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## **COMMISSION IMPLEMENTING DECISION**

**of 3.2.2025**

**on a standardisation request to the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) and the European Telecommunications Standards Institute (ETSI) as regards products with digital elements in support of 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 (Cyber Resilience Act)**

(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 Council,<sup>1</sup> and in particular Article 10(1) thereof,

Whereas:

- (1) 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 (Cyber Resilience Act)<sup>2</sup> lays down rules for the placing on the market of products with digital elements and essential requirements for their design, development and production to ensure security of those products throughout their life cycle. It also lays down essential requirements for the vulnerability handling processes put in place by manufacturers.
- (2) Harmonised standards play an important role in facilitating the assessment of conformity with those requirements. Products with digital elements which are in conformity with harmonised standards, which translate those essential requirements into detailed technical specifications, should therefore be presumed in conformity with the Cyber Resilience Act.
- (3) Annex I of the Cyber Resilience Act sets out the essential requirements the manufacturers have to demonstrate conformity with, in order to ensure that the

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<sup>1</sup> OJ L 316, 14.11.2012, p. 12.

<sup>2</sup> OJ L 2847, 20.11.2024

products they place on the market are secure from a cybersecurity standpoint and that vulnerabilities are handled appropriately.

- (4) The presumption of conformity provided by harmonised standards or parts thereof whose reference have been cited in the Official Journal of the European Union is particularly relevant for the products with digital elements listed in Annex III of the Cyber Resilience Act. In order to prepare the technical environment for the implementation of the Cyber Resilience Act it is necessary to develop harmonised European standards in the technical areas covered by that Regulation.
- (5) The European standards requested in this Decision are based on discussions with relevant stakeholders, including the European Standardisation Organisations, the Annex III organisations, as well as business associations and manufacturers of products with digital elements.
- (6) Taking into account the broad scope of the Cyber Resilience Act, a two-fold approach for developing the standards in response to this request is appropriate. On the one hand, a set of horizontal standards should provide a coherent generic framework, methodology and taxonomy that can be used to develop further product-specific standards responding to market needs. On the other hand, certain vertical standards are needed, notably as regards the products listed in Annex III of the Cyber Resilience Act, covering a specific set of risks appropriate to a particular intended purpose and reasonably foreseeable use.
- (7) When considering the scope of products covered by the Cyber Resilience Act for the purposes of the development of horizontal harmonised standards, CEN, Cenelec and ETSI should, where appropriate, take into consideration that the essential requirements laid down in Annex I of the Cyber Resilience Act will apply to products with digital elements that are also in the scope of other legal acts. These include electronic health record systems, high-risk AI systems under the Regulation (EU) 2024/1689<sup>3</sup>, machinery products under Directive 2006/42/EC of the European Parliament and of the Council<sup>4</sup> and Regulation (EU) 2023/1230<sup>5</sup>, or trusted chips under Regulation (EU) 2023/1781<sup>6</sup>.
- (8) CEN, Cenelec and ETSI should ensure good coordination among different technical committees working on the vertical harmonised standards. Consultations and other measures to ensure fair and diverse participation in the development of standards should especially target manufacturers of products with digital elements that are small

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<sup>3</sup> 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>).

<sup>4</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24, ELI: <http://data.europa.eu/eli/dir/2006/42/oj>).

<sup>5</sup> Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1230/oj>).

<sup>6</sup> Regulation (EU) 2023/1781 of the European Parliament and of the Council of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem and amending Regulation (EU) 2021/694 (Chips Act) (OJ L 229, 18.9.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1781/oj>).

and medium enterprises (SMEs). Where relevant, particular account should be given to the needs of the free and open source software community.

