

AIB 2025-doc 2

SG Standards 2025-1

**Harmonised Standards for High-Risk
AI Systems under the EU AI Act:
Progress and Availability (in
response to the European
Commission Standardisation
Request C(2025) 3871, repealing
C(2023)3215)**

March 2026

This document has been prepared by the Sub-group on Standards of the Artificial Intelligence Board (AIB). The sub-group is composed of representatives of all Member States and chaired by a representative of the European Commission.

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1. INTRODUCTION

Purpose

This section orients a public audience to: (a) what the EU AI Act is, (b) what qualifies as high-risk AI, (c) where GPAI (general-purpose AI) fits, (d) what the European Commission’s standardisation request does, (e) how CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) via JTC 21 (their Joint Technical Committee on AI) are organising the work, and (f) how an OJEU (Official Journal of the European Union) citation turns

a European Standard into a harmonised one that offers a presumption of conformity with legal requirements.

The EU AI Act—what it is

The Artificial Intelligence Act (Regulation (EU) 2024/1689) is the EU’s horizontal, product-safety framework for AI. It prohibits a narrow set of unacceptable uses, imposes specific requirements on high-risk AI systems (including risk management, data governance, logging, transparency, human oversight, accuracy/robustness/cybersecurity, and a provider QMS—Quality Management System), and establishes duties for GPAI models (with additional measures for models presenting systemic risk). A core mechanism is presumption of conformity: if a system complies with a harmonised European standard (hEN) which has been referenced in the OJEU, it is presumed to meet the corresponding AI Act requirements.

High-risk AI systems

High-risk AI systems are (i) safety components of products regulated under certain existing EU product laws set out in Annex I AI Act or (ii) use-cases listed in Annex III of the AI Act. These systems must meet the Chapter III, Section 2 requirements and undergo conformity assessment (CA) under Article 43 (which may involve a notified body—a third-party conformity-assessment organisation notified by a notifying authority—depending on the route chosen).

The Commission’s standardisation request

On 23 June 2025, the European Commission adopted Implementing Decision C(2025) 3871 (which repeals C(2023)3215). It formally requests CEN and CENELEC to develop European standards (ENs) and related deliverables that technically operationalise Articles 9–15 and 17 (and relevant aspects of 43) for high-risk AI systems. Draft standards prepared under this request include an Annex ZA that maps individual technical clauses to specific AI Act requirements—this mapping is what the Commission relies on when deciding whether to cite the standard’s reference in the OJEU.

CEN-CENELEC/JTC 21—who does the work and how

JTC 21 coordinates and drafts the hENs that will support the AI Act. Some hENs are “home-grown,” while others may adopt or align with ISO/IEC (international) work—provided the result is compatible with EU law. Each hEN intended to provide a presumption of conformity includes an Annex ZA to show legal coverage clearly.

From standard to presumption of conformity—how approval works

Within CEN and CENELEC, the development process begins with drafting and proceeds through committee stages to the public enquiry (Enquiry) on a draft European standard (prEN / draft hEN). At this stage, the draft is formally published and opened for public comment, allowing all stakeholders to submit feedback through national standardisation bodies without needing to participate in a national mirror committee. The public enquiry phase is particularly important for SMEs, academic stakeholders, and civil-society organisations with limited resources, as it gives them a structured opportunity to engage with the draft hEN and have their comments considered by the relevant working group in JTC 21. Where the Commission's preliminary assessment indicates gaps or a need for greater regulatory alignment, the working group may further elaborate the draft provisions before moving forward. Public enquiry is usually followed by a formal vote on the draft EN by national standardisation bodies, who evaluate how comments were addressed. A positive vote typically signals technical consensus within the European standardisation system, subject to final editorial and quality checks coordinated by the CEN-CENELEC Management Centre. Once the hEN is finalised, the European Commission assesses whether it fulfils the applicable standardisation request in accordance with Regulation (EU) No 1025/2012. A central element of this assessment is the clarity and completeness of Annex ZA, which must map the clauses of the standard to the relevant requirements of the AI Act.

If the assessment is favourable, the Commission will propose an implementing act to publish the reference of the hEN in the Official Journal of the European Union (OJEU). From that moment, compliance with the cited hEN confers a presumption of conformity with the corresponding AI Act requirements identified in Annex ZA. However, the presumption of conformity may also be withdrawn if the European Parliament or Member States express concerns as provided for by Art. 11 Regulation 1025/2012.

