



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems III: Construction, Machinery and Standardisation
Standards Policy

Brussels, 14.1.2025

A Notification under Article 12 of Regulation (EU) No 1025/2012¹

Subject matter related to

<input type="checkbox"/>	Annual Union Work Programme for European standardisation (Art. 12, point a)
<input checked="" type="checkbox"/>	Possible future standardisation requests to the European standardisation organisations (Art. 12, point b)
<input type="checkbox"/>	Formal objections to harmonised standards (Art. 12, point c)
<input type="checkbox"/>	Identifications of ICT technical specifications (Art. 12, point d)
<input type="checkbox"/>	Delegated acts to modify Annexes I or III of Regulation (EU) No 1025/2012 (Art. 12, point e)

Title of the initiative

Draft standardisation request amending implementing decision C(2023)3215 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence

Additional information

Legislative/Policy reference(s)	Regulation (EU) 2024/1689 of the European Parliament and of the Council Council laying down harmonised rules on artificial intelligence OJ L 2024/1689, 12.7.2024
EN reference(s)	-
Status	Draft
Other information	This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.
Deadline for feedback	11.2.2025

Commission contact point for this notification

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¹ OJ L 316, 14.11.2012, p. 12

Brussels, XXX
[...] (2025) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

on amending implementing decision C(2023)3215 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence

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COMMISSION IMPLEMENTING DECISION

of **XXX**

on amending implementing decision C(2023)3215 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council¹, and in particular Article 10(1) thereof,

Whereas:

- (1) Regulation (EU) 2024/1689 of the European Parliament and of the Council (Artificial Intelligence Act)² establishes a uniform legal framework for the development, placing on the market, the putting into service and the use of artificial intelligence systems (AI systems) in the Union, in accordance with Union values, to promote the uptake of human-centric and trustworthy artificial intelligence while ensuring a high level of protection of health, safety, and fundamental rights as enshrined in the Charter of Fundamental Rights of the European Union, including democracy, the rule of law and environmental protection, to protect against the harmful effects of AI systems in the Union, and to support innovation.
- (2) The requirements for high-risk AI systems are laid down in Articles 8 to 15 of the Artificial Intelligence Act (AI Act). The obligations of providers and deployers of high-risk AI systems and other parties, including on the quality management system, logging and documentation keeping are laid down in Articles 16 to 27 of the AI Act.
- (3) Based on the New Legislative Framework³ for Union product safety, the AI Act sets the essential requirements and provides that the technical details for AI systems meeting the essential requirements set out in legislation shall be laid down in harmonised standards. The operation of Union harmonisation legislation under the

¹ OJ L 316, 14.11.2012, p. 12.

² OJ L 2024/1689, 12.7.2024. Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directive 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

³ Harmonised rules applicable to the placing on the market, the putting into service and the use of high-risk AI systems should be laid down consistently with Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision No 768/2008/EC of the European Parliament and of the Council and Regulation (EU) 2019/1020 of the European Parliament and of the Council (New Legislative Framework).

New Legislative Framework approach requires harmonised standards to offer a guaranteed level of protection with regard to the essential requirements established by the legislation⁴. Accordingly, harmonised standards and standardisation deliverables adopted in support of the AI Act shall facilitate implementation of the AI Act, and, in particular, ensure a high level of protection of health, safety and fundamental rights for all persons in the Union. Those standards shall also support the establishment of equal conditions of competition and promote innovation and a level playing field for the design and development of AI systems, in particular for small and medium-sized enterprises that develop AI solutions.

