



Digital Omnibus on AI: *The trilogue deal is done – What made it, what didn't, and what changed?*

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AI Omnibus approaches the finish line

On May 6, 2026, the European Parliament, the Council, and the European Commission (**EC**) reached a trilogue agreement on the Digital Omnibus on Artificial Intelligence, confirmed by COREPER on May 13, 2026. The deal lands ahead of August 2, 2026 applicability date for the AI Act's high-risk system obligations, a timeline many considered unrealistic when the Commission tabled the proposal on November 19, 2025. Formal adoption and publication in the Official Journal are expected over the summer.

This alert maps the final trilogue outcome against the EC initial proposal, leading to three categories.

- ◆ What was adopted with limited refinements?
- ◆ What was substantively tweaked during negotiations?
- ◆ What emerged in trilogue?

1. WHAT WAS ADOPTED?

Several core elements of the Commission proposal were maintained, with only targeted alignment during negotiations:

- ◆ **Proportionality benefits extended to small mid-caps (SMCs)**

All three institutions supported extending the proportionality measures currently available to SMEs, simplified technical documentation (Article 11), proportional quality management systems (Article 17), proportionate penalties (Article 99), and the simplified Quality Management System (**QMS**) option (Article 63), to SMCs. The final text confirms this and adds definitions of SME and SMC to Article 3, with specific penalty caps for each category.

- ◆ **Bias detection with a strict-necessity threshold**

Providers of high-risk systems may exceptionally process special categories of personal data only where strictly necessary for bias detection or correction. The same legal basis is extended to other systems/models and to deployers in narrowly defined high-impact scenarios. Overall, the new Article 4a stresses that it does not create an obligation to run bias detection or correction.

- ◆ **Sandboxes strengthened and real-world testing expanded**

At least one national sandbox must be operational by August 2, 2027. An EU-level sandbox may be set up with priority access for SMEs, start-ups, and SMCs. Sandbox plans can combine sandbox and real-world testing plans, and relevant authorities—including Data Protection Authorities (**DPAs**) where personal data is involved—must be associated. Real-world testing is broadened beyond the original scope, and Member States may establish notified frameworks for real-world testing in certain regulated product sectors.

- ♦ **AI Office powers and national competences:** exclusive but bounded

The AI Office receives exclusive competence over:

- ♦ AI systems based on general-purpose AI models where the model and system are developed by the same provider or providers in the same undertaking; and
- ♦ AI systems that constitute or are integrated into designated VLOPs/VLOSEs, with specified carve-outs for products covered by Annex I and other listed exceptions.

This exclusive competence applies to providers, and to deployers only where they are also the provider or are in the same undertaking.

New provisions also set out the AI Office's supervisory and enforcement powers, including investigations, information requests, inspections with safeguards, commitments, non-compliance decisions, fines, periodic penalties, and procedural safeguards. The text also requires the AI Office to be allocated sufficient resources.

- ♦ **Notified body designation:** unified pathway with transition

The final text enables a unified designation pathway where sectoral law provides for it, supported by a structured list of codes defining notification scope. Existing sectoral notified bodies may temporarily cover relevant AI requirements where assessed through existing notification but must complete AI Act designation within a defined transition period.

- ♦ **Technical correction and alignment of conformity assessment (Article 43(3)):** Sectoral conformity confirmed; manufacturer choice preserved

For regulated products, the applicable sectoral conformity assessment procedure remains the way, with AI-specific requirements integrated into that assessment. Where sectoral law allows self-assessment routes using harmonized standards, those routes remain available where the relevant AI-related standards and specifications are also applied.

2. WHAT WAS SUBSTANTIVELY TWEAKED DURING NEGOTIATIONS?

On several politically charged topics, the final text reflects material departures from the Commission proposal:

- ♦ **Fixed high-risk timelines:** the Commission's readiness-based mechanism is removed.

The final text introduces fixed deadlines:

- December 2, 2027 for Chapter III obligations on stand-alone high-risk AI systems under Annex III (Article 6(2)); and
- August 2, 2028 for AI systems embedded in regulated products under Annex I (Article 6(1)).

Providers and deployers should plan against these hard dates.

- ♦ **Synthetic content marking:** a four-month transition

Neither the Council's six-month nor the Parliament's three-month extension survived intact. The text introduces a four-month transition for Article 50(2) synthetic-content marking for systems already on the market before August 2, 2026, requiring compliance from providers by December 2, 2026.

