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Law and Policy Brief

The Digital Omnibus on AI: provisional agreement of 7 May 2026 and its implications for High Risk AI Systems

Oreste Pollicino,[1] Federica Paolucci,[2] Ettore Russo[3]

Executive Summary

The provisional agreement reached on 7 May 2026 by the Council presidency and European Parliament negotiators introduces three sets of amendments to Regulation (EU) 2024/1689 (AI Act) that affect the determination of applicable obligations for high-risk AI systems.

First, it postpones the application of obligations for high-risk systems listed in Annex III to 2 December 2027, and for AI systems embedded in products covered by Union harmonisation legislation (Annex I) to 2 August 2028.

Second, it removes AI systems embedded in machinery from the direct scope of the AI Act by transferring the Machinery Regulation from Section A to Section B of Annex I. The Commission is required to introduce corresponding AI-related requirements into the Machinery Regulation through delegated acts by 2 August 2028.

Third, it introduces a mechanism allowing the Commission to limit the application of specific AI Act obligations for high-risk systems where sectoral legislation provides an equivalent or higher level of protection. This mechanism is set out in the new Article 2(13) and must be operationalised through Commission acts specifying the systems concerned, the obligations affected, and the conditions of limitation.

The provisional agreement must now be endorsed by the Council and the European Parliament before being finalised.

[1] Managing Partner, Pollicino AIdvisory.
[2] Post-doctoral Research Fellow, Bocconi University.
[3] Senior Policy Manager, Anitec-Assinform.

Pollicino AIdvisory
Corso Europa 10
20122, Milano, Italy
info@pollicinoaidvisory.eu

1. Political context

The agreement politically closes the negotiations around the Digital Omnibus VII, that aimed at adopting modifications to Reg. (EU) 2024/1689, AI Act. After a spiraling of the debate around the proposed amendments (see here the policy brief), and after a first failure of the trilogues, a provisional agreement was found.
A notable feature of the final phase of negotiations was the political escalation of the dossier. What had been treated as a largely technical discussion on the interplay between the AI Act and sectoral product safety legislation rapidly rose to the level of a political confrontation, with direct engagement from Member State leaders. The intervention of German Chancellor Friedrich Merz in support of a machinery-sector carve-out was decisive in shaping the final compromise on Annex I (cfr. Politico, 6 May 2026). The shift in altitude of the discussion, from technical interlocution to head-of-government advocacy, is itself a meaningful indicator of the structural stakes attached to the file.

As expected, the agreement defers the application of key obligations, as already proposed by the European Commission.
High-risk AI systems listed in Annex III become subject to the relevant requirements from **2 December 2027.** AI systems that qualify as safety components of products covered by Annex I become subject to the relevant requirements from **2 August 2028.** In addition, providers of AI systems generating synthetic content that were placed on the market before 2 August 2026 must comply with transparency obligations (Article 50(2)) by a deadline that, on the basis of the political agreement, should be set at **2 December 2026**. The deadline represents a compromise between the Commission's original proposal of 2 February 2027 and the European Parliament's preference for a shorter timeline, reflecting the political salience of the topic.
These deferrals are linked to the need to adopt delegated acts and develop harmonised standards. Without such measures, the application of the Regulation would be incomplete in sectors where the interaction with product legislation is central.

2. Scope and Function of the Amendments

The amendments address the situation in which an AI system qualifies as a safety component of a product subject to Union harmonisation legislation.[4] Indeed, this is most politically sensitive and structurally impactful element of the agreement concerns the interplay between the AI Act and the body of EU sectoral product safety legislation built on the New Legislative Framework (NLF). Under the original

[4] In particular, are noteworthy amendments that to Art. 3 para 14, Art. 43 para. 3, Art. 96.

architecture of the AI Act, an AI system used as a safety component in an NLF-regulated product could trigger the high-risk regime alongside the applicable sectoral framework, generating overlapping conformity assessment procedures and duplicative compliance burdens.

