before that AI system is placed on the market or put into service. National competent authorities should be able to request that assessment.

(23)

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 also include real-world testing, the real-world testing plan should be integrated into the sandbox plan agreed by the providers or prospective providers and the competent authority.

(24)

In addition, it is appropriate to provide for the possibility of the European Artificial Intelligence Office (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. To ensure coherence, legal certainty and an efficient allocation of supervisory responsibilities between Union and national levels, the scope of the Union-level AI regulatory sandbox should be clearly defined in order to avoid any overlap with national AI regulatory sandboxes established pursuant to that Regulation. 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.

(25)

Moreover, the provisions on the cooperation between relevant competent authorities for the operation of an AI regulatory sandbox should be clarified in order to ensure their effective functioning. For that reason, the empowerment of the Commission to adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation and supervision of the AI regulatory sandboxes should be extended to also cover governance aspects of such sandboxes. In addition, where AI regulatory sandboxes involve innovative AI systems that process personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the relevant competent supervisory authorities should be associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.

(26)

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, subject to sufficient safeguards. 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.

(27)

It is also appropriate to ensure that real-world testing of high-risk AI systems covered by the Union harmonisation legislation listed in Section B of Annex I to Regulation (EU) 2024/1689 is possible. Those systems are subject to the requirements and procedures of the relevant sectoral legislation and are, for most purposes, not directly subject to that Regulation. Those sectoral acts will, in due course, incorporate requirements corresponding to the requirements set out in Articles 8 to 15 of that Regulation. Therefore, it is appropriate to ensure that Member States can allow real-world testing of these AI systems with a view to assessing and verifying the conformity of those systems with the requirements set out in Articles 8 to 15 of that Regulation. If Member States decide to allow such testing, that Regulation should require them to adopt frameworks setting out the detailed requirements for such testing. That Regulation should provide for essential elements to be contained in such frameworks. When designing such frameworks, Member States should ensure a high level of protection of health safety and fundamental rights of natural persons. Before implementing the framework, Member States should notify it to the Commission. The real-world testing should comply with the relevant Union harmonisation legislation listed in Section B of Annex I to Regulation (EU) 2024/1689, including any applicable provisions regarding testing. However, this should not affect the application of the new article regarding real-world testing.

(28)

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.

(29)

In light of the important role of the AI Office for the effective and coordinated governance of Regulation (EU) 2024/1689, as further reinforced by this Regulation, and without prejudice to the next Multiannual Financial Framework and to the budgetary procedure, the Commission should allocate adequate human, financial and technical resources to the AI Office to ensure that it can effectively, and within reasonable timeframes, perform its tasks in relation to the enforcement of Regulation (EU) 2024/1689, including the allocation of a sufficient number of permanent personnel with in-depth competences and technical expertise.

(30)

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 to the experts should be equivalent to the remuneration the Commission is obliged to pay in similar circumstances.

(31)

In order to strengthen the governance system for AI systems, it is necessary to clarify the role of the AI Office in

monitoring and supervising the compliance of such AI systems with Regulation (EU) 2024/1689. The Commission has exclusive competence as regards general-purpose AI models under Article 88 of that Regulation. To increase coherence, clarity and effectiveness, and in light of the reach and impacts of AI systems linked to those competences, the scope of the AI Office's exclusive competence to supervise systems should be refined. In particular, the AI Office should have exclusive competence over AI systems built on general-purpose AI models, not only where both the system and the model are developed by the same provider, but also where they are developed by providers that form part of the same undertaking. However, in certain cases, in particular where there is specific sectoral supervision, responsibility should remain with the relevant national competent authority. Accordingly, certain exceptions should be laid down. The personal scope of this exclusive competence should extend to the providers of those AI systems and to their deployers within the same undertaking. Other deployers should remain subject to national supervision and enforcement. Moreover, 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.

(32)

Additionally, considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council (16) , it is appropriate to grant the Commission the powers of a competent market surveillance authority pursuant to Regulation (EU) 2024/1689 where an AI system qualifies as a very large online platform or a very large online search engine in accordance with 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 pursuant to 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, is carried out in a coherent and effective manner. This is also appropriate in light of the importance of such platforms and search engines, in view of their reach, impact and potential to cause complex and large societal harms. The personal scope of this exclusive competence should extend to the providers of those AI systems and to their deployers within the same undertaking. 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 Regulation (EU) 2024/1689. 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 in accordance with Regulation (EU) 2024/1689 and the applicability of prohibitions pursuant to Regulation (EU) 2024/1689. In addition, the AI Office and the competent national authorities should, in accordance with Regulation (EU) 2024/1689, 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 ne bis in idem are respected, while information obtained pursuant to one Regulation is to 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.

(33)

When supervising and enforcing obligations in relation to AI systems under its competence, the AI Office has the same role and responsibility as a market surveillance authority pursuant to Regulation (EU) 2024/1689. Consequently, it is necessary for the AI Office to have all of the powers and responsibilities that market surveillance authorities have pursuant to that Regulation and Regulation (EU) 2019/1020 of the European Parliament and of the Council (17) ('the general powers'). These should ensure the appropriate and effective enforcement of the requirements and obligations set out in Regulation (EU) 2024/1689. However, it is necessary to specify, complement, and frame certain essential elements and other aspects of the general powers, as well as their safeguards ('the specifying provisions'). In particular, it is necessary to lay down provisions governing the relationship between the AI Office and national authorities; provisions specifying, complementing, and constraining the powers to request information and conduct on-site inspections; provisions governing

investigations, including the possibility to make commitments binding; and provisions specifying and constraining power to find non-compliance, impose fines and impose periodic penalties. Where a type of general power has been so specified, the AI Office may not circumvent the conditions and limits of those powers by relying on a related general power. Conversely, types of general power that are not specified and framed in respect of the AI Office, such as the power to adopt measures referred to in Article 16(3) of Regulation (EU) 2019/1020, may be relied on by the AI Office. As necessary for the proper implementation of Regulation (EU) 2024/1689, the Commission should be able to adopt implementing acts further defining the rules and the procedures concerning the application of limitation periods and, the access to the file and the negotiated disclosure of information. In exercising all of these powers, the AI Office must comply with the Charter. Additionally, the AI Office is subject to the safeguards and protection for fundamental rights laid down in the specifying provisions.

(34)

In addition to those procedural and fundamental rights safeguards 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. When national market surveillance authorities, through the single point of contact, request that the AI Office takes supervisory and enforcement measures with regards to AI systems under its exclusive supervision, the AI Office should no later than four months following the receipt of that request, inform the single point of contact of its intention to exercise its supervisory and enforcement powers or of its reasons for not exercising its powers. If the AI Office decides to exercise its supervisory and enforcement powers, it should also inform the single point of contact about the final outcome of such proceedings and of intermediate developments that the AI Office considers as having a major impact in the investigation, including the decision to open proceedings, to impose a fine, and to withdraw or recall the AI system from the market.

