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COMMISSION IMPLEMENTING DECISION

of 20.1.2025

on a standardisation request to the European Committee for Standardization and to the European Committee for Electrotechnical Standardization as regards machinery and related products in support of Regulation (EU) 2023/1230 of the European Parliament and of the Council

(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) Directive 2006/42/EC of the European Parliament and of the Council² lays down harmonised rules for the placing in the market of machinery. That Directive is repealed with effect from 20 January 2027 by Regulation (EU) 2023/1230 of the European Parliament and of the Council³. That Regulation lays down essential health and safety requirements for the design, construction and placing on the market of machinery, related products and partly completed machinery ('machinery products') in order to ensure a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, of domestic animals and property, and, where applicable, of the environment while guaranteeing the functioning of the internal market for these products.
- (2) In accordance with Article 20(1) of Regulation (EU) 2023/1230, machinery products 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* are to be

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

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

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/2023/1230/2023-06-29).

- presumed to be in conformity with the essential health and safety requirements of that Regulation covered by those standards or parts thereof.
- (3) Harmonised standards help ensuring a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property, and, where applicable, the environment throughout the Union and thus also contribute to the free movement of machinery products 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, in particular small and medium-sized enterprises. Indirectly, those standards also contribute to lower development, production, operating and maintenance costs, benefitting consumers in particular.
- (4) In 2006, the Commission adopted mandate M/396⁴, in which it requested the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) to check the existing body of harmonised standards supporting Directive 98/37/EC of the European Parliament and of the Council⁵ and make the necessary adjustments to those harmonised standards to ensure that they fully comply with Directive 2006/42/EC, and to provide specifications enabling manufacturers to comply with the relevant essential health and safety requirements of that Directive.
- (5) In 2010, following the amendment of Directive 2006/42/EC, as regards machinery for pesticide application, by Directive 2009/127/EC of the European Parliament and of the Council⁶, the Commission adopted mandate M/471⁷ in which it requested CEN to develop harmonised standards to support the new essential health and safety requirements for the protection of the environment introduced in Directive 2006/42/EC.
- (6) New health and safety requirements set out in Regulation (EU) 2023/1230, compared to those set out in Directive 2006/42/EC are: to ensure 1) safety of systems that have safety-related functions with self-evolving behaviour; 2) protection against corruption of safety functions in machinery products with digital elements; 3) that the user of machinery products, where applicable, can test the safety functions; 4) avoidance of the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity; 5) avoidance of risk of contact in case of human-machine interaction or coexistence in a shared space; 6) adequate machine access dimensioning; 7) appropriate contents and format of instructions for use; 8) portable hand-held or hand-guided machinery products having exhaust fume provisions; 9)

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Mandate M/396 of 19 December 2006 to CEN and Cenelec for standardisation in the field of machinery (available online in https://www.cencenelec.eu/media/CEN-CENELEC/Areas%20of%20Work/CEN%20sectors/Mechanical%20and%20Machines/Agricultural/m396.pdf).

Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.7.1998, p. 1, ELI: http://data.europa.eu/eli/dir/1998/37/oj).

Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (OJ L 310, 25.11.2009, p.29, ELI: http://data.europa.eu/eli/dir/2009/127/oj).

Mandate M/471 of 29 June 2010 to CEN for standardisation in the field of machinery for pesticide application (available online in https://www.cencenelec.eu/media/CEN-CENELEC/Areas%20of%20Work/CEN%20sectors/Mechanical%20and%20Machines/Agricultural/m471.pdf).

safety of autonomous mobile machinery; 10) safety belt reminder or inhibition of operating certain mobile machinery when the safety belt is not used; 11) filtration of hazardous substances for operators of ride-on mobile machinery applying such substances; 12) prevention of risk of contact with overhead powerlines for mobile machinery, as well as 13) inclusion of provisions covering reasonably foreseeable misuse.

- (7) On 23 October 2024, the European Parliament and the Council adopted Regulation (EU) 2024/28478 laying 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. Regarding the cyber safety of machinery products, where they include digital elements, CEN and CENELEC should also take into account any standardisation request to European standards organisations in support of Union legislation on cybersecurity requirements for products with digital elements, in developing those specific standards. This is necessary to achieve a coherent cybersecurity framework across the Union market, avoiding duplication of efforts for specific product categories and facilitating compliance under both acts, wherever products covered by Regulation (EU) 2023/1230 are also covered by that Regulation.
- (8) There is a public interest in ensuring the proper functioning of the European standardisation system. In order to ensure that the standardisation work under this request, as well as under the upcoming standardisation request to European standards organisations in support of upcoming Union legislation on cybersecurity requirements for products with digital elements, builds consensus amongst all interested parties, the utmost transparency should be ensured by CEN and CENELEC, in line with the provisions of that request.
- (9) Where a ballot leads to a parallel development process under the Vienna⁹ or Frankfurt¹⁰ 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 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 European legislation, in accordance with Annex II to this standardisation request.
- (10) In the case of standards that could be subject to a development process under the Vienna or Frankfurt Agreements, a CEN or CENELEC engagement should be ensured. To this aim, 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 guiding the process.

