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Plenary sitting

A8-0148/2015

30.4.2015

***I
REPORT

on the proposal for a regulation of the European Parliament and of the Council on personal protective equipment
(COM(2014)0186 – C7-0110/2014 – 2014/0108(COD))

Committee on the Internal Market and Consumer Protection

Rapporteur: Vicky Ford

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on personal protective equipment
(COM(2014)0186 – C7-0110/2014 – 2014/0108(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2014)0186),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0110/2014),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinion of the Committee on Employment and Social Affairs (A8-0148/2015),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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

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	*Amendment*
(6) Decision No 768/2008/EC of the European Parliament and of the Council[17] ***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 concerning procedures to deal with products presenting a risk should be aligned to that Decision.	(6) Decision No 768/2008/EC of the European Parliament and of the Council[1] ***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 procedures to deal with products presenting a risk should be aligned to that Decision.
[17] 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).	[17] 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[18] 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***
[18] [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	*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. In order to ensure ***as*** high level of protection ***for the user of those***	(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***

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.	***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	*Amendment*
(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.	(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	*Amendment*
(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.	(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	*Amendment*
(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	(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

the importer would have to open the packaging to put his name and address on the ***product***.	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[19] , 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[19], 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.***

[19] 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).

[19] 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	*Amendment*
(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***.	(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	*Amendment*
(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.	(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	(28) In order to ensure compliance with the essential ***health and*** safety requirements

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 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.

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 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	*Amendment*
(a) specifically designed for use by the armed forces or ***for*** the maintenance of law and order;	(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	*Amendment*
(b) ***intended*** to be used for self-defence;	(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	*Amendment*
(c) intended for private use to protect against atmospheric conditions that are not of an extreme nature;	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	*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.***	(e) for head, face or eye protection of 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	*Amendment*
(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***;	(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	*Amendment*
2. ***'individually adapted PPE' means PPE produced in series where each item is manufactured to fit an individual user***;	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	*Amendment*
5. 'placing on the market' means the first making available of ***PPE*** on the Union market;	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	*Amendment*
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.	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	*Amendment*
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***.	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	*Amendment*
5. Manufacturers shall ensure that the PPE which they place on the market bears 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.	5. Manufacturers shall ensure that the PPE which they place on the market bears ***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	*Amendment*
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***.	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	*Amendment*
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.	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, 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.	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 ***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	*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 ***placed*** on the market;	(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	*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***, 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***.	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	*Amendment*
4. Importers shall ensure that ***the*** PPE is	4. Importers shall ensure that 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.	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 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	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 ***manufacturer and the competent national*** authorities of the Member States

available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.	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	*Amendment*
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.	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 68

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

Text proposed by the Commission	*Amendment*
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).	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	*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 ***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.	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	*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 ***the conformity with the applicable essential health and safety requirements set out in Annex II*** may be affected.	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	*Amendment*
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.	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	*Amendment*
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.	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	*Amendment*
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***	3. The CE marking shall be affixed before the PPE is placed on the market.

is intended to protect.

Amendment 76

Proposal for a regulation
Article 16 – paragraph 4

Text proposed by the Commission	*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.	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	*Amendment*
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.	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	*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 this Regulation and shall apply ***as general guidance the administrative*** decisions and documents produced as a result of the work of that group.	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	*Amendment*
2. The application for notification shall be accompanied by a description of the conformity assessment activities, the	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.	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	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.	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 (EU) No 1025/2012.

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	*Amendment*
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***.	***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	*Amendment*
However, Articles 19 to 35 shall apply from [six months after entry into force].	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	*Amendment*
(b) contact with water or cleaning materials of weak action;	(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	*Amendment*
(b) made-to-measure PPE except where such PPE is intended to protect users against risks listed in Category I.	***deleted***

Amendment 103

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

Text proposed by the Commission	*Amendment*
PPE intended to protect users against very serious risks. Category III includes exclusively PPE intended to protect users against the following risks:	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 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*
	(ia) 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	*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, 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	*Amendment*
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.	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	*Amendment*
Where PPE incorporates components which can be adjusted or removed by the	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.	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	*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 ***the official*** language***(s) of*** the Member State where the equipment is ***to be used***.	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	*Amendment*
3.4. Protection in ***the water***	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	*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 ***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 from danger or to rescue other persons.	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 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	*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 ***retain most of the stored heat*** until after the user has left the danger area and removed his PPE.	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	*Amendment*
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	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

when exposed to flames nor contribute to flame propagation.	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	*Amendment*
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.	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	*Amendment*
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.	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	*Amendment*
The relevant protection factor number must be marked on all specimens of filtering ***glasses*** by the manufacturer.	The relevant protection factor number must be marked on all specimens of filtering ***eye 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	*Amendment*
3.10. Protection against ***dangerous*** substances and ***infectious*** agents	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	*Amendment*
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.	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	*Amendment*
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 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.	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 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	*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 ***essential health and safety*** requirements ***referred to in Article 5 and set out in Annex II***.	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	*Amendment*
The manufacturer shall establish the technical documentation described in Annex III. ***The documentation shall make 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.***	The manufacturer shall establish the technical documentation described in Annex III.

