



Brussels, 23.6.2025
C(2025) 3871 final

COMMISSION IMPLEMENTING DECISION

of 23.6.2025

on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards high-risk AI-systems in support of Regulation (EU) 2024/1689 of the European Parliament and of the Council and repealing Implementing Decision C(2023)3215

(Text with EEA relevance)

(Only the English, French and German texts are authentic)

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(Only the English, French and German texts are authentic)

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) By Implementing Decision C(2023)3215², the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the drafting of European standards and European standardisation deliverables addressing the key technical areas covered by the proposal for a regulation laying down harmonised rules on artificial intelligence and thus supporting the Union policy on artificial intelligence.
- (2) CEN and Cenelec accepted the request and the standardisation work is ongoing.
- (3) Regulation (EU) 2024/1689 of the European Parliament and of the Council³ has subsequently been adopted and entered into force on 1 August 2024. It establishes a uniform legal framework for the development, the placing on the market, the putting into service and the use of artificial intelligence (AI) systems in the Union.

¹ OJ L 316, 14.11.2012, p. 12, ELI: <http://data.europa.eu/eli/reg/2012/1025/oj>.

² Commission Implementing Decision C(2023)3215 of 22.5.202 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

³ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 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 Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>).

- (4) In accordance with Article 40 of Regulation (EU) 2024/1689, high-risk AI systems which 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) 2024/1689, are to be presumed to be in conformity with the essential requirements set out in Articles 9 to 15 of that Regulation, covered by those standards or parts thereof.
- (5) 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’⁴.
- (6) Following the adoption of Regulation (EU) 2024/1689, the request should concern the development of harmonised standards and the content of the request, in particular the requirements set out in Annex II to Implementing Decision C(2023) 3215, should reflect the final text of that Regulation. In addition, CEN and Cenelec have, in their joint semestrial report of September 2024, informed the Commission about significant delays in the standardisation activities under the request made by Implementing Decision C(2023)3215. Since the matters that need to be addressed by the harmonised standards and European standardisation deliverables are technically complex and novel, a new deadline should be set for the completion of the standardisation work. In order to take into account the new deadline, it is also necessary to extend the expiration date of the request set out in Implementing Decision C(2023)3215 and to extend the deadline for CEN and Cenelec to provide the Commission with the final report. Even though the scope of the standards, the deliverables requested and the technical content of the standards should be the same as indicated in Annex I to Implementing Decision C(2023)3215, that Implementing Decision should be repealed and replaced having regard to the extent of the amendments required and in the interest of clarity.
- (7) Harmonised standards help to ensure a high level of protection of health, safety and the environment throughout the Union and thus contribute to free movement of high-risk AI-systems in the Union. Given that such standards are technology-neutral and performance-based, they also contribute to ensuring equal conditions of competition among relevant economic operators dealing with high-risk AI systems, in particular small and medium-sized enterprises. Indirectly those standards also contribute to lower costs benefitting consumers in particular.
- (8) In accordance with Article 8 of Regulation (EU) 2024/1689, the essential requirements are to be applied in such a way as to take into account their intended purpose as well as the generally acknowledged state of the art on AI and AI-related technologies.
- (9) It is therefore appropriate to request CEN and Cenelec to draft harmonised standards and European standardisation deliverables in support of Regulation (EU) 2024/1689 in continuation of the work started on the basis of the request made under Implementing Decision C(2023)3215.
- (10) The harmonised standards should include detailed technical specifications of the essential requirements covered in Articles 9 to 15, and the requirements set out in Articles 17 of Regulation (EU) 2024/1689. They should also indicate clearly the correspondence between the technical specifications and the requirements they aim to cover. In addition, they should be based on risk assessment and risk reduction methodologies and reflect the generally acknowledged state of the art.

⁴ COM (2024) 541 of 15 February 2024.