The framework for codes of practice is adjusted so the Commission facilitates codes and assesses adequacy, with further common rules only if a code is found inadequate.

- ♦ **AI literacy: binding**, but recalibrated

The final text rejects the Council’s purely voluntary model but also stops short of the Parliament’s more prescriptive formulation. The result is a recast Article 4 imposing a binding obligation of means: providers and deployers must take “measures to support the development AI literacy” for 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 the context in which the AI systems are to be used, but with no requirement to guarantee any specific level of literacy. Public authorities at EU and national level must support implementation, including through practical examples, and the AI Board will issue recommendations.

- ♦ **Registration of “exempted” high-risk systems maintained**

The Commission had proposed deleting the obligation for Annex III AI systems assessed by the provider as non-high risk to be registered in the EU database. Both co-legislators reinstated it, and the final text confirms the registration obligation, though with simplified content. Providers must still document the Article 6(3) assessment before placing the system on the market or putting it into service.

3. WHAT EMERGED IN TRILOGUE?

Several provisions in the final text were not part of any institution’s pre-trilogue mandate, appearing for the first time in the compromise:

- ♦ **Prohibition of “nudifier” generative AI systems**

The new prohibited practices under Article 5(1)(ha) targeting AI systems that generate, manipulate, or reproduce non-consensual intimate images (NCII or audio content) and child sexual abuse material (**CSAM**) are confirmed. For providers, this applies where generation or manipulation is the system’s intended purpose or a reasonably foreseeable reproducible outcome without significant technical modification and without reasonable and adequate safeguards. For deployers, use is prohibited where the system is used for that purpose. The new bans apply as of December 2, 2026.

- ♦ **AI value chain cooperation and written agreements (Article 25)**

The final text imposes structured contractual and operational cooperation across the AI value chain. Where a high-risk AI system is modified or integrated by another provider, the initial provider is no longer considered the provider of that system but must cooperate closely with the new provider and provide all necessary information, technical access, and assistance to ensure compliance with the AI Act, unless the initial provider has clearly specified that its AI system is not to be changed into a high-risk AI system. In parallel, high-risk AI system providers and third parties supplying AI systems, models, tools, services, components, or processes used or integrated in the high-risk system must agree in writing on the necessary information, capabilities, technical access and other assistance, based on the generally acknowledged state of the art, needed to enable compliance. This written-agreement requirement does not apply to third parties making publicly accessible tools, services, processes, or components, other than general-purpose AI models, under a free and open-source licence. This has direct implications for supplier agreements and intra-group arrangements.

- ♦ **Fundamental rights impact assessment/data protection impact assessment linkage and AI Office support (Article 27)**

Where relevant elements are already addressed in a data-protection impact assessment, deployers may cross-reference or reuse those sections in the fundamental rights impact assessment. The AI Office will provide a questionnaire and template, including via automated tools, to support simplified completion.

- ◆ **Safety component redefined:** high-risk scope narrowed

The Parliament's provision clarifying that AI features used purely for convenience, automation, or optimization do not constitute safety functions, unless their failure creates actual safety risks, was refined in the final text through a revised definition of "safety component" under Article 3(14). Complementary clarifications have been introduced under Article 6(1) preventing "pull-in" based on non-health/safety conformity assessment. Therefore, a product is not treated as meeting the Article 6(1)(b) condition merely because it undergoes third-party conformity assessment for risks other than health and safety.

- ◆ **Product safety architecture:** targeted, not horizontal

The Parliament's ambitious proposal to move all Annex I-A product categories into Annex I-B and horizontally integrate AI Act requirements into multiple sectoral laws did not survive in its original form. Instead, the final text adopts a targeted sectoral approach for machinery, with a mechanism to limit duplicated requirements in other regulated product sectors. For Annex I product sectors, the application of specific AI Act high-risk requirements may be limited where sectoral EU harmonization legislation provides an equivalent or higher level of protection. Delegated measures are due by August 2, 2027, and machinery-sector integration aligns to August 2, 2028.

