

EUROPEAN COMMISSION Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems III: Construction & machinery Standards Policy

Brussels, 11.1.2024

A Notification under Article 12 of Regulation (EU) No 1025/2012¹

Subject matter related to

| | Annual Union Work Programme for European standardisation (Art. 12, point a) |
|-----------|--|
| \square | Possible future standardisation requests to the European standardisation organisations |
| | (Art. 12, point b) |
| | Formal objections to harmonised standards (Art. 12, point c) |
| | Identifications of ICT technical specifications (Art. 12, point d) |
| | Delegated acts to modify Annexes I or III of Regulation (EU) No 1025/2012 (Art. 12, |
| | point e) |

Title of the initiative

Draft standardisation request amending Implementing Decision C(2020)7924 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards personal protective equipment in support of Regulation (EU) 2016/425 of the European Parliament and of the Council

Additional information

| Legislative/Policy reference(s) | Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, OJ L 81, 31.3.2016 | |
|------------------------------------|--|--|
| EN reference(s) | - | |
| Status | Draft | |
| Other information | This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material. | |
| Deadline for feedback | 9.2.2024 | |

Commission contact point for this notification

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¹ OJ L 316, 14.11.2012, p. 12

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111 http://ec.europa.eu/growth/single-market/european-standards/notification-system/index_en.htm

Brussels, XXX [...](2024) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

amending Implementing Decision C(2020)7924 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards personal protective equipment in support of Regulation (EU) 2016/425 of the European Parliament and of the Council

(Text with EEA relevance)

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COMMISSION IMPLEMENTING DECISION

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amending Implementing Decision C(2020)7924 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards personal protective equipment in support of Regulation (EU) 2016/425 of the European Parliament and of the Council

(Text with EEA relevance)

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(2020) 7924², the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) for the revision of existing harmonised standards on personal protective equipment developed in support of Directive 89/686/EEC³ and the drafting of new harmonised standards in support of Regulation (EU) 2016/425⁴.
- (2) CEN and CENELEC have accepted the standardisation request set out in Implementing Decision C(2020) 7924 and the standardisation work is ongoing.
- (3) CEN and CENELEC informed the Commission that it is necessary to adapt the scope of the request by adding certain standardisation items and remove certain other items, in order to take into account the latest technical and scientific progress, as well as the latest developments of standardisation activities in the field of personal protective equipment at international and European levels.

¹ OJ L 316, 14.11.2012, p. 12.

² Commission Implementing Decision C(2020)7924 of 19 November 2020 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards personal protective equipment in support of Regulation (EU) 2016/425 of the European Parliament and of the Council

³ Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).

⁴ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

- (4) Moreover, CEN and CENELEC has informed the Commission that it is necessary to extend the deadline of certain standardization items as the work on some of those items could not be completed by the date initially set in Implementing Decision C(2020) 7924.
- (5) The Commission examined the information provided by CEN and CENELEC.
- (6) Harmonised standards EN 149, EN 342, EN 397, EN 443, EN 511, EN 564, EN 568, EN 659, EN 958, EN 1486, EN 1891, EN ISO 10819, EN ISO 10862, EN ISO 12401, EN 12477, EN 12492, EN 13034, EN 14021, EN 14058, EN 14605, EN 15151, EN 16471, EN 16473 EN ISO 16602, EN ISO 19818, EN ISO 22615 and EN ISO 27065 need to be revised to support Regulation (EU) 2016/425.
- (7) Standards on personal belay lanyards for mountaineering (EN 17520), on load sharing devices for mountaineering (EN 17961), on hand protective devices against the thermal hazards of an electric arc (EN IEC 63232), on interfaces between mountaineering boots for adults and crampons (WI 00136445), on helmets for ski mountaineers (WI 00158117), on warning clothing with active lighting (WI 00162478), on respiratory infection prevention devices (WI 00205368), on helmets for high speed-cycling, on surface wetsuits and on visibility garments for hunting activities need to be drafted to support Regulation (EU) 2016/425.
- (8) The intention to request revision of existing standards and development of new standards in support of Regulation (EU) 2016/425 is stated in point 81 of the Annex to the 2023 annual Union work programme for European Standardisation⁵.
- (9) CEN and CENELEC have indicated that the work covered by the standardisation request falls within their area of competence.
- (10) It is therefore appropriate to request CEN and CENELEC to revise the existing harmonised standards and to draft new harmonised standards in support of Regulation (EU) 2016/425.
- (11) CEN informed the Commission that the references of standards EN ISO 16602, EN ISO 23388, EN ISO 23407, EN ISO 24232, EN 17092 and EN 17353 would replace respectively the following references EN 14325, EN 388, EN 407, EN 343, EN 13595 and EN 1150 which were listed in Annex I to Implementing Decision C(2020) 7924. It is therefore appropriate to update Annex I to reflect these changes.
- (12) Annex I to Implementing Decision C(2020) 7924 includes two tables which are respectively listing the standards to be revised and the new standards to be drafted. The Commission has identified many standards in Table 2 of Annex I to Implementing Decision C(2020) 7924 that should be listed in Table 1 of that Annex.
- (13) Therefore, in the interest of clarity and rationality, and since further amendment needs to be made to Annex I, that Annex should be replaced by the Annex I to this Decision.
- (14) Annex II to Implementing Decision C(2020) 7924 lists the requirements for the standards referred to Annex I to that Decision. As Annex I of Implementing Decision C(2020) 7924 will be replaced by the Annex I to this Decision, it is necessary, to replace Annex II to Implementing Decision C(2020) 7924 to update the references to the standards listed in the respective tables in Annex I and to take into account the requirements for the new standards there included.