Amendment 139

Proposal for a regulation
Annex IV – section 1 – point 4 – point 4.1

Text proposed by the Commission	*Amendment*
4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable ***essential health and safety requirements***.	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	*Amendment*
(e) for ***individually adapted*** PPE, a description of the measures to be taken by the ***manufacturer*** during the ***fitting and***	(e) for ***made-to-measure*** PPE, a description of the ***possible variations and the*** measures to be taken by the ***economic***

production process to ensure that each item of PPE complies with the approved type and with the applicable ***essential*** health and safety requirements.	***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	***deleted***

the last renewal);

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	*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	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***.	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	*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 ***essential health and safety*** requirements ***referred to in Article 5 and set out in Annex II***.	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 the business name and address of the manufacturer]:***	2. Name and address of the manufacturer or***, where applicable, his*** authorised representative**.**

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:

EXPLANATORY STATEMENT

Background

Since 1989, the placing of personal protective equipment (PPE) on the EU market has been fully harmonised through Council Directive 89/686/EEC). In the intervening 25 years, this directive has enabled a functioning single market. Despite this, the existing PPE legislation is in need of updating in line with the New Legislative Framework (NLF) which is a package of measures designed to streamline and simplify regulations of goods across the Single Market.

In particular, in response to concerns that current regulatory requirements are confusing and duplicative, the Regulation clarifies the role of economic operators, reinforces cooperation between actors and introduces common definitions. The common approach under the NLF also clarifies the powers of market surveillance authorities enabling the tracking and returning of unsafe goods placed on the single market.

The existing PPE Directive provides in Articles 2 and 4 that Member States must allow the marketing of all products compliant with the Directive and must not allow the marketing of non-compliant products. Given that neither lower nor higher standards are allowed by the existing Directive, it is unlikely that there will be significant practical operational implications by replacing it with a Regulation.

Key Amendments of the Rapporteur

The Rapporteur supports strong requirements regarding personal protective equipment. Given that this proposal deals primarily with the modernisation and simplification of an already well-functioning system, the Rapporteur believes that significant amendments to its objectives are unnecessary. Instead, building on concerns expressed by member states and safety industry federations, amendments have focused on ensuring clarity in a number of areas.

These technical clarifications cover:

- Connexion systems (Art3.1.c) as items essential to the PPE's function;
- Adding a definition of 'demonstration' (Art3.21) and 'field test' (Art3.22) and permitting field testing to take place (Art. 7.2-3);
- Requiring importers and distributors to inform the manufacturer, as well as Market Surveillance Authorities, where they believe there is a risk of non-conforming PPE;
- Requiring Member States to notify manufacturers if a notified body has ceased activity (Art.29.2);
- Requiring any appeal procedure to be transparent and accessible (Art.32)

The Rapporteur proposes deleting the five years maximum validity of the EU type-examination certificate, due to concerns expressed by economic operators that such a period is too short given the usual product life of PPE.

An area of concern is the Commission's decision to adjust the scope of the original Directive, an issue noted by Parliament's Ex-Ante Impact Assessment of this proposal. The Rapporteur does not believe significant adjustments to scope are necessary since this draft proposal is primarily about ensuring the proper functioning and implementation of the regulatory framework, not about its objectives. Therefore to ensure there is legal clarity for operators in this sector, the Rapporteur has sought to keep the scope close to that of the original Directive

The Rapporteur has therefore made amendments, in particular:

- Amendments to include equipment to protect against oxygen deficiency (e.g. diving equipment), chemicals, biological agents and radiation/radioactive contamination are now included in category III.

- Amendments regarding PPE for private use. Administrative burdens should be proportionate to the safety risk. Therefore the Rapporteur has maintained the exclusion from the scope for PPE for private use which protects against atmosphere conditions that are not of an extreme nature, against damp or water. PPE for private use against heat, such as oven gloves, will continue to be excluded unless the economic operator explicitly claims a protective function. The Rapporteur also believes a clear exclusion from the scope of this regulation is required for artisanal products.

In order to ensure a speedy resolution of negotiations on this file, the Rapporteur believes that many of the Council's suggestions on aligning the proposal with the NLF are to be welcomed. These amendments concern:

- The Declaration of Conformity, which gives economic operators a choice of providing a paper copy or a link to a website providing the relevant information, taking into account technological developments since the directive's introduction in 1989.

- A new chapter that will take into account the requirements of the market surveillance regulation when it has been finalised.

- Clarifying the requirements upon employers who provide PPE to their employees (Recital 21)

- Including sporting equipment as PPE (Art.2.2b)

- Linguistic changes to provide clarity throughout the text (Recitals 11 and 12)

7.4.2015

OPINION OF THE COMMITTEE ON EMPLOYMENT AND SOCIAL AFFAIRS

for the Committee on the Internal Market and Consumer Protection

on the proposal for a regulation of the European Parliament and of the Council on personal protective equipment
(COM(2014)0186 – C7-0110/2014 – 2014/0108(COD))

Rapporteur: Laura Agea

SHORT JUSTIFICATION

In our work on the proposal for a regulation on PPE, our primary objective was to table amendments that will ensure that the existing directive cannot give rise to interpretations which may undermine its effectiveness and legal certainty. The key assumption is that genuinely effective instruments are the only way of guaranteeing workers' safety, given that accidents in the workplace are often caused by a failure not only to use appropriate protective equipment but also to use it correctly.