(35)

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

(36)

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 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 authorities or bodies involved 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, 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 Union or national law.

(37)

The requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 address specific risks inherent to AI systems, including bias, unpredictable model behaviour, poor robustness or accuracy, vulnerabilities to attacks by third parties, and a lack of transparency of the AI system. By addressing AI-specific risks, that Regulation complements the requirements laid down in Union harmonisation legislation listed in Annex I to that Regulation, without duplicating them. Regulation (EU) 2024/1689 provides mechanisms for economic operators to minimise the compliance burden. In particular, Article 8(2) on the interplay with the sectoral legislation, Article 9(10) on risk management and Article 17(3) on quality management, allow economic operators to integrate, when necessary and appropriate, an assessment of AI-specific risks into existing risk and quality management systems. Article 40 of Regulation (EU) 2024/1689 further requires the Commission to specify that harmonised standards developed pursuant to that Regulation are to be consistent with standards developed pursuant to the Union harmonisation legislation listed in Annex I to that Regulation. The Commission should provide guidelines to

assist economic operators of high-risk AI systems covered in Annex I to Regulation (EU) 2024/1689 in complying with that Regulation, including by providing guidance on the application of Article 8(2), Article 9(10) and Article 17(3) of that Regulation as mechanisms to minimise the compliance burden, in line with principles of complementarity and proportionality. Those guidelines should be published, at the latest, by 1 August 2027.

(38)

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 four months for providers who have already placed their systems on the market before the 2 August 2026.

(39)

To provide sufficient time for providers of high-risk AI systems and to clarify rules applicable to the AI systems already placed on the market or put into service before the relevant provisions of Regulation (EU) 2024/1689 apply, it is appropriate to clarify the scope of the grace period provided in Article 111(2) of that Regulation. For the purpose of that Article 111(2), the grace period should apply where the type and model of AI system has already been placed on 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 that 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 the 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 fully comply with all relevant provisions of that Regulation applicable to high-risk AI systems, including the conformity assessment requirements.

(40)

Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, in particular 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 the effective entry into application of those obligations and that risk a significant increase in implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. Therefore, it is appropriate that the date of application of Sections 1, 2 and 3 of Chapter III is set 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. 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. The timely availability of support instruments, including guidance, relevant standards, common specifications and codes of practice is important in order to facilitate compliance and reduce the risk of divergent interpretation and uneven application of the rules across Member States. In order to ensure legal certainty and to avoid further delays in the application of Regulation (EU) 2024/1689, the Commission should ensure that measures in support of compliance with regard to Chapter III, Sections 1, 2, and 3 of that Regulation are in place in due time to ensure timely and effective implementation of the necessary provisions.

(41)

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 that is not the case. Article 50(7), Article 56(6), and Article 72(3) of Regulation (EU) 2024/1689 should therefore be amended to remove the empowerments conferred on the Commission to adopt implementing acts. Given that the codes of

practice referred to in Article 50(7) and Article 56(6) have limited legal effect, and in particular do not grant a presumption of conformity, it is not strictly necessary for these codes to be approved by an implementing act. Providers should be able to rely, pursuant to Article 53(4) and Article 54(2) of Regulation (EU) 2024/1689, on codes of practice assessed as adequate pursuant to Article 56(6) thereof. 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 the additional benefit of offering 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 regarding how providers of high-risk AI systems are required to comply with their obligation set out in Article 72(1) of Regulation (EU) 2024/1689, the Commission should be required to publish guidance, including a voluntary template, on the post-market monitoring plan by 2 September 2027.

(42)

The use of artificial intelligence in machinery can help foster innovation and improve the efficiency of those machines. The application of Regulation (EU) 2023/1230 of the European Parliament and of the Council (18) and Regulation (EU) 2024/1689 might lead to overlaps. At the same time, it is important to ensure a level of protection with regard to risks related to the use of artificial intelligence in machinery that is consistent with the level of protection provided in Regulation (EU) 2024/1689 with regard to high-risk AI systems. Given the specific nature of machinery and the machinery sector, and in order to address the need to simplify the regulatory framework for AI-enabled machinery, it is appropriate to move to a sectoral approach by moving Regulation (EU) 2023/1230 from Section A to Section B of Annex I to Regulation (EU) 2024/1689. Accordingly, first, the application of Regulation (EU) 2024/1689 to those machines should be limited to the provisions referred to in Article 2(2) of that Regulation. The reference to Directive 2006/42/EC should be moved from Section A to Section B of Annex I to Regulation (EU) 2024/1689 and updated so as to refer to Regulation (EU) 2023/1230. Second, it is crucial to ensure that Regulation (EU) 2023/1230 incorporates essential health and safety requirements for high-risk AI systems classified pursuant to Article 6(1) of Regulation (EU) 2024/1689 and used as a safety component in machinery or high-risk AI systems constituting machinery that ensure a level of protection consistent with Regulation (EU) 2024/1689. To that end, the Commission should be required to adopt delegated acts amending Annex III to Regulation (EU) 2023/1230 in order to reflect the relevant requirements set out in Chapter III, Section 2, and Articles 17, 19, 72 and 73 of Regulation (EU) 2024/1689. To avoid a legal gap and ensure alignment with the entry into application of the relevant high-risk AI system rules set out in Regulation (EU) 2024/1689, those delegated acts should apply by 2 August 2028. For the same reasons, manufacturers should be free to rely on harmonised standards or common specifications referenced or adopted pursuant to Regulation (EU) 2024/1689 that cover the relevant essential requirements for the presumption of conformity within the meaning of Article 20 of Regulation (EU) 2023/1230 until harmonised standards or common specifications regarding AI are referenced or adopted pursuant to Regulation (EU) 2023/1230.

(43)

Conformity assessments of high-risk AI systems pursuant to Regulation (EU) 2024/1689 can require the involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated pursuant to that Regulation are able to 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 pursuant to 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 to Regulation (EU) 2024/1689 (referred to as ‘AIP codes’, for AI systems covered by product legislation), or a system listed in Annex III to that Regulation, 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 that provide a link to the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689. The AIB codes are new codes specific to Regulation (EU) 2024/1689 that identify biometric AI systems referred to in point (1) of Annex III to 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 the underlying types and technologies of AI systems. The list of codes, comprising 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 in regard to the AI systems they are required to assess.

(44)

Regulation (EU) 2018/1139 of the European Parliament and the Council (19) lays down common rules in the field of civil aviation. Article 108 of Regulation (EU) 2024/1689 amends Regulation (EU) 2018/1139 to ensure that the Commission, when adopting any relevant delegated or implementing acts pursuant to Regulation (EU) 2018/1139, 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. A technical correction to amend additional Articles of Regulation (EU) 2018/1139 is necessary to ensure that the mandatory requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 are fully covered when adopting relevant delegated or implementing acts pursuant to Regulation (EU) 2018/1139.