⁵ OJ C 93, 13.3.2023, p. 2–31

- (15) Moreover, harmonised standards should be inclusive, so that they aim to ensure equal performance regarding all essential requirements laid down in Annex II to Regulation (EU) 2016/425 across the Union's diverse population, i.e. regardless of gender, age, height as well as other anthropometric and biomechanical considerations.
- (16) Moreover, in order to take into account the individual deadlines of the references of standards listed in Annex I to this Decision, it is necessary to extend the expiration date of the standardisation request set out in Implementing Decision C(2020) 7924.
- (17) 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 lay down rules on the validity of this Decision in the event that CEN or CENELEC does not accept the amendments to Implementing Decision C(2020) 7924 set out in this Decision. Implementing Decision C(2020) 7924 should therefore be amended accordingly.
- (18) The European standardisation organisations, the European stakeholders' organisations receiving Union financing and the Committee on personal protective equipment established by Article 44 of Regulation (EU) 2016/425 have been consulted.
- (19) 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

Implementing Decision C(2020)7924 is amended as follows:

(1) in Article 3, the fourth paragraph is replaced by the following:

'CEN and CENELEC shall provide the Commission with the final report by 30 April 2027.'

(2) In Article 5, the second paragraph is replaced by the following:

'This Decision shall expire on 30 April 2027.'

- (3) Annex I is replaced by the text in Annex I to this Decision;
- (4) Annex II is replaced by the text in Annex II to this Decision.

Article 2

If the European Committee for Standardization or the European Committee for Electrotechnical Standardization does not accept the amendments set out in Article 1 of this Decision in accordance with Article 10(3) of Regulation (EU) No 1025/2012, this Decision shall cease to apply and Implementing Decision (2020)7924 in its version of 19 November 2020 shall continue to apply for the standardisation organisation concerned.

Article 3

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

Done at Brussels,

For the Commission

ANNEX I

Annex I of Implementing Decision C(2020)7924 is amended as follows:

(1) Table 1 is replaced by the following table :

'Table 1. List of existing standards to be revised and deadline for their availability

| | Reference information | Date of availability by CEN-CENELEC |
|-----|---|---|
| 1. | EN 137 Respiratory protective devices — Self-contained open-circuit compressed air breathing apparatus with full face mask — Requirements, testing, marking | 30.4.2025 |
| 2. | EN 140 Respiratory protective devices — Half masks and quarter masks — Requirements, testing, marking | 30.4.2024 |
| 3. | EN 143 Respiratory protective devices - Particle filters - Requirements, testing, marking | 30.4.2024 |
| 4. | EN 149 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking | 30.4.2027 |
| 5. | EN 341 Personal fall protection equipment - Descender devices for rescue | 30.4.2027 |
| 6. | EN 342 Protective clothing - Ensembles and garments for protection against cold | 30.4.2026 |
| 7. | EN 352 Hearing protectors - Safety requirements and testing | 30.4.2027 |
| 8. | EN 353 Personal protective equipment against falls from a height | 30.12.2024 |
| 9. | EN 355 Personal protective equipment against falls from a height - Energy absorbers | 30.4.2027 |
| 10. | EN 358 Personal protective equipment for work positioning and prevention of falls from a height - Belts and lanyards for work positioning or restraint | 30.4.2024 |