- (4) In accordance with Article 40 paragraph 1, high-risk AI systems that are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) 1025/2012 shall be presumed to be in conformity with the requirements set out in Articles 9 to 15 of the AI Act, to the extent that those standards cover those requirements.
- (5) Through the Implementing Decision C(2023)3215, the Commission requested the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) to work on European standards and European standardisation deliverables addressing the key technical areas covered by the AI Act proposal and thus support the Union policy on artificial intelligence.
- (6) CEN and CENELEC have accepted the standardisation request set out in the Implementing Decision C(2023)3215. The corresponding standardisation work is ongoing.
- (7) The Artificial Intelligence Act was published in the Official Journal of the European Union on 12 July 2024 and entered into force on 1 August 2024.
- (8) The matters that need to be addressed by the harmonised standards and standardisation deliverables, relating to high-risk AI systems, in support of essential requirements set out in Articles 9 to 15 of the AI Act, are technically complex, and the New Legislative Framework product safety approach of the AI Act is novel for the standardisation work on AI systems. It is also the first time that, building on product safety legislation, detailed technical specifications such as appropriate test methods or equivalent verifiable and reproducible approaches for high-risk AI systems, in particular related to the identification and mitigation of risks to fundamental rights, are being developed.
- (9) In their joint semestrial report of September 2024 on the implementation of the above-mentioned request, CEN and CENELEC have informed the Commission about the significant delays in the related activities.
- (10) The Implementing Decision C(2023)3215 needs to be amended to allow for the adoption of harmonised standards and alignment of the standardisation request with the final text of the AI Act.
- (11) The intention to seek the revision of Implementing Decision C(2023)3215 is mentioned as Action 15 of the Commission Notice on ‘The 2024 annual Union work programme for European standardisation’⁵.

⁴ 2022/C 247/01, Commission Notice - The ‘Blue Guide’ on the implementation of EU product rules 2022, p. 8.

⁵ COM (2024) 541 of 15 February 2024.

- (12) Following the adoption of the AI Act it is appropriate to replace all references by the ‘European Standards and standardisation deliverables’ in the Implementing Decision C(2023) 3215 and its Annexes I and II to ‘Harmonised standards and standardisation deliverables’. Similarly, all references to the ‘Artificial Intelligence Act proposal’ shall be replaced by the ‘Artificial Intelligence Act, and all references to ‘in support of Union policy on artificial intelligence’ shall be amended to ‘in support of Regulation (EU) 2024/1689’.
- (13) Article 40 paragraph 2 of the AI Act provides that the requested harmonised standards and standardisation deliverables shall be clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I of the AI Act, and aimed at ensuring that high-risk AI systems placed on the market or put into service in the Union meet the relevant requirements or obligations laid down in the AI Act.
- (14) In accordance with Article 40 paragraph 2 subparagraph 3 of the AI Act, given the importance of harmonised standards and standardisation deliverables for the successful implementation of the AI Act, CEN and CENELEC shall provide evidence of their best efforts to fulfil the objectives referred to in Article 40 of the AI Act in accordance with Article 24 of Regulation (EU) 1025/2012.
- (15) In accordance with Article 40 paragraph 3 of the AI Act, recognising their central role in the standardisation process, CEN and CENELEC shall seek to promote investment and innovation in AI, including through increasing legal certainty, as well as competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) 1025/2012.
- (16) Reiterating the full support for international cooperation and in line with the well-established practices of cooperation between European and international standardisation organisations, harmonised standards developed by CEN and CENELEC may be based fully or partially on international ISO or IEC standards. However, conditions to base harmonised standards in support of the AI Act on international ISO or IEC standards, fully or partially, include compatibility with the AI Act’s regulatory purpose and approach. This compatibility requires in particular, consistency with definitions, objectives, including to ensure a high level of protection of health, safety and fundamental rights, the requirements and obligations of the AI Act, as well as with the Union values and principles.
- (17) In line with Article 7 of the of Regulation (EU) No 1025/2012 and the Vademecum on European standardisation in support of Union legislation and policies⁶, due to the importance of standardisation as a key tool to provide technical solutions to providers to ensure compliance with the AI Act, considering the timeline provided in the AI Act for the entry into application of the requirements for high-risk AI systems, and in order to avoid ex-post objections to and modifications of harmonised standards, it is important that public authorities participate in standardisation at all stages of the development of harmonised standards and standardisation deliverables developed in response to this standardisation request.

