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

2025/0359(COD) - 19/11/2025 - Legislative proposal

PURPOSE: to simplify the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI).

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the current drive for simplification and digitalisation is anchored in the Union's political agenda. In its Communication on a Simpler and Faster Europe, the Commission announced its commitment to an ambitious programme to promote forward-looking, innovative policies that strengthen the EU's competitiveness and lighten the regulatory burdens on people, businesses and administrations, while maintaining the highest standard in promoting its values.

Regulation (EU) 2024/1689 of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (AI Act), which entered into force on 1 August 2024, establishes a single market for trustworthy and human-centric artificial intelligence across the EU. Its purpose is to promote innovation and the uptake of AI while ensuring a high level of protection for health, safety, and fundamental rights, including democracy and the rule of law.

This proposal is part of a broader Digital Package on simplification composed of measures to reduce the administrative costs of compliance for businesses and administrations in the EU, which applies to several regulations of the EU's digital acquis without compromising the objectives of the underlying rules. The proposal builds on Regulation (EU) 2024/1689 and is aligned with existing policies to make the EU a global leader in AI, to make the EU an AI continent and to promote the uptake of human-centric and trustworthy AI.

CONTENT: with this draft regulation, the Commission is proposing targeted simplification measures to ensure timely, smooth, and proportionate implementation of certain of the AI Act's provisions. These include:

- linking the implementation timeline of high-risk rules to the availability of standards or other support tools;

- extending regulatory simplifications granted to small and medium-sized enterprises (SMEs) to small mid-caps (SMCs), including simplified technical documentation requirements and special consideration in the application of penalties;

- requiring the Commission and the Member States to foster AI literacy instead enforcing unspecified obligation on providers and deployers of AI systems in this respect, while training obligations for high-risk deployers remain;

- offering more flexibility in the post-market monitoring by removing a prescription of a harmonised post-market monitoring plan;

- reducing the registration burden for providers of AI systems that are used in high-risk areas but for which the provider has concluded that they are not high-risk as they are only used for narrow or procedural tasks;

- centralising oversight over a large number of AI systems built on general-purpose AI models or embedded in very large online platforms and very large search engines with the AI Office;

- facilitating compliance with the data protection laws by allowing providers and deployers of all AI systems and models to process special categories of personal data for ensuring bias detection and correction, with the appropriate safeguards;

- a broader use of AI regulatory sandboxes and real-world testing that will benefit European key industries such as the automotive industry, and facilitating an EU-level AI regulatory sandbox which the AI Office will set up as from 2028;

- targeted changes clarifying the interplay between the AI Act and other EU legislation and adjusting the AI Act’s procedures to improve its overall implementation and operation.