| 11. | EN 360 | 30.4.2024 |
|-----|--|------------|
| | Personal fall protection equipment - Retractable type fall arresters | |
| 12. | EN 361 | |
| | Personal protective equipment against falls from a height - Full body | 30.4.2027 |
| | harnesses | |
| 13. | EN ISO 374 | 30.4.2027 |
| | Protective gloves against dangerous chemicals and micro-organisms | 30.4.2027 |
| 14. | EN 397 | |
| | Industrial protective helmets | 30.4.2025 |
| 15. | EN 405 | |
| 15. | Respiratory protective devices — Valved filtering half masks to protect | 30.4.2024 |
| | against gases or gases and particles — Requirements, testing, marking | |
| 16. | EN 443 | |
| 10. | Helmets for firefighting in buildings and other structures | 30.4.2027 |
| | | |
| 17. | EN 469 | 20.10.2025 |
| | Protective clothing for firefighters - Performance requirements for protective | 30.10.2025 |
| | clothing for firefighting activities | |
| 18. | EN 510 | 20.4.2024 |
| | Specification for protective clothing for use where there is a risk of entanglement with moving parts | 30.4.2024 |
| 10 | | |
| 19. | EN 511 | 30.4.2027 |
| | Protective gloves against cold | |
| 20. | EN 564 | |
| | Mountaineering equipment — Accessory cords — Safety requirements and | 30.4.2024 |
| | test methods | |
| 21. | EN 568 | |
| | Mountaineering equipment — Ice anchors — Safety requirements and test | 07.4.2026 |
| | methods | |
| 22. | EN 659 | 20.0.2025 |
| | Protective gloves for firefighters | 30.9.2025 |
| l | 1 | |

| 23. | EN 795 | 31.5.2025 |
|-----|--|-----------|
| | Personal fall protection equipment - Anchor devices | |
| 24. | EN 813 | 30.4.2024 |
| | Personal fall protection equipment - Sit harnesses | |
| 25. | EN 892 | |
| | Mountaineering equipment - Dynamic mountaineering ropes - Safety requirements and test methods | 30.4.2024 |
| 26. | EN 893 Mountaineering equipment - Crampons - Safety requirements and test methods | 30.4.2024 |
| 27. | EN 943 Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols | 30.4.2027 |
| 28. | EN 958 | |
| | Mountaineering equipment - Energy absorbing systems for use in klettersteig (via ferrata) climbing - Safety requirements and test methods | 2.8.2024 |
| 29. | EN 1073 | 30.4.2027 |
| | Protective clothing against radioactive contamination | 30.4.2027 |
| 30. | EN 1078 Helmets for cyclists | 30.4.2025 |
| 31. | EN 1080 Impact protection helmets for young children | 30.4.2025 |
| 32. | EN 1082 Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives | 30.4.2027 |
| 33. | EN 1149 Protective clothing - Electrostatic properties | 30.4.2027 |
| 34. | EN 1384 Helmets for equestrian activities | 30.4.2023 |
| 35. | EN 1486 | 30.4.2027 |
| | Protective clothing for fire-fighters - Test methods and requirements for | |

| | reflective clothing for specialised fire-fighting | |
|-----|--|------------|
| 36. | EN 1621 Motorcyclists' protective clothing against mechanical impact | 30.4.2027 |
| 37. | EN 1827 Respiratory protective devices — Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only — Requirements, testing, marking | 30.4.2024 |
| 38. | EN 1891 Personal protective equipment for the prevention of falls from a height - Low stretch kernmantel ropes | 30.4.2027 |
| 39. | EN 1938 Personal eye protection - Goggles for motorcycle and moped users | 30.4.2027 |
| 40. | EN ISO 10256 Protective equipment for use in ice hockey | 30.4.2025 |
| 41. | EN ISO 10819 Mechanical vibration and shock - Hand-arm vibration - Measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand | 30.4.2027 |
| 42. | EN ISO 10862 Small craft - Quick release system for trapeze harness | 30.4.2027 |
| 43. | EN ISO 11393 Protective clothing for users of hand-held chain-saws | 30.4.2027 |
| 44. | EN ISO 11611 Protective clothing for use in welding and allied processes | 30.10.2025 |
| 45. | EN ISO 11612 Protective clothing - Clothing to protect against heat and flame - Minimum performance requirements | 30.4.2027 |
| 46. | EN 12277 Mountaineering equipment - Harnesses - Safety requirements and test methods | 30.4.2024 |
| 47. | EN ISO 12312 Eye and face protection - Sunglasses and related eyewear | 30.4.2027 |