(45)

In order to amend certain non-essential elements of Regulations (EU) 2024/1689 and (EU) 2023/1230, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of:

—

limiting the application of specific requirements or obligations laid down in Regulation (EU) 2024/1689 where Union harmonisation legislation listed in Section A of Annex I of that Regulation lays down requirements providing for an equivalent level of protection,

—

amending the list of codes, categories, and corresponding types of AI systems in Annex XIV of Regulation (EU) 2024/1689, and

—

amending Annex III of Regulation (EU) 2023/1230 to reflect the relevant requirements of Regulation (EU) 2024/1689.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (20) . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(46)

In order to ensure legal certainty without delay, with a view to the imminent general application of Regulation (EU) 2024/1689, this Regulation should enter into force as a matter of urgency on the third day following that of its publication in the Official Journal of the European Union .

(47)

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)

Article 2 is amended as follows:

(a)

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 and Articles 102 to 112 shall apply. Articles 57, 58 and 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.’

;

(b)

paragraph 7 is replaced by the following:

‘7. Union law on the protection of personal data, privacy and the confidentiality of communications applies to personal data processed in connection with the rights and obligations laid down in this Regulation. Without prejudice to Articles 4a and 59 of this Regulation, this Regulation shall not affect Regulation (EU) 2016/679 or (EU) 2018/1725, or Directive 2002/58/EC or (EU) 2016/680.’

;

(3)

in Article 2, the following paragraph is added:

‘13. For high-risk AI systems referred to in Article 6(1), the application of specific requirements or obligations laid down in Articles 9 to 15 and 17 to 25 may be limited, where and to the extent that:

(a)

Union harmonisation legislation listed in Section A of Annex I lays down requirements or obligations providing an equivalent or higher level of protection of health, safety or fundamental rights as the requirement or obligation concerned; and

(b)

such limitation does not reduce the overall level of protection provided for by this Regulation.

By 2 August 2027, the Commission shall adopt delegated acts in accordance with Article 97 in order to supplement this Regulation by specifying the high-risk AI systems concerned, the requirements or obligations that may be limited, the conditions under which such limitation applies, and the scope of the limitation.’

;

(4)

Article 3 is amended as follows:

(a)

point (14) is amended as follows:

‘(14)

“safety component” means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property; for the purposes of this definition, a component fulfils a safety function where its intended purpose is to prevent or mitigate risks to health and safety of persons or property;’

;

(b)

the following points are inserted:

‘(14a)

“micro, small and medium-sized enterprise” or “SME” means a micro, small or medium-sized enterprise as defined in Article 2 of the Annex to Recommendation 2003/361/EC;

(14b)

“small mid-cap enterprise” or “SMC” means a small mid-cap enterprise as defined in point (2) of the Annex to Recommendation (EU) 2025/1099;’

;

(5)

Article 4 is replaced by the following:

‘Article 4

AI literacy

1. Providers and deployers of AI systems shall take measures to support the development of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used. This obligation does not require providers or deployers to guarantee any specific level of AI literacy of any individual.

2. The Commission and the Member States shall support and facilitate the efforts of providers and deployers of AI systems, in particular SMEs, in fulfilling their obligation under paragraph 1 of this Article. For that purpose, the Commission shall publish practical examples of how to comply with that obligation on the single information platform referred to in Article 62(3), point (b).

3. The Board shall adopt recommendations, taking into account European competence frameworks, to support the Commission and Member States in the promotion of AI literacy required under paragraph 1, including by setting out common objectives.’

;

(6)

the following Article is inserted:

‘Article 4a

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

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 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 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 and protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and to 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; and

(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 strictly necessary to detect and correct biases, and why that objective could not be achieved by processing other data.

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)

such 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 pursuant to 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.’

;

(7)

Article 5 is amended as follows:

(a)

in paragraph 1, the first subparagraph, the following points are inserted:

‘(ba)

the placing on the market, the putting into service or the use of an AI system that generates or manipulates realistic images, videos, audio or similar material of an identifiable natural person’s intimate parts, or of an identifiable natural person engaged in sexually explicit activities, without that person’s freely-given, specific, informed, unambiguous and explicit consent for that generation or manipulation;

(bb)

the placing on the market, the putting into service or the use of an AI system that generates or manipulates material or performance within the meaning of Article 2, points (c) and (e), of Directive 2011/93/EU, except where a “without right” defence applies under national law;’

;

(b)

the following paragraphs are inserted:

‘1a. For the purposes of paragraph 1, first subparagraph, points (ba) and (bb):

(a)

the placing on the market or putting into service of an AI system that generates or manipulates the material or performance referred to in paragraph 1, first subparagraph, point (ba) or (bb) is only prohibited where:

(i)

that generation or manipulation is the intended purpose of the AI system; or

(ii)

the system's design, training, architecture, capabilities or user-facing functionalities make that generation or manipulation a reasonably foreseeable and reproducible outcome, without requiring significant technical modification, and the system does not have reasonable and adequate technical safety measures and other safeguards to reliably prevent that generation or manipulation, taking into account reasonably foreseeable misuse, and to correct observed or reported misuse;

(b)

the use of an AI system that generates or manipulates the material or performance referred to in paragraph 1, first subparagraph, points (ba) and (bb) is only prohibited where the deployer uses the system for the purpose of generating or manipulating such material or performance.

1b. For the purposes of paragraph 1, first subparagraph, point (ba), an AI system that manipulates material in a way that does not increase the exposure of any depicted intimate parts or alter the nature of any depicted sexually explicit activities shall not constitute manipulation.'

;

(8)

in Article 6, the following paragraphs are inserted:

'1a. For the purposes of this Regulation, including paragraph 1 of this Article, AI systems that are solely used for non-safety related aspects of user assistance, performance optimisation, service efficiency, automation or convenience or quality control shall not qualify as safety components.

1b. Notwithstanding paragraph 1a, AI systems the failure or malfunctioning of which would endanger health and safety shall qualify as safety components.

1c. A product that is required to undergo a third-party conformity assessment solely due to risks other than risks to health and safety, in particular risks relating to the distribution of radio spectrum or electromagnetic interference that do not affect health and safety, shall not be considered as fulfilling the condition in paragraph 1, point (b).'

;

(9)

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.’

;

(10)

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. SMEs, including start-ups, and SMCs, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of SMEs, including start-ups, and SMCs. Where an SME, including a start-up, or an SMC, 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.’ ;

(11)

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 SME, including a start-up, or an SMC. 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.’

