

13.1.2016

A8-0148/ 001-157

**AMENDMENTS 001-157**

by the Committee on the Internal Market and Consumer Protection

**Report**

**Vicky Ford**

**A8-0148/2015**

Personal protective equipment

Proposal for a regulation (COM(2014)0186 – C7-0110/2014 – 2014/0108(COD))

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**Amendment 1**

**Proposal for a regulation**

**Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

*(3a) This Regulation covers PPE which is new to the Union market when it is placed on the market; that is to say it is either new PPE made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.*

**Amendment 2**

**Proposal for a regulation**

**Recital 3 b (new)**

*Text proposed by the Commission*

*Amendment*

*(3b) This Regulation should apply to all forms of supply, including distance selling.*

## Amendment 3

### Proposal for a regulation Recital 5

*Text proposed by the Commission*

(5) Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>16</sup> lays down **horizontal provisions** on the accreditation of conformity assessment bodies **and on** the CE marking.

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<sup>16</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L 218, 13.8.2008, p. 30).

*Amendment*

(5) Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>16</sup> lays down **rules** on the accreditation of conformity assessment bodies, **provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of** the CE marking.

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<sup>16</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L 218, 13.8.2008, p. 30).

## Amendment 4

### Proposal for a regulation Recital 6

*Text proposed by the Commission*

(6) Decision No 768/2008/EC of the European Parliament and of the Council<sup>17</sup> **provides** common principles and reference provisions **for the purposes of** legislation **based on the New Approach principles**. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions

*Amendment*

(6) Decision No 768/2008/EC of the European Parliament and of the Council<sup>1</sup> **lays down** common principles and reference provisions **intended to apply across sectoral** legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning

concerning procedures to deal with products presenting a risk should be aligned to that Decision.

procedures to deal with products presenting a risk should be aligned to that Decision.

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<sup>17</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC(OJ L 218, 13.8.2008, p. 82).

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<sup>17</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC(OJ L 218, 13.8.2008, p. 82).

## Amendment 5

### Proposal for a regulation Recital 8

*Text proposed by the Commission*

*Amendment*

***(8) Regulation (EU) No xx/xxxx of the European Parliament and of the Council<sup>18</sup> provides detailed rules on market surveillance and on controls of harmonised products, including PPE, entering the Union from third countries. In accordance with that Regulation, Member States are to organise and carry out market surveillance, to appoint market surveillance authorities, to specify their powers and duties, and to set up general and sector-specific market surveillance programmes. That Regulation also sets out a safeguard clause procedure.***

***deleted***

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<sup>18</sup> [Regulation (COM/2013/075 final - 2013/0048 (COD))on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament

and of the Council (OJ L XXXX)].

## Amendment 6

### Proposal for a regulation

#### Recital 9

*Text proposed by the Commission*

(9) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. In order to ensure *as high level of protection for the user of those products as for the PPE covered by Directive 89/686/EEC, the scope of this Regulation should include PPE* for private use against *damp, water and heat (e.g. dish-washing gloves, oven gloves), in line with similar PPE for professional use which is already covered by Directive 89/686/EEC. Artisanal products, such as handmade gloves, for which the manufacturer does not explicitly claim a protective function are not personal protective equipment; they are therefore not concerned by this inclusion.* It is also appropriate to clarify the exclusion list set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore are excluded from the PPE Regulation.

*Amendment*

(9) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. ***Artisanal or decorative products for which the manufacturer does not explicitly claim a protective function are not personal protective equipment; they should therefore not be covered by this Regulation.*** In order to ensure *a high level of protection, the scope of this Regulation should include products which are explicitly described and marketed accordingly by their manufacturers* for private use *to protect* against heat. ***In the case of products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including but not limited to seasonal clothing, umbrellas and dishwashing gloves, these should be outside of the scope of this Regulation.*** It is also appropriate to clarify the exclusion list set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore are excluded from the PPE Regulation.

## Amendment 7

### Proposal for a regulation

#### Recital 10 a (new)

*Text proposed by the Commission*

*Amendment*

***(10a) During field demonstrations and field tests, adequate measures should be taken to ensure the protection of persons.***

*Field tests should not be designed to test the protection performance of the PPE but to evaluate other non-protective aspects such as comfort, ergonomics and design. All concerned parties, for instance the employer as well as the wearer or the consumer, should be informed in advance concerning the scope and purpose of the test.*

## Amendment 8

### Proposal for a regulation

#### Recital 11

*Text proposed by the Commission*

(11) Economic operators should be responsible for the compliance of **products**, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of users and to guarantee fair competition on the Union market.

*Amendment*

(11) Economic operators should be responsible for the compliance of **the PPE**, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of users **and, where appropriate, other persons**, and to guarantee fair competition on the Union market.

## Amendment 9

### Proposal for a regulation

#### Recital 12

*Text proposed by the Commission*

(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that **PPE protects the health and safety of persons and that** they make available on the market only **products** which **comply** with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution chain.

*Amendment*

(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only **PPE** which **is in conformity** with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each **economic** operator in the supply and distribution chain.

## Amendment 10

### Proposal for a regulation Recital 12 a (new)

*Text proposed by the Commission*

*Amendment*

***(12a) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.***

## Amendment 11

### Proposal for a regulation Recital 14

*Text proposed by the Commission*

*Amendment*

(14) It is necessary to ensure that PPE entering the Union market complies with this Regulation and, in particular, that appropriate assessment procedures have been carried out by manufacturers. Provision should therefore be made ***for*** importers ***to make sure that the PPE they*** place on the market complies with the requirements of this Regulation and ***that they do not place on the market PPE which does not comply with such requirements or which*** present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the market surveillance authorities.

(14) It is necessary to ensure that PPE entering the Union market complies with this Regulation and, in particular, that appropriate ***conformity*** assessment procedures have been carried out by manufacturers. Provision should therefore be made ***to the effect that*** importers ***shall*** place on the market ***only PPE which*** complies with the requirements of this Regulation and ***does not*** present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the market surveillance authorities.

## Amendment 12

### Proposal for a regulation Recital 16

*Text proposed by the Commission*

(16) When placing PPE on the market, importers should indicate on the **product** their name and the address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow for **such an indication**. This includes cases where the importer would have to open the packaging to put his name and address on the **product**.

*Amendment*

(16) When placing PPE on the market, importers should indicate on the **PPE** their name, **registered name or trademark** and the **postal** address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow for **it**. This includes cases where the importer would have to open the packaging to put his name and address on the **PPE**.

**Amendment 13**

**Proposal for a regulation**  
**Recital 16 a (new)**

*Text proposed by the Commission*

*Amendment*

***(16a) Efforts should be made by economic operators to ensure that all relevant documentation, such as the user's instructions, whilst ensuring precise and comprehensible information, are easily understandable, take into account technological developments and changes to end-user behaviour, and are as up to date as possible.***

**Amendment 14**

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

*Amendment*

(19) Ensuring traceability of PPE throughout the supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant product available on the market.

(19) Ensuring traceability of PPE throughout the **whole** supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant product available on the market. ***When keeping the information required under***

*this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with PPE or to whom they have supplied PPE unless such updated information has been supplied to them.*

## **Amendment 15**

### **Proposal for a regulation Recital 20 a (new)**

*Text proposed by the Commission*

*Amendment*

*(20a) 'Field test' means a trial period by the user of non-compliant PPE, before it is placed on market and for which all the necessary information of tests carried out by accredited or authorised laboratories is available in the technical file to ensure the protection of the user and meets the applicable requirements in Annex II, is made available in a very limited number for a limited time and whose principal purpose is to undertake a final evaluation of its non-protection characteristics.*

## **Amendment 16**

### **Proposal for a regulation Recital 21**

*Text proposed by the Commission*

*Amendment*

(21) It is necessary to clearly specify the relationship and scope of this Regulation with the entitlement of Member States to lay down requirements for the use of PPE at workplace, in particular pursuant to Council Directive 89/656/EEC<sup>19</sup>, in order to avoid any confusion and ambiguity and hence ensure the free movement of compliant PPE.