⁶ SWD (2015) 205 final

- (18) The list of requested standards and standardisation deliverables in Annex I of the Implementing Decision C(2023) 3215 remains unchanged. However, following the entry into force the AI Act, the reference to the ‘European standards and standardisation deliverables’ is amended to ‘Harmonised standards and standardisation deliverables’.
- (19) Annex II of Implementing Decision C(2023) 3215 sets the requirements for the list of harmonised standards and standardisation deliverables referred to in Annex I to that Decision. The AI Act provides further clarification in the relevant Articles and accompanying recitals compared to the AI Act proposal. In order to align and fully take into account the AI Act provisions on essential requirements and obligations, it is necessary to replace Annex II of Implementing Decision C(2023) 3215.
- (20) Based on the examination of the CEN and CENELEC joint semestrial report of September 2024, the Commission considers that more time is required for the development of the standards and standardisation deliverables provided in Annex I. Article 1 setting the deadline for the development of harmonised standards and standardisation deliverables, Article 3 setting the deadline for the final report, as well as Article 4 setting the validity of the standardisation request of Implementing Decision C(2023) 3215 shall therefore be amended.
- (21) However, in order to further enhance and facilitate the execution of the requested standardisation activities, Article 2 on work programme and Article 3 on reporting by CEN and CENELEC shall be amended to ensure more detailed planning and more regular reporting to the Commission.
- (22) CEN and CENELEC shall continue and intensify work started on the basis of the Implementing decision C(2023) 3215 and draft harmonised standards and standardisation deliverables in support of Regulation (EU) 2024/1689 to ensure their availability by the new deadline.
- (23) In accordance with the judgement of the European Court of Justice of 5 March 2024, Public.Resource.Org, C-588/21, CEN and CENELEC recognise that the European standard(s) adopted in response to this standardisation request may be subject to access to documents requests in accordance with Regulation (EU)1049/2001 and, should that be the case, the access to the standard(s) has to be granted.
- (24) The European standardisation organisations, the European stakeholders' organisations receiving Union financing, the AI Board established by Article 65 of the AI Act have been consulted.
- (25) In accordance with Article 10(3) of Regulation (EU) No 1025/2012, each standardisation request is subject to acceptance by the relevant European standardisation organisations. It is therefore necessary to lay down rules on the validity of this Decision in the event that CEN or CENELEC would not accept the amendments to Implementing Decision C(2023)3215 set out in this Decision.
- (26) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 22 of Regulation (EU) No 1025/2012,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision C(2023)3215 is amended as follows:

(1) in Article 1, the first subparagraph is replaced by the following:

“The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) are requested to draft the new harmonised standards or standardisation deliverables, as listed in Annex I, in support of the Regulation (EU) 2024/1689 of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directive 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) by 31 August 2025.”;

(2) in Article 2, a new paragraph 5 is added:

“CEN and CENELEC shall prepare a revised work programme indicating all the harmonised standards and standardisation deliverables listed in Annex I and a detailed timetable for the execution of the requested standardisation activities in line with the deadline set out in Article 1. The actions that shall be covered in the work programme as referred in paragraph 1 shall also apply to the revised work programme.”;

(3) In Article 2, a new paragraph 6 is added:

“CEN and CENELEC shall submit the revised work programme to the Commission at the latest 2 months after the notification of this Decision by the Commission.”

(4) Article 3, paragraph 1, replaced by the following:

“CEN and CENELEC shall provide a detailed report every 3 months to the Commission on the execution of the request referred to in Article 1, including an assessment of the progress made in the implementation of the revised work programme referred to in Article 2 paragraph 5 and shall provide detailed evidence of their best efforts to fulfil this Decision and deliver harmonised standards and standardisation deliverables listed in Annex I to the Implementing Decision C(2023)3215.”;

(5) in Article 3, paragraph 3, ‘30 April 2025’ is replaced by ‘31 August 2025’;

(6) in Article 4, second subparagraph, ‘28 February 2026’ is replaced by ‘28 February 2027’;

(7) in recitals 5, 6, 8, 9, 14, 15 and 16, Articles 1, 2 and 3 and title of the Annex I ‘European standards and European standardisation deliverables’ is replaced by ‘harmonised standards and standardisation deliverables’;

(8) in recitals 4 and 5 ‘Artificial Intelligence Act proposal’ is replaced by ‘Artificial Intelligence Act’;

(9) in recital 9 and in the title of the of Implementing Decision C(2023)3215 ‘Union policy on artificial intelligence’ is replaced by ‘Regulation (EC) 2024/1689’;

(10) Annex II is replaced by the text in Annex to this Decision.