;

(12)

Article 25 is amended as follows:

(a)

paragraph 2 is replaced by the following:

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

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

In particular, the obligation laid down in the second subparagraph shall include, where relevant for the purposes specified therein, the following:

(a)

making available of technical documentation sufficient to assess compliance with the requirements laid down in Article 16;

(b)

informing the new providers about known limitations and failure modes; and

(c)

providing the new providers with targeted technical access, including for testing and validation.

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 cooperate with the new providers and hand over the documentation.’

;

(b)

in paragraph 4, the first subparagraph is replaced by the following:

‘4. The provider of a high-risk AI system and the third party that supplies an AI system, AI model, tools, services, components, or processes that are used or integrated in a high-risk AI system shall, by written agreement, specify the necessary information, capabilities, technical access and other assistance based on the generally acknowledged state of the art, in order to enable the provider of the high-risk AI system to fully comply with the obligations set out in this Regulation. This paragraph shall not apply to third parties making accessible to the public tools, services, processes, or components, other than general-purpose AI models, under a free and open-source licence.’

;

(13)

Article 27 is amended as follows:

(a)

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 may, when conducting the fundamental rights impact assessment referred to in paragraph 1 of this Article, include cross-references to the relevant sections of that data protection impact assessment or include relevant parts thereof in the fundamental rights impact assessment.’

;

(b)

paragraph 5 is replaced by the following:

‘5. The AI Office shall develop a template for a questionnaire, including through an automated tool, to facilitate deployers in complying with their obligations under this Article in a simplified manner. This template shall, where relevant, give deployers the possibility to include cross-references to the relevant sections of the data protection impact assessment or include relevant parts thereof in the fundamental rights impact assessment pursuant to paragraph 4.’

;

(14)

in Article 28, the following paragraphs are added:

‘8. Notifying authorities designated pursuant to this Regulation that are responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall ensure that the conformity assessment body that applies for designation both pursuant to this Regulation and the Union harmonisation legislation listed in Section A of Annex I is provided with the possibility to submit a single application and undergoes a unified assessment procedure to be designated pursuant to 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 unified assessment procedure. To that end, notifying authorities designated pursuant to this Regulation and those designated pursuant to the Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments.

The single application and the unified assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated pursuant to the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation pursuant to this Regulation, provided that the relevant Union harmonisation legislation provides for such a procedure.

A conformity assessment body that is designated pursuant to more than one piece of Union harmonisation legislation listed in Section A of Annex I shall have to apply only once to be designated pursuant to this

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

9. A notifying authority that has been designated pursuant to the Union harmonisation legislation listed in Section A of Annex I is also the notifying authority for the application of the single application and unified assessment procedure referred to in paragraph 8, unless the Member State designates another notifying authority for this Regulation.'

;

(15)

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

'4. For notified bodies which are designated pursuant to 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 pursuant to any of the Union harmonisation legislation listed in Section A of Annex I and which undergo the unified assessment procedure referred to in Article 28(8), shall submit the single application for assessment to the notifying authority designated pursuant to 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.'

;

(16)

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 in order to amend Annex XIV, in 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.'

;

(17)

in Article 40(2), the following subparagraph is added:

'The Commission shall request, in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council (*1) and without undue delay, the European standardisation organisations to develop standardisation deliverables, including, as appropriate, harmonised standards, to facilitate the joint compliance and presumption of conformity with the requirements or obligations set out in Chapter III, Sections 2 and 3 of this Regulation, and the relevant requirements and obligations laid down in the Union harmonisation legislation listed in Annex I to this Regulation.'

(*1) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/

EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12 , ELI: http://data.europa.eu/eli/reg/2012/1025/oj)."

;

(18)

in Article 42, the following paragraph is added:

‘3. Where high-risk AI systems fall within the scope of Regulation (EU) 2024/2847 and the conditions laid down in Article 12(1) of that Regulation are fulfilled, such systems shall be deemed to comply with the cybersecurity requirements set out in Article 15 of this Regulation.’

;

(19)

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

‘3. 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 in accordance with 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 shall also be undertaken, and points 3, 4.3, 4.4. and 4.5, the fifth paragraph of point 4.6 and point 5 of Annex VII shall 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 of this Chapter, 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 in accordance with the relevant Union harmonisation legislation, which is evidenced through the assessment as part of the existing notification. 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 of this Chapter by 28 January 2028.

Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option to rely on a conformity assessment that does not involve a third-party, provided that that manufacturer has applied harmonised standards to ensure compliance with 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. The classification of a product as a high-risk AI system in accordance with Article 6(1) does not affect the choice of the conformity assessment procedure provided to the manufacturers of products covered by Union harmonisation legislation listed in Section A of Annex I, including, where applicable, an option to rely on harmonised standards. The manufacturers of such products are not required to choose a conformity assessment procedure involving third-party conformity assessment only because the product includes a high-risk AI system as a safety component, if this is not required by the Union harmonisation legislation listed in Section A of Annex I.

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 that system shall follow the relevant conformity assessment procedure as required pursuant to the relevant Union harmonisation legislation listed in Section A of Annex I.’

;

(20)

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

‘7. The Commission shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the detection, marking and labelling of artificially generated or manipulated content. The Commission, taking utmost account of the opinion of the Board, shall assess whether adherence to those codes of practice is adequate to ensure compliance with the obligations laid down in paragraphs 2 and 4 of this Article, in accordance with the procedure laid down in Article 56(6). If it deems

the code of practice to be inadequate, 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).'

;

(21)

in Article 56, paragraph 6 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.'

;

(22)

Article 57 is amended as follows:

(a)

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

'1. Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at national level, which shall be operational by 2 August 2027. That sandbox may also be established jointly with the competent authorities of other Member States. The Commission may provide technical support, advice and tools for the establishment and operation of AI regulatory sandboxes.'

;

(b)

paragraph 3 is replaced by the following:

'3. The European Data Protection Supervisor may establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies. For this purpose, references to national competent authorities in this Chapter shall be construed as references to the European Data Protection Supervisor.'

;

(c)

the following paragraph is inserted:

'3a. The AI Office may establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). For this purpose, references to national competent authorities in this Chapter shall be construed, where relevant, as references to the AI Office. That AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular where compliance with Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs, including start-ups, and SMCs.

The establishment of a Union level AI regulatory sandbox by the AI Office shall be without prejudice to the competences of Member States to establish and supervise AI regulatory sandboxes for AI systems under their supervision.'

;

(d)

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 authorities, ensuring that appropriate safeguards are in place. Such sandboxes may include testing in real world conditions supervised therein. Where applicable, the sandbox plan shall incorporate the real-world testing plan referred to in Articles 60 and 60a.’

;

(e)

in 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 SMEs, including start-ups, and SMCs.’

;

(f)

paragraph 10 is replaced by the following:

‘10. National competent authorities shall ensure that, to the extent the innovative AI systems involve the processing of personal data or otherwise fall under the supervisory remit of other national authorities or competent authorities providing or supporting access to data, the competent data protection authorities and those other national or competent authorities are associated with the operation of the AI regulatory sandbox and involved in the supervision of those aspects to the extent of their respective tasks and powers.’