| 48. | EN ISO 12401 Small craft - Deck safety harness and safety line - Safety requirements and test methods | 30.4.2027 |
|-----|--|-----------|
| 49. | EN ISO 12402 Personal flotation devices | 30.4.2027 |
| 50. | EN 12477 Protective gloves for welders | 30.9.2025 |
| 51. | EN 12492 Mountaineering equipment - Helmets for mountaineers - Safety requirements and test methods | 30.4.2026 |
| 52. | EN 12841 Personal fall protection equipment - Rope access systems - Rope adjustment devices | 30.4.2024 |
| 53. | EN 12941 Respiratory protective devices - Powered filtering devices incorporating a loose fitting respiratory interface - Requirements, testing, marking | 30.4.2024 |
| 54. | EN 12942 Respiratory protective devices - Power filtering devices incorporating full face masks, half masks or quarter masks - Requirements, testing, marking | 30.4.2024 |
| 55. | EN 13034 Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment) | 30.4.2027 |
| 56. | EN 13089 Mountaineering equipment - Ice-tools - Safety requirements and test methods | 30.4.2024 |
| 57. | EN 13138 Buoyant aids for swimming instruction | 30.4.2024 |
| 58. | EN 13158 Protective clothing - Protective jackets, body and shoulder protectors for equestrian use, for horse riders and those working with horses, and for horse drivers - Requirements and test methods | 30.4.2027 |

| 59. | EN 13178 | 30.4.2027 |
|-----|---|------------|
| | Personal eye-protection - Eye protectors for snowmobile users | |
| 60. | EN 13595 Protective clothing for professional motorcycle riders - Jackets, trousers and one piece or divided suits | 30.4.2024 |
| 61. | EN 13634 Protective footwear for motorcycle riders - Requirements and test methods | 30.4.2027 |
| 62. | EN ISO 13688 Protective clothing - General requirements | 30.4.2024 |
| 63. | EN 13794 Respiratory protective devices — Self-contained closed-circuit breathing apparatus for escape — Requirements, testing, marking | 30.4.2025 |
| 64. | EN 13832 Footwear protecting against chemicals | 30.4.2026 |
| 65. | EN 13911 Protective clothing for firefighters - Requirements and test methods for fire hoods for firefighters | 30.4.2027 |
| 66. | EN ISO 13982 Protective clothing for use against solid particulates | 30.4.2027 |
| 67. | EN 14021 Stone shields for off-road motorcycling suited to protect riders against stones and debris - Requirements and test methods | 30.9.2026 |
| 68. | EN 14058 Protective clothing - Garments for protection against cool environments | 30.4.2024 |
| 69. | EN ISO 14116 Protective clothing - Protection against flame - Limited flame spread materials, material assemblies and clothing | 30.10.2026 |
| 70. | EN 14387 Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking | 30.4.2024 |
| 71. | EN 14404 | 30.12.2025 |

| | Personal protective equipment - Knee protectors for work in the kneeling position | |
|-----|--|------------|
| 72. | EN 14458 Personal eye-equipment - High performance visors intended only for use with protective helmets | 30.4.2027 |
| 73. | EN ISO 14460 Protective clothing for automobile racing drivers - Protection against heat and flame - Performance requirements and test methods | 30.10.2026 |
| 74. | EN 14605 Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4]) | 30.4.2027 |
| 75. | EN ISO 15027 Immersion suits | 30.4.2027 |
| 76. | EN 15090 Footwear for firefighters | 30.4.2026 |
| 77. | EN 15151 Mountaineering equipment – Braking devices | 30.4.2024 |
| 78. | EN ISO 16321 Eye and face protection for occupational use | 30.4.2027 |
| 79. | EN 16350 Protective gloves - Electrostatic properties | 30.4.2027 |
| 80. | EN 16471 Firefighters helmets - Helmets for wildland fire fighting | 30.4.2027 |
| 81. | EN 16473 Firefighters helmets - Helmets for technical rescue | 30.4.2027 |
| 82. | EN ISO 16602 Protective clothing against chemicals | 30.4.2027 |
| 83. | EN 16689 Protective clothing for firefighters - Performance requirements for protective | 30.4.2027 |

