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Proposal for a Regulation as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

I. Executive summary

The European Commission has just presented a proposal to simplify the implementation of the AI Act. This initiative seeks to amend both Regulation (EU) 2024/1689 and Regulation (EU) 2018/1139, with the clear objective of making the harmonised rules on artificial intelligence more manageable.

This proposal is not just cosmetic. It introduces concrete simplification measures aimed at ensuring the timely and proportionate implementation of the more complex provisions of the AI Act. The changes address five key issues:

- **Greater temporal flexibility:** The implementation schedule for high-risk systems will no longer be rigid, but rather will be linked to the actual availability of standards and supporting tools.
- **New proportionality rules for small mid-cap companies:** Simplifications that previously only benefited small and medium-sized enterprises (SMEs) are now also being extended to small mid-cap companies (SMCs). This includes simpler technical documentation and a more comprehensive approach to sanctions.
- **Re-introduction of AI literacy obligations:** The obligation for AI literacy is no longer the sole responsibility of providers and deployers, but has been shifted to the Commission and the Member States, which will have to promote training. However, those responsible for the deployment of high-risk systems maintain their specific training obligations.
- **Expansion of the competences of the European AI Office:** The oversight of AI systems based on general-purpose models or embedded in large platforms will be concentrated in the European AI Office, thus avoiding the dispersion of competences among multiple national authorities.
- **Restriction of the obligation to register in the EU public database:** The possibility has been introduced to remove the obligation to register systems used in high-risk areas in the European database when the provider has concluded and documented that, due to the specific nature of the use, the system should not be considered high-risk. However, it must provide evidence of this assessment when requested to do so by the competent authorities.

Initial estimates project potential savings of approximately €297.2 million to €433.2 million. In particular, SMEs and SMCs are expected to benefit from these simplification measures.

II. Analysis of the rules

2.1. Most significant changes

A. New definitions

Specific definitions for SMEs and SMCs, which correspond to those set out in Commission Recommendation 2003/361/EC and Commission Recommendation (EU) 2025/1099, have been introduced to clarify the treatment of these companies in the AI Act.

B. AI literacy - a fundamental change in the approach

Here, we find one of the most striking changes. Until now, the regulations directly obliged all providers and deployers of AI systems to ensure that their staff had sufficient knowledge of the functioning and risks of artificial intelligence. The new proposal takes a different approach: the Commission and the Member States must now encourage companies to adopt these training measures, rather than imposing them directly.

C. Processing of sensitive personal data

The proposal establishes a legal basis which allows the processing of special categories of personal data where necessary to detect and eliminate bias in AI systems. This exception applies to both providers and users of all AI systems and models, but always under strict safeguards.

The conditions are strict: first, it must be demonstrated that bias detection cannot be effectively carried out with other data. In addition, technical limitations on re-use, state-of-the-art security measures, strict access controls, the prohibition against transfers to third parties, the deletion of data once biases have been corrected, and detailed documentation in records of processing activities are required.

D. High-risk systems: exemption from registration

Not all systems that appear on the list of high-risk applications will have to be compulsorily registered in the European database. Providers may avoid this registration when they demonstrate that their system does not pose significant risks to health, safety or fundamental rights. However, they must carefully document this assessment before marketing the system and must make it available to the authorities upon request.

E. Simplified technical documentation for SMCs and SMEs

SMCs and SMEs, including start-ups, will have significant breathing space. They may submit the required technical documentation (design, performance and risk assessment information) using a simplified form to be designed by the Commission specifically for their needs and capabilities.

F. Quality management system

Quality management systems must be proportionate to the size of the organisation. This means that SMCs and SMEs, including start-ups, will not have to implement the same complex procedures as large corporations.

G. Conformity assessment bodies - single application and assessment procedure

Bodies that wish to be designated under both the AI Act and other European harmonisation legislation may submit a single application and undergo a single assessment procedure. This eliminates unnecessary duplication and streamlines the process.

Notifying authorities will work with a new systematic classification which includes codes, categories and types of AI systems. This tool will facilitate the identification and categorisation of different types of systems, making communication between the Commission and the Member States more efficient.

H. AI regulatory sandboxes at EU level

The AI Office may create regulatory sandboxes at European level for systems that require specialised supervision. These test environments will be implemented in close cooperation with the competent authorities and will give priority access to SMEs.

These sandboxes will provide a controlled environment that fosters innovation, allowing companies to develop, train, test and validate innovative AI systems for a limited time before bringing them to market. This will be done in accordance with a specific plan agreed between the providers and the competent authority.