- (11) The European standardisation deliverables should include any other technical specifications which are necessary and suitable for the support of the essential requirements covered in Articles 9 to 15, and the requirements set out in Articles 17 and 43 of Regulation (EU) 2024/1689.
- (12) In accordance with Article 10(5) and (6) of Regulation (EU) No 1025/2012, the Commission is to assess the compliance of documents drafted by the European standardisation organisations with its initial request and to publish the references of harmonised standards, where a harmonised standard satisfies the requirements which it aims to cover, and which are set out in the corresponding Union harmonisation legislation. That assessment requires information regarding which essential requirements are covered by a harmonised standard. Such information is also required to enable the Commission to publish the references of harmonised standards in the *Official Journal of the European Union* in accordance with Article 10(6) of Regulation (EU) No 1025/2012. CEN and Cenelec should therefore describe, in each harmonised standard, the extent to which it covers one or several essential requirements set out in Regulation (EU) 2024/1689.
- (13) Article 40(2), subparagraph 3, of Regulation (EU) 2024/1689, provides that the Commission is to request evidence from CEN and Cenelec of their best efforts to fulfil the objectives referred to in that Regulation in accordance with Article 24 of Regulation (EU) 1025/2012. Such evidence should be part of the reporting on the execution of the request. Moreover, in order to further enhance and facilitate the execution of the requested standardisation activities, the work programme that has been provided by CEN and Cenelec under Implementing Decision C(2023)3215 should be updated so that it includes detailed planning and so that it reflects the requirements laid down in this Decision. For the same reason, the report on the execution of the request should be presented regularly every three months.
- (14) Article 40(2) of Regulation (EU) 2024/1689 requires that the requested harmonised standards and European standardisation deliverables are clear, consistent, including with the standards developed in the various sectors for products covered by the existing Union harmonisation legislation listed in Annex I to that Regulation, 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 therein.
- (15) In accordance with Article 40(3) of Regulation (EU) 2024/1689, CEN and Cenelec are to 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, in accordance with Commission Notice (2022/C247/01), harmonised standards developed by CEN and Cenelec may be based fully or partially on international ISO or IEC standards. However, harmonised standards in support of Regulation (EU) 2024/1689 should not be based on such international standards unless compatibility with the purpose and approach of that Regulation can be ensured. Such

compatibility requires, in particular, consistency with the definitions, objectives, requirements and obligations of Regulation (EU) 2024/1689, as well as with 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 policies, 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.
- (18) The European standardisation organisations have agreed to follow the Guidelines for the execution of standardisation requests⁵.
- (19) In order to enable the Commission to better monitor the requested standardisation work, CEN and Cenelec should provide the Commission with access to an overall project plan containing detailed information on the execution of the standardisation request.
- (20) Experience shows that during the execution of the standardisation request, it may be necessary to adjust the scope of the request, or the deadlines set therein. CEN and Cenelec should therefore promptly report to the Commission if they consider that more time is required to draft the harmonised standards or the European standardisation deliverables than what was initially expected or that it is appropriate to adapt the scope of the request, in order to allow the Commission to take appropriate action.
- (21) In accordance with Article 10(3) of Regulation (EU) No 1025/2012, each standardisation request is subject to acceptance by the relevant European standardisation organisation. It is therefore necessary to provide for rules on the validity of this request if it is not accepted by CEN or Cenelec.
- (22) In order to ensure legal certainty as to the validity of the request after its execution, it is appropriate to provide for a date of expiry of this Decision.
- (23) The harmonised standards adopted in response to the standardisation request set out in this Decision may be subject to access to documents requests in accordance with Regulation (EC) 1049/2001 of the European Parliament and of the Council⁶. In its judgment of 5 March 2024⁷, the Court of Justice recognised that there is an overriding public interest, within the meaning of Article 4(2) of Regulation (EU) 1049/2001, justifying the disclosure of harmonised standards.
- (24) The European standardisation organisations, the European stakeholders' organisations receiving Union financing, the European Artificial Intelligence Board established by Article 65 of Regulation (EU) 2024/1689 have been consulted.

⁵ SWD(2015) 205 final of 27 October 2015.

⁶ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: <http://data.europa.eu/eli/reg/2001/1049/oj>).

⁷ Judgment of the Court of Justice of 5 March 2024, Public.Resource.Org and Right to Know v. Commission and Others, C-588/21 P, ECLI:EU:C:2024:201, paragraph 85.