| | clothing for technical rescue | |
|-----|---|-----------|
| 84. | EN 17092 Protective garments for motorcycle riders | 30.4.2024 |
| 85. | EN 17109 Mountaineering equipment – Individual safety systems for rope courses – Safety requirements and test methods | 30.4.2024 |
| 86. | EN ISO 17249 Safety footwear with resistance to chainsaw cutting | 30.4.2026 |
| 87. | EN 17353 Protective clothing - Visibility clothing for non-professional use - Test methods and requirements | 30.5.2025 |
| 88. | EN ISO 18527 Eye and face protectors for sports use | 30.4.2027 |
| 89. | EN ISO 19818 Eye and face protection - Protection against laser radiation | 30.4.2025 |
| 90. | EN ISO 20320 Protective clothing for use in Snowboarding - Wrist Protectors - Requirements and test methods | 30.4.2027 |
| 91. | EN ISO 20345 Personal protective equipment - Safety footwear | 30.4.2024 |
| 92. | EN ISO 20346 Personal protective equipment – Protective footwear | 30.4.2024 |
| 93. | EN ISO 20347 Personal protective equipment - Occupational footwear | 30.4.2024 |
| 94. | EN ISO 20349 Personal protective equipment - Footwear protecting against risk in foundries and welding | 30.4.2027 |
| 95. | EN ISO 21420 Protective gloves - General requirements and test methods | 30.4.2027 |
| 96. | EN ISO 22615 | 30.4.2026 |

| | Protective clothing - Performance requirements and tests methods for protective clothing against infective agents | |
|------|--|------------|
| 97. | EN ISO 23388 Protective gloves against mechanical risks | 30.4.2027 |
| 98. | EN ISO 23407 Protective gloves against thermal risks (heat and/or fire) | 30.4.2027 |
| 99. | EN ISO 24232 Protection against rain | 30.8.2024 |
| 100. | EN ISO 27065 Protective clothing - Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers | 30.04.2027 |
| 101. | EN 50286 Electrical insulating protective clothing for low-voltage installations | 30.4.2026 |
| 102. | EN 50365 Electrically insulating helmets for use on low voltage installations | 30.4.2026 |
| 103. | EN 60903 Live working - Gloves of insulating material | 30.4.2026 |
| 104. | EN 60984 Sleeves of insulating material for live working | 30.4.2026 |
| 105. | EN 61482 Live working - Protective clothing against the thermal hazards of an electric arc | 30.4.2026 |
| 106. | EN IEC 62819 Live working - Eye, face and head protectors against the effects of electric arc - Test methods and performance requirement | 30.4.2026 |
| 107. | EN IEC 63247 Live working – Footwear for electrical protection | 30.4.2026' |

(2) Table 2 is replaced by the following table :

'Table 2. List of standards to be drafted and deadline for their availability

| | Reference information | Date of availability by CEN- CENELEC |
|----|---|--|
| 1. | EN ISO 12609 Eye and face protection against intense light sources used on humans and animals for cosmetic and medical applications | 30.4.2027 |
| 2. | EN 17487 Garments with permethrin as-treated articles supporting the protection against tick bites | 30.10.2024 |
| 3. | EN 17520 Mountaineering equipment — Personal belay lanyards — Safety requirements and test methods | 30.4.2024 |
| 4. | EN 17961 Mountaineering equipment – Load sharing devices – Safety requirements and test methods | 30.4.2026 |
| 5. | EN ISO 21353 Overboots, overshoes and gaiters intended to provide protection | 30.4.2027 |
| 6. | EN IEC 63232 Live working - Hand protective devices against the thermal hazards of an electric arc | 30.4.2026 |
| 7. | WI 00136445 Interface between mountaineering boots for adults and crampons - Requirements and test methods | 30.4.2025 |
| 8. | WI 00158117 Mountaineering equipment - Helmets for ski mountaineers - Safety requirements and test methods | 30.4.2026 |

| 9. | WI 00162478 Warning clothing with active lighting in addition to EN ISO 20471 and EN 17353 – Equipment for active luminous warning clothing – Test methods and requirements | 30.4.2027 |
|-----|--|------------|
| 10. | WI 00205368 Respiratory infection prevention devices for self- and third party protection - Requirements for different performance classes and test methods | 30.4.2026 |
| 11. | Helmets for high-speed cycling | 30.4.2027 |
| 12. | Surface wetsuits | 30.4.2027 |
| 13. | Protective clothing — Visibility garments for hunting activities | 30.4.2027' |