We also noted that the way of ensuring that protective equipment is genuinely effective is to develop and introduce products that are geared to the needs of their end-users. This is why we have stipulated that the person who wears or uses the equipment must be taken into account, distinguishing between the following categories of user: men, women, young workers and people with disabilities. When establishing the 'young workers' category we had to be mindful of the fact that young people's working conditions and developments in their working environment, mostly related to the economic crisis, have caused the number of young people leaving school early to increase exponentially and have resulted in an ever-growing population of young workers whose physical characteristics must be taken into consideration.

We also considered it appropriate to review certain aspects of the regulation's technical provisions, so that they cover all risk categories and all eventualities, with a view to reducing as far as possible the potential for ambiguity and misinterpretation.

Our analysis of the regulation was fuelled by the belief that uncertainty leads to the misinterpretation, and, as a result, misapplication of regulations.

Moreover, in view of recent developments in the communications sphere and the need to tailor PPE to the end-user, we have provided for the possibility of establishing specific instruments which enable end-users to understand how to use PPE products correctly and outline their vital importance for the end-user's protection against workplace risks.

Awareness-raising and the provision of accurate and relevant information help to protect workers and encourage them to engage and become involved in issues that concern them directly.

We have also stressed that any risks or doubts about product compliance that arise should be reported and the products concerned should be taken off the market in order to minimise the risks associated with their use.

We also deemed it necessary to stress the need for transparent, ongoing monitoring of implementation of the regulation, with penalties for anyone who contravenes it.

We believe that investment policies alone are not enough to enhance the work environment; watertight protective measures are also needed, from minimum safety requirements for workers to measures designed to protect workers and bring the quality of the working environment up to an appropriate level.

AMENDMENTS

The Committee on Employment and Social Affairs calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital -1 (new)

Text proposed by the Commission	*Amendment*
	(-1) The right to health and safety is a fundamental right and all workers enjoy a legal guarantee of working conditions which respect their health, safety and dignity. Considering that the cost to enterprises and social security systems of occupational accidents and diseases is estimated at 5,9 % of gross domestic product and that adequate worker prevention promotes wellbeing, quality of work and productivity, risk prevention, in particular through the use of quality personal protective equipment, is essential to reducing the rate of work-related accidents and sickness.

Amendment 2

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) Attention should be paid to the correlation between this Regulation and Directive 89/391/EEC and Directive 89/656/EEC, especially with regard to the provisions relating to assessment of PPE, to information and consultation of workers and to workers' participation.

Amendment 3

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) However, experience with its application has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. In order to take account of this experience and to provide clarification in relation to the framework within which products covered by this Regulation may be marketed, certain aspects of Directive 89/686/EEC should be revised and enhanced.	(3) However, experience with its application has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. In order to take account of this experience and to provide clarification in relation to the framework within which products covered by this Regulation may be marketed, certain aspects of Directive 89/686/EEC should be revised and enhanced ***while maintaining the overarching principle of health and safety protection***.

Amendment 4

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) This Regulation should apply to all forms of supply, including distance selling.

Amendment 5

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) Since the scope, the essential health and safety requirements and conformity assessment procedures are to be identical	(4) Since the scope, the essential health and safety requirements and conformity assessment procedures are to be identical

in all the Member States there is almost no flexibility in transposing Directives based on the New Approach principles into national law. Directive 89/686/EEC should therefore be replaced by a Regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States.	in all the Member States there is almost no flexibility in transposing Directives based on the New Approach principles into national law. Directive 89/686/EEC should therefore be replaced by a Regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States***; this should be done through a clear and target-based approach with the aim, in particular, of safeguarding public health, improving safety at work and ensuring user protection***.

Amendment 6

Proposal for a regulation
Recital 9

Text proposed by the Commission	*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***. 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***.	(9) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC ***where they are only intended for private use. In order to provide a high level of protection, items for protecting the hands*** against ***extreme heat in a domestic environment should be included within the scope of this Regulation if they specifically make a protective claim***. Artisanal products, such as handmade gloves ***and oven gloves***, for which the manufacturer does not explicitly claim a protective function are not personal protective equipment; they ***should*** therefore not ***be included within the scope of this Regulation. Instead, self-certification should be encouraged for those*** products***. Many manufacturers are already doing this today***.

Amendment 7

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) On 6 June 2014 the Commission adopted its communication on an EU Strategic Framework on Health and Safety at work 2014-2020 in order to better protect Union workers from work-related accidents and diseases.