I. Expanding the scope for testing under real conditions

The testing of high-risk systems under real-world conditions will not be limited to sandboxes. Providers may also perform these tests outside these controlled environments, provided that they are systems that have been included on the official lists or regulated by specific European sectoral regulations.

In addition, a new path has been opened for testing systems regulated by additional sector-specific legislation through written voluntary agreements between interested Member States and the Commission. This additional flexibility will facilitate innovation in specific sectors.

J. Supervision and control - exclusive competence of the AI Office

The AI Office will assume exclusive competence in two clearly defined scenarios: firstly, where an AI system is based on a general-purpose AI model and both the model and the system have been developed by the same provider (excluding products covered by sector-specific regulations); and secondly, where AI systems constitute or are integrated into very large online platforms or very large search engines designated under the Digital Services Act (DSA).

In exercising these functions, the AI Office will have all the powers of a market surveillance authority, with the provisions on cooperation between authorities that already exist in applicable market surveillance legislation.

K. An enhanced cooperation mechanism with fundamental rights authorities

National authorities that supervise compliance with obligations related to fundamental rights will have the power to request and access any information or documentation from the relevant market surveillance authorities.

Market surveillance authorities must grant such access, including by requesting additional information from providers or users where necessary. Close cooperation and mutual assistance will be essential for the effective implementation of their respective mandates.

L. The role of national supervisory authorities

The proposal redistributes competences between the national supervisory authorities already designated in countries such as Spain and the AI Office, thus maintaining a hybrid system that combines national and European supervision. National authorities will retain competence over AI systems that do not fall under the centralised supervision of the AI Office.

M. Sanctions - special consideration for SMCs and SMEs

Member States must take into account the interests and economic viability of SMCs and SMEs, including start-ups, when imposing sanctions. For these companies, each fine will be at the lowest percentage or amount set out in the general sanctioning regime.

2.2. Timeline for implementation

The Regulation will enter into force twenty days after its publication in the Official Journal of the European Union.

A. Flexible implementation schedule for high-risk systems linked to the availability of tools

The rules on high-risk systems will apply following a Commission decision confirming the availability of adequate compliance support measures: 6 months after for systems on the official list of applications, and 12 months after for systems covered by sector-specific regulations. In the absence of this decision, the cut-off dates will be 2 December 2027 for systems on the official list and 2 August 2028 for sectoral systems.

B. Transitional period for generative systems

Providers of AI systems that generate synthetic content (audio, image, video or text) and which are placed on the market before 2 August 2026 will have until 2 February 2027 to comply with transparency obligations, i.e. to clearly identify the synthetic content generated.

C. Grace period for existing systems

The grace period for existing systems shall apply per type and model of AI system. If at least one individual unit of the high-risk system was lawfully placed on the market before the specified date, other units of the same type and model may continue to be placed on the market without additional obligations, provided that the design remains unchanged.

III. Strategic considerations and impact analysis

The centralisation of supervision in the European AI Office aims to ensure consistency in the application of the Regulation across the EU, thus reducing conflicting interpretations. However, this concentration of competences also introduces new challenges: companies will have to adapt their compliance processes to interact with one supranational authority rather than multiple national authorities, which may create additional complexities in compliance management.

This proposal represents a considerable effort to balance regulatory protection with the practical feasibility of implementation. The changes address real challenges identified during stakeholder consultations, but they also introduce new complexities that organisations must carefully consider.

- **Temporary flexibility with persistent uncertainty**

The mechanism linking the implementation of high-risk rules to the availability of standards represents a pragmatic approach that recognises the current limitations of the regulatory ecosystem. This will provide greater certainty to companies as to when they must actually comply with the more complex obligations. However, the Commission's decision mechanism

on the availability of support measures introduces uncertainty about exact compliance dates. Companies must prepare for multiple temporal scenarios and maintain continuous supervision, which can complicate strategic and budgetary planning.

- **Substantial benefits for SMEs and SMCs**

The extension of regulatory privileges to small mid-cap companies is especially valuable, as these companies face similar challenges to SMEs but have lacked specific protections. Simplified technical documentation and proportional quality management systems represent tangible reductions in their administrative burden.

- **Centralised supervision: simplification, but potentially more control**

The AI Office's unique competence concerning general-purpose model-based systems significantly simplifies the regulatory landscape for companies that operate across borders, eliminating the need to navigate multiple national authorities. The concentration of specialised expertise may result in more consistent and technically sound assessments. However, the transfer of competences may also result in more rigorous scrutiny and more standardised enforcement procedures that may be less flexible than national approaches.

- **Complexity of risk assessments**

The exemption from registration for certain systems requires providers to document risk assessments without completely clear criteria. This can lead to inconsistencies in the application and risks of misclassification, especially for companies without specialised technical-legal expertise.

- **New data protection obligations**

The exceptional processing of special categories of personal data for the detection and correction of biases is subject to strict conditions, and requires the implementation of robust technical and organisational safeguards. These new obligations can be costly and technically challenging, especially for smaller companies that lack advanced data protection infrastructure.

3.1. Differentiated sectoral impact

- » **Providers of general-purpose AI models:** These providers will face more intense centralised supervision, but also greater regulatory predictability. The concentration of expertise in the AI Office may result in more consistent but potentially more rigorous assessments, especially for systems that integrate a model and an application from the same vendor.
- » **Large digital platforms:** Specific oversight for systems integrated into very large platforms creates a dual regulatory regime that requires careful coordination between different regulatory frameworks (the Digital Services Act and the AI Act). This may lead to procedural complexities and risks of regulatory overlap.
- » **Traditional regulated sectors:** Voluntary agreements for real-world testing offer valuable opportunities for sectors such as aviation and medical devices, but require complex coordination between sectoral and AI authorities. The integration of AI requirements into existing sectoral regulatory frameworks presents regulatory harmonisation challenges.

3.2. Key implications for implementation

A. Preparing for multiple scenarios

Organisations must develop flexible implementation plans that consider different effective dates depending on the availability of standards. This requires systems for continuous supervision of regulatory developments and the ability to adapt quickly.

B. Investment in technical capabilities

New requirements for simplified documentation and the processing of sensitive data require the development of specific technical capabilities. Companies must carefully assess whether to develop these capabilities in-house or outsource to specialists, taking into account costs, control and available expertise.

C. Seizing opportunities

The sandbox at EU level represents a unique opportunity for innovative companies, but requires forward planning given that it will be operational in 2028. Companies must begin to identify appropriate pilot projects and develop capabilities to participate in experimental regulatory environments.

D. Proactive management of compliance risks

The centralisation of supervision requires the fundamental adaptation of internal compliance processes to interact effectively with the AI Office. This includes preparing for new notification procedures, cooperating with authorities and managing centralised investigations.

Business organisations must adopt a proactive approach that combines compliance readiness with seizing opportunities. The window for preparation is limited, and companies that act early will have significant competitive advantages in the post-implementation European AI market.

The key to success lies in balancing regulatory risk management with capitalising on the simplifications and opportunities offered by the proposal, while maintaining flexibility to adapt to future regulatory developments.

IV. Next steps in the legislative procedure

The proposal for a Regulation COM (2025) 836 final, presented on 19 November 2025, will follow the ordinary legislative procedure (co-decision between the European Parliament and the Council), based on internal market harmonisation powers.

After sending the draft legislative act to national parliaments, the proposal will be examined by the European Parliament and the Council of the European Union. Both institutions will have to adopt the act under the same conditions for it to enter into force.

The procedure includes mandatory consultation with the European Economic and Social Committee and the European Committee of the Regions, whose opinions will be considered during the adoption process.

Given the proximity of the general application of the AI Act, the proposal provides that this Regulation must enter into force as a matter of urgency. It will enter into force three days after its publication in the Official Journal of the European Union.

The timetable is particularly significant considering that the provisions on high-risk systems must apply from 2 August 2026, and the proposal introduces a temporary relaxation mechanism linking this date to the availability of measures to support compliance.

Given the complexity of the proposed amendments and their impact on the AI regulatory ecosystem, close supervision of the legislative process is recommended, especially in relation to the final dates of application of the temporary relaxation mechanism; the development of the necessary implementing acts to implement the new powers of the AI Office; the coordination between national authorities and the AI Office; and the effective implementation of the regulatory sandbox at EU level planned for 2028.

V. Our strategic support services

- **Monitoring the ordinary legislative procedure:** Detailed monitoring of first-reading amendments by the European Parliament, analysis of the Council's position at first reading, monitoring of implementing and delegated acts, and early warnings on sector-specific relevant amendments during the processing.
- **Stakeholder engagement strategy:** Preparation of specialised technical position papers and coordination with European sectoral associations.
- **Participation in public consultations:** Drafting of specialised technical responses, sector-specific impact analysis and coordination of collective responses with other market actors.
- **Implementation advice:** Development of compliance frameworks, identification of future delegated and implementing acts, and transition strategies.

We are available to provide any clarifications or specific advice on the application of these rules to your business.

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