10 IEC-CENELEC Frankfurt Agreement.

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) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

⁹ Agreement on technical cooperation between the ISO and CEN (Vienna Agreement).

- (11) Following a risk-based approach, manufacturers of machinery products should carry out a risk assessment considering, among others, the relevant cybersecurity risks, which in the case of Regulation (EU) 2023/1230 concern risks to health and safety. The harmonised standards for machinery products addressing the essential requirements of Regulation (EU) 2024/2847 may benefit from being developed jointly with the harmonised standards under Regulation (EU) 2023/1230, in cooperation between the European standards organisations concerned. This joint development should be emphasised in this request.
- (12) On 13 June 2024, the European Parliament and the Council adopted Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence¹¹. This Regulation sets out requirements for the placing on the market and the putting into service of high-risk Artificial Intelligence systems. In terms of machinery products, this means systems ensuring safety functions, with fully or partially self-evolving behaviour using machine learning approaches.
- (13) To ensure consistency and avoid an unnecessary administrative burden or unnecessary costs, CEN and CENELEC should develop specific standards covering machinery products taking into account, as regards Artificial Intelligence systems, Regulation (EU) 2024/1689. This helps providers of machinery or related products that contain high-risk Artificial Intelligence systems, to which the requirements of both Regulation (EU) 2023/1230 and Regulation (EU) 2024/1689 apply, to be flexible and efficient in their approach to ensure compliance with the applicable requirements.
- (14) Numerous harmonised standards have been drafted in support of Directive 2006/42/EC on the basis of standardisation mandates M/396 and M/471 to CEN and CENELEC concerning standards for machinery. A large proportion of the harmonised standards need to be amended or revised to take into account the new or updated essential health and safety requirements set out in Regulation (EU) 2023/1230.
- (15) The intention to request drafting of harmonised standards in support of Regulation (EU) 2023/1230 is stated in point 61 of the table 'Actions for the development and revision of European standards or European standardisation deliverables supporting the internal market for services and products' set out in the Annex to Commission Notice of 15 February 2024 C/2024/1364 'The 2024 annual Union work programme for European standardisation' 12.
- (16) CEN and CENELEC have indicated that the work covered by the standardisation request falls entirely within their area of competence.
- (17) It is therefore appropriate to request CEN and CENELEC to amend or revise the relevant existing harmonised standards under Directive 2006/42/EC, to complete the work on harmonised standards that are already under preparation and to draft new harmonised standards, in support of Regulation (EU) 2023/1230.
- (18) Moreover, given the extraordinary number of product categories and technological fields covered, as well as the related number of harmonised standards and European

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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).

Commission Notice of 15 February 2024 – The 2024 annual Union work programme for European standardisation (OJ C, C/2024/1364, 15.02.2024, ELI: https://eur-lex.europa.eu/eli/C/2024/1364/oj).

standardisation deliverables, it is appropriate to present the list of new harmonised standards and European standardisation deliverables, as well as the list of existing harmonised standards and European standardisation deliverables to be amended or revised, based on a thematic list covering the relevant product categories and technological fields.

- (19) Harmonised standards should include detailed technical specifications, including appropriate test methods or equivalent verifiable and reproducible approaches, in support of the essential health and safety requirements set out in Regulation (EU) 2023/1230, especially with respect to the design, construction and manufacture of machinery products. They should also clearly indicate the correspondence between technical specifications and the essential health and safety requirements they aim to cover. They should also be based on risk assessment and risk reduction methodologies and reflect the generally acknowledged state of the art.
- (20) To ensure equal performance regarding all essential health and safety requirements set out in Regulation (EU) 2023/1230 across the Union's diverse population, i.e. regardless of gender, age, height as well as other anthropometric and biomechanical considerations, harmonised standards should be inclusive and consider persons with special needs, as appropriate.
- (21) In accordance with Article 8 of Regulation (EU) 2023/1230, the essential health and safety requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture, as well as technical and economic considerations which are consistent with a high degree of health and safety and environmental protection.
- (22) Information as to which essential health and safety requirements are covered by a harmonised standard is necessary when assessing the compliance of the documents drafted by CEN and CENELEC in accordance with Article 10(5) of Regulation (EU) No 1025/2012. Such information is necessary for the publication of references of harmonised standards in the *Official Journal of the European Union* in accordance with Article 10(6) of Regulation (EU) No 1025/2012. In each harmonised standard, CEN and CENELEC should therefore specifically describe which essential health and safety requirements set out in Annex III to Regulation (EU) 2023/1230 are relevant for the products covered by that harmonised standard and the extent to which it aims to cover those essential health and safety requirements. CEN and CENELEC should therefore also document which relevant essential health and safety requirements are not covered.
- (23) The ESOs have agreed to follow the Guidelines for the execution of standardisation requests¹³.
- (24) 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.
- (25) 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.

