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Report

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On 29 June 2026, the Council of the European Union gave its final approval to Regulation (EU) 2026/1744 of the European Parliament and of the Council,¹ on the simplification of the regulatory framework for artificial intelligence, known as the Digital AI Omnibus (hereinafter **the “Omnibus Regulation”**), which amends Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (hereinafter **the “Artificial Intelligence Regulation”** or **“AI Act”**)².

The **final text was published on 24 July 2026** in the Official Journal of the European Union; the Omnibus Regulation therefore entered into force on 27 July 2026, three days after that publication. As part of the Omnibus VII package, this reform is one of the central elements of the European Union’s regulatory simplification agenda.

¹ 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 Regulation), available at: <https://www.boe.es/buscar/doc.php?id=DOUE-L-2024-81079>

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 Regulation), available at: <https://www.boe.es/buscar/doc.php?id=DOUE-L-2024-81079>

The Omnibus Regulation introduces a series of far-reaching amendments to the AI Act, centred on three main areas: the revision of the compliance timetable for high-risk AI systems, the extension of simplification measures to small and medium-sized enterprises, and the introduction of new prohibitions regarding AI-generated sexual content. In addition, the reform strengthens the role of the AI Office as the centralised supervisory authority, establishes a mechanism for resolving overlaps with harmonised sectoral legislation, broadens the scope of regulatory sandboxes, and introduces various additional amendments regarding transparency, post-market surveillance and data processing.

The most significant aspects of the reform are set out below:

Change to the timetable for the implementation of the AI Act

Some of the obligations that were originally due to come into force on 2 August 2026 have been postponed under the Omnibus Regulation. The new implementation dates are as follows:

2 December 2026

Transparency obligations

→ Providers of generative AI systems that have placed their systems on the market before 2 August 2026 will have a transitional period until 2 December 2026 to comply with the labelling requirements for artificially generated content set out in Article 50(2) of the AI Act. For systems placed on the market on or after 2 August 2026, these obligations apply from that date in accordance with the original timetable of the AI Act.

2 December 2027

Standalone high-risk AI systems (Annex III)

→ The obligations for high-risk AI systems classified in accordance with Annex III of the AI Act are fully applicable.

2 August 2028

High-risk systems in regulated products (Annex I)

→ The obligations for high-risk AI systems incorporated into products covered by sector-specific harmonisation legislation are fully applicable.

The application of the obligations for high-risk systems will be subject to the availability of harmonised standards, common specifications or Commission guidelines, which the Commission must confirm by means of a formal decision. Systems lawfully placed on the market prior to those dates may remain on the market without the need for recertification, provided that no substantial changes are made to their design or intended purpose.

New prohibitions: non-consensual sexual deepfakes and AI-generated child sexual abuse material

The Omnibus Regulation incorporates two new express prohibitions in Article 5 of the AI Act, applicable from 2 December 2026.

The first prohibits the placing on the market, putting into service or use of AI systems that generate or manipulate realistic images, videos or audio, or similar material, of the private parts of an identifiable natural person, or of an identifiable natural person engaged in sexually explicit activities, without that person's free, specific, informed, unambiguous and explicit consent.

The second prohibits AI systems that generate or manipulate child sexual abuse material. Both prohibitions apply differently to providers and deployers: for providers, the prohibition on placing on the market or putting into service applies where the generation or manipulation of the prohibited material constitutes the intended purpose of the system, or where such generation or manipulation is a reasonably foreseeable and reproducible outcome and the system lacks reasonable and adequate technical safeguards to prevent it; for deployers, the prohibition on use is limited to cases where the deployer uses the system for the purpose of generating or manipulating such material.

The change to the timetable does not affect the existing prohibitions, which have been in force since 2 February 2025.

Simplifications for SMEs and small mid-cap companies

The Omnibus Regulation extends the support measures previously reserved for SMEs to small mid-cap companies (SMCs). Among the most notable are the following:

- a) **Simplified technical documentation.** SMEs and SMCs will be able to submit the technical documentation required under Annex IV of the AI Act in a simplified format to be drawn up by the European Commission.
- b) **Proportionate quality management system.** The implementation of the quality management system provided for in Article 17 of the AI Act must take into account the size and nature of the provider.
- c) **Reduction of penalties.** The special consideration in determining administrative penalties provided for SMEs in Article 99 of the AI Act is extended to small mid-cap companies.
- d) **Specific guidance.** The competent national authorities must also direct their support and information activities towards SMCs, on the same terms as for SMEs.

