



Brussels, 22.5.2023
C(2023) 3215 final

COMMISSION IMPLEMENTING DECISION

of 22.5.2023

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

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

COMMISSION IMPLEMENTING DECISION

of 22.5.2023

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

(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) In April 2021, the Commission published its AI package, proposing new rules and actions to make the Union a global hub for trustworthy AI. That package consists of a Commission Communication on Fostering a European Approach to Artificial Intelligence², the updated 2021 Coordinated Plan on Artificial Intelligence and the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)³.
- (2) The EU's approach to artificial intelligence puts also emphasis on the advancement of a human rights-based approach to such technology in cooperation with other like-minded countries on a global level and acknowledges the importance of standard-setting efforts and normative frameworks set in relevant multilateral fora, for example the OECD's Recommendations on AI, adopted in May 2019 and the Recommendations on the Ethics of AI by UNESCO, adopted in November 2021.
- (3) Standards are important instruments to support the implementation of Union policies and legislation and to ensure a high level of protection of safety and fundamental rights for all persons in the Union. Standards can also support the establishment of equal conditions of competition 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) Building on the work of a high level expert group set up by the Commission in June 2018 to support the implementation of the Commission Communication on Artificial

¹ OJ L 316, 14.11.2012, p. 12.

² COM(2021) 205 final of 21 April 2021.

³ COM(2021) 206 final of 21 April 2021.

Intelligence for Europe⁴, the Artificial Intelligence Act proposal presents requirements for the placing on the market and the putting into service of high-risk AI systems. These requirements cover areas related to risk management, data quality and governance, technical documentation, record keeping, transparency and provision of information to users, human oversight, accuracy, robustness and cybersecurity. The proposal also includes certain obligations for providers of high-risk AI systems, notably the obligations to establish a quality management system and to carry out a conformity assessment procedure to demonstrate the compliance of both the system and the provider's organisation with the requirements and a post-market monitoring system.

- (5) To advance technical harmonisation in the field of artificial intelligence and to prepare the necessary technical environment for the implementation of the Artificial Intelligence Act, it is necessary to start the work on European standards and European standardisation deliverables to support the key technical areas covered by the Artificial Intelligence Act proposal. Such standards should include the specifications for the design and the development of AI systems identified as high-risk in the proposal, for AI providers' quality management systems and for the conformity assessment of AI systems.
- (6) The intention to request the preparation of European standards or European standardisation deliverables in support of safe and trustworthy artificial intelligence systems is stated in point 63 of the table entitled 'Standardisation urgencies set by the Commission on the Standardisation strategy' in the Annex to Commission Notice on 'The 2022 annual Union work programme for European standardisation'⁵.
- (7) The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) have indicated that the work covered by the request falls within their area of competence.
- (8) International standardisation can help to consolidate a common vision of trustworthy AI across the globe and to facilitate trade and removing possible technical barriers in relation to products and services that are powered by artificial intelligence. Certain standards developed at international level by the International Organization for Standardisation (ISO) and the International Electrotechnical Commission (IEC) in relevant areas may be adopted as European standards by CEN and CENELEC on the basis of the Vienna⁶ agreement and the Frankfurt⁷ agreement. The standards and standardisation deliverables to be developed in answer to this request are of strategic importance for the Union. Appropriate modes of cooperation between CEN-CENELEC and ISO, IEC or other international standardisation organisations may be established provided that those modes ensure that European standards or European standardisation deliverables produced as a result of this request are fully in line with European values and specificities.
- (9) It is therefore appropriate to request CEN and CENELEC to draft new European standards or European standardisation deliverables in support of Union policy on artificial intelligence.

⁴ COM(2018) 237 final of 25 April 2018.

⁵ COM(2022) 546 final of 2 February 2022.

⁶ Agreement on technical cooperation between the ISO and CEN (Vienna Agreement).

⁷ IEC-CENELEC Frankfurt Agreement.

