

EU Digital Omnibus Proposal – Key AI Proposals

December 2025

The European Commission released its Digital Omnibus Package on 19 November 2025, a reform that seeks to overhaul significant parts of the EU's digital regulatory framework. In our table below, we highlight some of the key changes proposed by the Digital Omnibus on AI and their effects, if implemented.

AI Act Articles affected by the Proposal	Digital Omnibus on AI Proposal Reference	AI Act Current Text	Omnibus Proposal Amendment (Emphasis added)	What is being Changed?	What does this mean?
Article 113 (Stop the clock mechanism)	Article 1 (31)	<p>"[...] It shall apply from 2 August 2026.</p> <p>However:</p> <ul style="list-style-type: none"> (a) Chapters I and II shall apply from 2 February 2025; (b) Chapter III Section 4, Chapter V, Chapter VII and Chapter XII and Article 78 shall apply from 2 August 2025, with the exception of Article 101; (c) Article 6(1) and the corresponding obligations in this Regulation shall apply from 2 August 2027." 	<p>"[...] It shall apply from 2 August 2026.</p> <p>However:</p> <p>(a) Chapters I and II shall apply from 2 February 2025;</p> <p>(b) Chapter III Section 4, Chapter V, Chapter VII and Chapter XII and Article 78 shall apply from 2 August 2025, with the exception of Article 101;</p> <p>(c) Article 6(1) and the corresponding obligations in this Regulation shall apply from 2 August 2027.</p> <p>(d) Chapter III, Sections 1, 2, and 3, shall apply following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates:</p>	<p>High-risk AI would no longer be in force from August 2026, and would come in six months after a European Commission decision to the effect that adequate harmonised standards are in place. We don't know when these will be in place, or when such a decision would be made. Given that it is not even clear on if the Omnibus will pass, our recommendation is to continue working on high-risk AI compliance implementation.</p>	<p>Prevents a compliance gap where companies are legally required to comply but technical standards do not yet exist, aiming to provide legal certainty.</p>

AI Act Articles affected by the Proposal	Digital Omnibus on AI Proposal Reference	AI Act Current Text	Omnibus Proposal Amendment (Emphasis added)	What is being Changed?	What does this mean?
			<p>i. 6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and</p> <p>ii. 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.</p> <p>In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:</p> <ul style="list-style-type: none"> i. on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and ii. on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.' <p>(e) 3. Articles 102 to 110 shall apply from [the date of entry into application of this Regulation]."</p>		
Article 1(2) (g) (Subject matter)	Article 1(1)	"measures to support innovation, with a particular focus on SMEs, including start-ups."	<p>"measures to support innovation, with a particular focus on <u>small mid-cap enterprises (SMCs)</u> and small and medium-sized enterprises (SMEs), including start-ups."</p> <p><i>In line with this addition, the Digital Omnibus Proposal proposes a number of related changes to expand these rights, e.g. under Article 11 (Technical documentation), Article 99 (Penalties), etcetera.</i></p>	Expands the scope of innovation support measures and reduced fines to explicitly include Small Mid-Caps (SMCs).	SMCs will legally gain access to the support mechanisms (such as sandboxes and simplified compliance) and reductions in fines previously reserved solely for SMEs, acknowledging their role in the EU economy.
Article 4 (AI Literacy)	Article 1(4)	"Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf..."	"The Commission and Member States shall encourage providers and deployers of AI systems to take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf..."	AI Literacy would no longer be a legal obligation and would merely be "encouraged" by the EU.	Removes the direct burden for companies regarding staff AI literacy, treating it instead as a strategic priority to be fostered by the Commission and Member States.

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New Article 4a (Bias detection)	Article 1 (5)	No equivalent Article 4a exists. Bias detection using special categories of personal data is currently restricted to high-risk AI systems under Article 10(5).	<p><i>“1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems [...] providers of such systems may exceptionally process special categories of personal data [...].</i></p> <p>2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.”</p> <p><i>In addition, there are a number of related amendments to Article 10, as set out in Article 1(7) of the Digital Omnibus Proposal.</i></p>	Expands the legal basis to process sensitive data for bias testing to all AI systems (including non-high-risk), subject to safeguards and includes both providers and deployers of AI systems.	Provides legal certainty vis-à-vis the GDPR for all AI developers to test for bias without fearing data protection violations, promoting fairer AI across the market.
Article 6(4) (Registration rules for high-risk AI systems)	Article 1 (6)	“A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. <u>Such provider shall be subject to the registration obligation set out in Article 49(2).</u> Upon request of national competent authorities, the provider shall provide the documentation of the assessment.”	<p>“A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.”</p> <p><i>In addition, Article 49(2) is deleted by Article 1(14) of the Digital Omnibus Proposal.</i></p>	Removes the requirement to register AI systems in the EU database if the provider claims they are exempt from high-risk classification.	Significantly reduces the administrative burden for companies claiming derogations; they must keep internal records but need not publicly register the system.
Article 57 (AI regulatory sandboxes)	Article 1 (17)	New paragraph 3a inserted.	<p>“The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1). Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to SMEs.’</p>	Empowers the central AI Office to run a pan-European sandbox, rather than relying solely on national initiatives.	Enables cross-border testing and consistent regulatory guidance for major AI projects; reduces fragmentation between Member States.

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Article 75 (1) (Moving DSA AI regulatory responsibility to the AI Office)	Article 1 (25)	<p>“Where an AI system is based on a general-purpose AI model, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation. To carry out its monitoring and supervision tasks, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020.”</p>	<p>“Where an AI system is based on a general-purpose AI model, <u>with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I</u>, and that model and that system are developed by the same provider, the AI Office <u>shall be exclusively competent for the supervision and enforcement of that system</u> with the obligations of this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. <u>The AI Office shall also be exclusively competent for the supervision and enforcement of the obligations under this Regulation in relation to AI system that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.</u></p>	<p>The AI Office becomes responsible for AI systems that are integrated within very large online platforms and search engines (as defined by reference to the Digital Services Act).</p>	<p>Ensures consistent, EU-wide enforcement for major tech companies, preventing diverging rulings from 27 national regulators.</p>
Article 111 (Further grandfathering provisions)	Article 1 (30)	<p>Article 111 (2): “Without prejudice to the application of Article 5 as referred to in Article 113(3), 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 <u>before the date of application of Chapter III and corresponding obligations referred to in Article 113</u>, 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.”</p> <p><i>There is no existing Article 111 (4)</i></p>	<p>Article 111 (2): “Without prejudice to the application of Article 5 as referred to in Article 113(3), 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 <u>before the date of application of Chapter III and corresponding obligations referred to in Article 113</u>, 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.”</p> <p>Article 111 (4) <u>“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 February 2027.”</u></p>	<p>Introduces a further 6-month transitional period for providers who need to retroactively include technical solutions in their generative AI systems, to make them machine readable and detectable as artificially generated or manipulated.</p>	<p>Provides further time for providers time to implement technical solutions for content provenance where the AI system is already on the market.</p>

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