2. AI ACT ARTICLES, HARMONISED STANDARDS, AND PUBLICATION MILESTONES

Introduction

This chapter maps the AI Act's high-risk requirements (Arts. 9–15, 17, 43) to the ten standardisation-request (SR) areas and the corresponding CEN-CENELEC/JTC 21 deliverables intended for harmonisation. It follows the Commission's request structure and keeps the view horizontal across the AI lifecycle (risk, data, logging, transparency, human oversight, accuracy/robustness, cybersecurity, QMS, conformity assessment). Status and milestone dates are taken from the JTC 21 public work programme; they are indicative and may change.

Table 1. Harmonised-standards track

SR area*	AI Act article(s)	Core candidate**	Status	Initial Date	Current Stage	Next Stage	Forecasted voting date
SR1 — Risk management	Art. 9	prEN 18228 – AI Risk Management (WI JT021024)	Under Drafting	3/20/2024	6/4/2025	8/13/2025	9/30/2026
SR2 — Data quality & governance	Art. 10	prEN 18284 – Quality & governance of datasets in AI (WI JT021037)	Under Drafting	9/5/2024	9/5/2024	1/2/2025	3/18/2027
SR2 — Bias management	Art. 10	prEN 18283 – Managing bias in AI systems (WI JT021036)	Under Drafting	8/21/2024	8/21/2024	12/18/2024	3/3/2027
SR3 — Record-keeping	Art. 12	prEN ISO/IEC 24970 – AI system logging (WI JT021021)	Under Approval	8/21/2024	9/30/2025	—	10/12/2026
SR4 — Transparency	Art. 13	prEN 18229-1 — AI trustworthiness framework – Part 1: Logging, transparency and human oversight. (WI JT021008)	Under Drafting	3/20/2024	11/12/2024	8/31/2025	11/30/2026
SR5 — Human oversight	Art. 14	prEN 18229-1 — AI trustworthiness framework – Part 1: Logging, transparency and human oversight. (WI JT021008)	Under Drafting	3/20/2024	11/12/2024	8/31/2025	11/30/2026
SR6 — Accuracy	Art. 15	prEN 18229-2 — AI trustworthiness framework – Part 2: Accuracy and robustness (WI JT021047)	Under Drafting	5/15/2025	5/15/2025	9/11/2025	2/25/2027

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SR7 — Robustness	Art. 15	prEN 18229-2 — AI trustworthiness framework – Part 2: Accuracy and robustness (WI JT021047)	Under Drafting	5/15/2025	5/15/2025	9/11/2025	2/25/2027
SR8 — Cybersecurity	Art. 15	prEN 18282 – Cybersecurity specifications for AI systems (WI JT021029)	Under Drafting	10/2/2024	2/10/2025	8/31/2025	7/15/2026
SR9 — Provider QMS	Art. 17	prEN 18286 – QMS for EU AI Act regulatory purposes (WI JT021039)	Under Drafting	10/16/2024	5/27/2025	9/30/2025	7/29/2026
SR10 — Conformity assessment	Art. 43	prEN 18285 – AI Conformity assessment framework (WI JT021038)	Under Drafting	10/16/2024	10/16/2024	2/12/2025	7/29/2026

* Entries are candidate harmonised standards; legal effect follows OJEU citation

** SR4–SR7 are covered by two parts of the AI trustworthiness framework; SR2 is covered by two standards (datasets and bias). Hence 10 SR areas correspond to 9 EN projects.

Source for statuses/milestones: CEN-CENELEC JTC 21 work programme (public).
URL:

https://standards.cencenelec.eu/ords/f?p=205:22:::FSP_ORG_ID,FSP_LANG_ID:2916257,25&cs=114251C6C0B684FBBBC069923513BF6348

Last updated: 20 Oct 2025.