- (25) This Decision is without prejudice the need for consultation of the Advisory Forum, when this Advisory Forum is established in accordance with Article 67 of Regulation (EU) 2024/1689.
- (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

Requested standardisation activities

1. The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are requested to draft the [new] harmonised standards and European standardisation deliverables listed in Annex I to this Decision, in support of Regulation (EU) 2024/1689, by 31 August 2025.
2. The harmonised standards and European standardisation deliverables referred to in paragraph 1 shall meet the requirements set out in Annex II.

Article 2

Work programme

1. CEN and Cenelec shall update the work programme adopted under Implementing Decision C(2023)3215 to the extent necessary in order to adapt it to the new requirements and deadlines laid down in this Decision. The updated work programme shall contain detailed planning of the work for each of the harmonized standards and European standardisation deliverables listed in Annex I to this Decision and shall be submitted to the Commission at the latest two months after notification of this Decision by the Commission.
2. CEN and Cenelec shall inform the Commission of any other subsequent amendments to the work programme related to the execution of the request referred to in Article 1.
3. CEN and Cenelec shall provide the Commission with access to an overall project plan.

Article 3

Reporting

1. CEN and Cenelec shall every three months report to the Commission on the execution of the request referred to in Article 1, indicating the progress made in the implementation of the work programme referred to in Article 2.
2. CEN and Cenelec shall provide the Commission with the final report by 31 August 2025.
3. CEN and Cenelec shall promptly report to the Commission any major concerns relating to the execution of the request referred to in Article 1 or the deadlines set out in that Article.
4. The reports referred to in paragraphs 1, 2 and 3 shall in particular describe how CEN and Cenelec have:

- (a) facilitated an appropriate representation and effective participation of the relevant stakeholders, including small and medium-sized enterprises and societal stakeholders, in accordance with Article 5 of Regulation (EU) No 1025/2012;
- (b) ensured that the harmonised standards and European standardisation deliverables are in conformity with Union law on fundamental rights and data protection, in accordance with Annex II;
- (c) taken into account, as appropriate, the work of ETSI, in accordance with Annex II;
- (d) used their best efforts to fulfil the objectives referred to in Regulation (EU) 2024/1689.

Article 4

Repeal

Implementing Decision C(2023)3215 is repealed.

Article 5

Validity of the standardisation request

Where, in accordance with Article 10(3) of Regulation (EU) No 1025/2012, CEN and Cenelec have indicated that they do not accept the request referred to in Article 1, this Decision shall cease to apply and Implementing Decision C(2019) 4281 in its version of 22 May 2023 shall continue to apply.

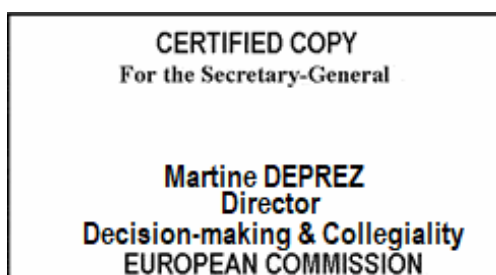
This Decision shall expire on 28 February 2027.

Article 6

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

Done at Brussels, 23.6.2025

For the Commission
Henna VIRKKUNEN
Executive Vice-President





Brussels, 23.6.2025
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ANNEXES 1 to 2

ANNEXES

to the

Commission Implementing Decision

on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards high-risk AI-systems in support of Regulation (EU) 2024/1689 of the European Parliament and of the Council and repealing Implementing Decision C(2023)3215

ANNEX I

List of new harmonised standards and European standardisation deliverables to be drafted

Reference information	
1.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on risk management systems for AI systems
2.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on governance and quality of datasets used to build AI systems
3.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on record keeping through logging capabilities by AI systems
4.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on transparency and information provisions for users of AI systems
5.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on human oversight of AI systems
6.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on accuracy specifications for AI systems
7.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on robustness specifications for AI systems
8.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on cybersecurity specifications for AI systems
9.	Harmonised standard(s) and if necessary European standardisation deliverable(s) on quality management systems for providers of AI systems, including post-market monitoring processes
10.	Harmonised standard(s) or European standardisation deliverable(s) on conformity assessment for AI systems

ANNEX II

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

1. General requirements for all harmonised standards and European standardisation deliverables

The harmonised standards and the European 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.