The Omnibus addresses this overlap not through a single intervention, but through three moves whose combined effect is best understood if read together:

1. Modifications on the application of the Regulation to Machinery Products;
2. The application of the AI Act to sectors under Section A, Annex I;
3. The new definition of the safety component.

The result is that the overlap between regimes is no longer addressed at the level of classification alone, but also through mechanisms that affect the content of the applicable obligations.

3. Removal of Machinery from the AI Act

The amendment to Annex I removes the Machinery Regulation from Section A and places it in Section B.[5]
As a result, AI systems embedded in machinery are no longer subject to the AI Act as high-risk systems under Article 6(1). Instead, the Commission is required to amend the Machinery Regulation by introducing AI-related requirements corresponding to those of the AI Act. These amendments must be adopted through delegated acts and apply from 2 August 2027.[6]
The delegated acts must ensure that requirements equivalent to those set out in Chapter III, Section 2, and in specific provisions of the AI Act are reflected in the Machinery Regulation.[7]
The legal effect of this change is that compliance for AI systems in machinery will be assessed exclusively under sectoral legislation, even where those systems perform safety functions.[8]

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[5] The distinction between Sections A and B of Annex I concerns the mode of interaction between the AI Act and Union harmonisation legislation. So far, for products listed in Section A, the AI Act applies directly in conjunction with sectoral legislation: AI systems qualifying as safety components may trigger the high-risk regime under Article 6(1), with the possibility, introduced by the Omnibus, of limiting specific obligations where equivalent protection is ensured (Article 2(13)). By contrast, for products listed in Section B, the AI Act does not apply cumulatively: AI-related requirements are to be integrated into the relevant sectoral legislation itself, typically through delegated acts, and compliance is assessed exclusively within that sectoral framework.
[6] Art. 2, para. 13, AI Act.
[7] New Art. 110a, AI Act.
[8] Modifications to Art. 20, Machinery Regulation, "high-risk AI systems within the scope of this Regulation which comply with the relevant harmonised standards or common specifications referenced or adopted under Articles 40 and 41 of Regulation (EU) 2024/1689 shall be presumed to

4. Limitation of AI Act obligations through Article 2(13)

For sectors that remain in Section A of Annex I, the AI Act continues to apply. However, the new Article 2(13) introduces a mechanism that allows the Commission to limit the application of specific obligations.
This limitation is subject to two conditions. First, the relevant Union harmonisation legislation must provide requirements **ensuring an equivalent or higher level of protection of health, safety, or fundamental rights.** Second, the limitation must not reduce the overall level of protection ensured by the AI Act.
The provision does not operate automatically. It requires the Commission to adopt acts (by 2 August 2027) specifying:

- the categories of high-risk AI systems concerned,
- the obligations that may be limited, and
- the conditions and scope of the limitation.

Until such acts are adopted, the AI Act applies in full.
This mechanism introduces a dependency between the application of the AI Act and subsequent Commission decisions. The extent to which obligations are reduced or maintained is not defined in the Regulation itself.

5. Definition of safety component

The agreement amends the definition of "safety component" in Article 3(14) and introduces additional provisions in Article 6.[9]
The revised definition clarifies that a component qualifies as a safety one where its intended purpose is to prevent or mitigate risks to health and safety. The notion of intended purpose is determined by the provider.[10]
At the same time, the amended Article 6(1a) excludes AI systems used exclusively for non-safety-related functions, including user assistance, performance