- (10) Experience shows that during execution of the standardisation request, it could 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 standards or the standardisation deliverables than what was initially foreseen, or that it is necessary to adapt the scope of the request, in order to allow the Commission to take appropriate action, notably in order to ensure that appropriate technical specifications are still available on time to support the future EU rules on AI.
- (11) CEN and CENELEC have agreed to follow the Guidelines for the execution of standardisation requests⁸.
- (12) In order to ensure transparency and facilitate the execution of the requested standardisation activities, CEN and CENELEC should prepare a work programme and submit it to the Commission.
- (13) 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 and should report regularly on the execution of that request.
- (14) The policy objectives of the Commission in the field of artificial intelligence should be taken into account when drafting European standards and European standardisation deliverables in reply to this request. Such policy objectives include ensuring that AI systems placed on the market or put into service in the Union are safe, are used in compliance with fundamental rights and in full respect of Union values. They should also promote investment and innovation in AI, and competitiveness and growth of the Union market, while strengthening global cooperation on standardisation in the field of AI that is consistent with Union values and interests. The public interest should take a prominent role when executing this standardisation request, given its importance for the development and the deployment of AI. CEN and CENELEC should ensure that the European Standards and European standardisation deliverables produced are consistent with the legal framework and the international obligations of the Union. The United Nations Convention on the Rights of Persons with Disabilities should also be taken into account when drafting the relevant standards.
- (15) In accordance with Article 5 of Regulation (EU) 1025/2012, European standardisation organisations are expected to take the necessary steps to facilitate an appropriate representation and effective participation of relevant stakeholders, representative of all sectors covered by the scope of this request, including but not limited to EU small and medium-sized enterprises and societal stakeholders, including consumer organisations and trade unions. Moreover, given the fundamental rights and data protection implications of the European standards and European standardisation deliverables requested, compliance with Union law on fundamental rights and Union data protection law should be also guaranteed.
- (16) Given that the European Telecommunications Standards Institute (ETSI) has already done work and possesses specific expertise on certain matters relevant to the request, such as security, it is appropriate that European standards or European standardisation deliverables drafted on the basis of this request take into account, as appropriate, the relevant ETSI's work.

⁸ SWD(2015) 205 final of 27 October 2015.

- (17) The Artificial Intelligence Act is currently subject to negotiations with the European Parliament and the Council in the context of the ordinary legislative procedure. Given that future standardisation work will be necessary to support the application of the Artificial Intelligence Act, it is necessary to ensure that CEN and CENELEC take that into account when executing this standardisation request.
- (18) 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 the rules on validity of this request if it is not accepted by CEN and CENELEC.
- (19) 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.
- (20) The European standardisation organisations, the European stakeholder organisations receiving Union financing and the Member State experts who are part of the European multi-stakeholder platform on ICT standardisation have been consulted.
- (21) 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

The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) are requested to draft the new European standards or European standardisation deliverables, as listed in Annex I, in support of Union policy on artificial intelligence by 30 April 2025.

The European standards or 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 prepare a work programme indicating all the European standards and European standardisation deliverables listed in Annex I, the responsible technical bodies and a timetable for the execution of the requested standardisation activities in line with the deadline set out in Article 1.

The work programme shall include the actions to be undertaken regarding the following:

- (a) to facilitate 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) to ensure that European standards and European standardisation deliverables are in conformity with Union law on fundamental rights and Union data protection law, in accordance with Annex II;

- (c) to take into account, as appropriate, the work of ETSI, in accordance with Annex II.
2. CEN and CENELEC shall submit the work programme to the Commission at the latest 4 months after the notification of this Decision by the Commission.
 3. CEN and CENELEC shall inform the Commission of any amendments to the work programme.
 4. CEN and CENELEC shall provide the Commission with access to an overall project plan.

Article 3 *Reporting*

1. CEN and CENELEC shall report every 6 months 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 submit the first joint semestrial report to the Commission at the latest 10 months after the notification of this Decision by the Commission.
3. CEN and CENELEC shall provide the Commission with the joint final report by 30 April 2025.
4. CEN and CENELEC shall promptly report to the Commission any major concerns in relation to the execution of the request referred to in Article 1 or the deadlines laid down in that Article.
5. 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 European standards and European standardisation deliverables are in conformity with Union law on fundamental rights and Union data protection law, in accordance with Annex II;
 - (c) taken into account, as appropriate, the work of ETSI, in accordance with Annex II.

Article 4 *Validity of the standardisation request*

Where, in accordance with Article 10(3) of Regulation (EU) No 1025/2012, CEN and CENELEC indicate that they do not accept the request referred to in Article 1, that request may not constitute a basis for the standardisation activities referred to in that Article.

This Decision shall expire on 28 February 2026.

Article 5
Addressees

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

Done at Brussels, 22.5.2023

For the Commission
Thierry BRETON
Member of the Commission