Amendment 8

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) In order to facilitate the understanding and uniform application of this Regulation, new definitions for 'individually adapted PPE' and 'made-to-measure PPE' should be introduced and the conformity assessment procedures for these kinds of PPE should be adapted to the specific conditions of their manufacture.	(10) In order to facilitate the understanding and uniform application of this Regulation, new definitions for 'individually adapted PPE' and 'made-to-measure PPE' should be introduced ***including clear definitions of the end-user of PPE*** and the conformity assessment procedures for these kinds of PPE should be adapted to the specific conditions of their manufacture. ***In the definition of "individually adapted PPE" and "made-to-measure PPE" it should be clearly stated that the individualisation of PPE must have a material impact on the working environment and safety at work.***

Amendment 9

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 10

Proposal for a regulation
Recital 11

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

Amendment 11

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure ***that***	(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure they

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.

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 12

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12 a) In order to facilitate implementation and raise awareness of the requirements laid down in this Regulation, Member States should be encouraged to create a website and/or a smartphone application to include all the relevant information concerning this Regulation, including data on the notifying authorities and conformity assessment bodies authorised to carry out tasks under this Regulation; in order to enable communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to provide a website address in addition to the postal address.

Amendment 13

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	(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.

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 ***competent*** surveillance authorities.

Amendment 14

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(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.	(16) When placing PPE on the market, importers should indicate on the product their name and the address at which they can be contacted ***as well as indications of webpages on which the end-user of the PPE can access additional information on how to correctly use the PPE***. 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 15

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Any economic operator that either places PPE on the market under its own name or trademark or modifies ***a product*** in such a way that compliance with the requirements of this Regulation may be affected ***should be*** considered to be the manufacturer and should assume the obligations of the manufacturer.	(17) Any economic operator that either places PPE on the market under its own name or trademark or modifies ***PPE*** in such a way that compliance with the requirements of this Regulation may be affected ***is*** considered to be the manufacturer and should assume the obligations of the manufacturer.

Amendment 16

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.	(18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, ***only if it is ensured that any conflict of interests are avoided***, and ***must*** be prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.

Amendment 17

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	(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 ***PPE***

product available on the market.	available on the market ***and to determine precisely, clearly and transparently the share of responsibility borne by each operator***.

Amendment 18

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[19] , 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[19], 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.***
[19] 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).	[19] 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 19

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(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.	(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. ***Such review should consist of a simple and expedient procedure.*** 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 27

Text proposed by the Commission	*Amendment*
(27) The CE marking should be the only marking indicating that PPE is in conformity with Union harmonisation legislation. However, other markings should be allowed as long as they contribute to the improvement of consumer protection and are not covered by Union harmonisation legislation.	(27) The CE marking should be the only marking indicating that PPE is in conformity with Union harmonisation legislation. However, other markings should be allowed as long as they contribute to the improvement of consumer ***health and safety*** protection and are not covered by Union harmonisation legislation.

Amendment 21

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	(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

89/686/EEC classifies PPE into three 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.

followed by the manufacturer. Directive 89/686/EEC classifies PPE into three 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 22

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) In order to take into account the progress of technical knowledge and new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to amend the list of PPE included in each category. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.	(31) In order to take into account the progress of technical knowledge and new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to amend the list of PPE included in each category. It is of particular importance that the Commission carries out appropriate consultations ***and assesses the impact of its proposals*** during its preparatory work, including at expert level ***and consult representatives of employee and employer's organisations from sectors that habitually make use of PPE in their operations***. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Amendment 23

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.	(33) Member States should lay down rules on ***guidance, surveillance, control, with a view to preventing infringements, and*** penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented ***bearing in mind that guidance is the best tool to avoid unintended mistakes by employers, manufacturers of PPE and end-users***. Those penalties ***and sanctions*** should be ***imposed expediently and should be*** effective, proportionate and dissuasive.

Amendment 24

Proposal for a regulation
Recital 33 a (new)

Text proposed by the Commission	*Amendment*
	(33a) Whereas Directive 89/656/EEC lays down minimum requirements for personal protective equipment used by workers at work and whereas national provisions relating to safety at work make the use of PPE compulsory, each Member State should take appropriate measures to encourage employers and employees to make use of appropriate PPE including by providing clear information on their compulsory use to employers, employees and employees' associations and through promoting, as examples of best practice, employers who apply these rules and observe general prevention principles as set out in Article 6(2) of Directive 89/391/EEC on the introduction of measures to encourage improvements in

the safety and health of workers at work.

Amendment 25

Proposal for a regulation
Recital 33 b (new)

Text proposed by the Commission	*Amendment*
	(33b) Member States should establish, preferably through cooperation between the surveillance authorities and the social partners, a single point of contact in which the end-users of the PPE can report flaws and errors concerning the PPE. The surveillance authorities are obliged to react to the report from the end-users in a fast and efficient manner.

Amendment 26

Proposal for a regulation
Recital 34 a (new)

Text proposed by the Commission	*Amendment*
	(34a) It is of the utmost importance to fully correlate the different aspects linked with PPE, in particular their production and use, with the wider Union action on occupational safety and health (OSH) which is crucial to ensuring a high level of protection for workers and to creating a framework for action for all companies regardless of their size, location or sector of activity.

Amendment 27

Proposal for a regulation
Recital 34 b (new)

Text proposed by the Commission	*Amendment*
	(34b) Special attention should be drawn to the field of undeclared work as, due to the impossibility of checking compliance with health and safety at work provisions, the conditions in that field make workers more exposed to high health risks and accidents at work and enable employers to escape liability. Domestic work, mainly performed by women, poses a particular challenge, as the work is in the informal sector, singularised and is, by its nature, invisible.