Table 1 shows the current JTC 21 public work-programme track for candidate harmonised European standards (hENs) supporting key AI Act requirements across the AI system lifecycle (risk management, data governance, logging/record-keeping, transparency, human oversight, accuracy/robustness, cybersecurity, provider QMS, and conformity assessment). Each row links an SR area and relevant AI Act article(s) to a core hEN candidate. The Status column reports the overall project position in the CEN-CENELEC/JTC 21 programme, using the values Under drafting (technical drafting ongoing in the working group), Under approval (the draft in a formal approval route after Enquiry/Formal Vote), Published (the EN/hEN has been issued), or Withdrawn (the project stopped or removed). The Current stage column specifies the active development phase, shown as NP/NWI (New Work Item Proposal), WD (Working Draft), CRM (Comment Resolution Meeting), ENQ (Public Enquiry on prEN), FV (Formal Vote), Proofing/Editing (final editorial checks), or Publication (release milestone). Initial date records when the project entered the programme, Next stage indicates the upcoming phase with its planned start date, and forecasted voting date gives the indicative timing for the Formal Vote. Column headings follow the official JTC 21/CEN-CENELEC terminology for transparent mapping to the public

work programme, and all milestone dates are indicative and may change as drafting and comment resolution progress.

While Table 1 focuses on the administrative timeline and status of the work programme, the technical architecture of the harmonised standards is highly interconnected. For a detailed visual map illustrating how specific standards map to multiple AI Act articles—for instance, how the Quality Management System standard (prEN 18286) addresses both Article 17 and Article 72—readers are encouraged to consult the public summary available at <https://ai-act-standards.com/>.

Articles of the AI Act covered by the standardisation request (SR)

In table 1, the rows follow the ten SR areas in the Commission’s standardisation request for the AI Act, covering: Art. 9 (risk), Art. 10 (data), Art. 12 (record-keeping), Art. 13 (transparency), Art. 14 (human oversight), Art. 15 (accuracy, robustness, cybersecurity), Art. 17 (QMS), Art. 43 (conformity assessment). The resulting portfolio is intentionally horizontal, giving providers one coherent set of lifecycle standards to address the Chapter III, Section 2 requirements plus organisational QMS and conformity assessment. (A presumption of conformity only applies only once the hEN has been cited in the OJEU.)

Harmonised standards emphasis

Each listed hEN is being developed to offer a presumption of conformity with particular requirements. In practice, many obligations (e.g., logging, transparency, oversight, accuracy/robustness) are consolidated in the AI Trustworthiness Framework parts, with dedicated standards for risk, data, cybersecurity, QMS, and conformity assessment filling out the legal coverage. This design minimises fragmentation for implementers by structuring requirements around the AI lifecycle while continuing to allow providers to take a modular approach and select specific legal requirements for which they would like to make use of a presumption of conformity.

Additional standardisation requests may follow (see also: AI Board report on potential elements of a future standardisation request). The Commission can update or extend the request as regulatory or technological needs evolve; further parts or domain-specific methods may be mandated later to complement this horizontal set.

About the dates

In the CEN-CENELEC work programme, the “forecasted voting date” indicates the committee’s indicative target for the formal vote on a draft European Standard (FprEN) after a public enquiry phase. Following a successful vote and completion of editorial checks, the European Commission may assess whether the standard fulfils the standardisation request and propose an implementing act for publication of its reference in the OJEU. Only once cited in the OJEU can a standard confer presumption of conformity for the AI Act requirements it maps to. It should therefore be noted that the forecasted completion dates by CEN-CENELEC do not reflect when the assessment by the Commission, the negotiation of the implementing act with Member States and the final publication of the standard in the OJEU will be completed, which will likely take several months after the hEN is published. For planning purposes in this report, we assume that the core high-risk obligations of the AI Act begin to apply from August 2026. Harmonised standards that reach a positive vote and subsequent OJEU citation before or around that date will immediately support presumption of conformity for providers. Where relevant standards are not yet cited, providers may still demonstrate compliance through the applicable conformity-assessment route using state-of-the-art methods and internal technical documentation; harmonised standards are preferred because they reduce uncertainty, but they are not the sole path to compliance.

Based on the current public work programme, some items are forecast to reach their committee votes after August 2026. In particular, the accuracy and robustness package (prEN 18229-2) and the data governance/bias standards (prEN 18284 and prEN 18283) are presently forecast for 2027 committee votes, which would place their OJEU citation after the obligations start date. By contrast, risk management (prEN 18228), cybersecurity (prEN 18282), provider QMS (prEN 18286) and conformity assessment (prEN 18285) are currently targeted for votes in mid-to-late 2026, although the precise availability of presumption of conformity will ultimately depend on the timing of the Commission’s assessment and OJEU citation.