Article 2

If the European Committee for Standardisation or the European Committee for Electrotechnical Standardisation indicates that it does not accept the amendments set out in Article 1 and Article 2 of this Decision, this Decision shall cease to apply and Implementing Decision C(2023)3215 in its version of 22 May 2023 shall continue to apply.

Article 3

This Decision is addressed to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation.

Done at Brussels,

For the Commission

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ANNEX

Requirements for the harmonised standards and standardisation deliverables referred to in Article 1

1. Requirements for all harmonised standards and standardisation deliverables

The harmonised standards and standardisation deliverables shall contribute to the achievement of public policy objectives set in Regulation (EU) 2024/1689 to foster the development, use, and uptake of AI in the internal market while ensuring a high level of protection of public interests, such as health and safety and the protection of fundamental rights, including democracy, the rule of law, and environmental protection, as recognised and protected by Union law.

To mitigate the risks from high-risk AI systems placed on the market or put into service and to ensure a high level of trustworthiness, Regulation (EU) 2024/1689 lays down certain essential requirements for high-risk AI systems. These requirements cover risk management, data quality and governance, technical documentation, record-keeping, transparency

The harmonised standards and standardisation deliverables shall support the application of relevant essential requirements for high-risk AI systems set out in Regulation (EU) 2024/1689.

The harmonised standards and standardisation deliverables shall be aligned with the framework set by Regulation (EC) No 765/2008 of the European Parliament and of the Council¹, Decision No 768/2008/EC of the European Parliament and of the Council², and Regulation (EU) 2019/1020 of the European Parliament and of the Council³ (New Legislative Framework). The alignment with the New Legislative Framework product safety legislation shall be without prejudice to any additional and specific policy objectives of Regulation (EU) 2024/1689, as provided in Article 1 of Regulation (EU) 2024/1689, such as ensuring a high level of protection of fundamental rights.

The harmonised standards and standardisation deliverables shall provide technology-based, process-based or methodology-based technical specifications of safety and performance requirements with an appropriate level of detail to ensure compliance with the essential requirements for AI systems set in Regulation (EU) 2024/1689. Where applicable, the harmonised standards shall include methods for verification, validation and testing procedures, objectively verifiable criteria and implementable methods to assess compliance with such specifications.

The harmonised standards and standardisation deliverables, in particular, shall contribute to eliminating or minimising risks to the health and safety and fundamental rights of persons as guaranteed in the Charter of Fundamental Rights of the European Union as well as in applicable EU law aiming to protect fundamental rights that arise from the design and development of AI systems in view of their intended purpose.

The harmonised standards and standardisation deliverables shall be proportionate and effective to meet the objectives of Regulation (EU) 2024/1689, in particular, to ensure that high-risk AI systems available in the Union or whose output is otherwise used in the Union do not pose unacceptable risks to important Union public interests recognised and protected by Union law, and shall take into account the generally acknowledged state-of-the-art on AI. ‘State-of-the-art’ should be understood as a developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience and which is accepted as good practice in technology. The ‘state-of-the-art’ does not necessarily imply the latest scientific research still in an experimental stage or with insufficient technological maturity. For the purpose of ensuring

that the harmonised standards and standardisation deliverables are in line with Union law on fundamental rights and Union data protection law, CEN and CENELEC shall gather relevant expertise in those areas.

The harmonised standards and standardisation deliverables shall take international standardisation efforts into account, to the extent appropriate and without prejudice to the requirements of this Annex, and to the safeguard EU values and fundamental rights of persons as guaranteed in the Charter of Fundamental Rights of the European Union as well as in applicable EU law aiming to protect fundamental rights.