(21) It is necessary to clearly specify the relationship and scope of this Regulation with the entitlement of Member States to lay down requirements for the use of PPE at workplace, in particular pursuant to Council Directive 89/656/EEC<sup>19</sup>, in order to avoid any confusion and ambiguity and hence ensure the free movement of compliant PPE. *Article 4 of that Directive obliges employers to provide PPE which complies with the relevant Union*

*provisions on design and manufacture with respect to safety and health. Pursuant to that Article, manufacturers of PPE who provide that PPE to their employees must ensure that such PPE fulfils the requirements laid down in this Regulation.*

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<sup>19</sup> Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (OJ L 393, 30.12.1989, p. 18).

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<sup>19</sup> Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (OJ L 393, 30.12.1989, p. 18).

## **Amendment 17**

### **Proposal for a regulation Recital 22**

*Text proposed by the Commission*

*(22) The requirement in other internal market legislation to supply an EU declaration of conformity with the equipment has been found to facilitate and to enhance the efficiency of market surveillance and should therefore also be introduced into this Regulation. It should be possible to provide a simplified EU declaration of conformity in order to reduce the burden associated with this requirement without reduction of its effectiveness. Both possibilities should therefore be provided for in this Regulation.*

*Amendment*

*(22) Market surveillance authorities should have easy access to the declaration of conformity. In order to fulfil that requirement, manufacturers should ensure PPE is accompanied either by a full copy of the declaration of conformity or the internet address where the EU declaration of conformity can be accessed. Alternatively, the manufacturer should be able to choose to provide a simplified declaration of conformity.*

## **Amendment 18**

### **Proposal for a regulation Recital 22 a (new)**

*Text proposed by the Commission*

*Amendment*

*(22a) To ensure effective access to information for market surveillance*

*purposes, in cases where PPE is covered by one or more Union harmonisation legal acts the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.*

## Amendment 19

### Proposal for a regulation Recital 24

#### *Text proposed by the Commission*

(24) *In order to ensure that* PPE is examined on the basis of the state of the art *the limit* of validity of the EU type-examination certificate should *set to a maximum of* five years. A process for reviewing the certificate should be provided for. A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.

#### *Amendment*

(24) PPE *should be* examined on the basis of the state of the art. *The maximum period* of validity of the EU type-examination certificate should *be* five years *and a* process for reviewing the certificate should be provided for. *Following a positive review, a renewed certificate may continue to be valid for further periods, each of which should be for a maximum of five years.* A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.

## Amendment 20

### Proposal for a regulation Recital 24 a (new)

#### *Text proposed by the Commission*

#### *Amendment*

(24a) *A simplified procedure should be applied for re-certification of the EU-type examination certificate when the product, applied harmonised standards or other technical solutions applied by the manufacturer have not been changed and continue to meet the essential health and*

*safety requirements in the light of the state of the art, making additional tests or technical examinations unnecessary and thereby keeping the administrative burden and related costs to a minimum.*

## Amendment 21

### Proposal for a regulation Recital 24 b (new)

*Text proposed by the Commission*

*Amendment*

*(24b) The withdrawal of a harmonised standard should not invalidate existing certificates issued by notified bodies; it only concerns the conformity that is conferred onto new conformity assessments that follow the new harmonised standard. Products produced in accordance with the existing certificate should still benefit from the continuing conformity with the essential requirements and it should continue to be possible to place them on the market until the end of the validity of the relevant certificates issued by notified bodies.*

#### *Justification*

*To avoid legal uncertainty regarding cases where the harmonized standard on the certificate has been replaced by a revised version, this text has been added to the text from the Commission's 'Blue Guide' on the implementation of EU product rules.*

## Amendment 22

### Proposal for a regulation Recital 28

*Text proposed by the Commission*

*Amendment*

(28) In order to ensure compliance with the essential safety requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Directive 89/686/EEC classifies PPE into three categories that are subject to different

(28) In order to ensure compliance with the essential **health and** safety requirements ***laid down in this Regulation***, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Directive 89/686/EEC classifies PPE into three

conformity assessment procedures. In order to ensure a consistently high level of safety for all PPE, the list of products subject to one of the conformity assessment procedures relating to the production phase should be enlarged. The conformity assessment procedures for each category of PPE should be set, as far as possible, on the basis of the conformity assessment modules laid down in Decision No 768/2008/EC.

categories that are subject to different conformity assessment procedures. In order to ensure a consistently high level of safety for all PPE, the list of products subject to one of the conformity assessment procedures relating to the production phase should be enlarged. The conformity assessment procedures for each category of PPE should be set, as far as possible, on the basis of the conformity assessment modules laid down in Decision No 768/2008/EC.

## **Amendment 23**

### **Proposal for a regulation**

#### **Recital 29 a (new)**

*Text proposed by the Commission*

*Amendment*

***(29a) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards it should be presumed to comply with the corresponding requirements set out in this Regulation.***

## **Amendment 24**

### **Proposal for a regulation**

#### **Recital 30 a (new)**

*Text proposed by the Commission*

*Amendment*

***(30a) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.***

## Amendment 25

### Proposal for a regulation Recital 30 b (new)

*Text proposed by the Commission*

*Amendment*

***(30b) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.***

## Amendment 26

### Proposal for a regulation Recital 30 c (new)

*Text proposed by the Commission*

*Amendment*

***(30c) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the PPE to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the***

*performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.*

#### **Amendment 27**

##### **Proposal for a regulation Recital 30 d (new)**

*Text proposed by the Commission*

*Amendment*

*(30d) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.*

#### **Amendment 28**

##### **Proposal for a regulation Recital 30 e (new)**

*Text proposed by the Commission*

*Amendment*

*(30e) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.*

## **Amendment 29**

### **Proposal for a regulation Recital 30 f (new)**

*Text proposed by the Commission*

*Amendment*

*(30f) Member States should take all appropriate measures to ensure that products covered by this Regulation may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and or safety of users or, where applicable, of other persons. Products covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.*

## **Amendment 30**

### **Proposal for a regulation Recital 30 g (new)**

*Text proposed by the Commission*

*Amendment*

*(30g) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to products covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.*

## **Amendment 31**

### **Proposal for a regulation Recital 30 h (new)**

*Text proposed by the Commission*

*Amendment*

***(30h) Directive 89/686/EC already provides for a safeguard procedure which is necessary to allow the possibility for contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.***

## **Amendment 32**

### **Proposal for a regulation Recital 30 i (new)**

*Text proposed by the Commission*

*Amendment*

***(30i) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to PPE presenting a risk to the health or safety of users or, where applicable, of other persons. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such PPE.***

## **Amendment 33**

### **Proposal for a regulation Recital 30 j (new)**

*Text proposed by the Commission*

*Amendment*

***(30j) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.***

## Amendment 34

### Proposal for a regulation Recital 32 a (new)

*Text proposed by the Commission*

*Amendment*

***(32a) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant PPE which presents a risk to the health or safety of persons, imperative grounds of urgency so require.***

## Amendment 35

### Proposal for a regulation Article 1 – paragraph 1

*Text proposed by the Commission*

*Amendment*

This Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) in order to ensure the ***health and safety*** protection of users and rules on its free movement in the Union.

This Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) ***which is being made available on the market*** in order to ensure the protection of users and rules on its free movement in the Union.

## Amendment 36

### Proposal for a regulation Article 2 – paragraph 1

*Text proposed by the Commission*

*Amendment*

This Regulation shall apply to personal protective equipment (PPE), as defined in Article 3.

This Regulation shall apply to personal protective equipment (PPE), as defined in Article 3 ***and classified into the risk categories set out in Annex I.***

## Amendment 37

### Proposal for a regulation Article 2 – paragraph 2 – point a

*Text proposed by the Commission*

(a) specifically designed for use by the armed forces or **for** the maintenance of law and order;

*Amendment*

(a) specifically designed for use by the armed forces or **in** the maintenance of law and order;

**Amendment 38**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) **intended** to be used for self-defence;

*Amendment*

(b) **designed** to be used for self-defence, **with the exception of PPE intended for sporting activities**;

**Amendment 39**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) intended for private use to protect against atmospheric conditions that are not of an extreme nature;

*Amendment*

c) intended for private use to protect against:

(i) atmospheric conditions that are not of an extreme nature;

(ii) **damp and water not of an extreme nature**;

(iii) **heat, for which the economic operator does not explicitly describe and market the products as having a protective function**;

**Amendment 40**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point e**

*Text proposed by the Commission*

(e) for head, face or eye protection of

*Amendment*

(e) for head, face or eye protection of

users, subject to *the relevant Regulation* of the United Nations Economic Commission for Europe (UNECE), *of two- or three-wheeled motor vehicles*.

users, subject to **Regulation 22** of the United Nations Economic Commission for Europe (UNECE), *on uniform provisions concerning the approval of protective helmets and of their visors for drivers and passengers of motor cycles and mopeds;*

## Amendment 41

### Proposal for a regulation

#### Article 2 – paragraph 2 – point e a (new)

*Text proposed by the Commission*

*Amendment*

*(ea) in the form of clothing intended for private use, with reflective or fluorescent garments which are exclusively included for reasons of design or decoration, and for which the economic operator does not describe and market the products as having a protective function;*

## Amendment 42

### Proposal for a regulation

#### Article 2 – paragraph 2 – point e b (new)

*Text proposed by the Commission*

*Amendment*

*(eb) designed and placed on the market as artisanal products which are decorative in nature.*

## Amendment 43

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 1 – point a

*Text proposed by the Commission*

*Amendment*

(a) equipment *intended* to be worn or held by a person for protection against one or more risks for his or her health or safety that is placed on the market separately or combined with personal non-protective equipment;

(a) equipment ***designed and manufactured*** to be worn or held by a person for protection against one or more risks for his or her health or safety that is placed on the market separately or combined with personal non-protective equipment;

#### Amendment 44

##### Proposal for a regulation

##### Article 3 – paragraph 1 – point 1 – point c

*Text proposed by the Commission*

(c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are *intended* to connect that equipment to an external device or *structure, that are removable and not intended* to be permanently fixed *to a structure*;

*Amendment*

(c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, *but which are essential to the equipment's function*, that are *designed* to connect that equipment to an external device or *to a reliable anchorage point, that are not designed* to be permanently fixed *and that do not require fastening works before use*;

#### Amendment 45

##### Proposal for a regulation

##### Article 3 – paragraph 1 – point 2

*Text proposed by the Commission*

2. *'individually adapted PPE' means PPE produced in series where each item is manufactured to fit an individual user*;

*Amendment*

2. *'PPE type' means the series of PPE that is equal to the PPE described in the technical documentation and to the PPE subject to the EU type examination (in the case of category II or III)*;

#### Amendment 46

##### Proposal for a regulation

##### Article 3 – paragraph 1 – point 5

*Text proposed by the Commission*

5. 'placing on the market' means the first making available of *PPE* on the Union market;

*Amendment*

5. 'placing on the market' means the first making available of *the PPE type* on the Union market;

#### Amendment 47

##### Proposal for a regulation

##### Article 3 – paragraph 1 – point 18 a (new)

*Text proposed by the Commission*

*Amendment*

***18a. 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;***

#### **Amendment 48**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 20 a (new)**

*Text proposed by the Commission*

*Amendment*

***20a. 'Demonstration' means any showing of PPE, not in a hazardous setting, for promotional purposes;***

#### **Amendment 49**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 20 b (new)**

*Text proposed by the Commission*

*Amendment*

***20b. 'Field test' means an event in which a non-certified PPE for which all the necessary test documents (tests carried out by accredited or authorised laboratories) supporting the technical file to ensure the protection of the wearer are available and met is made available in a very limited number to carry out a final evaluation. A field test is limited in time, with time and purpose defined and motivated before the start of the test and confirmed by the concerned parties;***

#### **Amendment 50**

**Proposal for a regulation**

**Article 7 – title**

*Text proposed by the Commission*

*Amendment*

Free movement

Free movement, ***demonstrations and field tests***

## **Amendment 51**

### **Proposal for a regulation**

#### **Article 7 – paragraph 2 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

At trade fairs, exhibitions, ***and demonstrations***, Member States shall not prevent the showing of PPE which does not comply with this Regulation ***provided that a visible sign clearly indicates that the PPE does not comply with this Regulation and is not available on the market until it has been brought into conformity.***

At trade fairs, exhibitions, ***demonstrations or field tests***, Member States shall not prevent the showing of PPE which does not comply with this Regulation ***and is not available on the market. Field tests shall not be designed to test the protection performance of the PPE, but to evaluate other non-protective aspects such as comfort, ergonomics and design.***

## **Amendment 52**

### **Proposal for a regulation**

#### **Article 7 – paragraph 2 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

During demonstrations, adequate measures shall be taken to ensure the protection of persons.

During demonstrations, ***and field tests***, adequate measures shall be taken to ensure the protection of persons.

## **Amendment 53**

### **Proposal for a regulation**

#### **Article 7 – paragraph 2 – subparagraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***PPE covered by this paragraph may be displayed or field tested provided that a visible sign clearly indicates that the PPE does not comply with this Regulation.***

## Amendment 54

### Proposal for a regulation Article 8 – paragraph 3

*Text proposed by the Commission*

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least **10** years after the PPE has been placed on the market.

*Amendment*

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least **five** years after the PPE has been placed on the market.

*Justification*

*The requirement for technical documentation to be kept for 10 years is excessive, particularly because the period of validity of the conformity certificate is only five years.*

## Amendment 55

### Proposal for a regulation Article 8 – paragraph 4

*Text proposed by the Commission*

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. ***Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.***

*Amendment*

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. ***When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.***

## Amendment 56

### Proposal for a regulation Article 8 – paragraph 5

*Text proposed by the Commission*

5. Manufacturers shall ensure that the PPE which they place on the market bears a

*Amendment*

5. Manufacturers shall ensure that the PPE which they place on the market bears

type, batch or serial number or other element allowing its identification or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or a document accompanying the PPE.

*either* a type, batch or serial number or other element allowing its identification or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or a document accompanying the PPE.

## Amendment 57

### Proposal for a regulation Article 8 – paragraph 6

#### *Text proposed by the Commission*

6. Manufacturers shall indicate, ***on the PPE***, their name, registered trade name or registered trade mark ***and*** the postal address at which they can be contacted ***or, where that is not possible, on*** its packaging or in a document accompanying the PPE. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in ***a*** language ***easily understood by end-users and market surveillance authorities.***

#### *Amendment*

6. Manufacturers shall indicate, their name, registered trade name or registered trade mark, the postal ***or e-mail*** address at which they can be contacted ***on the PPE***, its packaging or in a document accompanying the PPE. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in ***the language or languages of the Member State in which the PPE is to be marketed.***

## Amendment 58

### Proposal for a regulation Article 8 – paragraph 7

#### *Text proposed by the Commission*

7. Manufacturers shall ensure that ***the*** PPE is accompanied by the instructions set out in point 1.4 of Annex II in a language which can be easily understood by end-users, as determined by the Member State concerned.

#### *Amendment*

7. Manufacturers shall ensure that PPE is accompanied by the instructions set out in point 1.4 of Annex II in a language which can be easily understood by ***consumers and*** end-users, as determined by the Member State concerned ***in which the PPE is made available on the market. Such instructions, as well as any labelling, shall be clear, understandable and intelligible. Where PPE is available in packages containing multiple units, such instructions shall accompany each smallest commercially available unit.***

## Amendment 59

### Proposal for a regulation

#### Article 8 – paragraph 7 a (new)

*Text proposed by the Commission*

*Amendment*

***7a. Manufacturers shall ensure that performance as recorded during relevant technical tests to check the levels of classes of protection provided by the PPE is available electronically or upon request.***

## Amendment 60

### Proposal for a regulation

#### Article 8 – paragraph 8

*Text proposed by the Commission*

*Amendment*

8. Manufacturers shall ensure that the PPE is accompanied by a copy of the EU declaration of conformity referred to in Article (15)(2). Manufacturers may choose to fulfil this requirement by accompanying the PPE with the simplified EU declaration of conformity referred to in Article (15)(3). Where only the simplified EU declaration of conformity is provided, it shall ***be immediately followed by*** the exact internet address where the full text of the EU declaration of conformity can be obtained.

8. Manufacturers shall ensure that the PPE is accompanied by a copy of the EU declaration of conformity referred to in Article (15)(2). Manufacturers may choose to fulfil this requirement by accompanying the PPE with the simplified EU declaration of conformity referred to in Article (15)(3) ***or include in the instructions and information the internet address where the EU declaration of conformity can be accessed.*** Where only the simplified EU declaration of conformity is provided, it shall ***contain*** the exact internet address where the full text of the EU declaration of conformity can be obtained.

## Amendment 61

### Proposal for a regulation

#### Article 8 – paragraph 10

*Text proposed by the Commission*

*Amendment*

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the PPE,

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the PPE,

in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

in ***paper or electronic form, in*** a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

## Amendment 62

### Proposal for a regulation

#### Article 9 – paragraph 2 – point a

##### *Text proposed by the Commission*

(a) keep the EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for at least 10 years after the PPE has been ***placed*** on the market;

##### *Amendment*

(a) keep the EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for at least 10 years after the PPE has been ***made available*** on the market;

##### *Justification*

*If adopted, this change will be made throughout the text.*

## Amendment 63

### Proposal for a regulation

#### Article 10 – paragraph 3

##### *Text proposed by the Commission*

3. Importers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted, ***or where that is not possible***, on its packaging or in a document accompanying the PPE. The contact details shall be in ***a language easily understood by end-users and market surveillance authorities***.

##### *Amendment*

3. Importers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted on its packaging or in a document accompanying the PPE. The contact details shall be in ***the official language or languages of the Member State(s) in which the PPE is to be marketed***.

## Amendment 64

### Proposal for a regulation Article 10 – paragraph 4

*Text proposed by the Commission*

4. Importers shall ensure that ***the*** PPE is accompanied by the instructions ***referred to*** in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

*Amendment*

4. Importers shall ensure that PPE is accompanied by the instructions ***and safety information as set out*** in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. ***Where PPE is available in packages containing multiple units, such instructions shall accompany each smallest commercially available unit.***

## Amendment 65

### Proposal for a regulation Article 10 – paragraph 5 a (new)

*Text proposed by the Commission*

*Amendment*

***5a. When deemed appropriate with regard to the risks presented by PPE, importers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.***

## Amendment 66

### Proposal for a regulation Article 10 – paragraph 6

*Text proposed by the Commission*

*Amendment*

6. Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the

6. Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the

PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the **market surveillance** authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

## Amendment 67

### Proposal for a regulation Article 10 – paragraph 7

#### *Text proposed by the Commission*

7. Importers shall, for at least 10 years after the PPE has been placed on the market, **keep** a copy of the EU declaration of conformity **at the disposal of the market surveillance authorities and ensure that** the technical documentation can be made available to **those** authorities, upon request.

## Amendment 68

### Proposal for a regulation Article 11 – paragraph 2 – subparagraph 1

#### *Text proposed by the Commission*

Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the **EU declaration of conformity or a simplified EU declaration of conformity, and that it is accompanied** by the instructions set out in point 1.4 of Annex II in a language which can be easily understood by end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3).

PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the **manufacturer and the competent national** authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

#### *Amendment*

7. Importers shall, for at least 10 years after the PPE has been placed on the market, **ensure that** a copy of the EU declaration of conformity **and** the technical documentation can be made available to **the market surveillance** authorities upon request.

#### *Amendment*

Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the **required documents**, by the instructions **and other information** set out in point 1.4 of Annex II in a language which can be easily understood by **consumers and other** end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3).

## Amendment 69

### Proposal for a regulation Article 11 – paragraph 4

#### *Text proposed by the Commission*

4. Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with the requirements of this Regulation shall make sure that the necessary corrective measures are taken to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, distributors shall immediately inform the **market surveillance** authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

#### *Amendment*

4. Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with the requirements of this Regulation shall make sure that the necessary corrective measures are taken to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, distributors shall immediately inform the **manufacturer or importer and the competent national** authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

## Amendment 70

### Proposal for a regulation Article 12 – paragraph 1

#### *Text proposed by the Commission*

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that **the conformity with the applicable essential health and safety requirements set out in Annex II** may be affected.

#### *Amendment*

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that **compliance with this Regulation** may be affected.

## Amendment 71

### Proposal for a regulation

#### Article 14 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***Unless otherwise provided for by Union harmonisation legislation, the withdrawal of a harmonised standard shall not invalidate existing certificates issued by notified bodies. Such withdrawal shall only concern the conformity that is conferred onto new conformity assessments that follow the new harmonised standard. Products produced in accordance with the existing certificate shall still benefit from continuing conformity with the essential requirements and may continue to be placed on the market until the end of the validity of the relevant certificates issued by notified bodies.***

#### *Justification*

*The current wording provides legal uncertainty regarding cases where the harmonized standard on the certificate has been replaced by a revised version. To avoid any legal uncertainty, the clarifications provided in the "Blue Guide" on the implementation of EU product rules 2014, 4.1.2.6, p.41 should be introduced in the PPE Regulation directly.*

## Amendment 72

### Proposal for a regulation

#### Article 15 – paragraph 2

*Text proposed by the Commission*

*Amendment*

2. The EU declaration of conformity shall ***have the*** structure ***and*** shall contain the elements set out in ***Annex IX*** and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is made available on the market.

2. The EU declaration of conformity shall ***be based on the model*** structure ***set out in Annex IX***, shall contain the elements ***specified in the relevant modules*** set out in ***Annexes IV, VI, VII and VIII*** and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is ***placed or*** made available on the market.

## Amendment 73

### Proposal for a regulation Article 15 – paragraph 3

*Text proposed by the Commission*

3. A simplified EU declaration of conformity shall **contain the elements** set out in Annex X and it shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is made available on the market. The EU declaration of conformity accessible through internet address shall be available in the language or languages required by the Member State in which the PPE is made available on the market.

