

ORDINARY LEGISLATIVE PROCEDURE

Follow up to the European Parliament legislative resolution on simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

- 1. Rapporteurs:** Arba KOKALARI (EPP / SE) and Michael MCNAMARA (Renew/ IE)
- 2. References:** 2025/0359(COD) / A10-0073/2026 / P10_TA(2026)0198
- 3. Date of adoption of the resolution:** 16 June 2026
- 4. Legal basis:** Article 114 of the Treaty on the Functioning of the European Union (TFEU)
- 5. Competent Parliamentary Committees:** Committee on Internal Market and Consumer Protection (IMCO) and Committee on Civil Liberties, Justice and Home Affairs (LIBE)
- 6. Commission's position:** accepts the amendments, while it has issued the following statement expressing concern about the choice of the deadlines set for tasks entrusted to the Commission, namely the development of guidelines and the adoption of delegated acts concerning the interplay between the AI Act's high-risk requirements and Union harmonisation legislation.

Commission statement regarding the agreement on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence

The Commission welcomes the political agreement reached by the European Parliament and the Council on the Digital Omnibus on AI.

At the same time, the Commission is deeply concerned with the choice of the deadlines attached to two important follow-up tasks entrusted to the Commission. The agreed Regulation foresees, among other things, that the Commission should:

1. adopt delegated acts by 2 August 2027 specifying whether and under what conditions certain AI Act requirements may be limited for high-risk AI systems referred to in Article 6(1) AI Act because sectoral

legislation already ensures an equivalent or higher level of protection, and

2. develop guidelines by 1 August 2027 on the interplay between high-risk AI requirements and sectoral legislation.

The Commission fully supports the objective of improving complementarity between the AI Act and sectoral product legislation. Avoiding unnecessary duplication is essential for legal certainty, competitiveness and effective implementation. The Commission notes that the agreement reached on the AI Omnibus is coherent with its proposal for a revision of the Medical Devices Regulations (COM(2025)1023) and therefore it does not affect this proposal.

As regards point 1 above, the Commission considers that the value of this new mechanism lies precisely in its ability to address issues of complementarity on an ongoing basis, as new sector-specific rules relevant for AI systems are adopted under the Union harmonisation legislation listed in Annex I AI Act and concrete overlaps arise. The deadline is therefore problematic, as it risks turning this mechanism into a one-time exercise and may limit the Commission's ability to act where new overlaps are identified after the sector-specific assessment has been carried out by the abovementioned date.

Second, in relation to point 2 above, the development of guidelines on the interplay between high-risk AI requirements and sectoral legislation will require careful analysis, and the outcome must be robust, practical and legally clear. Since the entry into application of high-risk requirements to high-risk AI systems referred to in Article 6(1) AI Act has been postponed to 2 August 2028, a deadline for the adoption of the guidelines on the practical application of some of those requirements a full year before that entry into application may jeopardise the development of reliable support tools for industry and authorities.