<u>ANNEX II</u>

Annex II to Commission Implementing Decision C(2020)7924 is replaced by the following text:

'Part A. General requirements for standards listed in Annex I

1. Legal requirements to be supported by the harmonised standards

The harmonised standards shall support application of relevant essential health and safety requirements set out in Annex II to Regulation (EU) 2016/425.

The harmonised standards shall provide detailed technical specifications of essential health and safety requirements, with regard to the design and manufacture of personal protective equipment with the purpose of allowing compliance with relevant essential health and safety requirements.

The structure of a harmonised standard shall be such that a clear distinction can be made between its clauses and sub-clauses which are necessary for compliance with the essential health and safety requirements and those which are not. The essential health and safety requirements shall be taken into account from the beginning and throughout the process of developing of standards.

Harmonised standards shall be inclusive, so that they aim to ensure equal performance regarding all essential requirements laid down in Annex II to Regulation (EU) 2016/425 across the Union's diverse population, i.e., regardless of gender, age, height as well as other anthropometric and biomechanical considerations. When equal performance for all is not possible, the advantages and disadvantages shall be fairly distributed. To this end, such standards shall be based on recent data that is representative of the Union's population, both for the design of products, processes and services as well as for testing them. In this context, preference shall be given to ranges rather than averages to describe product users or operators. Regarding anthropometric and biomechanical characteristics, all relevant body dimensions and physical capabilities representing body size, body structure, body composition, physical strength limits, operating postures and movements shall be considered.

2. Legal requirements to be covered by an individual harmonised standard

When a harmonised standard does not cover all the essential health and safety requirements, which are applicable to the PPE falling under its scope, the standard shall indicate the essential health and safety requirements applicable to those PPE that are not covered by it. Where a harmonised standard contains technical specifications which do not support application of essential health and safety requirements set out in Annex II to Regulation (EU) 2016/425, such technical specifications shall be clearly distinguished from the specifications supporting the essential health and safety requirements.

3. Risk assessment and risk reduction to include safety aspects in harmonised standards

The harmonised standards concerning health and safety of PPE shall be drafted or revised by applying the iterative process of risk assessment and risk reduction as set out in point 4 of the preliminary remarks of Annex II to Regulation (EU) 2016/425, by following the design principles set out in point 1.1. of the general requirements applicable to all PPE set out in Annex II to Regulation (EU) 2016/425 and by considering the intended use and the reasonably foreseeable uses of PPE as set out in point 5 of the preliminary remarks of Annex II to Regulation (EU) 2016/425.

Part B. Specific requirements for revision of existing standards listed in Table 1 of Annex I

1. Requirements for all standards

Standards shall reflect the state of art. CEN and CENELEC shall update the information on the correspondence between the clauses of the standard and the applicable essential safety requirements in standards listed in Table 1 of Annex I.

2. Requirements for specific standards

2.1 Standards on protection against heat and/or fire - PPE constituent materials and other components listed in points 16, 17, 22, 35, 45, 50, 65, 69, 73, 76, 80, 81, 83, 94, 98 and 104 of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering PPE protecting against heat and/or fire. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the types of PPE which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment to ensure conformity with at least point 3.6.1 of Annex II to Regulation (EU) 2016/425.

2.2. Standards on protection against mechanical impact - Helmets listed in points 14, 16, 30, 31, 34, 51, 80 and 81 of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering the requirements on helmets, in particular those for equestrian activities, for cyclists and for young children. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical impact, in particular impact caused by falling or ejected objects and collisions of parts of the body with an obstacle, to ensure conformity with at least point 3.1.1. of Annex II to Regulation (EU) 2016/425.

2.3. Standards on protection against mechanical impact - Gloves listed in point **97** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering protective gloves against mechanical risks. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical impact, in particular impact caused by falling or ejected objects and collisions of parts of the body with an obstacle, to ensure conformity with at least point 3.1.1. of Annex II to Regulation (EU) 2016/425.