Implementing without cited hENs

Publishing a standard ahead of the obligations date does not guarantee organisations have enough time to implement it. Conversely, if a relevant hEN is not yet cited, providers are not blocked: under the AI Act’s conformity-assessment rules, they may rely on self-assessment or third-party assessment (as applicable) using state-of-the-art methods and internal technical documentation to demonstrate conformity. hENs are a preferred route because they provide

presumption of conformity, but they are not the only route. (When hENs become available and are cited, they simplify evidence expectations and reduce legal uncertainty.)

3. REVIEW OF STANDARDS THAT REFERENCE OTHER STANDARDS

This chapter introduces how the candidate harmonised European standards (hENs) for high-risk AI systems reference other standards—both within the CEN-CENELEC portfolio and, where appropriate, international deliverables (e.g., ISO/IEC). The analysis focuses on normative references that create binding implementation obligations versus informative references that provide guidance, and explains how these cross-references are handled in Annex ZA to preserve a clear mapping to AI Act requirements. It also highlights common dependency patterns—such as horizontal “framework” standards citing specialised methods (e.g., logging, data governance, cybersecurity), and management-system standards aligning with established quality frameworks—while noting the implications for OJEU citation (only the cited EN confers presumption of conformity, not its informative sources). Finally, the chapter outlines good practice for implementers—version control of referenced documents, consistency across the AI lifecycle, and contingency where referenced materials evolve on different timelines—so that organisations can plan conformity evidence coherently even when underlying source standards are updated.

Table 2. Normative references appearing in the draft candidate harmonised standard

Candidate harmonised standard	Normative references in the draft
prEN 18228 – AI Risk Management (WI JT021024)	No normative references in the current draft
prEN 18284 – Quality & governance of datasets in AI (WI JT021037)	CEN/CLC ISO/IEC/TS 12791:2024Information technology - Artificial intelligence - Treatment of unwanted bias in classification and regression machine learning tasks (ISO/IEC TS 12791:2024)
	EN ISO/IEC 22989:2023Information technology - Artificial intelligence - Artificial intelligence concepts and terminology (ISO/IEC 22989:2022)
prEN 18283 – Managing bias in AI systems (WI JT021036)	CEN/CLC ISO/IEC/TS 12791:2024Information technology - Artificial intelligence - Treatment of unwanted bias in classification and regression machine learning tasks (ISO/IEC TS 12791:2024)
	AI Risk Management
prEN ISO/IEC 24970 – AI system logging (WI JT021021)	No normative references in the current draft
prEN 18229-1 – AI Trustworthiness Framework: Logging, transparency & human oversight (WI JT021008)	ISO/IEC FDIS 9868Information technology — Design, development, use and maintenance of biometric identification systems involving passive capture subjects
	ISO/IEC 22989:2022Information technology - Artificial intelligence - Artificial intelligence concepts and terminology

	ISO/IEC 24029-2:2023 Artificial intelligence (AI) — Assessment of the robustness of neural networks — Part 2: Methodology for the use of formal methods
	ISO/IEC 12792:2025 Information technology — Artificial intelligence — Transparency taxonomy of AI systems
prEN 18229-2 — AI trustworthiness framework – Part 2: Accuracy and robustness (WI JT021047)	Under drafting; normative references not yet consolidated
prEN 18282 – Cybersecurity specifications for AI systems (WI JT021029)	CEN/CLC JT021039 Artificial intelligence — Quality management system for EU AI Act regulatory purposes
prEN 18286 – QMS for EU AI Act regulatory purposes (WI JT021039)	No normative references in the current draft
prEN 18285 – AI Conformity assessment framework (WI JT021038)	EN ISO/IEC 17000:2004, Conformity assessment — Vocabulary and general principles
	EN AI Quality management System
	EN AI Risk Management System
	EN AI Cybersecurity
	EN AI Trustworthiness framework

Last updated: 20 Oct 2025.

Normative references inside a candidate harmonised European standard are binding: conformity with the standard presupposes conformity with the referenced document, at the edition specified in the text. Where a referenced document is later updated, the cited edition continues to govern until the European standard is revised or amended. Implementers should therefore maintain clear version control and retain evidence of the exact editions applied when demonstrating conformity.