Centralised supervision: strengthening the role of the AI Office

The Commission's AI Office has exclusive competence for supervision and enforcement in relation to AI systems based on general-purpose AI models (hereinafter 'GPAI'), where the model and the system are developed by the same provider or by providers forming part of the

same undertaking. This exclusive competence extends to the providers of such systems and, as regards deployers, only where they are also the provider or form part of the same undertaking as the provider. However, national market surveillance authorities retain their competence in the following cases:

- a) AI systems relating to law enforcement, border management and regulated financial institutions.
- b) AI systems relating to critical infrastructure (Annex III, point 2 of the AI Act).
- c) AI systems listed in Annex III, point 8, in relation to the administration of justice.
- d) AI systems covered by the European Union's harmonisation legislation listed in Annex I to the AI Act (regulated products).

Furthermore, the AI Office has exclusive competence over AI systems integrated into very large online platforms (hereinafter “**VLOPs**”) or very large online search engines (hereinafter “**VLOSEs**”), in accordance with the definitions set out in Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a single market for digital services (“**Digital Services Act**” or “**DSA**”)³.

Interaction with sector-specific legislation and mechanism for resolving overlaps

A mechanism is established to address situations where sector-specific legislation (for example, on medical devices, toys, lifts or recreational craft) already sets out specific AI requirements similar to those of the AI Act. By means of delegated acts, the Commission may limit the application of the AI Act in such cases, thereby avoiding regulatory duplication, and shall provide guidance to the economic operators concerned to facilitate compliance and minimise the administrative burden. Products covered by machinery legislation⁴ are exempt from the direct application of the AI Act, with the Commission being delegated the power to adopt the corresponding secondary legislation.

AI regulatory sandboxes and real-world testing: extension of deadlines and scope

The deadline for competent national authorities to establish AI regulatory sandboxes has been extended to 2 August 2027. Furthermore, the Omnibus Regulation introduces the following new provisions:

- a) The AI Office may establish an EU-wide regulatory sandbox for AI systems falling under its exclusive supervision.
- b) The possibility of conducting real-world testing outside sandboxes is extended to high-risk AI systems covered by Section A of Annex I to the AI Act.

³ Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a single market for digital services (Digital Services Regulation), available at: <https://www.boe.es/buscar/doc.php?id=DOUE-L-2022-81573>

⁴ Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery, available at: <https://www.boe.es/buscar/doc.php?id=DOUE-L-2023-80916>

Other relevant amendments

The Omnibus Regulation also introduces the following additional significant amendments:

- a) **Registration of non-high-risk AI systems.** Providers who have concluded that their system does not qualify as high-risk are no longer required to register it in the European Union database, although they must document this assessment and make it available to the competent national authorities upon request.
- b) **Post-market surveillance plan.** The obligation to follow a harmonised Commission model is removed, giving providers greater flexibility in designing the plan, guided by guidelines rather than binding implementing acts.
- c) **Processing of special categories of data for the purpose of correcting bias.** An explicit legal basis is introduced to allow providers and deployers, on an exceptional basis, to process special categories of personal data within the meaning of Article 9 of the GDPR, where this is necessary for the detection and correction of bias.
- d) **Notified bodies.** Notified bodies will be able to submit a single application and undergo a single assessment procedure to obtain designation under both the AI Act and other sector-specific harmonisation legislation, thereby reducing duplication and streamlining notification times.

Recommended measures for corporate regulatory compliance

In light of the changes described, operators, providers and deployers of AI systems are advised to adopt the following measures:

1. **Inventory and classification of AI systems.** Identify and classify all the organisation's AI systems in accordance with the new application dates set out in Annex I and Annex III of the AI Act.
2. **Verification of the simplified regime for SMEs and SMCs.** Check whether the organisation meets the criteria to qualify for the simplified regime and, where applicable, adapt the technical documentation and quality management system to the format to be drawn up by the Commission.
3. **Adaptation of generative systems to transparency obligations.** Providers of generative AI systems placed on the market before 2 August 2026 must implement technical solutions for labelling artificially generated content by 2 December 2026.
4. **Review of the compliance strategy in regulated sectors.** Operators with AI systems subject to concurrent sector-specific legislation should assess whether their conformity assessment procedures require updating and ensure that contracts with providers include clauses on compliance with the AI Act and adequate data protection safeguards.
5. **Regulatory monitoring.** Actively monitor Commission decisions that trigger compliance deadlines for high-risk AI systems, as well as the publication of harmonised standards, common specifications and guidelines under the AI Act.

6. Promotion of AI literacy. Take measures to support the development of AI literacy among staff who operate or interact with AI systems, in accordance with the revised wording of Article 4 of the AI Act as amended by the Omnibus Regulation. Note that the obligation does not require guaranteeing a specific level of literacy for any particular individual, but rather adopting measures to promote the development of such literacy.
7. **Participation in regulatory sandboxes.** Consider participating in regulatory sandboxes established by the competent national authorities or the AI Office as a means of pre-market validation.
8. **Processing of special categories of data to correct bias.** Providers and deployers who need to process special categories of personal data for the detection and correction of bias must assess the new legal basis introduced by the Omnibus Regulation and implement appropriate safeguards in accordance with applicable data protection legislation.

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