

EU's AI Omnibus Proposal Offers 10 Key Changes For Cos.

By **Patrick Van Eecke and Jack Eastwood** (December 12, 2025)

On Nov. 19, the European Commission published its proposal for a digital omnibus on artificial intelligence.[1]

The commission's proposal forms part of the European Union's simplification drive and aims to streamline the EU Artificial Intelligence Act's implementation, ease compliance burdens and adjust compliance deadlines ahead of the EU AI Act's full application on Aug. 2, 2026.[2]

The targeted amendments have important implications for businesses that place, put into service and/or use AI systems in the EU, as well as for product manufacturers that integrate AI systems into their hardware products.

We unpack some of the key changes and simplification measures proposed by the digital omnibus on AI, and examine what these might mean for businesses' AI compliance road maps.

Key Changes and Simplification Measures

The targeted amendments to the EU AI Act proposed by the digital omnibus on AI include the following.

Extended Compliance Timelines

Under the current EU AI Act, the rules on high-risk AI systems apply from Aug. 2, 2026, for Annex III use cases, or from Aug. 2, 2027, for high-risk systems embedded into or comprising regulated products.

The omnibus proposal seeks to delay the application date for these requirements, making application conditional on the readiness of applicable harmonized standards, common specifications or guidelines.

A new long-stop date means that the rules on high-risk systems would apply, at the latest, from Dec. 2, 2027, for Annex III systems, and from Aug. 2, 2028, for systems comprising or embedded into regulated products, even if standards are still lagging.

The commission could bring the application of these requirements forward if it decides that "adequate measures in support of compliance" exist, but there is no clear test for adequacy, leaving timing uncertain.[3] After that decision, businesses would then have six months to comply for Annex III use cases or 12 months for product and safety components.

Extended Grace Periods

The omnibus proposal introduces targeted grace periods for certain AI systems already on the EU market.

Providers of generative AI systems released before Aug. 2, 2026, would have an additional



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six months until Feb. 2, 2027, to retrofit their systems to meet new transparency obligations, such as marking artificially generated or manipulated content using watermarks, metadata or other digital tags.

The EU AI Act's Article 111 grace period for legacy high-risk systems placed on the market or put into service before the high-risk rules start to apply is also clarified, marking a significant divergence from the compliance approach taken for physical products, such as electronics, with effects on compliance strategies.

If at least one unit of a high-risk AI system was lawfully placed on the EU market before the new rules apply, identical units of that system can continue to be placed or used without the need to retrofit or triggering requirements for additional certification, provided the design of that high-risk AI system remains unchanged.

For most businesses, this will encourage the accelerated launch of products in advance of deadlines for high-risk AI compliance. However, if such legacy systems are intended for use by public authorities, providers must nevertheless bring them into full compliance by Aug. 2, 2030.

Broader Application of Bias Mitigation Derogation

The omnibus proposal would expand the current exemption, allowing certain AI providers to process sensitive data to detect and correct bias. Under the new rules, all AI providers and deployers — regardless of risk level or training method — could use this exemption to reduce bias, provided they meet the same processing conditions.

For high-risk systems that do not involve model training, the derogation would remain limited to dataset testing.

Deletion of Registration Requirements

Currently, AI providers that demonstrate an Annex III use case is not high-risk — such as when the system is used only for preparatory tasks — must still register the system in the EU database. The omnibus proposal would remove this requirement. Providers would, however, remain obligated to document their risk assessments and make them available to regulators upon request.

Codes of Practice

The commission would lose its powers to adopt binding codes of practice for general-purpose AI models and the marking of artificially generated or manipulated content. Codes could still be adopted, but they would remain nonbinding soft law, serving as guidance rather than establishing enforceable legal obligations.

Clarifications on Conformity Assessment

The omnibus proposal clarifies that when a high-risk AI system is both subject to product regulation and classified as a high-risk Annex III use case, the conformity assessment required under the relevant product regulation will take precedence.[4]

Increased Flexibility

Post-market monitoring remains mandatory, but businesses would no longer be required to

follow a template plan previously scheduled for adoption in February 2026.

Relief for Small and Midsize Enterprises and Small Midcaps

The EU AI Act already provides reduced obligations for small and midsize enterprises. The omnibus proposal would extend certain SME carve-outs to include small midcaps — those that do not qualify as SMEs, but employ fewer than 750 persons and have either an annual turnover not exceeding €150 million (\$175.7 million) or an annual balance sheet total not exceeding €129 million.[5]

Under the proposal, small midcaps would benefit from simplified technical documentation requirements when demonstrating compliance with high-risk AI requirements, more proportionate expectations for quality management systems, and caps on penalties for noncompliance.

SMEs would themselves benefit from the further simplified quality management system requirements, currently reserved for microenterprises.

New Regulatory Sandboxes

The omnibus proposal introduces an EU-level regulatory sandbox alongside existing national sandboxes for general-purpose AI models, creating a dual-layer structure. This will allow businesses — particularly SMEs and small midcaps — to pilot high-impact AI solutions under regulatory guidance in real-world conditions for a limited period.

Beyond formal sandboxes, Article 60 of the EU AI Act, which permits premarket, real-world testing of certain high-risk AI, is broadened. Providers of high-risk AI covered by product regulation under Annex I, such as machinery, toys, radio equipment, vehicles and medical devices — would be allowed to conduct controlled live trials before full certification, subject to safeguards and oversight.

Greater Enforcement Coordination

The omnibus proposal centralizes enforcement by granting the commission's new AI office exclusive supervisory authority over certain AI systems, including those based on general-purpose AI models and systems embedded in or constituting very large online platforms, known as VLOPs, or very large online search engines, known as VLOSEs, under the Digital Services Act.

This also means that providers of systems that are high-risk and subject to third-party conformity assessment could now face premarket conformity testing by the commission. Meanwhile, the omnibus proposal clarifies that enforcement for high-risk AI systems embedded in regulated products listed in Annex I, Section A would remain with the relevant national product safety regulators.

Enhanced cooperation requirements for regulators should meanwhile reduce administrative burdens for business. Regulators investigating fundamental rights violations will need to make information requests to the relevant market surveillance authority rather than the business.

What's Next?

The digital omnibus on AI is currently only a proposal. It will now proceed to the EU Council

and Parliament, where, given the political interest, further amendments are likely, meaning trilogue negotiations are expected.

With implementation targeted for 2026-2027, there is considerable time pressure to finalize changes to the EU AI Act before the current compliance deadline of Aug. 2, 2026. If adopted in its current form, the digital omnibus on AI would enter into force three days after publication in the Official Journal of the EU.

The bundling together of all amendments and the absence of a separate stop-the-clock proposal raises the stakes. Failure to reach political agreement and to adopt amending legislation before August 2026 would mean the existing high-risk AI requirements apply as originally drafted, possibly before the supporting standards or tools are ready.

Delays in adoption risk uneven enforcement across the EU, as well as the danger of litigation for companies. While retroactive pardons might be possible, they would face tight legal constraints and judicial scrutiny.

Practical Takeaways

It is advisable for businesses to remap timelines by planning for delayed high-risk AI compliance dates while modeling an early activation scenario in case the commission deems compliance tools as adequate.

Businesses should meanwhile closely track standards, as the real trigger for high-risk AI requirements may be the availability of standards, common specifications or guidance.

It is important to prepare for gaps by building contingency for an applicability gap if the omnibus proposal slips, including exposure to claims and national enforcement variance.

Businesses should also update data strategies by reassessing lawful bases under the General Data Protection Regulation for model training and sensitive data use. In addition, they should ring-fence model-level versus system-level bias processing through data protection impact assessments and necessity or proportionality analyses.

Businesses should anticipate labeling friction, expecting a lag between developer tooling and user disclosure duties, and they should think about how best to document reasonable efforts and technical constraints.

Maintaining robust records remains critical; even without registration of out-of-scope high-risk AI systems, businesses will need to preserve self-assessment evidence and risk rationales to withstand supervisory scrutiny.

Finally, it is prudent to watch governance changes. Centralized assessments and softer codes of conduct will alter how compliance is evidenced, and which stakeholders are engaged with before market entry.

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[1] Available at: <https://digital-strategy.ec.europa.eu/en/library/digital-omnibus-ai-regulation-proposal>.

[2] For additional insights on the EU AI Act and its compliance implications, see <https://www.cooley.com/events/2025/2025-04-30-ai-talks-understanding-the-eu-ai-act--what-it-means-for-companies-worldwide> and <https://cdp.cooley.com/the-eu-ai-act-key-milestones-compliance-challenges-and-the-road-ahead/>.

[3] European Commission's Digital Omnibus on AI proposal, Article 1(31)(a).

[4] Annex I, Section A.

[5] See Annex to Commission Recommendation (EU) 2025/1099.