Amendment 28

Proposal for a regulation
Recital 35 a (new)

Text proposed by the Commission	*Amendment*
	(35a) It is of the highest importance to include the promotion of PPE use in the awareness-raising initiatives carried out at Union and national levels, as part of strengthening a culture of risk prevention. Improving working conditions has a positive impact on productivity and competitiveness, as emphasised by the Employment Package.

Amendment 29

Proposal for a regulation
Recital 35 b (new)

Text proposed by the Commission	*Amendment*
	(35b) Given the variety of situations on the ground, as regards company size and diversity of the workforce, non-legislative tools, such as benchmarking, identifying and exchanging good practices, awareness-raising and user-friendly IT

tools should be used to contribute to a high level protection of workers.

Amendment 30

Proposal for a regulation
Recital 35 c (new)

Text proposed by the Commission	*Amendment*
	(35c) Raising awareness about health and safety, including PPE, should be included in education curricula from an early age so as to bring down accident rates and increase health and safety; training on health and safety and PPE should be integrated especially into vocational training, fully recognised and attested by a diploma. Efforts should be made also to substantially improve information and training for entrepreneurs. The results of research for new PPE, as the consequence of technology advances and new challenges, should be better disseminated.

Amendment 31

Proposal for a regulation
Recital 35 d (new)

Text proposed by the Commission	*Amendment*
	(35d) The Union's working population is ageing, according to Eurostat population projections (Europop, 2010), which will require appropriate working conditions including workplace accessibility and workplace interventions targeted at older workers. This requires the creation of a safe and healthy environment, throughout the working life of an increasingly diversified workforce, for which the promotion of a culture of prevention is

essential.

Amendment 32

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) ***intended to be placed on the market*** in order to ensure the health and safety protection of users and rules on its free movement in the Union.

Amendment 33

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

Text proposed by the Commission	*Amendment*
(c) intended for private use to protect against ***atmospheric conditions that are not of an extreme nature;***	(c) intended for private use to protect against***:***

Amendment 34

Proposal for a regulation
Article 2 – paragraph 2 – point c – point i (new)

Text proposed by the Commission	*Amendment*
	(i) atmospheric conditions that are not of an extreme nature (seasonal clothing, umbrellas etc.);

Amendment 35

Proposal for a regulation
Article 2 – paragraph 2 – point c – point ii (new)

Text proposed by the Commission	*Amendment*
	(ii) damp and water (dish-washing gloves etc.);

Amendment 36

Proposal for a regulation
Article 2 – paragraph 2 – point c – point iii (new)

Text proposed by the Commission	*Amendment*
	(iii) heat (gloves etc.) for which the economic operator does not explicitly claim a protective function against extreme heat;

Amendment 37

Proposal for a regulation
Article 2 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) intended for use in situations where the elements with potential protective characteristics are only incorporated for design reasons;

Amendment 38

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

Text proposed by the Commission	*Amendment*
d) for use on seagoing vessels or aircraft that are subject to the relevant international	d) for use ***solely*** on seagoing vessels or aircraft that are subject to the relevant

treaties applicable in Member States;	international treaties applicable in Member States;

Amendment 39

Proposal for a regulation
Article 2 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In those cases, the health and safety of users shall be ensured as far as possible in the light of the objectives of this Regulation and in accordance with Council Directive 89/391/EEC[1a].
	[1a] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p.1).

Justification

Exemptions must be reduced to the absolute necessary, we therefore introduce a parallel provision to Directive 89/391/EC Art. 2.2

Amendment 40

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 41

Proposal for a regulation
Article 3 – paragraph 1 – point 1 – point c

Text proposed by the Commission	*Amendment*
(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;	(c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, ***which are essential to the equipment's function,*** 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 42

Proposal for a regulation
Article 3 – paragraph 1 – point 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. 'PPE type' means the series of PPE that are 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 43

Proposal for a regulation
Article 3 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
2. 'individually adapted PPE' means PPE produced in series where each item is manufactured to fit ***an individual user***;	2. 'individually adapted PPE' means PPE produced in series where each item is manufactured to fit ***a specific*** individual user ***in accordance with his or her specific needs, for example man, woman and young worker, as well as person with disabilities, with a proven added value for health and safety at work;***

Amendment 44

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3. 'made-to-measure PPE' means PPE produced ***as a single unit*** to accommodate the special needs of ***an*** individual ***user*** according to a basic model, following the instructions of the designer of that basic model and respecting the range of permissible variations;	3. 'made-to-measure PPE' means PPE produced to accommodate the special needs of ***a specific i***ndividual ***person*** according to a basic model, following the instructions of the designer of that basic model and respecting the range of variations;

Amendment 45

Proposal for a regulation
Article 3 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
5. 'placing on the market' means the first making available ***of PPE*** on the Union market;	5. 'placing on the market' means the first making available ***of the PPE type*** on the Union market;