The harmonised standards and standardisation deliverables produced shall be clear and consistent, including with the harmonised standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I of Regulation (EU) 2024/1689, and with the legal framework and international obligations of the Union.

The structure of a harmonised standard shall be such that a clear distinction can be made between its clauses and sub-clauses which are necessary for compliance with the safety and performance requirements of Regulation (EU) 2024/1689 that the standard aims to cover, and those which are not. The relationship between the clauses and sub-clauses of a harmonised standard and the requirements of Regulation (EU) 2024/1689 shall be indicated in the Annexes Z to each standard. The relevant requirement of Regulations (EU) 2024/1689 shall be taken into account from the beginning and throughout the process of development of the standards.

Supporting specifications, including those on terminology, shall also be identified and provided when necessary to ensure the consistency and ability to implement the harmonised standards and standardisation deliverables. All the harmonised standards and standardisation deliverables prepared on the basis of this request should rely on a common set of terms. Supporting specifications on terminology must build as much as possible on terminology adopted at international level and notably in international standards, provided those supporting specifications on terminology are in line with the purpose, objectives, definitions, requirements and obligations of Regulation (EU) 2024/1689 and Union values and principles.

The normative body of a harmonised standard shall not contradict any definition set out in Regulation (EU) 2024/1689. A harmonised standard shall also not define terms that are not defined in this Regulation or the New Legislative Framework, in a way that contradicts the legislative intent or objectives of the Regulation (EU) 2024/1689.

Where a definition in a harmonised standard does not contradict but still differs from a definition of the same term set out in Regulation (EU) 2024/1689, the differences shall be indicated in the foreword of that standard and in its Annex Z. That Annex shall also state that, for the purpose of using the standard in support of the requirements set out in Regulation (EU) 2024/1689, the definitions set out in this Regulation prevail.

The normative body of a harmonised standard shall not contradict the purpose, scope and the New Legislative Framework approach of Regulation (EU) 2024/1689. If the harmonised standard requires the use of another standard to meet the legal requirements of Regulation (EU) 2024/1689, and that other standard while covering similar technical specifications has a different focus or objectives, such as a different approach to product safety or protection of health, safety, and fundamental rights, these differences shall be clearly indicated in the foreword of the harmonised standard and its Annex Z. That Annex shall also state that, for the purpose of using the standard in support of the requirements set in Regulation (EU) 2024/1689, the purpose and scope set out in this Regulation must be fully taken into

consideration and the provisions of the standard in support of the requirements must be interpreted and understood in the context of the purpose, scope and approach set in the Regulation (EU) 2024/1689.

Each harmonised standard developed on the basis of the standardisation request referred to in Article 1 shall refer to this Decision.

When one of the harmonised standards listed in Annex I does not cover all relevant requirements applicable to AI systems or process requirements falling under its scope, or when it covers such requirements only partially, that standard shall include in its Annex Z information on the relevant applicable requirements or parts thereof that are not covered by it.

Normative references included in a harmonised standard shall be clear and specific and ensure the identification of all specifications covered by the standard. Where a standard refers to another standard or a clause in that standard, and that standard or clause contains a further normative reference or references ('a normative reference chain'), the whole normative reference chain shall be clear and specific. Normative reference chains shall nevertheless be avoided.

Clauses of a standard which do not provide for technical, scientific or methodological specifications, but are limited to a normative reference to another standard or a clause in that standard, shall not claim coverage of the legal requirements that are addressed in the standard normatively referred to.

Standards which do not ensure compliance with legal requirements on their own, but require application of another standard, shall contain a clear statement to that effect. They shall not claim coverage of the legal requirements covered by that other standard.

The harmonised standards and standardisation deliverables shall primarily focus on the AI systems' specific hazards and risks, including AI systems that continue to learn after being placed on the market or put into service that the Commission has identified as posing a high-risk in the context of Regulation (EU) 2024/1689.