;

(g)

paragraph 14 is replaced by the following:

‘14. National competent authorities, the European Data Protection Supervisor and the AI Office, shall, as appropriate and within their respective competences, coordinate their activities and cooperate within the framework of the Board. They may support the joint establishment and operation of AI regulatory sandboxes, including in different sectors, and exchange best practices on related matters.’

;

(23)

in Article 58(1), the first subparagraph is amended as follows:

(a)

the introductory part 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. Those implementing acts shall include common principles on the following issues:’

;

(b)

the following point is added:

‘(d)

the detailed rules applicable to the governance of AI regulatory sandboxes covered pursuant to Article 57, including as regards the involvement of and supervision by the competent data protection authorities, where relevant, and the coordination and cooperation at national and Union level.’

;

(24)

Article 60 is amended as follows:

(a)

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

‘1. 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 high-risk AI system on their own or in partnership with one or more deployers or prospective deployers.’

;

(25)

the following Article 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. Member States may allow, in accordance with this Article, the testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes by providers or prospective providers of AI enabled products covered by the Union harmonisation legislation listed in Section B of Annex I, with a view to assessing and verifying the conformity of those systems with the requirements laid down in Articles 8 to 15.

2. Member States that choose to allow testing as referred to in paragraph 1 shall, individually or jointly, adopt frameworks for real-world testing.

3. Each Member State shall notify the Commission of any real-world testing framework it adopts before implementing it. This shall not affect the competences of the Commission under the Union harmonisation legislation listed in Section B of Annex I.

4. Member States that have adopted real-world testing frameworks shall ensure that the relevant national competent authorities, relevant 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 cooperate closely with each other in good faith and remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement those real-world testing frameworks and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I.

5. The frameworks for real-world testing shall lay down the requirements under which testing in real-world conditions shall occur. Those frameworks shall:

(a)

include the provision of a mandatory real-world testing plan to be agreed between the provider or prospective provider and the national competent authority or relevant authority in accordance with the Union harmonisation legislation listed in Section B of Annex I;

(b)

ensure compliance with the requirements laid down in Article 60(2), (3), (4)(d)-(j) and (5)-(9), where any reference to market surveillance authorities in those provisions shall be read as a reference to the national competent

authority or relevant authority, as appropriate in accordance with the Union harmonisation legislation listed in Section B of Annex I;

(c)

include effective governance and accountability arrangements;

(d)

ensure a high level of protection of health safety and fundamental rights.

6. The real-world testing shall comply with the applicable provisions laid down in the Union harmonisation legislation listed in Section B of Annex I. Any requirements laid down in those provisions shall not affect the application of this Article to the extent necessary to enable the testing referred to in paragraph 1.'

;

(26)

in Article 63, paragraph 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, provided that they do not have partner enterprises or linked enterprises within the meaning of Recommendation 2003/361/EC. 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.'

;

(27)

in Article 64, the following paragraph is added:

'3. Without prejudice to the budgetary procedure, the AI Office shall be allocated adequate resources to effectively perform its duties and exercise its powers in relation to the enforcement of this Regulation.'

;

(28)

in Article 69, 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).'

;

(29)

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 SMEs, including start-ups, and SMCs, 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.'

;

(30)

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, taking utmost account of the opinion of the Board, shall adopt guidance, including a template, on the post-market

monitoring plan by 2 September 2027.’

;

(31)

Article 75 is amended as follows:

(a)

the heading is replaced by the following:

‘Market surveillance and control of AI systems and mutual assistance’ ;

(b)

paragraph 1 is replaced by the following:

‘1. The AI Office shall be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to the following AI systems:

(a)

AI systems based on general-purpose AI models where the model and the system are developed by the same provider, or by providers forming part of the same undertaking as that provider, with the exception of:

(i)

AI systems related to products covered by the Union harmonisation legislation listed in Annex I;

(ii)

AI systems referred to in point 2 of Annex III;

(iii)

AI systems provided by law enforcement authorities, border management authorities and financial institutions, insofar as those AI systems fall under Article 74(6); and

(iv)

AI systems referred to in point 8 of Annex III as regards the administration of justice;

(b)

AI systems that constitute or that are integrated into a very large online platform or very large online search engine designated in accordance with Regulation (EU) 2022/2065.

The exclusive competence referred to in the first subparagraph shall apply to the providers of those systems. It shall apply to the deployers of those systems only when they are also the provider or form part of the same undertaking as the provider.’

;

(c)

the following paragraphs are inserted:

‘1a. By way of derogation from Article 73, providers of high-risk AI systems subject to the competence of the AI Office pursuant to paragraph 1 of this Article shall report any serious incidents to the AI Office. Article 73 (2) to (9), shall apply mutatis mutandis . The AI Office shall promptly transmit the relevant information to the market surveillance authority of the Member State in the territory of which the provider or its legal representative is situated.

1b. The authorities involved in the application of this Regulation shall cooperate actively with the AI Office and provide the AI Office the necessary assistance for the exercise of its powers, including, where necessary, in connection with inspections or other enforcement measures carried out in the territory of a Member State. To that end, those authorities shall enjoy the powers provided for pursuant to 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.

1c. When taking investigatory or enforcement action in the territory of a Member State that involves access to a public authority's data or AI system, the AI Office shall be assisted by the relevant market surveillance authority.

1d. Before taking a decision that would have the effect of prohibiting or restricting the AI system being made available or put into service on a national market, or a decision to withdraw or recall the AI system from such market, the AI Office shall, without undue delay, notify the market surveillance authority competent for that market of its intention to take such a decision. The AI Office shall consult the authorities involved in the application of this Regulation, where appropriate, on any matter relating to the application and enforcement of this Regulation.

1e. The AI Office shall be responsible for conformity assessments and tests of AI systems referred to in paragraph 1 of this Article that are classified as high-risk and subject to a third-party conformity assessment pursuant to Article 43 before such AI systems are placed on the market or put into service. Those 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 shall entrust the performance of those tests or assessments to notified bodies designated in accordance with this Regulation, in which case the notified body shall act on behalf of the Commission. If a notified body to which the Commission has delegated tasks under this paragraph does not perform those tasks adequately, the Commission may withdraw the delegation with immediate effect.

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

;

(d)

the following paragraph is inserted:

'2a. Where a market surveillance authority has well-founded and sufficient reasons to suspect that a provider or a deployer of an AI system referred to in paragraph 1 of this Article has infringed this Regulation, it may request, through the relevant single point of contact designated in accordance with Article 70(2), the AI Office to assess the matter in order to take the necessary supervisory and enforcement measures to ensure prompt compliance with this Regulation. Such a request shall be duly reasoned and shall include at least:

(a)

the name of the provider or the deployer concerned;

(b)

a description of the relevant facts, the provisions of this Regulation that have allegedly been infringed, and any well-founded and sufficient reasons for suspecting an infringement, including, where applicable, the description of the negative effects of the alleged infringement;

(c)

the market surveillance authority making the request.