Amendment 46

Proposal for a regulation
Article 3 – paragraph 1 – point 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. 'end user' means the person who wears or uses the PPE;

Amendment 47

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 48

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 is used in a very limited number and for a very limited period of time for a (final) evaluation. Prior to the start of the test, the manufacturer shall lay down the duration and purpose of the testing, and state the reasons why testing is required, and shall have those details confirmed by the parties concerned. The test is made in non-dangerous situations exclusively and is performed to evaluate inter alia comfort, ergonomics or design. The parties concerned shall have access to the requisite test documents drawn up by accredited or authorised laboratories, which shall be attached to the technical documentation, with a view to ensuring that wearers are protected;

Amendment 49

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall take all appropriate measures to ensure that PPE is made available on the market only if, where properly maintained and used for its intended purpose, it complies with this Regulation**.**	Member States shall take all appropriate ***and necessary*** measures to ensure that PPE is made available on the market only if, where properly maintained***, where its functioning is clearly explained*** and ***where it is*** used for its intended purpose, it complies with this Regulation.

Amendment 50

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
PPE shall fulfil the applicable essential health and safety requirements set out in Annex II.	PPE shall fulfil the applicable essential health and safety requirements set out in Annex II ***and shall be in full compliance with Directive 89/391/EEC***.

Justification

It is of utter importance that protective equipment is fully compliant with the framework Health and Safety Directive.

Amendment 51

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation shall not affect Member States' entitlement, in particular when implementing Directive 89/656/EEC, to lay down requirements concerning the use of PPE ***provided that these requirements*** do not affect the design of PPE which is placed on the market in accordance with this Regulation.	This Regulation shall not affect Member States' entitlement, in particular when implementing Directive 89/656/EEC, to lay down requirements concerning the use of PPE ***which they consider necessary to ensure the protection of end-users and third parties or which are justified by an added value in terms of health and safety***

	of the user and do not affect the design of PPE which is placed on the market in accordance with this Regulation.

Amendment 52

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***, similar events and field tests***, Member States shall not prevent the showing of PPE which does not comply with this Regulation provided that visible ***signs can be found within the area assigned to the exhibiting party that clearly indicate*** that the PPE does not comply with this Regulation and is not available on the market until it has been brought into conformity.

Amendment 53

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 ***and to raise their awareness. Field tests shall not be designed to test the protection performance of the PPE, but to evaluate for instance comfort, ergonomics and design. All concerned parties (e.g. the employer as well as the wearer or end-user) shall be formally informed in advance concerning the scope and the purpose of this test. A 'for field test only' marking shall be clearly and indelibly***

	affixed to the PPE. Once the testing period is over, the PPE used shall be returned to the manufacturers.

Amendment 54

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.	1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential ***and necessary*** health and safety requirements set out in Annex II.

Amendment 55

Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least 10 years after the PPE has been ***made available*** on the market.

Amendment 56

Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Manufacturers shall ensure that ***the*** PPE which they place on the market bears 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	5. Manufacturers shall ensure that ***every single*** PPE which they place on the market bears 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.	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	*Amendment*
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***.	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 ***the official language of the*** end-users ***in the Member State in which PPE is to be made available on the market***.

Amendment 58

Proposal for a regulation
Article 8 – paragraph 7

Text proposed by the Commission	*Amendment*
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.	7. Manufacturers shall ensure that ***every PPE, included its smallest unit,*** is accompanied by the instructions ***and other information*** set out in point 1.4 of Annex II in ***the official*** language ***of the*** end-users, ***in*** the Member State ***in which the PPE is made available on the market, as well as, where possible, by pictograms.***

Amendment 59

Proposal for a regulation
Article 8 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Manufacturers 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 necessary corrective measures to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers 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.	9. Manufacturers 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 necessary corrective measures to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers 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. ***The market surveillance authorities then have the obligation to inform the public of the risk as long as the corrective measure is not in place. During the setting in conformity period, manufacturers shall recall the PPE in order to ensure a high level protection of end-users.***

Amendment 60

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***,*** 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	10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary***, in paper or preferably electronic form,*** to demonstrate the conformity of the PPE, in ***the official language of that*** authority. They shall cooperate with that authority, at its request, on any action taken to eliminate

posed by PPE which they have placed on the market.	the risks posed by PPE which they have placed on the market.

Amendment 61

Proposal for a regulation
Article 9 – paragraph 2 – point a

Text proposed by the Commission	*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 ***placed*** on the market;	(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;

Amendment 62

Proposal for a regulation
Article 9 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) further to a reasoned request from a national ***market surveillance*** authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;	(b). further to a request from a ***competent*** national authority, provide that authority with all the information and documentation necessary***, in paper or preferably electronic form,*** to demonstrate the conformity of the PPE;

Amendment 63

Proposal for a regulation
Article 9 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) cooperate with the national ***market surveillance*** authorities, at their request, on any action taken to eliminate the risks	(c) cooperate with the ***competent*** national authorities, at their request, on any action taken to eliminate the risks posed by PPE

posed by PPE covered by the authorised representative's mandate.	covered by the authorised representative's mandate.