2.4. Standards on protection against mechanical impact - Protective equipment for use in motorcycling listed in points **36, 39, 60, 61, 67 and 86** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering protective equipment for use in ice hockey, snowboarding and other sports. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical impact, in particular impact caused by falling or ejected objects and collisions of parts of the body with an obstacle, to ensure conformity with at least point 3.1.1. of Annex II to Regulation (EU) 2016/425.

2.5. Standards on protection against mechanical impact - Protective equipment for use in ice hockey, equestrian sports, snowboarding and other sports listed in points **40, 58, 88 and 90** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering protective equipment for use in ice hockey, equestrian sports, snowboarding and other sports. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical impact, in particular impact caused by falling or ejected objects and collisions of parts of the body with an obstacle, to ensure conformity with at least point 3.1.1. of Annex II to Regulation (EU) 2016/425.

2.6. Standards on protection against mechanical impact and mechanical injuries -Protective clothing and footwear for users of hand-held chain-saws listed in points 45 and 86 of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering protective clothing and footwear for users of hand-held chain-saws against mechanical risks. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical impact and mechanical injuries, to ensure conformity with at least points 3.1.1. and 3.3. of Annex II to Regulation (EU) 2016/425.

2.7. Standards on protection against mechanical injuries - Gloves and arm guards listed in point **22, 32 and 97** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering protective gloves and arm guards against mechanical injuries. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical injuries, to ensure conformity with at least point 3.3. of Annex II to Regulation (EU) 2016/425.

2.8. Standards on protection against mechanical vibration - Gloves listed in point **41** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering protective gloves against mechanical vibration. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical vibration, to ensure conformity with at least point 3.1.3. of Annex II to Regulation (EU) 2016/425.

2.9. Standards on protection against falls from a height - Mountaineering equipment listed in points **20, 21, 25, 26, 28, 46, 77 and 85** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering mountaineering equipment. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against falls from a height, to ensure conformity with at least point 3.1.2.2. of Annex II to Regulation (EU) 2016/425.

2.10. Standards on protection against falls from a height - listed in points 5, 8, 9, 10, 11, 12, 23, 24, 38, and 52 of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering equipment protecting against falls from a height. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against falls from a height, to ensure conformity with at least point 3.1.2.2. of Annex II to Regulation (EU) 2016/425.

2.11. Standards on protection against electric shock - Insulating equipment listed in points 79, 101, 102, 103, 104 and 107 of Table 1 of Annex I

CEN and CENELEC shall complete the work on draft harmonised standards covering insulating equipment. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the types of PPE designed to protect all or part of the body against the effects of electric current to ensure conformity with at least point 3.8.1. of Annex II to Regulation (EU) 2016/425.

2.12. Standards on protection against non-ionising radiation - Personal eye-protection listed in points **47, 59, 72, 78, 88 and 89** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering personal eye protection against non-ionising radiation. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against non-ionising radiation, to ensure conformity with at least point 3.9.1. of Annex II to Regulation (EU) 2016/425.

2.13. Standards on protection against ionising radiation - Protection against external radioactive contamination listed in point **29** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering equipment protecting against external radioactive contamination. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against ionising radiation, to ensure conformity with at least point 3.9.2.1. of Annex II to Regulation (EU) 2016/425.

2.14. Standards on PPE capable of signalling the user's presence visually listed in point **87** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering PPE capable of signalling the user's presence visually. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of this type of PPE designed to signal the user's presence visually, to ensure conformity with at least point 2.13. of Annex II to Regulation (EU) 2016/425.

2.15. Standards on protection against substances and mixtures which are hazardous to health and against harmful biological agents - Protective clothing, gloves and footwear listed in points 13, 27, 55, 64, 66, 74, 82 and 100 of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering protective clothing, gloves and footwear against substances and mixtures which are hazardous to health and against harmful biological agents. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of these types of PPE designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents, to ensure conformity with at least point 3.10.2. of Annex II to Regulation (EU) 2016/425.

2.16. Standards on protection against substances and mixtures which are hazardous to health and against harmful biological agents - Respiratory protection listed in points 1, 2, 3, 4, 15, 37, 53, 54, 63 and 70 of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering respiratory protective equipment. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents, to ensure conformity with at least point 3.10.1. of Annex II to Regulation (EU) 2016/425.