*Amendment*

3. A simplified EU declaration of conformity shall **be based on the model structure** set out in Annex X and it shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is made available on the market. The EU declaration of conformity accessible through internet address shall be available in the language or languages required by the Member State in which the PPE is **placed or** made available on the market.

## Amendment 74

### Proposal for a regulation Article 15 – paragraph 5

*Text proposed by the Commission*

5. By drawing up the EU declaration of conformity, the manufacturer shall assume the full responsibility for the **conformity** of the PPE with the requirements **of** this Regulation.

*Amendment*

5. By drawing up the EU declaration of conformity, the manufacturer shall assume the full responsibility for the **compliance** of the PPE with the requirements **laid down in** this Regulation.

## Amendment 75

### Proposal for a regulation Article 16 – paragraph 3

*Text proposed by the Commission*

3. The CE marking shall be affixed before the PPE is placed on the market. **It may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.**

*Amendment*

3. The CE marking shall be affixed before the PPE is placed on the market.

## Amendment 76

### Proposal for a regulation Article 16 – paragraph 4

*Text proposed by the Commission*

4. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure for ensuring conformity to type based on product verification or the procedure for ensuring conformity to type based on quality assurance of the production process.

*Amendment*

4. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure for ensuring conformity to type based on product verification or the procedure for ensuring conformity to type based on quality assurance of the production process. ***The identification number of the notified body shall be affixed under its instructions, by the manufacturer or his authorised representative.***

## Amendment 77

### Proposal for a regulation Article 16 – paragraph 4 a (new)

*Text proposed by the Commission*

*Amendment*

***4a. The CE marking and, where applicable, the identification number of the notified body may be accompanied by a pictogram or other marking indicating the risk against which the PPE is intended to protect.***

## Amendment 78

### Proposal for a regulation Article 16 – paragraph 4 b (new)

*Text proposed by the Commission*

*Amendment*

***4b. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.***

## Amendment 79

### Proposal for a regulation Article 17

*Text proposed by the Commission*

*Amendment*

#### *Article 17*

*deleted*

#### *Risk categories of PPE*

*The PPE shall be classified into the risk categories set out in Annex I.*

## Amendment 80

### Proposal for a regulation Article 23 – paragraph 2

*Text proposed by the Commission*

*Amendment*

2. A conformity assessment body shall be established under national law and have legal personality.

2. A conformity assessment body shall be established under national law *of a Member State* and have legal personality.

## Amendment 81

### Proposal for a regulation Article 23 – paragraph 7 – point c

*Text proposed by the Commission*

*Amendment*

(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the corresponding harmonised standards and of the relevant provisions of Union harmonisation legislation;

(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the corresponding harmonised standards and of the relevant provisions of Union harmonisation legislation *and of relevant national legislation*;

## Amendment 82

### Proposal for a regulation Article 23 – paragraph 9

*Text proposed by the Commission*

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

*Amendment*

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the **Member** State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

**Amendment 83**

**Proposal for a regulation  
Article 23 – paragraph 11**

*Text proposed by the Commission*

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under this Regulation and shall apply **as general guidance the administrative** decisions and documents produced as a result of the work of that group.

*Amendment*

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under **Article 35 of** this Regulation and shall apply **the** decisions and documents produced as a result of the work of that group.

**Amendment 84**

**Proposal for a regulation  
Article 26 – paragraph 2**

*Text proposed by the Commission*

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment **procedure(s)** and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 23.

*Amendment*

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment **module or modules** and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 23.

### *Justification*

*If adopted, this change will be made throughout the text.*

#### **Amendment 85**

##### **Proposal for a regulation Article 27 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

**4. Where a notification is not based on an accreditation certificate referred to in Article 26(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 23.** **deleted**

### *Justification*

*Accreditation should be the general rule for notified bodies*

#### **Amendment 86**

##### **Proposal for a regulation Article 29 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.**

**2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request. *The notifying Member State shall inform the manufacturers concerned and give them the possibility to select another notified body of their choice.***

## Amendment 87

### Proposal for a regulation

#### Article 30 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***1a. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.***

## Amendment 88

### Proposal for a regulation

#### Article 32 – paragraph 1

*Text proposed by the Commission*

*Amendment*

Member States shall ensure that ***an*** appeal procedure against decisions of the notified bodies is available.

Member States shall ensure that ***a transparent and accessible*** appeal procedure against decisions of the notified bodies is available.

## Amendment 89

### Proposal for a regulation

#### Article 35 – paragraph 2

*Text proposed by the Commission*

*Amendment*

***Member States shall ensure that the bodies notified by them*** participate in the work of that group, directly or by means of designated representatives.

Notified ***bodies shall*** participate in the work of that group, directly or by means of designated representatives. ***In the event that a notified body does not comply with this requirement, the notification shall be suspended or withdrawn.***

## Amendment 90

### Proposal for a regulation

#### Chapter V a (new)

*Text proposed by the Commission*

*Amendment*

**CHAPTER VA**

**UNION MARKET SURVEILLANCE,  
CONTROL OF PPE ENTERING THE  
UNION MARKET AND UNION  
SAFEGUARD PROCEDURE**

**Amendment 91**

**Proposal for a regulation  
Article 35 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 35a**

***Union market surveillance and control of  
PPE entering the Union market***

***Article 15(3) and Articles 16 to 29 of  
Regulation (EC) No 765/2008 shall apply  
to PPE covered by Article 2(1) of this  
Regulation.***

**Amendment 92**

**Proposal for a regulation  
Article 35 b (new)**

*Text proposed by the Commission*

*Amendment*

**Article 35b**

***Procedure for dealing with PPE  
presenting a risk at national level***

***1. Where the market surveillance  
authorities of one Member State have  
sufficient reason to believe that PPE  
covered by this Regulation presents a risk  
to the health or safety of users or, where  
applicable, of other persons, they shall  
carry out an evaluation in relation to the  
PPE concerned covering all relevant  
requirements laid down in this  
Regulation. The relevant economic  
operators shall cooperate as necessary***

*with the market surveillance authorities for that purpose.*

*Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the PPE does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the PPE into compliance with those requirements, to withdraw the PPE from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.*

*The market surveillance authorities shall inform the relevant notified body accordingly.*

*Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.*

*2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.*

*3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE concerned that it has made available on the market throughout the Union.*

*4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the PPE's being made available on their national market, to withdraw the PPE from that market or to recall it.*

*The market surveillance authorities shall*

*inform the Commission and the other Member States, without delay, of those measures.*

*5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, the origin of the PPE, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:*

*(a) failure of the PPE to meet requirements relating to the health or safety of persons; or*

*(b) shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.*

*6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned, and, in the event of disagreement with the adopted national measure, of their objections.*

*7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.*

*8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the PPE from the market, are taken in respect of the PPE concerned without delay.*

## **Amendment 93**

### **Proposal for a regulation Article 35 c (new)**

*Text proposed by the Commission*

*Amendment*

#### **Article 35c**

##### ***Union safeguard procedure***

***1. Where, on completion of the procedure set out in Article 35b(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.***

***The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.***

***2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant PPE is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.***

***3. Where the national measure is considered justified and the non-compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35b(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation***

**Amendment 94**

**Proposal for a regulation  
Article 35 d (new)**

*Text proposed by the Commission*

*Amendment*

**Article 35d**

***Compliant PPE which presents a risk***

- 1. Where, having carried out an evaluation under Article 35b(1), a Member State finds that although a PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to withdraw the PPE from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.***
- 2. The economic operator shall ensure that corrective action is taken in respect of all the PPE concerned that he has made available on the market throughout the Union.***
- 3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.***
- 4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national***

*measure is justified or not and, where necessary, propose appropriate measures.*

*The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 38(2a).*

*On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 38(2b).*

*5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.*

## **Amendment 95**

### **Proposal for a regulation Article 35 e (new)**

*Text proposed by the Commission*

*Amendment*

#### **Article 35e**

##### **Formal non-compliance**

*1. Without prejudice to Article 35b, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:*

*(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Regulation or has not been affixed;*

*(b) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 16 or has not been affixed;*

*(c) the EU declaration of conformity has not been drawn up or has not been drawn*

*up correctly;*

*(d) the technical documentation is either not available or not complete.*

*(e) the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;*

*(f) any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.*

*2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.*

## **Amendment 96**

### **Proposal for a regulation Article 36 – paragraph 1**

#### *Text proposed by the Commission*

The Commission shall be empowered to adopt delegated acts in accordance with Article 37 to amend Annex I *with respect to the category of a specific risk, in response to technical progress and knowledge or new scientific evidence and by taking into account the conformity assessment procedure that need to be followed for each category, in accordance with Article 18.*

#### *Amendment*

*In order to take into account technical progress and knowledge or new scientific evidence with respect to the category of a specific risk, the Commission shall be empowered to adopt delegated acts in accordance with Article 37 to amend Annex I by reclassifying the risk from one category to another.*

*A Member State which has concerns about the classification of a risk into a specific risk category referred to in Article 17 shall immediately inform the Commission of its concerns and provide reasons in support.*

*Prior to adopting a delegated act the Commission shall carry out a thorough assessment of the risks that require reclassification and of its impacts.*

## Amendment 97

### Proposal for a regulation

#### Article 38 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

**2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.**

## Amendment 98

### Proposal for a regulation

#### Article 38 – paragraph 2 b (new)

*Text proposed by the Commission*

*Amendment*

**2b. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.**

## Amendment 99

### Proposal for a regulation

#### Article 39 – paragraph 1

*Text proposed by the Commission*

*Amendment*

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are **implemented**. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Member States shall lay down the rules on penalties applicable to infringements **by economic operators** of the provisions of this Regulation and shall take all measures necessary to ensure that they are **enforced**. **Such rules may include criminal penalties for serious infringements.** The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them.

## Amendment 100

### Proposal for a regulation Article 42 – paragraph 3

#### *Text proposed by the Commission*

However, Articles 19 to 35 shall apply from [six months after entry into force].

#### *Amendment*

However, Articles 19 to 35 **and Articles 38 and 39** shall apply from [six months after entry into force].

## Amendment 101

### Proposal for a regulation Annex I – section 1 – paragraph 1 – point b

#### *Text proposed by the Commission*

(b) contact with water or cleaning materials of weak action;

#### *Amendment*

(b) contact with water or cleaning materials of weak action **or prolonged contact with water**;

## Amendment 102

### Proposal for a regulation Annex I – section 2 – paragraph 1 – point b

#### *Text proposed by the Commission*

**(b) made-to-measure PPE except where such PPE is intended to protect users against risks listed in Category I.**

#### *Amendment*

**deleted**

## Amendment 103

### Proposal for a regulation Annex I – section 3 – paragraph 1 – introductory part

#### *Text proposed by the Commission*

PPE intended to protect users against very serious risks. Category III includes exclusively PPE intended to protect users against the following risks:

#### *Amendment*

PPE intended to protect users against very serious risks, **such as death or irreversible damage to health**. Category III includes exclusively PPE intended to protect users

against the following risks:

#### **Amendment 104**

##### **Proposal for a regulation**

##### **Annex I – section 3 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) *inhalation of harmful* substances;

(a) substances *and mixtures which are hazardous to health*;

#### **Amendment 105**

##### **Proposal for a regulation**

##### **Annex I – section 3 – paragraph 1 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

(aa) *atmospheres with oxygen deficiency*;

#### **Amendment 106**

##### **Proposal for a regulation**

##### **Annex I – section 3 – paragraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

(b) *aggressive chemicals*;

(b) *harmful biological agents*;

#### **Amendment 107**

##### **Proposal for a regulation**

##### **Annex I – section 3 – paragraph 1 – point l a (new)**

*Text proposed by the Commission*

*Amendment*

(la) *occupational risk of severe impact to the head*.

#### **Amendment 108**

##### **Proposal for a regulation**

##### **Annex I – section 3 – paragraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

(c) ionising radiation;

(c) ionising radiation, ***laser radiation and radioactive contamination***;

**Amendment 109**

**Proposal for a regulation**

**Annex I – section 3 – paragraph 1 – point k**

*Text proposed by the Commission*

*Amendment*

(k) bullet wounds or knife stabs;

(k) bullet wounds, ***explosive fragments*** or knife stabs;

**Amendment 110**

**Proposal for a regulation**

**Annex II – part 1 – point 1.2 – point 1.2.1 – point 1.2.1.1 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users ***or result in the PPE no longer complying with the essential health and safety requirements laid down in this Regulation.***

**Amendment 111**

**Proposal for a regulation**

**Annex II – part 1 – point 1.3 – point 1.3.3 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

If the same manufacturer places on the market several models of PPE ***models*** of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

If the same manufacturer places on the market several models of PPE of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

## Amendment 112

### Proposal for a regulation

#### Annex II – part 1 – point 1.3 – point 1.3.3 a (new)

*Text proposed by the Commission*

*Amendment*

***1.3.3a. Protective clothing containing removable protectors***

***Protective clothing containing removable protectors constitute PPE and should be assessed as a combination during conformity assessment procedures.***

## Amendment 113

### Proposal for a regulation

#### Annex II – part 1 – point 1.4 – introductory part

*Text proposed by the Commission*

*Amendment*

1.4. Manufacturer's instructions

1.4. Manufacturer's instructions ***and information***

## Amendment 114

### Proposal for a regulation

#### Annex II – part 1 – point 1.4 – paragraph 1 – point b

*Text proposed by the Commission*

*Amendment*

***(b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE;***

***deleted***

*Justification*

*This information shall not necessarily be supplied in the instructions with each PPE. It shall be included in the technical documentation (see annex III), and shall be made available by the manufacturer in another way upon request (see amendment on article 8 paragraph 7a new)*

## Amendment 115

### Proposal for a regulation

#### Annex II – part 1 – point 1.4 – paragraph 1 – point c

*Text proposed by the Commission*

*Amendment*

(c) accessories that may be used with the PPE and the characteristics of appropriate spare parts;

(c) **where applicable**, accessories that may be used with the PPE and the characteristics of appropriate spare parts;

**Amendment 116**

**Proposal for a regulation**

**Annex II – part 1 – point 1.4 – paragraph 1 – point d**

*Text proposed by the Commission*

*Amendment*

(d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;

(d) **where applicable**, the classes of protection appropriate to different levels of risk and the corresponding limits of use;

**Amendment 117**

**Proposal for a regulation**

**Annex II – part 1 – point 1.4 – paragraph 1 – point e**

*Text proposed by the Commission*

*Amendment*

(e) the date or period of obsolescence of the PPE or of certain of its components;

(e) **where applicable**, the date or period of obsolescence of the PPE or of certain of its components;

**Amendment 118**

**Proposal for a regulation**

**Annex II – part 1 – point 1.4 – paragraph 1 – point f**

*Text proposed by the Commission*

*Amendment*

(f) the type of packaging suitable for transport;

(f) **where applicable**, the type of packaging suitable for transport;

**Amendment 119**

**Proposal for a regulation**

**Annex II – part 1 – point 1.4 – paragraph 1 – point h a (new)**

*Text proposed by the Commission*

*Amendment*

***(ha) risks against which the PPE is designed to protect;***

## **Amendment 120**

### **Proposal for a regulation**

#### **Annex II – part 1 – point 1.4 – paragraph 1 – point i a (new)**

*Text proposed by the Commission*

*Amendment*

***(ia) reference to the relevant harmonised standard(s) used, including the date of the standard(s) or references to the other technical specification used:***

## **Amendment 121**

### **Proposal for a regulation**

#### **Annex II – part 1 – point 1.4 – paragraph 1 – point i b (new)**

*Text proposed by the Commission*

*Amendment*

***(ib) the internet address where the EU declaration of conformity can be accessed.***

## **Amendment 122**

### **Proposal for a regulation**

#### **Annex II – part 1 – point 1.4 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

These instructions, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

These instructions, which must be precise and comprehensible ***and clearly legible***, must be provided at least in the official language(s) of the Member State of destination. ***The instructions shall be deemed to be clearly legible if they can be read easily from an appropriate distance and without artificial aids by a normal user with normal vision.***

## Amendment 123

### Proposal for a regulation

#### Annex II – part 1 – point 1.4 – paragraph 2

##### *Text proposed by the Commission*

These instructions, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

##### *Amendment*

These instructions, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination. ***Any additional relevant instructions for selection, use, care and maintenance of the PPE must be made available in a way that is easily accessible to any person concerned.***

## Amendment 124

### Proposal for a regulation

#### Annex II – part 2 – point 2.2 – paragraph 1

##### *Text proposed by the Commission*

As far as possible, PPE enclosing the parts of the body to be protected must be ***sufficiently ventilated*** to limit perspiration resulting from use; otherwise, ***it must be equipped with*** means of absorbing perspiration.

##### *Amendment*

As far as possible, PPE enclosing the parts of the body to be protected must be ***designed*** to limit perspiration resulting from use; otherwise, means of absorbing perspiration ***must be incorporated***.

## Amendment 125

### Proposal for a regulation

#### Annex II – part 2 – point 2.9 – paragraph 1

##### *Text proposed by the Commission*

Where PPE incorporates components which can be adjusted or removed by the user for replacement purposes, they must be designed and manufactured so that they can be easily attached and removed without tools.

##### *Amendment*

Where PPE incorporates components which can be adjusted or removed by the user for replacement purposes, they must be designed and manufactured so that they can be easily attached, ***adjusted*** and removed without tools.

## Amendment 126

### Proposal for a regulation

#### Annex II – part 2 – point 2.12 – paragraph 1

##### *Text proposed by the Commission*

The identification markings or indicators directly or indirectly relating to health and safety affixed to these types of PPE must, if possible, take the form of harmonized pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, these markings must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such markings include words or sentences, the latter must be written in ***the official*** language(s) ***of*** the Member State where the equipment is ***to be used***.

##### *Amendment*

The identification markings or indicators directly or indirectly relating to health and safety affixed to these types of PPE must, if possible, take the form of harmonized pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, these markings must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such markings include words or sentences, the latter must be written in ***a*** language ***easily understood by consumers and end-users, as determined by*** the Member State where the equipment is ***made available on the market***.

## Amendment 127

### Proposal for a regulation

#### Annex II – part 3 – point 3.4 – title

##### *Text proposed by the Commission*

3.4. Protection in ***the water***

##### *Amendment*

3.4. Protection in ***liquids***

## Amendment 128

### Proposal for a regulation

#### Annex II – part 3 – point 3.4 – point 3.4.2 – paragraph 1

##### *Text proposed by the Commission*

Clothing which will ensure an effective degree of buoyancy, depending on its foreseeable use, which is safe when worn and which affords positive support in ***water***. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable him, in particular, to swim or take action to escape

##### *Amendment*

Clothing which will ensure an effective degree of buoyancy, depending on its foreseeable use, which is safe when worn and which affords positive support in ***liquids***. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable him, in particular, to swim or take action to

from danger or to rescue other persons.

escape from danger or to rescue other persons.

## Amendment 129

### Proposal for a regulation

#### Annex II – part 3 – point 3.6 – point 3.6.1 – paragraph 3

##### *Text proposed by the Commission*

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material must also possess sufficient thermal capacity to ***retain most of the stored heat*** until after the user has left the danger area and removed his PPE.

##### *Amendment*

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material must also possess sufficient thermal capacity to ***protect from burns*** until after the user has left the danger area and removed his PPE.

## Amendment 130

### Proposal for a regulation

#### Annex II – part 3 – point 3.6 – point 3.6.1 – paragraph 5

##### *Text proposed by the Commission*

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of fire-fighting equipment must also possess a degree of non-flammability corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

##### *Amendment*

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of ***industrial or*** fire-fighting equipment must also possess a degree of non-flammability ***and thermal or arc heat protection*** corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

## Amendment 131

### Proposal for a regulation

#### Annex II – part 3 – point 3.6 – point 3.6.2 – paragraph 4

*Text proposed by the Commission*

The manufacturer's instructions accompanying PPE intended for ***brief*** use in high-temperature environments must in particular provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

*Amendment*

The manufacturer's instructions accompanying PPE intended for ***limited time*** use in high-temperature environments must in particular provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

**Amendment 132**

**Proposal for a regulation**

**Annex II – part 3 – point 3.9 – point 3.9.1 – paragraph 2**

*Text proposed by the Commission*

To this end, ***protective glasses*** must be so designed and manufactured as to possess, for each harmful wave length, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimized and, under no circumstances, exceeds the maximum permissible exposure value.

*Amendment*

To this end, ***eye protective equipment*** must be so designed and manufactured as to possess, for each harmful wave length, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimized and, under no circumstances, exceeds the maximum permissible exposure value. ***PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.***

*Justification*

*If adopted, this change of 'glasses' to 'eye protective equipment' will be made throughout the text.*

**Amendment 133**

**Proposal for a regulation**

**Annex II – part 3 – point 3.9 – point 3.9.1 – paragraph 5**

*Text proposed by the Commission*

The relevant protection factor number must be marked on all specimens of

*Amendment*

The relevant protection factor number must be marked on all specimens of filtering ***eye***

filtering *glasses* by the manufacturer.

*protective equipment* by the manufacturer.

## Amendment 134

### Proposal for a regulation

#### Annex II – part 3 – point 3.10 – introductory part

##### *Text proposed by the Commission*

3.10. Protection against *dangerous* substances and *infectious* agents

##### *Amendment*

3.10. Protection against substances and *mixtures which are hazardous to health and against biological* agents

## Amendment 135

### Proposal for a regulation

#### Annex II – part 3 – point 3.10 – point 3.10.2 – paragraph 1

##### *Text proposed by the Commission*

PPE intended to prevent the surface contact of all or part of the body with *dangerous* substances and *infective agents* must be capable of preventing the penetration or permeation of such substances and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

##### *Amendment*

PPE intended to prevent the surface contact of all or part of the body with substances and *mixtures which are hazardous to health or biological agents* must be capable of preventing the penetration or permeation of such substances *and mixtures* and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

## Amendment 136

### Proposal for a regulation

#### Annex II – part 3 – point 3.10 – point 3.10.2 – paragraph 3

##### *Text proposed by the Commission*

Where, by virtue of their nature and the foreseeable conditions of their use, certain *dangerous* substances *or infectious* agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of

##### *Amendment*

Where, by virtue of their nature and the foreseeable conditions of their use, certain *health hazardous* substances *and mixtures which are hazardous to health or biological* agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard

their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

## Amendment 137

### Proposal for a regulation Annex IV – section 1 – point 1

#### *Text proposed by the Commission*

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the PPE concerned satisfies the applicable ***essential health and safety*** requirements ***referred to in Article 5 and set out in Annex II***.

