

Position Paper

Status and challenges in the standardization of
high-risk requirements of the AI Act | December
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At a glance

The standardization of the high-risk requirements of the AI Act is of central importance for its successful implementation. In view of the complex process and the slow progress to date, it is crucial to identify key challenges and develop concrete solutions. Bitkom would like to use this paper to highlight some points that are critical to success.

The slow progress of the standardization process for the AI Act threatens to inhibit innovation.

The delay in the standardization process prolongs legal uncertainty, increases compliance costs and potentially inhibits the development and market launch of new AI systems and AI-based products.

The involvement of the EU Commission in the standardization process must be balanced and efficient.

The EU Commission should continue to be involved in the standardization process, but with a balance that preserves the efficiency and independence of the technical discussions.

More general standards and industry neutrality should take priority.

Horizontal standards should be flexible enough to take account of industry-specific circumstances and existing standards. The focus on more general standards can also speed up the standardization process.

International connectivity of standards must be prioritized.

European standards should be compatible with existing and new international ISO/IEC standards. Harmonization at a global level facilitates market access for companies and prevents barriers to trade.

Consistency in standardization is key.

Requirements and definitions should be designed to be consistent and as complementary as possible across all standards of the AI Act and in interaction with other horizontal legal acts.

1. The slow progress of the standardization process for the AI Act threatens to inhibit innovation.

AI systems covered by Annex III of the AI Act must comply with all high-risk requirements set out in the Regulation (AI Act Articles 9-15) from August 2026 (AI Act Article 113)¹. AI systems listed in Annex Ia (AI Act Article 6(1)) must fully comply with these requirements from August 2027 (Article 113c).

The technical specification of the high-risk requirements of the AI Act for AI systems is carried out by harmonized European standards (hEN), which are developed in the responsible European standardization committee CEN/CENELEC-JTC 21.² However, the development and coordination processes for the AI Act in this committee are proving to be very complex and lengthy. It should be noted that the AI Act differs from previous technical regulations in that not only the person placing a product on the market, but also the operator in particular, must ensure compliance with the legal requirements over the entire life cycle of an AI system.

At this stage, it is unclear whether all standards can be completed in time for the high-risk requirements to apply. A delay in the standardization work would mean that the harmonized European standards (hEN) for the AI Act might only be published at very short notice or even after the legal obligations come into force. The development and compliance cycles of AI systems and AI-based products usually require longer periods of time. Companies would therefore be forced to develop their AI systems, products and the associated compliance processes over a longer period of time under considerable legal uncertainty with regard to subsequent conformity with the high-risk requirements of the AI Act.

Subsequently, extensive and costly adjustments may be required to ensure compliance with the high-risk requirements of the AI Act. This would potentially significantly delay the market launch of new, innovative AI systems and products. In the worst-case scenario, the ongoing legal uncertainty could result in companies not starting to develop AI systems at all for an extended period of time.

To make matters worse, the preliminary development status of the standards cannot be viewed by companies that are not actively involved in the standardization process. This affects the majority of companies affected by the AI Act. Until the harmonized

¹ In addition, the providers and operators of such high-risk AI systems must also comply with the obligations set out in Articles 16-27 of the AI Act.

² On 22 May 2023, the EU Commission issued a standardization mandate for the development of European standards for the AI Act.

European standards are published, these companies are forced to develop their AI systems without guidance and with a greatly increased risk of incompatibility with the legal requirements.

2. The involvement of the EU Commission in the standardization process must be balanced and efficient.

Bitkom expressly welcomes the early involvement of the EU Commission in the standardization process in the CEN/CENELEC JTC 21 standardization committee in order to ensure that the standards are suitable for meeting the legal requirements at an early stage. However, the involvement of the Commission requires a careful balance in order to maintain the efficiency and independence of the process.

It can be observed that the very committed participation of non-technical representatives of the EU Commission influences the technical discussions within the standardization committee. This sometimes leads to experts being reluctant to fully contribute their views, which can affect the diversity of opinions and slow down progress.

It is of great importance that the standardization process is driven forward by those who are directly involved in the development of the technologies. This is the only way to develop practical and implementable requirements that ensure both effective regulation and the avoidance of over-regulation. In order to develop the urgently needed standards quickly, particular attention should therefore be paid to encouraging companies and their technical experts to actively participate in this process.

3. More general standards and industry neutrality should take priority.

The horizontally effective harmonized European standards (hEN) must be sector-neutral, i.e. equally applicable to all sectors. In some sectors, detailed standards already exist, for example in risk or quality management, which already cover the requirements of the standardization mandates on a sector-specific basis. However, these detailed standards differ due to the completely different industry circumstances. For example, fault tolerances and approaches to risk management naturally vary between the medical, automotive and IT sectors.

These differences make it necessary to formulate more general standards for the AI Act that do not set out cross-industry requirements down to the last detail but remain flexible and applicable to the respective industry-specific circumstances. Otherwise, there is a risk of regulatory contradictions and costly adjustments to existing product and compliance development processes, which would not increase the safety of AI systems and products. The focus on more general standards will also contribute to the urgently needed acceleration of standardization processes, as the large number of work items that are currently not sufficiently coordinated is latently overburdening the system.

4. International compatibility of standards must be prioritized.

The harmonized European standards (hEN) should be as compatible as possible with existing and newly developed international ISO/IEC standards in order to ensure global scalability of business models and avoid trade barriers for European AI providers. Initially, this means that the harmonization process will give clear priority to the adoption of existing ISO standards for AI. This is likely to significantly accelerate the standardization process. Furthermore, the European standardization body should always strive to harmonize newly developed standards globally as a matter of principle.

5. Consistency in standardization is key.

Consistent definitions and structural logics across all ten standardization requirements are necessary to ensure that the requirements for high-risk AI systems can be implemented efficiently and without contradictions. Inconsistencies in the standards cause uncertainty during implementation and significantly increase compliance costs for companies.

In addition, the standardization for the AI Act must be closely coordinated with other relevant legal acts of the New Legislative Framework or taken into account in them, such as the Cyber Resilience Act or the Data Act. This coordination should ensure that the requirements and definitions of the various pieces of legislation complement and do not contradict each other. Consistent standardization minimizes duplicate requirements and makes it easier for companies to comply with several regulations at the same time.

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