2.17. Standards on protection against cold – Protective clothing and gloves listed in points **6, 19, 68 and 75** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering clothing and gloves protecting against cold. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the correspondent types of PPE designed to protect all or a part of the body against the effects of cold, to ensure conformity with at least point 3.7.1. of Annex II to Regulation (EU) 2016/425.

2.18. Standards on protection against the harmful effects of noise – Hearing protectors listed in point **7** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering hearing protectors. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the correspondent types of PPE designed to protect against the harmful effects of noise, to ensure conformity with at least point 3.5. of Annex II to Regulation (EU) 2016/425.

2.19. Standards on protection in liquids - Prevention of drowning listed in points **49 and 75** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering personal flotation devices and immersion suits. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the correspondent types of PPE designed to prevent drowning, to ensure conformity with at least point 3.4.1. of Annex II to Regulation (EU) 2016/425.

2.20. Standards on protection in liquids - PPE buoyancy aids listed in point **57** of Table 1 of Annex I

CEN shall complete the work on draft harmonised standards covering buoyancy aids. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the correspondent types of PPE designed to provide an effective degree of buoyancy to ensure conformity with at least point 3.4.2. of Annex II to Regulation (EU) 2016/425.

Part C. Specific requirements for drafting new standards listed in Table 2 of Annex I

1. Requirements for all standards

Standards shall reflect the state of art.

2. Requirements for specific standards

2.1. Standards on protection against non-ionising radiation - Personal eye-protection listed in point **1** of Table 2 of Annex I

CEN shall draft harmonised standards covering eye-protective equipment against non-ionising radiation. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against non-ionising radiation, to ensure conformity with at least point 3.9.1. of Annex II to Regulation (EU) 2016/425.

2.2. Standards on prevention of falls from a height - Mountaineering equipment and other protective equipment listed in points **3** and **4** of Table 2 of Annex I

CEN shall draft harmonised standards covering protective equipment to prevent falls from a height. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed

to protect against falls from a height, to ensure conformity with at least point 3.1.2.2. of Annex II to Regulation (EU) 2016/425.

2.3 Standards on protection against the thermal hazards of an electric arc – Live working PPE listed in point **6** of Table 2 of Annex I

CEN and CENELEC shall draft harmonised standards covering protective equipment against the thermal hazards of an electric arc. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the correspondent types of PPE designed to protect against the thermal hazards of an electric arc to ensure conformity with at least point 3.6.1 of Annex II to Regulation (EU) 2016/425.

2.4. Standards on prevention of falls due to slipping - Mountaineering equipment listed in point **7** of Table 2 of Annex I

CEN shall draft harmonised standards covering mountaineering equipment to prevent falls due to slipping. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to prevent falls due to slipping to ensure conformity with at least point 3.1.2.1. of Annex II to Regulation (EU) 2016/425.

2.5. Standards on protection against mechanical impact - Helmets for ski mountaineers and high-speed cycling listed in points **8** and **11** of Table 2 of Annex I

CEN shall draft harmonised standards covering helmets for ski mountaineers and high-speed cycling. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against mechanical impact caused by falling or ejected objects and collisions of parts of the body with an obstacle, to ensure conformity with at least point 3.1.1. of Annex II to Regulation (EU) 2016/425.

2.6. Standards on PPE capable of signalling the user's presence visually listed in points **9** and **13** of Table 2 of Annex I

CEN shall draft harmonised standards covering PPE capable of signalling the user's presence visually. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to signal the user's presence visually to ensure conformity with at least point 2.13. of Annex II to Regulation (EU) 2016/425.

2.7. Standards on protection against substances and mixtures which are hazardous to health and against harmful biological agents - Respiratory infection prevention devices listed in point **10** of Table 2 of Annex I

CEN shall draft harmonised standards covering respiratory infection prevention devices. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture of the correspondent types of PPE designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents, to ensure conformity with at least point 3.10.1. of Annex II to Regulation (EU) 2016/425.

2.8. Standards on protection against cold – Surface wetsuits listed in point **12** of Table 2 of Annex I

CEN shall draft harmonised standards covering surface wetsuits. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the correspondent types of PPE designed to protect all or a part of the body

against the effects of cold, to ensure conformity with at least point 3.7.1. of Annex II to Regulation (EU) 2016/425.'