Amendment 64

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Importers shall place ***only compliant PPE on the market***.	1. Importers shall place ***on the market only PPE that fulfils the requirements of this Regulation and complies with the relevant Union provisions with respect to health and safety requirements***.

Amendment 65

Proposal for a regulation
Article 10 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Before placing PPE on the market, importers shall ensure that the ***appropriate*** conformity assessment procedure(s) referred to in Article 18 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE 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 referred to in Article 8(7)*** and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).	Before placing PPE on the market, importers shall ensure that the ***essential*** conformity assessment procedure(s) referred to in Article 18 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up ***and communicated*** the technical documentation, that the PPE bears the CE marking, is accompanied by the EU declaration of conformity ***and*** a simplified EU declaration of conformity, and that it is accompanied by the ***requisite documents*** and that the manufacturer has complied with ***all*** the requirements set out in Article 8(5) and (6).

Amendment 66

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission	*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, 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.	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 ***the official language of the*** end-users and market surveillance authorities.

Amendment 67

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. Importers shall ensure that ***every PPE, including its smallest unit,*** is accompanied by the instructions ***and other information set out*** in point 1.4 of Annex II in ***the official*** language ***of the*** end-users, ***in*** the Member State ***in which the PPE is made available on the market, and when possible should be language neutral***.

Amendment 68

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 69

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 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.	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. ***Such action shall be taken no later than five working days from the day on which importers become aware of that information***. Furthermore, where the PPE presents a risk, importers shall immediately inform the ***manufacturer and 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. ***The market surveillance authorities shall then have the obligation to inform the public of the risk as long as the corrective measure is not in place.***

Amendment 70

Proposal for a regulation

Article 11 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. 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).	2. 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 ***and other information*** set out in point 1.4 of Annex II in ***the official*** language ***of the*** 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 71

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

Text proposed by the Commission	*Amendment*
Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.	Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities. ***Thereafter the manufacturer shall immediately recall the PPE from the market***. ***The market surveillance authorities shall then have the obligation to inform the public of the risk as long as the corrective measure is not in place.***

Amendment 72

Proposal for a regulation
Article 11 – paragraph 4

Text proposed by the Commission	*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 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.	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 and importer as well as 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. ***The market surveillance authorities shall then have the obligation to inform the public of the risk as long as the corrective measure is not in place.***

Amendment 73

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission	*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 the conformity with ***the applicable essential health and safety requirements set out in Annex II*** may be	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.

affected.

Amendment 74

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.	1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated. ***The model structure of the EU declaration of conformity shall be easily accessible through an internet address to the economic operators***.

Amendment 75

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging ***and*** to the accompanying documents.	2. The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed ***visibly, legibly and indelibly*** to the packaging ***or*** to the accompanying documents.

Amendment 76

Proposal for a regulation
Article 16 – paragraph 3

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

Amendment 77

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 each Member State*** and have legal personality.

Amendment 78

Proposal for a regulation
Article 23 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses.	A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses ***and shall sign a declaration certifying its independence and impartiality. It shall duly take into account the health and safety requirements laid down in Directive 89/391/EEC and, in particular, Directive 89/656/EEC***.

Amendment 79

Proposal for a regulation
Article 23 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly or indirectly involved in the design,	A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly or indirectly involved in the design,

manufacture, making available, use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.	manufacture, making available, ***marketing,*** use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Amendment 80

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 81

Proposal for a regulation
Article 23 – paragraph 9

Text proposed by the Commission	*Amendment*
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.	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 82

Proposal for a regulation
Article 23 – paragraph 11

Text proposed by the Commission	*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 this Regulation and shall apply ***as general guidance the administrative*** decisions and documents produced as a result of the work of that group.	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 ***the*** decisions and documents produced as a result of the work of that group.

Amendment 83

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the ***subcontractor*** or the ***subsidiary meets*** the requirements set out in Article 23 and shall inform the notifying authority accordingly.	1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the ***subcontractors*** or the ***subsidiaries along the full compliance chain meet*** the requirements set out in Article 23 and shall inform the notifying authority accordingly.

Amendment 84

Proposal for a regulation
Article 39 – title

Text proposed by the Commission	*Amendment*
Penalties	***Surveillance, control and*** penalties

Amendment 85

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 ***guidance, surveillance, control and*** penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. ***To avoid inaccurate use of the PPE and unintended flaws, Member States shall first and foremost provide guidance on how to meet the requirements of this Regulation. If, however, after receiving the necessary guidance the requirements are still not met, penalties shall be the next step***. 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 86

Proposal for a regulation
Annex I – category III – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
PPE intended to protect users against very serious risks. Category III includes exclusively PPE intended to protect users against the following risks:	PPE intended to protect users against very serious risks, ***such as death or irreversible injuries and damage to health.*** Category III includes exclusively PPE intended to protect users against the following risks:

Amendment 87

Proposal for a regulation
Annex I – category 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) low-temperature environments the effects of which are ***comparable*** to those of an air temperature of -50°C or less;	(e) low-temperature environments the effects of which are ***equivalent*** to those of an air temperature of -50°C or less ***taking into account the wind-chill***;

Amendment 88

Proposal for a regulation
Annex II – point -1 (new)

Text proposed by the Commission	*Amendment*
	PRELIMINARY REMARKS
	1. The essential health and safety requirements laid down in this Regulation are compulsory.
	2. Obligations under essential health and safety requirements apply only where the corresponding risk exists for the PPE in question.
	3. The essential requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection.
	4. The manufacturer is under an obligation to carry out a risk assessment in order to identify all the risks which apply to the PPE. The manufacturer shall then design and manufacture it taking into account of the assessment.