Based on the New Legislative Framework, as clarified in Commission notice - The "Blue Guide" on the implementation of EU product rules 2022⁴ - the general rule is that more than one legal act of Union harmonisation legislation may be applicable to one product, since the making available or putting into service can take place only when the product complies with all applicable Union harmonisation legislation. The hazards of AI systems covered by the requirements of Regulation (EU) 2024/1689 concern different aspects from the existing Union harmonisation legislation and therefore the requirements of Regulation (EU) 2024/1689 and the harmonised standards and standardisation deliverables developed on the basis of this standardisation request would complement the existing body of the Union harmonisation legislation and harmonised standards.

Notwithstanding the horizontal nature of Regulation (EU) 2024/1689, the harmonised standards or European standardisation deliverables, as appropriate to meet the essential requirements of Regulation (EU) 2024/1689, may concern certain specific AI systems (use cases), covered in Annex III paragraph 1 of Regulation (EU) 2024/1689.

Notwithstanding the horizontal nature of Regulation (EU) 2024/1689, the harmonised standards or European standardisation deliverables may provide specifications that may concern certain specific sectors ("vertical specifications"), in consideration of the intended purpose and/or context of use of those systems. While it is not always possible to develop the harmonised standards and standardisation deliverables that consider each specific intended purpose, the harmonised standards and standardisation deliverables shall cover at the minimum a range of technical solutions and options, which the manufacturer can assess and

implement, taking into consideration the intended purpose of their specific system. The harmonised standards and standardisation deliverables shall also possibly include guidance on how such assessment and implementation of solutions and options shall be executed.

In the fields of human oversight and accuracy, specific requirements for vertical specifications are laid down in Sections 2.5 and 2.6.

The harmonised standards and standardisation deliverables shall take into account as appropriate work produced by the European Telecommunications Standards Institute (ETSI), notably with regard to:

- (a) preparation of the harmonised standards and standardisation deliverables referred to in point 8 of Annex I and integration of security aspects in the harmonised standards and standardisation deliverables listed in Annex I other than those referred to in its point 8;
- (b) preparation and elaboration of possible vertical specifications;
- (c) testing and validation procedures for AI systems.

To this purpose, CEN and CENELEC shall endeavour to establish appropriate modes of cooperation with ETSI.

In order to ensure a high level of trustworthiness of high-risk AI systems, the harmonised standards and standardisation deliverables produced shall take into account the interdependencies between the different requirements listed in Chapter III, Section 2 of the Regulation (EU) 2024/1689 and, to the extent possible, reflect them explicitly in the corresponding specifications, to ensure that risks for health, safety and fundamental rights are effectively mitigated.

In particular, Article 15 of the Regulation (EU) 2024/1689 sets requirements for accuracy, robustness and cybersecurity. While Annex I identifies three separate areas to be addressed through requested harmonised standards and standardisation deliverables, CEN and CENELEC shall ensure coherence among the harmonised standards in order to meet the requirement included in Article 15 paragraph 1 of the Regulation (EU) 2024/1689 that states “High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects through their lifecycle.”

While there is no specific request for harmonised standard and standardisation deliverable for technical documentation to support Article 11 of the Regulation (EU) 2024/1689, CEN and CENELEC shall ensure that provisions of Article 11 are fully covered in other harmonised standards and standardisation deliverables, particularly on the quality management system.

CEN and CENELEC shall ensure that the harmonised standards and standardisation deliverables produced are, when applicable, consistent with existing and future standards developed in the various relevant sectors, notably those related to products covered by existing Union safety legislation, including Directive 2001/95/EC on general product safety.

CEN and CENELEC shall ensure that the harmonised standards and standardisation deliverables are drafted in such a way so as to reflect an appropriate consideration of the specificities and costs of small and medium-sized enterprises, in particular in relation to quality management systems and conformity assessments (Sections 2.9 and 2.10).

2. Specific Requirements for harmonized standards and standardisation deliverables

In addition to the general requirements set in Section 1 of this Annex and applicable to all harmonised standards and standardisation deliverables, the following specific requirements apply. The below references to the specific provisions of Regulation (EU) 2024/1689 indicate the main applicable provision in the Regulation. The applicable explanatory recitals, as well as other relevant provisions of the Regulation necessary to give full effect to the relevant requirements, for example other provisions of the Regulation that are cross-referenced in the relevant provision of the Regulation, as well Articles 1, 2 and 3 of the Regulation, shall be fully taken into consideration in developing specific harmonised standards.

