

The “Digital Omnibus”: Ten Key Changes to AI Regulation



On Wednesday 19 November 2025, the European Commission (“**Commission**”) published [its Digital Omnibus on AI Regulation](#) proposal (the “**Digital Omnibus on AI**”) as part of its Digital Omnibus Package.

The Digital Omnibus on AI introduces proposed amendments to the EU Artificial Intelligence Act (“**EU AI Act**”) with targeted simplification measures to ensure its effective implementation and boost innovation, as well as to address certain challenges encountered since the EU AI Act was adopted in June 2024.

The EU AI Act, which has a phased implementation timeline, was designed with the aim of balancing innovation and flexibility for businesses with robust safeguards for citizens and the protection of fundamental rights.

However, there have been challenges with implementation including a lack of harmonised standards for high-risk AI systems, and concerns about disproportionate compliance costs, particularly for smaller companies.



With the Digital Omnibus on AI Regulation, the Commission aims to create a more innovation-friendly AI regulatory framework in Europe by:

- + extending certain simplifications that are granted to small and medium-sized enterprises (SMEs) to small mid cap companies (SMCs);
- + broadening compliance measures so more innovators can use regulatory sandboxes; and
- + reinforcing the AI Office's powers and centralise oversight of AI systems built on general-purpose AI models, reducing governance fragmentation.



TEN KEY CHANGES FOR AI

1. Delay to the EU AI Act's rules on high-risk AI.

The implementation of rules for high-risk AI systems, originally due to take effect in August 2026, will be postponed by a maximum of 16 months under the new proposals. Entry into force for high-risk obligations will only apply after the Commission confirms that adequate compliance support is available. Once confirmed, obligations will apply after six months for high-risk AI systems categorised under [Annex III](#), and 12 months for high-risk AI systems categories under [Annex I](#), of the EU AI Act, with backstop compliance dates of **2 December 2027** and **2 August 2028** respectively.

High-risk systems lawfully on the market before these rules apply can remain available without new certification if no significant design changes occur. For high-risk AI systems used by public authorities, providers and deployers still have until 2 August 2030 to comply with the requirements. These delays have been widely anticipated, following significant lobbying by businesses and technology companies.

2. Six-month grace period for marking obligations.

Providers of systems generating synthetic audio, image, video or text placed on the market before 2 August 2026 will have an extended six months until 2 February 2027 to implement machine readable detectability or marking for AI outputs.

3. Registration relief for non-high-risk AI systems.

Providers of AI systems that they assess to be non-high-risk will no longer need to register this assessment in the AI office's high-risk database, although they must document their assessment and provide it to authorities on request.

4. Centralised supervision for AI systems by the AI Office.

The AI Office will become exclusively competent for AI systems based on a general purpose AI (GPAI) model. It will also become exclusively competent for AI systems that constitute or are part of very large online

platforms (VLOPs) or very large search engines (VLOSEs), as defined under the DSA. The AI Office will have market surveillance powers and coordinate closely with national authorities and DSA enforcement.

5. Conformity assessment streamlining.

Conformity assessment bodies will be able to submit a single application and undergo a single assessment procedure when seeking designation under both the EU AI Act and other relevant EU harmonisation legislation. This ultimately aims to reduce duplication and speed up the designation process.

6. Increased post market monitoring flexibility.

The obligation to follow a harmonised Commission template for post market monitoring plans is to be removed; bringing increased flexibility. Providers will instead maintain a plan in their technical documentation, guided by Commission guidance rather than an implementing act.

7. Additional AI sandboxes established.

The AI Office may establish an EU level AI regulatory sandbox with integrated real world testing plans where applicable. Real world testing outside sandboxes would be extended to high risk AI systems under Annex I, Section A. For Section B, Member States and the Commission may enter voluntary agreements enabling real world testing.

8. AI literacy responsibilities fall to the Commission.

The former blanket requirement on providers and deployers to ensure staff AI literacy will be replaced with a duty on the Commission and Member States to foster AI literacy through non binding support.

9. SME and SMC relief extended and clarified.

Regulatory privileges that were previously solely for SMEs have now been extended to SMCs, including simplified technical documentation, lower fines, and tailored guidance. Micro enterprise simplifications for quality management systems will be broadened to all SMEs and start-ups.

10. Data protection exception for bias established.

Providers and deployers will be permitted to exceptionally process special categories of personal data to detect and correct bias across AI systems and models, subject to strict safeguards.



NEXT STEPS

It is important to bear in mind that the changes outlined in the Digital Omnibus on AI are only proposals at this stage.

The Digital Omnibus on AI will now enter the legislative process and will need to be approved by the Council of the EU and the European Parliament following trilogue negotiations before it comes into force.

To see our overview of the Ten Key Changes to the GDPR set out by the broader Digital Omnibus package, which includes a handy downloadable summary table comparing the proposals to the UK's position, click on the link below.



Read our article [here](#) on The “Digital Omnibus”: Ten Key Changes to the GDPR



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