- ◆ **Cybersecurity alignment:**

The Parliament's proposal for a presumption of compliance between the Cyber Resilience Act (**CRA**) and Article 15 of the AI Act is retained in substance: where high-risk AI systems fall within the scope of the CRA and its Article 12(1) conditions are fulfilled, they are deemed to comply with AI Act Article 15 cybersecurity requirements, to the extent covered. The text also promotes standardization deliverables to support joint compliance and reduce duplication across regimes.

- ◆ **Commission guidance obligation and post-market monitoring template**

The Commission is mandated to issue practical guidance by August 1, 2027 on how operators in regulated product sectors can integrate AI-specific risk and quality management into existing sectoral processes, with particular attention to SMEs, start-ups, SMCs, local public authorities, and highly affected sectors. A template for post-market monitoring plans is due by September 2, 2027.

4. KEY TAKEAWAYS

The AI Omnibus recalibrates the compliance calendar but does not dismantle the AI Act's core architecture. This means that companies should get ready to review their compliance calendar:

- ◆ Plan against the hard dates of either December 2, 2027 for Annex III and August 2, 2028 for Annex I.
- ◆ Review contractual arrangements in light of new value chain obligations where companies integrate or modify third-party AI systems.
- ◆ Reassess high-risk classification considering the revised definition of "safety component" and the clarifications under Article 6(1).
- ◆ Evaluate exposure to new prohibitions (**NCII/CSAM**) ahead of December 2, 2026.
- ◆ Leverage CRA alignment to streamline cybersecurity compliance where applicable.

Initial timeline vs new timeline based on the Digital Omnibus

Initial AI Act timeline						
<p>June 13</p> <ul style="list-style-type: none"> Adoption of AI Act <p>August 1</p> <ul style="list-style-type: none"> Entry into focus 	<p>February 2</p> <ul style="list-style-type: none"> <i>Prohibited AI practices and AI literacy general provisions chapter I</i> <p>August 2</p> <ul style="list-style-type: none"> Governance and enforcement framework Notified bodies/conformity assessment infrastructure Penalties regime Obligations on general-purpose AI modes <p>November 19</p> <ul style="list-style-type: none"> <i>Digital Omnibus on AI Proposal</i> 	<p>February 2</p> <ul style="list-style-type: none"> Post-market monitoring template due (late) <p>August 2, 2026</p> <ul style="list-style-type: none"> <i>High-risk AI regime fully applicable: Risk management (Art. 9) Data governance (Art. 10) Documentation, transparency, human oversight)</i> <i>Conformity assessments and CE marketing</i> Registration obligations (Art 49) <i>Transparency obligations (e.g., AI-generated content Art – 50)</i> <i>Deployers' obligations</i> 	<p>August 2</p> <ul style="list-style-type: none"> Certain high-risk classification rules linked to harmonized product law (Article 6 (1)) Deadline for existing GPAI models to comply 			<p>August 2</p> <ul style="list-style-type: none"> Final compliance deadline for public sector high-risk systems <p>December 31</p> <ul style="list-style-type: none"> Large EU IT systems
2024	2025	2026	2027	2028	2029	2030
		<p>May 6 & 13</p> <ul style="list-style-type: none"> Trilogue Agreement on the Digital Omnibus on AI COREPER confirmation of trilogue agreement <p>Summer</p> <ul style="list-style-type: none"> Formal adoption and publication in the EU Official Journal <p>December 2</p> <ul style="list-style-type: none"> <i>4-month transition for Art 50(2) synthetic-content marking for existing systems placed on the market before August 2, 2026</i> <i>New prohibited practices for NCII and CSAM</i> 	<p>August 1</p> <ul style="list-style-type: none"> Commission guidance <p>August 2</p> <ul style="list-style-type: none"> MS sandboxes <i>Delegated measures on sectoral integration</i> <p>September 2</p> <ul style="list-style-type: none"> Post-market monitoring template <p>December 2</p> <ul style="list-style-type: none"> <i>High-risk system obligations Article 6 (2) Annex III</i> 	<p>August 2</p> <ul style="list-style-type: none"> <i>High-risk system obligations Article 6 (2) Annex I</i> <i>Machinery sector alignment</i> 		
New timeline based on the Digital Omnibus on AI for selected items						

This alert follows our April 2026 briefing, “[Digital Omnibus on AI: What Is Really on the Table as Trilogues Begin?](#)”, and the initial alert of November 2025 on the “[Digital Omnibus Package: How will these changes affect your business?](#)”.

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