While this standardisation request covers ten different areas of harmonised standards and standardisation deliverables, CEN and CENELEC shall ensure that those deliverables are not isolated from each other, but rather form part of one system of harmonised standards that aim to ensure a high level of trustworthiness of high-risk AI systems and full and comprehensive coverage of all essential requirements listed in Chapter III, section 2 of Regulation (EC) 2024/1689.

2.1. Risk management system for AI systems

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for a risk management system for AI systems. Those specifications shall comprehensively cover all elements included in Article 9 of Regulation (EU) 2024/1689.

In line with Article 3 of Regulation (EU) 2024/1689, ‘risk’ should be understood as the combination of the probability of an occurrence of harm and the severity of that harm. Risk management shall be intended as a continuous, iterative process that is planned and run throughout the entire lifecycle of the AI system.

2.2. Data and data governance

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for data and data governance. Those specifications shall comprehensively cover all elements of Article 10 of Regulation (EU) 2024/1689.

2.3. Record keeping through logging capabilities

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for record keeping. Those specifications shall comprehensively cover all elements of Article 12 of Regulation (EU) 2024/1689.

2.4. Transparency and provision of information to deployers

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for transparency and provision of information to deployers. Those specifications shall comprehensively cover all elements of Article 13 of Regulation (EU) 2024/1689.

2.5. Human oversight

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for human oversight. Those specifications shall comprehensively cover all elements of Article 14 of the Regulation (EU) 2024/1689.

2.6. Accuracy specifications for AI systems

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for accuracy, to support the implementation of Article 15 paragraph 3 of the Regulation (EU) 2024/1689.

This (these) harmonised standard(s) and standardisation deliverable(s) shall lay down specifications ensuring an appropriate level of accuracy of AI systems and requiring providers to select, declare, and reliably measure and validate the effectiveness of accuracy metrics and levels for high-risk AI systems, taking into consideration the risks these may pose to health, safety or fundamental rights.

For the purpose of this (these) harmonised standard(s) and standardisation deliverable(s), “accuracy” shall be understood as referring to the capability of the AI system to perform the task for which it has been designed. This should not be confused with the narrower definition of statistical accuracy, which is one of several possible metrics for evaluating the performance of AI systems.

This (these) harmonised standard(s) and standardisation deliverable(s) shall also establish, where justified, a set of appropriate and relevant tools and metrics to measure accuracy against suitably defined levels, that are specific to certain AI systems in consideration of their intended purpose.

2.7. Robustness specifications for AI systems

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for robustness. Those specifications shall comprehensively cover all elements of Article 15 paragraph 4 of the Regulation (EU) 2024/1689.

2.8. Cybersecurity specifications for AI systems

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for cybersecurity. Those specifications shall comprehensively cover all elements of Article 15 paragraph 5 of the Regulation (EU) 2024/1689.

This (these) harmonised standard(s) and standardisation deliverable(s) shall take due account of the essential requirements for products with digital elements as listed in Regulation of the European Parliament and the Council on horizontal cybersecurity requirements for products with digital elements⁵.

2.9. Quality management system for providers of AI systems, including post-market monitoring process

This (these) harmonised standard(s) and standardisation deliverable(s) shall set up specifications for quality management systems. Those specifications shall comprehensively cover all elements of Article 17 of Regulation (EU) 2024/1689.

2.10. Conformity assessment for AI systems

This (these) harmonised standard(s) and standardisation deliverable(s) shall provide procedures and processes for conformity assessment activities related to AI systems and quality management systems of AI providers.

This (these) harmonised standard(s) and standardisation deliverable(s) shall also provide criteria for assessing the competence of persons tasked with the conformity assessment activities.

This (these) harmonised standard(s) and standardisation deliverable(s) shall consider both the scenarios whereby the conformity assessment is carried out by the provider itself or with the involvement of a professional external third-party organisation.