Regulation (EU) 2024/1689 lays down certain essential requirements for high-risk AI systems. Those requirements cover risk management, data quality and governance, technical documentation, record-keeping, and transparency. The harmonised standards and European standardisation deliverables shall provide technical specifications of the essential requirements for high-risk AI systems set out in Articles 9 to 15 of Regulation (EU) 2024/1689 and the requirements set out in Articles 17 and 43 of that Regulation.

The harmonised standards and European 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 that Regulation, 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 high-risk AI systems set out 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 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 Union law where such risks arise from the design and development of high-risk AI systems in view of their intended purpose.

The harmonised standards and European 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’ shall 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 protection of personal data, CEN and Cenelec shall gather relevant expertise in those areas.

¹ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

² Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

³ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 ([OJ L 169, 25.6.2019, p. 1](#)).

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

The harmonised standards and European standardisation deliverables 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.

Each harmonised standard shall include a clear and precise description of the relationship between its content and the corresponding requirements set out in Regulation (EU) 2024/1689 that it aims to cover. The structure of a harmonised standard shall be such that a clear distinction can be made between the 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 Annex Z to each standard. The relevant provisions of Regulation (EU) 2024/1689, in particular the provision set out in Chapter I, Chapter IV, and Chapter IX of that Regulation, 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 European standardisation deliverables. All the harmonised standards and European standardisation deliverables prepared on the basis of this request shall rely on a common set of terms. Supporting specifications on terminology shall build as much as possible on terminology adopted at international level and notably in international standards, provided that the terminology is in line with the purpose, objectives, definitions, requirements and obligations of Regulation (EU) 2024/1689 as well as with Union values and principles.

The harmonised standards shall not contradict any definition set out in Regulation (EU) 2024/1689 and shall not define terms that are not defined in that Regulation in a way that contradicts the legislative intent or objectives of 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. Annex Z to the standard 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 that Regulation prevail.

The harmonised standard shall not contradict the purpose and scope 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 different objectives, such as a different approach to product safety or protection of health, safety, and fundamental rights, those differences shall be clearly indicated in the foreword of the harmonised standard and its Annex Z. Annex Z to the standard shall also state that, for the purpose of using the standard in support of the requirements set out in Regulation (EU) 2024/1689, the purpose and scope set out in that Regulation shall be fully taken into consideration and the provisions of the standard in support of the requirements shall be interpreted and understood in the context of the purpose, scope and approach of 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 high-risk AI systems or process requirements falling under the scope of the relevant provisions of Regulation (EU) 2024/1689, 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 another standard, shall not claim to cover the legal requirements that are addressed in that other standard.

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 European standardisation deliverables shall primarily focus on the high-risk 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.

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 than the Union harmonisation legislation listed in Annex I to Regulation (EU) 2024/1689, and therefore the requirements of Regulation (EU) 2024/1689 and the harmonised standards and European standardisation deliverables developed on the basis of this standardisation request shall complement that harmonisation legislation and harmonised standards published in support of it.

Notwithstanding the horizontal nature of Regulation (EU) 2024/1689, the harmonised standards or European standardisation deliverables, where it is appropriate to meet the essential requirements of Regulation (EU) 2024/1689, may concern certain specific AI systems (use cases), covered in point 1 of Annex III to 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 European standardisation deliverables that consider each specific intended purpose, those standards and 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 European standardisation deliverables shall also possibly include guidance on how such assessment and implementation of solutions and options are to 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 European standardisation deliverables shall take into account, where 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 European standardisation deliverables referred to in points 1 to 7, 9 and 10 of that Annex;
- (b) preparation and elaboration of possible vertical specifications;
- (c) testing and validation procedures for high-risk AI systems.

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

The harmonised standards and European standardisation deliverables shall take into account the interdependencies between the different requirements set out in Chapter III, Section 2, of 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.

With regard to Article 15 of Regulation (EU) 2024/1689 which sets out requirements for accuracy, robustness and cybersecurity. Annex I identifies three separate areas to be addressed through the requested harmonised standards and European standardisation deliverables, CEN and Cenelec shall ensure coherence among those standards and deliverables in order to meet the requirement set out in Article 15(1) of Regulation (EU) 2024/1689, i.e. that high-risk AI systems are to 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 European standardisation deliverable for technical documentation to support Article 11 of Regulation (EU) 2024/1689, CEN and Cenelec shall ensure that the requirements set out in Article 11 are fully covered in other harmonised standards and European standardisation deliverables, particularly on the quality management system.