European Commission, Vademecum on European Standardisation in support of Union Legislation and policies (SWD(2015) 205 final of 27 October 2015, available online in https://single-market-economy.ec.europa.eu/single-market/european-standards/vademecum-european-standardisation en).

- (26) Experience shows that, during the execution of a 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 standards or the standardisation deliverables than initially foreseen, or that it is appropriate to adapt the scope of the request, in order to allow the Commission to take appropriate action.
- (27) In accordance with Article 10(3) of Regulation (EU) No 1025/2012, the standardisation request is subject to acceptance by the relevant ESO. It is therefore necessary to establish rules on validity of this request, if it is not accepted by CEN or CENELEC.
- (28) In order to ensure legal certainty as to the validity of this standardisation request after its execution, it is appropriate to provide for a date of expiry of this Decision.
- (29) 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 (EU) 1049/2001 of the European Parliament and of the Council¹⁴. In its judgement of 5 March 2024 *Public.Resource.Org and Right to Know v. Commission and Others*¹⁵, the Court of Justice recognised that there is an overriding public interest, within the meaning of Article 4(2) of Regulation (EC) 1049/2001, justifying the disclosure of harmonised standards.
- (30) Given that Directive 2006/42/EC is repealed with effect from 20 January 2027, it is appropriate to provide for the end of validity of standardisation mandates that have been issued by the Commission for drafting harmonised standards in support of that Directive.
- (31) The ESOs, the European stakeholders' organisations receiving Union financing and the Machinery Committee established by Article 48 of Regulation (EU) 2023/1230 have been consulted.
- (32) 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 Standardization ('CEN') and the European Committee for Electrotechnical Standardization ('CENELEC') are requested to draft new harmonised standards and European standardisation deliverables listed in Table 1 of Annex I to this Decision and to amend or revise the existing harmonised standards and European standardisation deliverables listed in Table 2 of Annex I to this Decision, in support of Regulation (EU) 2023/1230, for machinery, related products and partly completed machinery by the deadlines set out in that Annex.

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).

Judgement 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.

- 2. If CEN and CENELEC do not amend or revise the harmonised standards referred to in Annex I to Commission Implementing Decision (EU) 2023/1586¹⁶, they shall, by 20 January 2026, inform the Commission of the references of those standards and, where relevant, of the reasons why their amendment or revision is not under preparation.
- 3. The harmonised standards and European standardisation deliverables referred to in paragraph 1 shall meet the requirements set out in Annex II.
- 4. CEN and CENELEC shall provide the Commission with the titles of the requested harmonised standards in all the official languages of the Union.

Article 2 Work programme

- 1. CEN and CENELEC shall prepare a joint work programme indicating all the harmonised 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 deadlines set out in that Annex.
- 2. CEN and CENELEC shall submit the draft joint work programme to the Commission by 20 July 2025 and shall inform the Commission of any amendments to the joint work programme.
- 3. The draft work programme shall take into account the priorities set out in Annex II for the execution of the request referred to in Article 1(1).
- 4. CEN and CENELEC shall provide the Commission with access to the overall project plan.
- 5. The project plan shall include arrangements ensuring cooperation with the Commission for the execution of the requested standardisation activities.

Article 3 Reporting

- 1. CEN and CENELEC shall report annually to the Commission on the execution of the request referred to in Article 1(1), indicating the progress made in implementation of the work programme referenced to in Article 2.
- 2. CEN and CENELEC shall submit the first joint annual report to the Commission by 20 July 2026. Subsequent joint annual reports shall be submitted to the Commission by 20 July each year.
- 3. CEN and CENELEC shall provide to the Commission the final report by 20 January 2035.
- 4. CEN and CENELEC shall promptly report to the Commission any major concerns relating to the scope of the request referred to in Article 1 or the deadlines set out in Annex I.

Commission Implementing Decision (EU) 2023/1586 of 26 July 2023 on harmonised standards for machinery drafted in support of Directive 2006/42/EC of the European Parliament and of the Council (OJ L 194, 2.8.2023, p. 45, ELI: http://data.europa.eu/eli/dec_impl/2023/1586/oi).

Article 4 Validity of the standardisation request

- 1. Where, in accordance with Article 10(3) of Regulation (EU) No 1025/2012, CEN or CENELEC indicate that they do not accept the request referred to in Article 1(1) of this Decision, that request shall not constitute a basis for the standardisation activities referred to in Article 1(1) of this Decision for the standardisation organisation concerned.
- 2. This Decision shall expire on 20 January 2035.

Article 5
Expiry of existing standardisation mandates

Standardisation mandates M/396 of 19 December 2006 and M/471 of 29 June 2010 shall expire on 20 January 2027.

Article 6 Addressees

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

Done at Brussels, 20.1.2025

For the Commission Stéphane SÉJOURNÉ Executive Vice-President

> CERTIFIED COPY For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION