

KAN Position statement

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

March 2026

KAN, the Commission for Occupational Health and Safety and Standardisation, welcomes the opportunity to comment on the European Commission's proposal for a Regulation as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI).

Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act – AI Act) aims to provide legal certainty in technical innovation fields and to protect health, safety and fundamental rights. Although so far only parts of the AI Act's requirements are applicable, the European Commission published a proposal for a regulation to simplify the implementation of the rules on artificial intelligence, the Digital Omnibus on AI, in November 2025.

Occupational health and safety and standardisation

The implementation of the AI Act will be supported by European harmonised standards, which play a central role in ensuring the safe and trustworthy use of AI. From the perspective of stakeholders in occupational health and safety, these standards should primarily address the responsibilities of AI providers. Deployers and users should only be included to the limited extent defined in the AI Act. Worker's health and safety falls under Article 153 of the Treaty on the Functioning of the European Union (TFEU), according to which only minimum requirements may be laid down at European level. The Member States are responsible for specifying the details and may adopt stricter requirements in the process. No provision is made for the minimum requirements of the occupational safety and health directives described in Article 153 of the TFEU to be supported by standards.

A clear distinction must therefore be drawn between product safety, which is regulated under Article 114 TFEU and fully harmonised to support the EU Single Market, and workplace safety, which remains a national responsibility within a common EU framework. Product safety obligations lie with manufacturers and other economic operators placing products on the market. Here, harmonised standards play an important and well-established role under the New Legislative Framework (NLF). KAN emphasises that such standards must be coherent, carefully developed and free of contradictions, given the central role they play in ensuring a high level of protection.

Ensuring a high-level of safety for AI systems

A high level of protection is fundamental to safeguarding the health and safety of workers. AI systems placed on the market or put into service must therefore be safe and secure by design. Organisational or personal risk-mitigating measures should only be relied upon where safety and security cannot be ensured by design

or technical measures. For this reason, it is crucial that the AI Act maintain robust requirements that ensure a high level of protection for workers.

KAN therefore welcomes the changes that are proposed in Article 1(13) of the Digital Omnibus on AI, which envisages amendments to Article 43(3) of the AI Act. Among other elements, this proposal would incorporate the assessment of the quality management system set out in Article 17 and Annex VII of the AI Act into the conformity assessment procedure for high-risk AI systems falling under the Union legislation listed in Annex I, Section A. From KAN's point of view, this is a positive and important step, as it contributes to a higher level of safety.

KAN also supports the proposal to make it an obligation for providers to follow the relevant conformity assessment procedure under the applicable Union harmonisation legislation listed in Annex I, Section A for AI systems that fall within this legislation and are categorised as high-risk under Annex III. The legislation referenced in Annex I, Section A and the associated conformity assessment procedure have long been established and have proven reliable. This approach ensures that all sector-specific hazards are assessed with consistently high quality. Such a thorough assessment is particularly important for products incorporating a high-risk AI system that are derived from similar non-AI products.

Postponement of the dates of application

In contrast, KAN is critical of the amendments proposed in Article 1(31) of the Digital Omnibus on AI to Article 113 of the AI Act. The amendments aim to postpone the dates of application.

While the postponement of the application of Chapter III, Section 2 of the AI Act can be justified by the time required to complete the ongoing standardisation work, this reasoning does not apply to Sections 1 and 3 of Chapter III. Given that many harmonised European standards for AI are expected by the end of 2026, KAN also sees no convincing justification for delaying the application of Annex III by an additional year. Even more problematic is the proposal to postpone application of Annex I considerably longer, potentially until August 2028. While the AI Act itself sets out a one-year interval between the application dates of Annex III and Annex I, the publication of the Act in 2024 and the ongoing preparations by all market participants mean that sectors already subject to applicable Union legislation do not require such a prolonged transition period. To ensure the effective protection of workers' health and safety in a rapidly evolving technological landscape, KAN therefore advocates that the Digital Omnibus on AI synchronise the dates of application for Annex I and Annex III.

Registration obligation for providers of AI systems not considered high-risk

Article 1(6) of the Digital Omnibus on AI proposes abolishing the registration obligation for providers set out in Article 6(4) of the AI Act. In the case of an AI system for which the provider has concluded that it is not high-risk, that provider is required under Article 6(4) to register themselves and that system in the EU database.

KAN highlights that eliminating this registration requirement would significantly reduce transparency regarding AI systems that fall under the criteria of Article 6(3) and are not considered high-risk. This would also impose an additional and disproportionate burden on deployers. Without a mandatory disclosure by providers, deployers need to contact providers in advance to evaluate potential task-related hazards to fulfil their occupational health and safety obligations.

KAN therefore advocates retaining the registration obligation and keeping Article 6(4) of the AI Act in its original version. To further ease the burden on deployers and end-users, KAN recommends introducing an explicit information obligation requiring providers to inform deployers and end-users that an AI system is not considered high-risk. Ideally, this information should be included in the instructions for use of the AI system.

Exceptions for small mid-cap enterprises

The Digital Omnibus on AI introduces the recently established category of small mid-cap enterprises (SMCs) into the AI Act and proposes applying exceptions to them that were originally designed for small and medium-sized enterprises (SMEs).

According to point (2) of the Annex to Commission Recommendation (EU) 2025/1099, SMCs employ up to 749 persons and have an annual turnover of up to EUR 150 million. Extending SME-specific exceptions to companies of this size would considerably widen the group of providers benefiting from reduced regulatory obligations. Companies with up to 749 employees and substantial financial turnover exceed the operational scale at which such exemptions can be justified. Lowering requirements for these larger entities would not only dilute the level of protection intended by the AI Act but could also have negative impacts on workplace safety. In practical terms, this expansion would subject a significantly larger number of providers to simplified rules. As this particularly concerns the requirements laid down in Article 11 of the AI Act on technical documentation and in Article 17 on quality management systems, which are key instruments for ensuring the quality and safety of high-risk AI systems, KAN recommends that derogations from the AI Act's requirements remain limited to SMEs as originally intended.

About KAN

In the Commission for Occupational Health and Safety and Standardisation (KAN), the German representatives of employers, employees, the federal and state governments and the German Social Accident Insurance Institutions channel their interests and discuss them with DIN (German Institute for Standardization). KAN analyses standards and other outcomes of the work of standards organisations, and where applicable other bodies developing standards, that have a direct or indirect impact upon safety and health at work.

KAN's activities therefore include the monitoring of standardisation activity where it impacts upon occupational safety and health, and also the associated legislative activity in Europe, and drawing attention to needs for action. It is in KAN's interests that regulations and directives set out suitable and coherent statutory provisions and lead to corresponding standardisation mandates.

KAN is registered in the EU Transparency Register with the number **90520343621-73**.

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