The AI Office shall take utmost account of the request and the market surveillance authority shall cooperate actively and provide the AI Office the necessary assistance for the exercise of its powers in accordance with paragraph 1a.

The AI Office shall, without undue delay and in any event no later than four months following receipt of the request, inform the single point of contact of its intention to exercise its powers in accordance with Article 75a or of its reasons for not exercising its powers. If the AI Office decides to exercise its powers in accordance with Article 75a, it shall periodically inform that single point of contact about major developments in the proceedings and the outcome of such proceedings, without disclosing any confidential information.'

;

(32)

the following articles are inserted:

‘Article 75a

Supervisory and enforcement powers of the AI Office

1. When exercising its tasks of supervision and enforcement laid down in Article 75(1) of this Regulation, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Article 14(4) and Article 16(3) of Regulation (EU) 2019/1020. The AI Office shall be authorised to fully reclaim from the relevant operator the totality of the costs of its supervision and enforcement activities with respect to instances of non-compliance, including costs for human and technical resources, in accordance with Article 15 of Regulation (EU) 2019/1020. Article 17 of Regulation (EU) 2019/1020 shall apply mutatis mutandis .

2. Where the AI Office has reasonable grounds to suspect non-compliance with this Regulation by a provider or a deployer of an AI system referred to in Article 75(1) of this Regulation, it may adopt a decision to start an investigation into that non-compliance in accordance with Article 14(4), point (f) of Regulation (EU) 2019/1020. Upon starting such an investigation, the AI Office shall notify the operator of the AI system concerned. The AI Office may exercise the powers referred to in paragraph 1 of this Article on its own initiative or following a complaint received pursuant to Article 85 of this Regulation, even before starting an investigation pursuant to Article 14(4), point (f) of Regulation (EU) 2019/1020.

Where a market surveillance authority has reason to suspect non-compliance with this Regulation by a provider or a deployer of an AI system referred to in Article 75(1), it may send a request to the AI Office to assess the matter.

3. The AI Office may exercise the powers listed in Article 14(4), points (a), (b) and (c) of Regulation (EU) 2019/1020 and Article 74(12) and (13) of this Regulation by simple request or by decision.

When requesting information, 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. Where the request is a simple request, the AI Office shall additionally indicate that although there is no obligation to provide the information requested, in the case of a voluntary reply, the information must be correct and not misleading, and indicate the potential fines provided for in Article 99(5) for supplying incorrect or misleading information. Where the request is made by decision, the AI Office shall additionally indicate the fines provided for in Article 99(5) for supplying incorrect, incomplete or misleading information and indicate the right to have the decision reviewed by the Court of Justice of the European Union. The AI Office shall send a copy of the request to the market surveillance authority of the Member State in the territory of which the operator or its legal representative is situated.

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 pursuant to the powers laid down in Article 14(4), points (d) and (e) of Regulation (EU) 2019/1020 and Article 74(5) of this Regulation. When conducting an inspection, the AI Office shall inform the provider concerned of the subject matter and purpose of the investigation, the relevant fines referred to in Article 99(5) of this Regulation, and the right to have the decision reviewed by the Court of Justice of the European Union. Prior to conducting an inspection, the AI Office shall inform the market surveillance authority of the Member State in the territory of which the operator or its legal representative is situated.

During such an inspection, the officials of the AI Office shall be empowered to:

(a)

enter any of the business premises, land or property located in the Union of the operator concerned;

(b)

examine the books, data and other material relevant to the execution of their tasks, irrespective of the medium on which they are stored;

(c)

take or obtain in any form copies of or extracts from books, data and other records;

(d)

ask any of the persons subject to the inspection, or their representatives, or staff, for oral or written explanations on factors or documents relating to the subject matter and purpose of the inspection, and to record the answers;

(e)

seal any business premises and books or records for the duration of, and to the extent necessary for, the inspection.

Where the AI Office finds that a natural or legal person opposes or obstructs an inspection, the national competent authority of the Member State concerned shall afford it the necessary assistance, requesting, where appropriate, the assistance of the police or an equivalent enforcement authority, to enable it to conduct its on-site inspection.

Where an on-site inspection of business premises, land or property 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. Where such an authorisation 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. The national judicial authority shall not review the necessity of the investigation or inspection nor demand information from the case file of the AI Office. In accordance with the Treaties, the legality of the decision of the AI Office is subject to review only by the Court of Justice of the European Union.

5. At the request of the AI Office, the competent market surveillance authority of a Member State may in its own territory carry out any investigation, inspection or other fact-finding measure on behalf and for the account of the AI Office in order to establish whether there has been an infringement of this Regulation. The officials of the competent authorities of the Member States who are responsible for conducting such investigations, inspections, or fact-finding measures, as well as those authorised or appointed by them, shall exercise their powers in accordance with their national law.

6. In addition to the powers set out in paragraph 1 of this Article, the AI Office, in the exercise of its competences referred to in Article 75(1), may:

(a)

order operators to provide access to, and explanations relating to, their AI systems;

(b)

impose an obligation on an operator to retain all data and documents deemed to be necessary to assess the implementation of and compliance with the obligations under this Regulation.

7. To assist it in monitoring the effective implementation and compliance with the relevant provisions of this Regulation and to provide it with specific expertise or knowledge in the exercise of its competences under Article 75(1), the AI Office may appoint independent external experts and auditors, as well as experts, investigative teams and auditors from the Member State's competent authorities with the agreement of the authority concerned. Information obtained as a result of such monitoring actions shall be shared with the relevant competent authorities of the Member States.

8. Information collected pursuant to this Article shall be used only for the purpose of this Regulation.

Article 75b

Commitments

If, during proceedings under Article 75a(2), 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 where:

(a)

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

(b)

the operator acts contrary to its commitments; or

(c)

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.

Article 75c

Non-compliance, fines and periodic penalty payments

1. Where the AI Office finds that an operator falling within the scope of Article 75(1) does not comply with the relevant provisions of this Regulation or with commitments made binding pursuant to Article 75b, it shall adopt a decision establishing such non-compliance.

2. Before adopting a decision pursuant to paragraph 1, the AI Office shall communicate its preliminary findings to the operator concerned. In the preliminary findings, the AI Office shall explain the measures that it is considering taking, or that it considers that the operator concerned should take, in order to effectively address the preliminary findings.

3. In the decision pursuant to paragraph 1 of this Article, the AI Office shall, where relevant, order the operator concerned to take the necessary measures to ensure compliance with the relevant provisions of this Regulation 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 Article 75b.

