

#### **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 1025/2012<sup>1</sup>

### 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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<sup>&</sup>lt;sup>1</sup> OJ L 316, 14.11.2012, p. 12

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)

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.

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### **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)

### 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) By Implementing Decision C(2020) 7924<sup>2</sup>, 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/EEC<sup>3</sup> and the drafting of new harmonised standards in support of Regulation (EU) 2016/425<sup>4</sup>.
- (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.

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OJ L 316, 14.11.2012, p. 12.

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

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).

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 Standardisation<sup>5</sup>.
- (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.
- 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.

<sup>&</sup>lt;sup>5</sup> 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.

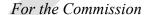
### Article 2

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,



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

23.	EN 795 Personal fall protection equipment - Anchor devices	31.5.2025
24.	EN 813 Personal fall protection equipment - Sit harnesses	30.4.2024
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 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 Protective clothing for fire-fighters - Test methods and requirements for	30.4.2027

	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
	EN 12277 Mountaineering equipment - Harnesses - Safety requirements and test methods EN ISO 12312	

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'

#### **ANNEX II**

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.'