#### *Amendment*

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the PPE concerned satisfies the applicable requirements ***of this Regulation***.

#### *Justification*

*If adopted, this change should be made throughout the text.*

## Amendment 138

### Proposal for a regulation Annex IV – section 1 – point 2 – paragraph 1

#### *Text proposed by the Commission*

The manufacturer shall establish the technical documentation described in Annex III. ***The documentation shall make***

#### *Amendment*

The manufacturer shall establish the technical documentation described in

*it possible to assess the conformity of the PPE to the applicable requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the PPE.*

Annex III.

## Amendment 139

### Proposal for a regulation

#### Annex IV – section 1 – point 4 – point 4.1

*Text proposed by the Commission*

4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable *essential health and safety requirements*.

*Amendment*

4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable *requirements of this Regulation*.

## Amendment 140

### Proposal for a regulation

#### Annex V – section 1 – point 3 – paragraph 2 – point e

*Text proposed by the Commission*

(e) for *individually adapted* PPE, a description of the measures to be taken by the *manufacturer* during the *fitting and* production process to ensure that each item of PPE complies with the approved type and with the applicable *essential* health and safety requirements.

*Amendment*

(e) for *made-to-measure* PPE, a description of the *possible variations and the* measures to be taken by the *economic operator* during the production process to ensure that each item of PPE complies with the approved *PPE* type and with the applicable health and safety requirements *laid down in Annex II*.

## Amendment 141

### Proposal for a regulation

#### Annex V – section 1 – point 6 – point 6.1 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

*The period of validity of a newly issued certificate and, where appropriate, of a*

*renewed certificate shall be not more than five years.*

## Amendment 142

### Proposal for a regulation

#### Annex V – section 1 – point 6 – point 6.2 – point i

*Text proposed by the Commission*

*Amendment*

(i) the date of issue and, where appropriate, the date(s) of renewal;

(i) the date of issue, ***the date of expiry*** and, where appropriate, the date(s) of renewal;

## Amendment 143

### Proposal for a regulation

#### Annex V – section 1 – point 6 – point 6.2 – point j

*Text proposed by the Commission*

*Amendment*

***(j) the date of expiry (a maximum of five years after the date of issue or the date of the last renewal);***

***deleted***

## Amendment 144

### Proposal for a regulation

#### Annex V – section 1 – point 7.1

*Text proposed by the Commission*

*Amendment*

7.1 The notified body shall keep itself ***apprised*** of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

7.1 The notified body shall keep itself ***appraised*** of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and ***without prejudice to paragraph 1a of point 6.1 of Annex V*** shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

## Amendment 145

### Proposal for a regulation

#### Annex V – section 1 – point 7.5 a (new)

*Text proposed by the Commission*

*Amendment*

*7.5a At the earliest 12 months and at the latest 6 months prior to the expiry date, the manufacturer may inform the notified body that a simplified procedure shall apply for the review, as no modification to the PPE referred to in point 7.2 has occurred. The manufacturer shall supply the notified body with the following information:*

*(a) confirmation of the current company name and address;*

*(b) confirmation that there has been no modification to the product, including materials, sub-components or sub-assemblies, nor to the solutions applied in the relevant harmonised standards or in other technical specifications;*

*(c) where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer; and*

*(d) for category III products, information on the status of the product verification or quality assurance of the production process.*

*When the notified body has confirmed that no change in the state of the art referred to in point 7.3 has occurred, the EU type-examination laid down in point 4 of Annex V shall not be carried out and the notified body shall renew the EU-type examination certificate. The notified body shall ensure that the simplified procedure for renewal is finalised before the expiry date of the EU type-examination certificate. The reference of the certificate will remain unchanged.*

*The costs associated with that renewal shall be proportionate to the administrative burden of the simplified*

*procedure.*

*If any of the information is missing or if a change in the state of the art referred to in point 7.3 has occurred, the procedure in point 7.5 shall apply.*

## **Amendment 146**

### **Proposal for a regulation**

#### **Annex VI – section 1 – point 2 – paragraph 2**

##### *Text proposed by the Commission*

For made-to-measure PPE the manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured made-to-measure PPE with the basic model described in the EU type-examination certificate and with the applicable *essential health and safety requirements*.

##### *Amendment*

For made-to-measure PPE the manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured made-to-measure PPE with the basic model described in the EU type-examination certificate and with the applicable *requirements of this Regulation*.

## **Amendment 147**

### **Proposal for a regulation**

#### **Annex VII – section 1 – point 1**

##### *Text proposed by the Commission*

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 5.2 and 6, and ensures and declares on his sole responsibility that the PPE, which has been subject to the provisions of point 4, is in conformity with the type described in the EU type-examination certificate and satisfies the applicable *essential health and safety requirements referred to in Article 5 and set out in Annex II*.

##### *Amendment*

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 5.2 and 6, and ensures and declares on his sole responsibility that the PPE, which has been subject to the provisions of point 4, is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements *of this Regulation*.

## Amendment 148

### Proposal for a regulation

#### Annex VII – section 1 – point 4 – point 4.4 a (new)

*Text proposed by the Commission*

*Amendment*

***4.4a. The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.***

## Amendment 149

### Proposal for a regulation

#### Annex VII – section 1 – point 5 – point 5.1

*Text proposed by the Commission*

*Amendment*

5.1. The notified body shall provide the manufacturer with a test report, ***and shall authorise the manufacturer to affix the notified body's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements.***

5.1. The notified body shall provide the manufacturer with a test report.

## Amendment 150

### Proposal for a regulation

#### Annex VII – section 1 – point 5 – point 5.2 a (new)

*Text proposed by the Commission*

*Amendment*

***5.2a. The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.***

## Amendment 151

### Proposal for a regulation Annex VIII – section 1 – point 8

*Text proposed by the Commission*

*Amendment*

**8. If the notified body referred to in point 3.1 agrees, the manufacturer may affix the notified body's identification number to the PPE during the manufacturing process.**

**deleted**

## Amendment 152

### Proposal for a regulation Annex IX – heading 1

*Text proposed by the Commission*

*Amendment*

EU declaration of conformity

EU declaration of conformity

***The EU declaration of conformity shall contain the following elements:***

## Amendment 153

### Proposal for a regulation Annex IX – point 1

*Text proposed by the Commission*

*Amendment*

1. PPE (product, batch, type or serial number):

**1. *Identification of the* PPE (product, batch, type or serial number), *including, where useful for the identification of the PPE, an image of sufficient clarity:***

## Amendment 154

### Proposal for a regulation Annex IX – point 2

*Text proposed by the Commission*

*Amendment*

2. Name and address of the manufacturer or ***his authorised representative*** [***The authorised representative must also give***

2. Name and address of the manufacturer or, ***where applicable, his*** authorised representative.

*the business name and address of the manufacturer]:*

#### **Amendment 155**

##### **Proposal for a regulation Annex IX – point 4**

*Text proposed by the Commission*

*Amendment*

**4. Object of the declaration (identification of PPE allowing traceability; it may, where necessary for the identification of the PPE, include a colour image of sufficient clarity):**

***deleted***

#### **Amendment 156**

##### **Proposal for a regulation Annex IX – point 6**

*Text proposed by the Commission*

*Amendment*

**6. References to the *relevant* harmonised standards, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:**

**6. References to the *applied* harmonised standards, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:**

#### **Amendment 157**

##### **Proposal for a regulation Annex X – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***The full text of the EU declaration of conformity is available at the following internet address:***