4. A decision adopted pursuant to paragraph 1 of this Article may be accompanied by the imposition of penalties in accordance with Article 99(3) to (7), which provisions shall apply mutatis mutandis to the AI Office in the execution of its supervision and enforcement tasks referred to in Article 75(1).

In particular, the following shall be subject to administrative fines as referred to in Article 99(4):

(a)

infringement of any applicable provision of this Regulation, including those not listed in Article 99(4);

(b)

failure to comply with decisions or measures adopted pursuant to the powers listed in Article 14(4) or Article 16(3) of Regulation (EU) 2019/1020, as well as those specified in Article 75a of this Regulation;

(c)

failure to comply with a commitment made binding by a decision pursuant to Article 75b.

The supply of incorrect, incomplete or misleading information to the AI Office in reply to a request shall be subject to administrative fines as referred to in Article 99(5).

5. The AI Office may adopt a decision imposing periodic penalty payments to compel the operators subject to its competence pursuant to Article 75(1) to the following:

(a)

to submit to an investigation;

(b)

to comply with an information request ordered by a decision adopted under Article 75a(3);

(c)

to submit to an inspection ordered by a decision pursuant to Article 75a(4);

(d)

to provide correct or complete answers or explanations in the context of an inspection ordered by a decision pursuant to Article 75a(4);

(e)

to comply with corrective actions ordered pursuant to the power listed in Article 16 of Regulation (EU) 2019/1020;

(f)

to comply with commitments made legally binding by a decision pursuant to Article 75b; or

(g)

to comply with a decision pursuant to the paragraph (1) of this Article.

Those penalty payments shall be effective and proportionate, and, where applicable, shall not exceed 5 % of the average daily income or worldwide annual turnover in the preceding financial year per day, calculated from the date appointed by the decision.

6. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions of the AI Office fixing a fine or periodic penalty payment pursuant to this Article. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

7. Funds collected through the imposition of fines or periodic penalty payments pursuant to this Article shall contribute to the general budget of the Union.

8. The powers conferred on the AI Office by this Article shall be subject to a limitation period of five years. The limitation period shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, the limitation period shall begin to run on the day on which the infringement ceases.

The power of the AI Office to enforce decisions taken pursuant to this Article shall be subject to a limitation period of five years. The limitation period shall begin to run on the day on which the decision becomes final.

The implementing act referred to in Article 75d(3) shall specify the first and second subparagraphs of this paragraph, including the circumstances in which the limitation periods shall be interrupted.

9. 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. That decision shall apply with immediate effect.

Article 75d

Safeguards and further specification

1. Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to operators subject to the AI Office's competence pursuant to Article 75(1) of this Regulation, without prejudice to more specific procedural rights provided for in this Regulation.

2. The rights of defence and of access to the file of operators falling within the scope of Article 75(1) shall be fully respected in proceedings. In view of the possible adoption of decisions on the basis of Article 75c(1), those operators shall be entitled to have access to the AI Office file under the terms of a negotiated disclosure, subject to the legitimate interest of the operator or other person concerned in the protection of their business secrets. The AI Office shall have the power to adopt decisions setting out such terms of disclosure in the case of disagreement between the parties. The right of access to the file shall not extend to confidential information and internal documents of the AI Office, the Board, competent market surveillance authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the AI Office and those authorities. Nothing in this paragraph shall prevent the AI Office from disclosing and using information necessary to prove an infringement.

3. The Commission may adopt implementing acts concerning the practical arrangements for access to the file

and the negotiated disclosure of information provided for in paragraph 2.

4. The AI Office shall publish the decisions it adopts pursuant to Articles 75b and 75c. Such publication shall state the names of the parties and the main content of the decision, including any penalties imposed. The publication shall have regard to the rights and legitimate interests of any person concerned in the protection of their confidential information.'

;

(33)

in Article 76(1), the following subparagraph is added:

'Where testing in real world conditions is based on Article 60a, any reference to a market surveillance authority in this Article shall be construed as a reference to the national competent authority or appropriate authority under the Union harmonisation legislation listed in Section B of Annex I, and references to Article 60 shall be construed as references to Article 60a, as appropriate.' ;

(34)

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 request and access any information or documentation created or maintained from the relevant market surveillance authority pursuant to 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 Article is without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates.'

;

(c)

the following paragraphs 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.

1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with the mutual assistance necessary to fulfil their respective mandates, with a view to ensuring the coherent application of this Regulation and Union law protecting fundamental rights and streamlining procedures, while respecting their respective competences, tasks, powers and independence. 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.'

;

(35)

in 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 SMEs, including start-ups, and SMCs, when encouraging and facilitating the drawing up of codes of conduct.'

;

(36)

in Article 96, paragraph 1 is amended as follows:

(a)

in the first subparagraph, point (a) is 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;’

;

(b)

in the first subparagraph, the following point is added:

‘(g)

the practical implementation of Article 8(2), Article 9(10) and Article 17(3) in accordance with the principle of complementarity and proportionality, with a view to ensuring consistency, avoiding duplication and minimising additional burdens when complying with the requirements of this Regulation and the requirements of the Union harmonisation legislation listed in Section A of Annex I; such guidelines shall be published by 1 August 2027.’

;

(c)

the second subparagraph is replaced by the following:

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

(37)

Article 97 is amended as follows:

(a)

paragraphs 2 and 3 are replaced by the following:

‘2. The power to adopt delegated acts referred to in Article 6(6) and (7), Article 7(1) and (3), Article 11(3), Article 43(5) and (6), Article 47(5), Article 51(3), Article 52(4) and Article 53(5) and (6) shall be conferred on the Commission for a period of five years from 1 August 2024. The power to adopt delegated acts referred to in Article 2(13) and Article 30(2) shall be conferred on the Commission for a period of five years from 27 July 2026. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.

3. The delegation of power referred to in Article 2(13), Article 6(6) and (7), Article 7(1) and (3), Article 11(3), Article 30(2), Article 43(5) and (6), Article 47(5), Article 51(3), Article 52(4) and Article 53(5) and (6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.’

;

(b)

paragraph 6 is replaced by the following:

‘6. Any delegated act adopted pursuant to Article 2(13), Article 6(6) or (7), Article 7(1) or (3), Article 11(3),

Article 30(2), Article 43(5) or (6), Article 47(5), Article 51(3), Article 52(4) or Article 53(5) or (6) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.’

;

(38)

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 administrative fines, warnings and non-monetary measures, applicable to any infringement 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 SMEs, including start-ups, and SMCs, and their economic viability when imposing penalties.’

;

(b)

in paragraph 4, the following point is inserted:

‘(da)

obligations of providers and operators pursuant to Article 25(2) and (4)’

;

(c)

the following paragraph is inserted:

‘6a. In the case of SMCs, each fine referred to in paragraphs 4 and 5 shall be up to the percentages or amount referred therein, whichever is lower.’