- (9) In order to achieve a relevant coverage of intended uses and respective risks, the deliverables prepared in support of this request should be subject to public consultation to support the standards development work. Attention should be given to ensure the inclusion of European stakeholders in the standardisation process, in particular encouraging the participation of SMEs.
- (10) 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 Vienna<sup>7</sup> and the Frankfurt<sup>8</sup> agreements, as long as those international standards are fit for the legal provisions of the Cyber Resilience Act, match the objectives of the cybersecurity policy of the Union and are adequate for accessing the Union's single market. Standards developed by other international consortia may also be considered in the development of the European standards under this request, provided that (i) the legal requirements set out in Regulation (EU) No 1025/2012 are fully met in their development, and (ii) those technical specifications are freely accessible, performance-based and technology neutral.
- (11) There is a large body of existing international standards that may be relevant to the scope of this request. Appropriate modes of cooperation between the European Standardisation Organisations, internal cooperation between technical committees, and cooperation with international standardisation organisations should therefore be established to benefit from possible synergies with existing or related European and international standards.
- (12) The standards and standardisation deliverables to be developed in response to this request are of strategic importance for the Union. CEN, Cenelec and ETSI should ensure that European standards or European standardisation deliverables produced as a result of this request are in conformity with the legal framework of the Union and its objectives and values.
- (13) There is a public interest to ensure the proper functioning of the European standardisation system. In order to ensure that the standardisation work subject to this request builds consensus amongst all interested parties, the utmost transparency should be ensured by CEN, Cenelec and ETSI. In particular, technical committee members should disclose in writing all interests, direct or indirect, that they represent or are associated with, including but not limited to professional interests and relationships.
- (14) Furthermore, attention should be paid to ensure that the positions or tasks of coordinating and leading the relevant work are assigned to representatives of organisations established in the Union as well as other individuals that can effectively meet the Union's interests. CEN, Cenelec and ETSI should thus ensure appropriate safeguards for the execution of this standardisation request.
- (15) In case of a ballot that would lead to a parallel development process under the Vienna or Frankfurt Agreements, CEN and Cenelec should inform the Commission. CEN and Cenelec should explain the possible impact of parallel standard development on the development of those standards. They should also explain what safeguards may be put

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<sup>7</sup> Agreement on technical cooperation between the ISO and CEN (Vienna Agreement).

<sup>8</sup> IEC-CENELEC Frankfurt Agreement.

in place to ensure those deliverables are in conformity with Union law, to safeguard European values and security interests and to respond to the specific needs stemming from Union legislation.

- (16) In the case of standards that could be subject to a development process under the Vienna or Frankfurt Agreements, a CEN or Cenelec lead should be ensured. To ensure that, and in order to comply with this request, CEN and Cenelec should take all measures available to them to ensure that standards developed on the basis of this request are developed either as European standards or as international ISO or IEC standards with CEN or Cenelec lead.
- (17) Given the sensitive nature of certain critical products, notably as identified in Annex IV of the Cyber Resilience Act, harmonised standards for those products under this request should be developed in a restricted setting with the participation of representatives of organisations established in the Union as well as other individuals that can effectively meet the Union interests. Furthermore, the European Commission reserves the right to request that any other deliverables also be developed in a restricted setting whenever the sensitive nature of the products could pose a risk to the security interests of the Union and its Member States.
- (18) The Commission's Joint Research Centre together with the European Cybersecurity Agency (ENISA) have carried out a mapping of existing international and European standards relevant for the scope of the Cyber Resilience Act. That has been shared with the European Standardisation Organisations to initiate a discussion and carry out a detailed gap analysis. In this context, CEN, Cenelec and ETSI are encouraged to establish good working relationships with ENISA and the Joint Research Centre as part of the process of development of standards in response to this request.
- (19) The essential cybersecurity requirements laid down in the Cyber Resilience Act are also meant to contribute to enhancing the protection of personal data and privacy of individuals. Synergies between data protection legislation and cybersecurity standardisation should be considered through cooperation with the European Data Protection Board (EDPB) established by Regulation (EU) 2016/679. CEN, Cenelec and ETSI are encouraged to establish good working relationships with the EDPB, as part of the process of standards development in response to this request.
- (20) During the execution of a standardisation request, it may be necessary to adjust the scope of the request or the deadlines set therein. CEN, Cenelec and ETSI 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.
- (21) CEN, Cenelec and ETSI have agreed to follow the Guidelines for the execution of standardisation requests<sup>9</sup>.
- (22) In order to ensure transparency and facilitate the execution of the requested standardisation activities CEN, Cenelec and ETSI should prepare a work programme and submit it to the Commission.
- (23) In order to enable the Commission to better monitor the requested standardisation work, CEN, Cenelec and ETSI should provide the Commission with access to an

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<sup>9</sup> SWD(2015) 205 final of 27 October 2015

overall project plan containing detailed information on the execution of the standardisation request and should report regularly on the execution of that request.

- (24) The standards should include detailed technical specifications of the relevant cybersecurity requirements, with respect to the design, development and production of products with digital elements as well as to the processes for vulnerability handling. They should also indicate clearly the correspondence between technical specifications and the cybersecurity requirements they aim to cover. CEN, Cenelec and ETSI should ensure that the developed harmonised European standards are consistent with the EU legal framework.
- (25) Without prejudice to needed improvements, CEN, Cenelec and ETSI should take into account, as appropriate, the standardisation work carried out in the context of Commission Implementing Decision (EU) 2023/2444,<sup>10</sup> Regulation (EU) 2024/1689, and also forthcoming standardisation requests such as for Directive 2006/42/EC of the European Parliament and of the Council, and Regulation (EU) 2023/1230, in the preparation and development of the requested harmonised European standards. CEN, Cenelec and ETSI should also consider any other relevant on-going European standardisation activities related to other Union legislation, such as Regulation (EU) 2023/1781.
- (26) 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 Council. In its judgement of 5 March 2024 (C-588/21 P), the Court 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.
- (27) 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, Cenelec and ETSI.
- (28) 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.
- (29) The European standardisation organisations, the European stakeholders' organisations receiving Union financing and the Member States experts in the Multi-stakeholder Platform on ICT standardisation have been consulted.
- (30) 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), the European Committee for Electrotechnical Standardisation (Cenelec) and the European Telecommunications

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<sup>10</sup> COMMISSION IMPLEMENTING DECISION on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2022/30

Standards Institute (ETSI) are requested to draft new or revise existing European standards, as listed in Annex I to this Decision, in support of the Cyber Resilience Act by the deadlines set out in that Annex.

2. European standards listed as entries 1 to 15 and 39 to 41 in Annex I shall be developed jointly or separately by CEN and Cenelec. European standards listed as entries 16 to 38 in Annex I shall be developed jointly by CEN, Cenelec and ETSI.
3. The European standards referred to in the first paragraph shall meet the requirements set out in Annex II.
4. CEN, Cenelec and ETSI shall provide the Commission with the titles of the requested European standards in all the official languages of the Union.

*Article 2*  
*Security Interests of the Union*

1. CEN, Cenelec and ETSI shall take any measures deemed necessary to safeguard the security interests of the Union, and shall at all times ensure that a European Standardisation Organisation leads on the development process of the European standards carried out in support of the request referred to in Article 1. Specific positions and tasks involved in the coordination and lead drafting of relevant European standards to be developed under this Decision shall be assigned to representatives of organisations established in the Union as well as other individuals that can effectively meet the Union's interests.
2. In order to ensure transparency in the standards development activities under this Decision, technical committee members shall promptly and accurately disclose in writing all interests, direct or indirect, that they represent or are associated with, including but not limited to professional interests and relationships.
3. European standards listed as entries 39, 40 and 41 identified in Annex I shall be developed in a restricted setting with participation of representatives of organisations established in the Union as well as other individuals that can effectively meet the Union interests.

*Article 3*  
*Work programme*

1. CEN, Cenelec and ETSI shall prepare a joint work programme indicating all the European standards listed in Annex I, the responsible technical bodies and a timetable for the execution of the requested standardisation activities in line with the deadlines set out in that Annex.
2. The draft work programme shall also indicate the actions to be undertaken to ensure effective participation of relevant stakeholders, including small and medium enterprises and civil society organisations and the open source community where relevant, in accordance with Article 5 of Regulation (EU) No 1025/2012.
3. The work programme shall include a description of all actions to be undertaken by CEN, Cenelec and ETSI to ensure that standards developed on the basis of this request are developed either as European standards or as international ISO or IEC standards with CEN or Cenelec lead.

4. CEN, Cenelec and ETSI shall submit the draft work programme to the Commission by [two months after the notification of this Decision by the Commission] and provide it with access to an overall project plan.

*Article 4*  
*Reporting*

1. CEN, Cenelec and ETSI shall report to the Commission on the execution of the request referred to in Article 1 every six months until all draft standards are submitted to Enquiry stage and thereafter annually, indicating the progress made in the implementation of the work programme referred to in Article 3.
2. CEN, Cenelec and ETSI shall submit the first joint report to the Commission by 10 months after the notification of this Decision by the Commission.
3. CEN, Cenelec and ETSI shall provide the Commission with the final joint report by 30 October 2027.
4. CEN, Cenelec and ETSI shall promptly report to the Commission any major concerns relating to the scope of the request referred to in Article 1 and the deadlines set out in Annex I. In particular, they shall report to the Commission any ballot that would lead to a parallel development of standards under the Vienna or Frankfurt Agreements.
5. The reports referred to in paragraphs 1 to 3 shall include evidence of how CEN, Cenelec and ETSI have:
  - (a) facilitated representation and participation of the relevant stakeholders, including SMEs, societal stakeholders and the open source community where relevant, 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.

*Article 5*  
*Validity of the standardisation request*

If CEN, Cenelec or ETSI do not accept the request referred to in Article 1 within a month of receiving it, the request may not constitute a basis for the standardisation activities referred to in that Article.

This Decision shall expire on 30 November 2027.



*Article 6*  
*Addressees*

This Decision is addressed to the European Committee for Standardisation, the European Committee for Electrotechnical Standardisation and the European Telecommunications Standards Institute.

Done at Brussels, 3.2.2025

*For the Commission*  
*Henna VIRKKUNEN*  
*Executive Vice-President*

