



EUROPEAN
COMMISSION

Brussels, 23.6.2025
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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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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 n 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

