

Simplification of the implementation of harmonised rules on artificial intelligence – Digital Omnibus on AI (Omnibus VII)

2025/0359(COD) - 16/06/2026 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 423 votes to 57, with 174 abstentions, a legislative resolution 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 (Digital Omnibus on AI).

Parliament adopted its position at first reading by amending the proposal as follows:

New deadlines

The amended text postpones the application of certain parts of the AI Act to ensure that the necessary standards and support measures are in place. Obligations on high-risk AI systems will apply:

- from **2 December 2027** for stand-alone high risk AI systems;
- from **2 August 2028** for AI systems embedded as safety components and covered by EU sectoral legislation on safety and market surveillance.

Concept of ‘safety component’

The definition is targeted to include only AI systems that are likely to have a negative impact on the health and safety of people or property. This means that products with AI functions that only assist users or optimise performance will not automatically face high-risk obligations, if their failure or malfunction does not pose health or safety risks.

Processing of personal data

The amended regulation introduces the possibility of processing personal data when strictly necessary to detect and correct biases that could harm the health and safety of individuals or adversely affect fundamental rights, subject to strict safeguards, both in high-risk and non-high-risk AI systems.

Prohibited practices in AI

The amended text prohibits AI systems that generate **child pornography** or create images, videos, and audio content depicting the **intimate parts** of an identifiable person, or sexually explicit activities, without their explicit consent. Suppliers will not be permitted to place these systems on the European market unless they have adequate technical safeguards in place to prevent the creation of such material.

Reduce overlaps

The monitoring, application, and follow-up of sectoral and national laws must not lead to overlaps, inconsistent interpretations, or discrepancies in implementation. Amendments to AI legislation remove overlapping requirements on AI for machinery products by clarifying that they only need to comply with sectoral safety, while ensuring an equivalent level of health and safety.

Registration

To streamline compliance and reduce associated costs, the registration of AI systems covered by Regulation (EU) 2024/1689 in the EU database should be simplified by streamlining the content required under Annex VIII to that Regulation.

Regulatory sandboxes

Member States must ensure that their competent authorities establish at least one AI regulatory sandbox at national level, which should be operational by **2 August 2027**. The AI Office may establish an AI regulatory sandbox at Union level for AI systems covered by Regulation (EU) 2024/1689. To foster innovation and facilitate the adoption of AI, SMEs, including startups, and small to medium-sized enterprises must be given priority access to the AI regulatory sandboxes established by the AI Office.

In general, the text provides for extending to **small and medium-sized enterprises** the exemptions granted to SMEs regarding certain rules, in order to support their growth. Furthermore, the Commission will be required to provide guidelines to assist economic operators of high-risk AI systems covered in Annex I to Regulation (EU) 2024/1689 in complying with that Regulation, including by providing guidance on the application of certain provisions of the Regulation as mechanisms to minimise the compliance burden.

Tests

It is also appropriate to ensure that real-world testing of high-risk AI systems covered by the Union harmonisation legislation listed in Section B of Annex I to Regulation (EU) 2024/1689 is possible.

Strengthening the role of the AI Office

The amended text provides for a streamlined implementation of certain rules relating to general-purpose AI systems within the EU AI Office, whose role is strengthened. The Commission will allocate adequate human, financial and technical resources to the AI Office to ensure that it can effectively, and within reasonable timeframes.

The AI Office will have exclusive competence over AI systems built on general purpose AI models, not only where both the system and the model are developed by the same provider, but also where they are developed by providers that form part of the same undertaking. However, in certain cases, in particular where there is specific sectoral supervision, responsibility should remain with the relevant national competent authority.

The AI Office will have all the powers and responsibilities of market surveillance authorities under this Regulation and Regulation (EU) 2019/1020 of the European Parliament and of the Council when it supervises and monitors compliance with obligations relating to AI systems within its remit.

In order to carry out the tasks assigned to it under this Section, the AI Office may conduct all necessary remote or on-site inspections.