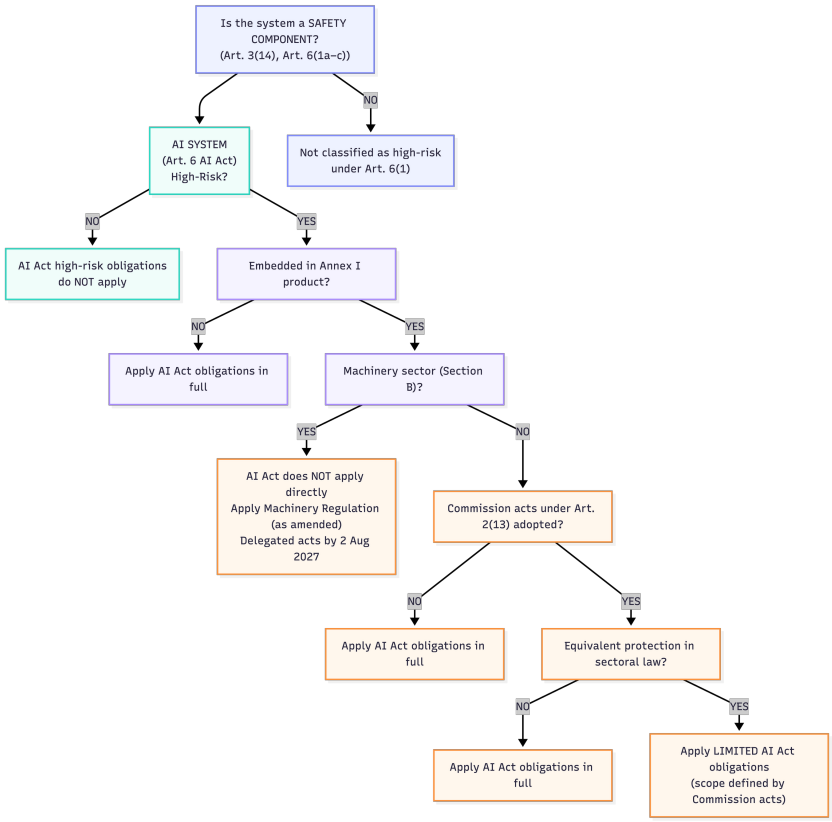
be in conformity with the essential health and safety requirements set out in Annex III as regards high-risk AI system".

[9] Explanatory Rec. 8(a): "In accordance with Article 6(1) of Regulation (EU) 2024/1689, AI systems are classified as high-risk where an AI system that is a component of a product covered by Union harmonisation legislation listed in Section A of Annex I to that Regulation is a safety component and that product requires a third-party conformity assessment".

[10] The accompanyng Rec. 4a specifies that "the safety function must be an intended purpose of the system, which is determined by the provider of the system. An AI system fulfils a safety function where its intended purpose, as determined by the provider, is to prevent or mitigate risks to health and safety of persons. In particular, this does not include AI systems which are intended to solely fulfil functions related to user assistance, performance optimisation, service efficiency, automation, convenience, or quality control operations of non-safety related aspects. The mere fact that an AI system is integrated into or operates within a product that is subject to safety regulation does not, in itself, mean that it fulfils a safety function".

optimisation, or quality control of non-safety aspects. Although Article 6(1b) ensures that systems whose failure would endanger health or safety remain classified as safety components.
Lastly, the modified Article 6(1c) further clarifies that the requirement of third-party conformity assessment for reasons unrelated to health, safety, or cybersecurity does not trigger high-risk classification.
These amendments reduce the number of AI systems that qualify as high-risk under Article 6(1), by restricting the conditions under which an AI system is considered a safety component.

The following diagram aims at synthetising the discussed modifications on the application of the AI Act to safety components.



6. Interaction with Conformity Assessment and Standardisation

Finally, the agreement clarifies that the classification of a product as containing a high-risk AI system does not alter the conformity assessment options available under sectoral legislation.

Where Union harmonisation legislation allows manufacturers to rely on procedures not involving a third party, this possibility remains available, provided that harmonised standards covering the relevant requirements are applied.[11]
In parallel, the Commission is required to request the development of harmonised standards that facilitate joint compliance with the AI Act and sectoral legislation: these standards are meant to "support and simplify the regulatory compliance pathways of such economic operators".[12]
Until such standards are available, conformity with AI Act standards may be used to presume conformity with sectoral requirements for high-risk AI systems within the scope of the Machinery Regulation.

[11] Art. 40, AI Act, new sub-para in paragraph 2.
[12] Explanatory Recital to Art. 40 modifications.