The cross-referencing pattern reflects the horizontal architecture of the portfolio. The AI trustworthiness framework—Part 1 on logging, transparency and human oversight, and Part 2 on accuracy and robustness—draws on foundational ISO/IEC sources for shared concepts, transparency taxonomy and robustness methodologies, thereby ensuring consistent interpretation across Articles 12–15 of the AI Act. The conformity assessment framework integrates the set by referencing the risk-management, quality-management, cybersecurity and trustworthiness documents to structure evidence under Article 43, while the data strand separates dataset governance from bias management to align with Article 10.

Some texts remain in development and their normative reference lists are not yet consolidated. In particular, Trustworthiness Framework Part 2 (accuracy and robustness) is still under drafting, and additional normative sources may be added as the text moves toward Enquiry and Formal Vote. Where a current draft shows “no normative references,” requirements are embedded directly or supported only by informative materials; this may change during editing. The table should therefore be treated as a living overview which may be updated as drafts evolve.

4. CONCLUSION AND RECOMMENDATIONS

Harmonised European standards are the main route to presumption of conformity, but they are not the only route. Once the European Commission cites the references of harmonised European standards in the Official Journal of the European Union, compliance with those standards confers presumption of conformity for the mapped requirements. Until that citation happens, providers and deployers can demonstrate conformity through the applicable assessment routes using state-of-the-art methods and well-structured technical documentation.

The portfolio of harmonised standards being developed to offer a presumption of conformity covers the full lifecycle of high-risk artificial intelligence systems: risk management; data quality and governance (including management of bias); record-keeping (logging); transparency; human oversight; accuracy and robustness; cybersecurity; provider quality management system; and conformity assessment. According to the public work programme, several core texts are targeting committee votes in mid to late 2026 (notably risk management, cybersecurity, provider quality management system, and conformity assessment). The accuracy and robustness part and the two data standards are forecast for 2027 votes. For planning, this report assumes core high-risk obligations start in August 2026, which means some obligations will apply before all relevant harmonised European standards are cited.

Market-facing recommendations

- 1. Treat harmonised European standards as one pathway to conformity rather than a prerequisite.** Organisations should recognise that harmonised European standards, once cited, provide a clear presumption of conformity, but products and systems can still be lawfully placed on the market by demonstrating compliance through other acceptable methods prior to citation. Maintain documentation that maps the legal requirements to your implemented controls so that evidence remains valid during the interim period.
- 2. Use alternatives now by applying your own technical expertise and recognised non-harmonised standards.** Until harmonised European standards are cited, you may rely on suitable state-of-the-art practices and other recognised standards (for example, from international standardisation bodies) to demonstrate compliance with requirements, provided you justify

the choice clearly in your technical file and remain attentive to differences in definitions.

3. **Choose and document the appropriate conformity-assessment route—self-assessment or third-party assessment—based on your system.** Depending on the legal route that applies and on the choice of the provider, both internal control (self-assessment) and assessment by a notified body are possible.
4. **Participate proactively in standardisation development.** In particular during the public enquiry phase, stakeholders can preview the harmonised standard, test its applicability within their own structures and provide feedback that can help shape the harmonised standard into a widely-usable tool for compliance.
5. **Collaborate proactively with national competent authorities and the European Union AI Office.** Early engagement for questions and alignment helps reduce rework, supports consistent interpretation of requirements, and can accelerate acceptance of your evidence set once harmonised European standards are available. Consider participating in consultations or information sessions when invited.
6. **Plan a smooth migration to harmonised European standards offering a presumption of conformity when they become available.** Maintain a simple “requirements-to-controls” table that links each legal requirement to your current controls, tests, and artefacts; when harmonised European standards are cited, update the references and test methods in that table rather than redesigning the entire system. This approach minimises disruption and leverages the work already completed. Note however that the specific approach of the AI Act as a product safety law may differ from standards that are already available, and differences e.g. in definitions or in the object of the standard may lead to significant adjustment needs once harmonised standards have been cited in the OJEU.
7. **Keep strict version control for all referenced materials and tests.** Because only the cited European standard confers presumption of conformity (not its informative sources), keep exact editions, datasets, scripts, and metrics under version control, and record when any underlying reference changes so you can show continuity of compliance.

Recommendations for Member States

1. Ensure broad participation in the development of harmonised standards in line with Art. 5-6 Regulation 1025/2012 and as required by Art. 62(1)d AI Act.
2. Encourage the participation of public authorities in the development of harmonised standards as required by Art. 7 Regulation (EU) 1025/2012.