CEN and Cenelec shall ensure that the harmonised standards and European standardisation deliverables are 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 of the European Parliament and of the Council⁴ which lays down rules on general product safety.

CEN and Cenelec shall ensure that the harmonised standards and European standardisation deliverables are drafted in such a way that they 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).

⁴ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 011, 15.01.2002, p.4, ELI: <http://data.europa.eu/eli/dir/2001/95/oj>).

2. Specific requirements for certain harmonised standards and European standardisation deliverables

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

While this standardisation request covers ten different areas of harmonised standards and European standardisation deliverables, CEN and Cenelec shall ensure that those standards and deliverables are not isolated from each other, but rather form part of one system of harmonised standards and European standardisation deliverables that aim to ensure a high level of trustworthiness of high-risk AI systems and full and comprehensive coverage of all essential requirements set out in Articles 9 to 15 as well as the requirements covered in Article 17 and Article 43 of Regulation (EC) 2024/1689.

2.1. Risk management system for AI systems

The harmonised standards and standardisation deliverables in this area shall set up specifications for a risk management system for AI systems. Those specifications shall comprehensively cover all elements referred to in Article 9 of Regulation (EU) 2024/1689.

In line with Article 3 of Regulation (EU) 2024/1689, ‘risk’ shall 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

The harmonised standards and standardisation deliverables in this area shall set up specifications for data and data governance. Those specifications shall comprehensively cover all elements referred to in Article 10 of Regulation (EU) 2024/1689.

2.3. Record keeping through logging capabilities

The harmonised standards and standardisation deliverables in this area shall set up specifications for record keeping. Those specifications shall comprehensively cover all elements referred to in Article 12 of Regulation (EU) 2024/1689.

2.4. Transparency and provision of information to deployers

The harmonised standards and standardisation deliverables in this area shall set up specifications for transparency and provision of information to deployers. Those specifications shall comprehensively cover all elements referred to in Article 13 of Regulation (EU) 2024/1689.

2.5. Human oversight

The harmonised standards and standardisation deliverables in this area shall set up specifications for human oversight. Those specifications shall comprehensively cover all elements referred to in Article 14 of the Regulation (EU) 2024/1689.

2.6. Accuracy specifications for high-risk AI systems

The harmonised standards and standardisation deliverables in this area shall set up specifications for accuracy, to support the implementation of Article 15(3) of Regulation (EU) 2024/1689.

The harmonised standards and standardisation deliverables shall lay down specifications ensuring an appropriate level of accuracy of high-risk 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 those systems may pose to health, safety or fundamental rights.

For the purpose of these specifications, '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 'statistical accuracy', which has a more limited meaning and is one of several possible metrics for evaluating the performance of AI systems.

The harmonised standards and standardisation deliverables 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 high-risk AI systems

The harmonised standards and standardisation deliverables in this area shall set up specifications for robustness. Those specifications shall comprehensively cover all elements referred to in Article 15(4) of Regulation (EU) 2024/1689.

2.8. Cybersecurity specifications for high-risk AI systems

The harmonised standards and standardisation deliverables in this area shall set up specifications for cybersecurity. Those specifications shall comprehensively cover all elements referred to in Article 15(5) of Regulation (EU) 2024/1689.

The harmonised standards and standardisation deliverables shall take due account of the essential requirements for products with digital elements listed in Annex I of Regulation (EU) 2024/2847 of the European Parliament and the Council⁵.

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

The harmonised standards and standardisation deliverables in this area shall set up specifications for quality management systems. Those specifications shall comprehensively cover all elements referred to in Article 17 of Regulation (EU) 2024/1689.

2.10. Conformity assessment for AI systems

The harmonised standards and standardisation deliverables in this area shall provide procedures and processes for conformity assessment activities related to high-risk AI systems and quality management systems of AI providers.

The harmonised standards and standardisation deliverables shall consider both the scenario in which the conformity assessment is carried out by the provider itself and the scenario in which the conformity assessment is carried out with the involvement of a professional external third-party organisation.

⁵ Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (OJ L, 2024/2847, 20.11.2024, p.1, ELI: <http://data.europa.eu/eli/reg/2024/2847/oj>).