;

(39)

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, 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 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 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 December 2026.’

;

(40)

in Article 113, the third paragraph is amended as follows:

(a)

point (a) is replaced by the following:

‘(a)

Chapters I and II shall apply from 2 February 2025, with the exception of Article 5(1), first subparagraph, points (ba) and (bb), and Article 5(1a) and (1b) which shall apply from 2 December 2026;’

;

(b)

point (c) is replaced by the following:

‘(c)

Chapter III, Sections 1, 2, and 3, with the exception of Article 6(5), shall apply from:

(i)

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

(ii)

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

;

(c)

the following point is added:

‘(d)

Articles 102 to 110 shall apply from 27 July 2026.’

;

(41)

Annex I is amended as follows:

(a)

in Section A, point 1 is deleted;

(b)

in Section B, the following point is added:

‘21.

Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1 , ELI: http://data.europa.eu/eli/reg/2023/1230/oj).’

;

(42)

in Annex VIII, section B, points 7 and 9 are deleted;

(43)

the following Annex 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 pursuant to this Regulation may require the 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.

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

a. AI systems subject to Annex I

AIA Code

AIP 0102

AI systems subject to point 2 of Section A of Annex I

AIP 0103

AI systems subject to point 3 of Section A of Annex I

AIP 0104

AI systems subject to point 4 of Section A of Annex I

AIP 0105

AI systems subject to point 5 of Section A of Annex I

AIP 0106

AI systems subject to point 6 of Section A of Annex I

AIP 0107

AI systems subject to point 7 of Section A of Annex I

AIP 0108

AI systems subject to point 8 of Section A of Annex I

AIP 0109

AI systems subject to point 9 of Section A of Annex I

AIP 0110

AI systems subject to point 10 of Section A of Annex I

AIP 0111

AI systems subject to point 11 of Section A of Annex I

AIP 0112

AI systems subject to point 12 of Section A of Annex I

b. AI systems subject to point 1 of Annex III

AIA Code

AIB 0201

Remote biometric identification systems

AIB 0202

Biometric categorisation AI systems

AIB 0203

Emotion recognition AI systems

3. AI technology-specific codes

a. Symbolic AI and expert systems

AIA Code

AIH 0101

AI systems based on symbolic AI, expert and knowledge-based systems, and AI systems based on search and optimisation

b. Machine learning, excluding generative AI and general-purpose AI systems

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 AI systems covered under AIH 0401

c. AI systems based on general-purpose AI models or generative AI

AIA Code

AIH 0301

generative AI systems, including AI systems based on general-purpose AI models

d. Emerging AI technologies

AIA Code

AIH 0401

AI systems based on other emerging AI technologies not covered by other codes, including Agentic AI

4. 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.'.

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 (AI) systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*2) , the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.

(*2) 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)

in Article 31, the following paragraph is added:

‘3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning AI systems which are safety components within the meaning of Regulation (EU) 2024/1689, 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:

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

Article 3

Amendments to Regulation (EU) 2023/1230

Regulation (EU) 2023/1230 is amended as follows:

(1)

in Article 8, the following paragraphs are added:

‘The Commission shall adopt delegated acts in accordance with Article 47 of this Regulation to amend Annex III to this Regulation by adding health and safety requirements in respect of Artificial Intelligence (AI) systems that are classified as high-risk pursuant to Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*3) due to the fact that they are a safety component in a product covered by this Regulation, or they are themselves a product covered by this Regulation. Those requirements shall ensure that the relevant requirements set out in Chapter III, Section 2, and Articles 17, 19, 72 and 73 of Regulation (EU) 2024/1689 are reflected.

When adopting the delegated acts referred to in the third paragraph, the Commission shall take into account the objectives of Regulation (EU) 2024/1689 and ensure a level of protection consistent with that Regulation. Those delegated acts shall apply by 2 August 2028.

(*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)

in Article 20, the following paragraph is added:

‘10. Until harmonised standards or common specifications are referenced or adopted pursuant to this Article as regards high-risk AI systems, high-risk AI systems within the scope of this Regulation which comply with the relevant harmonised standards referenced, or common specifications adopted pursuant to Articles 40 and, respectively, 41 of Regulation (EU) 2024/1689 shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III to this Regulation as regards high-risk AI systems.’

;

(3)

Article 47 is amended as follows:

(a)

paragraphs 2 and 3 are replaced by the following:

‘2. The power to adopt delegated acts referred to in Article 6(2) and (11) and Article 7(2), shall be conferred on the Commission for a period of five years from 19 July 2023. The power to adopt delegated acts referred to in Article 8, third paragraph, shall be conferred on the Commission for a period of five years from 27 July 2026. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.

3. The delegation of power referred to in Article 6(2) and (11), Article 7(2) and Article 8, third paragraph, may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the

decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.’

;

(b)

paragraph 6 is replaced by the following:

‘6. A delegated act adopted pursuant to Article 6(2) and (11), Article 7(2) or Article 8, third paragraph, shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.’.

Article 4

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 Strasbourg, 8 July 2026.

For the European Parliament

The President

R. METSOLA

For the Council

The President

T. BYRNE

(1) OJ C, C/2026/2285, 15.4.2026, ELI: http://data.europa.eu/eli/C/2026/2285/oj .

(2) Opinion of 18 March 2026 (not yet published in the Official Journal).

(3) Opinion of 7 May 2026 (not yet published in the Official Journal).

(4) Position of the European Parliament of 16 June 2026 (not yet published in the Official Journal) and decision of the Council of 29 June 2026.

(5) 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).

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

(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).

(8) 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)

(9) 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).

(10) 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, p. 89 , ELI: http://data.europa.eu/eli/dir/2016/680/oj).

(11) Directive 2011/93/EU of the European Parliament and of the Council of 13 December 2011 on combating the sexual abuse and sexual exploitation of children and child pornography, and replacing Council Framework Decision 2004/68/JHA (OJ L 335, 17.12.2011, p. 1 , ELI: http://data.europa.eu/eli/dir/2011/93/oj).

(12) Directive (EU) 2024/1385 of the European Parliament and of the Council of 14 May 2024 on combating violence against women and domestic violence (OJ L, 2024/1385, 24.5.2024, ELI: http://data.europa.eu/eli/dir/2024/1385/oj).

(13) 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).

(14) 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).

(15) Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

(16) 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).

(17) 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).

(18) Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1 , ELI: http://data.europa.eu/eli/reg/2023/1230/oj).

(19) 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, p. 1 , ELI: http://data.europa.eu/eli/reg/2018/1139/oj).

(20) OJ L 123, 12.5.2016, p. 1 , ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj .

ELI: http://data.europa.eu/eli/reg/2026/1744/oj

ISSN 1977-0677 (electronic edition)