	5. When designing and manufacturing the PPE, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the PPE, but also the reasonably foreseeable uses. Where applicable, the health and safety of persons other than the user shall be ensured.

Amendment 89

Proposal for a regulation
Annex II – point 1 – paragraph 1

Text proposed by the Commission	*Amendment*
PPE must provide adequate protection against the risks ***against which it is intended to protect***.	PPE must provide adequate ***and complete*** protection against the risks ***in order to ensure and preserve the health and safety of users and third parties***.

Amendment 90

Proposal for a regulation
Annex II – point 1 – point 1.2. – point 1.2.1. – point 1.2.1.1.

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 91

Proposal for a regulation
Annex II – point 1 – point 1.2. – point 1.2.1. – point 1.2.1.2. – heading

Text proposed by the Commission	*Amendment*
1.2.1.2. ***Satisfactory*** surface condition of all PPE parts in contact with the user	1.2.1.2. ***Optimal*** surface condition of all PPE parts in contact with the user

Amendment 92

Proposal for a regulation
Annex II – point 1 – point 1.4. – heading

Text proposed by the Commission	*Amendment*
1.4. Manufacturer's instructions	1.4. Manufacturer's instructions ***and information***

Amendment 93

Proposal for a regulation
Annex II – point 1 – point 1.4. – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products ***recommended*** by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;	(a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products ***indicated*** by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;

Amendment 94

Proposal for a regulation
Annex II – point 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) the date or period of obsolescence of the PPE or of its components;

Amendment 95

Proposal for a regulation
Annex II – point 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, must be provided in the official language(s) of the Member State of destination ***in order to allow the end-user to safely and correctly use the PPE. 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 concerned person.***

Amendment 96

Proposal for a regulation
Annex II – point 2 – point 2.3. – paragraph 3

Text proposed by the Commission	*Amendment*
If necessary, they must be treated or provided with means to prevent misting up.	They must be treated or provided with means to prevent misting up.

Amendment 97

Proposal for a regulation
Annex II – point 2 – point 2.4. – paragraph 2

Text proposed by the Commission	*Amendment*
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence date, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.	***deleted***

Amendment 98

Proposal for a regulation
Annex II – point 2 – point 2.4. – paragraph 3

Text proposed by the Commission	*Amendment*
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must***, if possible,*** affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded***; failing that, the manufacturer must give this information in his instructions***.	Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded.

Amendment 99

Proposal for a regulation
Annex II – point 2 – point 2.4. – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	Storage conditions must have no adverse effect on the PPE in order to preserve its complete efficiency and protect properly the end-user.

Amendment 100

Proposal for a regulation
Annex II – point 2 – point 2.8. – heading

Text proposed by the Commission	*Amendment*
2.8. PPE for intervention in ***very dangerous*** situations	2.8. PPE for intervention in ***high-risk*** situations

Amendment 101

Proposal for a regulation
Annex II – point 2 – point 2.8. – paragraph 1

Text proposed by the Commission	*Amendment*
The instructions supplied by the manufacturer with PPE for intervention in ***very dangerous*** situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.	The instructions supplied by the manufacturer with PPE for intervention in ***high-risk*** situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

Amendment 102

Proposal for a regulation
Annex II – point 2 – point 2.8. – paragraph 3

Text proposed by the Commission	*Amendment*
Where the PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be designed and placed so that it can be perceived by the user in ***the*** foreseeable ***conditions*** of use.	Where the PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be designed and placed so that it can be perceived by the user in ***every*** foreseeable ***condition*** of use.

Amendment 103

Proposal for a regulation
Annex II – point 2 – point 2.9. – paragraph 1

Text proposed by the Commission	*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*** and removed without tools.	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 ***adjusted*** and removed without tools.

Amendment 104

Proposal for a regulation
Annex II – point 2 – point 2.12. – paragraph 1

Text proposed by the Commission	*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 ***the official language(s) of*** the Member State where the equipment is ***to be used***.	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 105

Proposal for a regulation
Annex II – point 2 – point 2.12. – paragraph 2

Text proposed by the Commission	*Amendment*
Where the PPE (or the interchangeable component for PPE) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.	Where the PPE (or the interchangeable component for PPE) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and ***clearly and properly mentioned*** in the manufacturer's instructions.

Amendment 106

Proposal for a regulation
Annex II – point 2 – point 2.14. – paragraph 1

Text proposed by the Commission	*Amendment*
PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured to satisfy, in particular, the essential health and safety requirements specific to each of those risks.	PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured to satisfy, in particular, the essential health and safety ***all*** requirements specific to each of those risks.

Amendment 107

Proposal for a regulation
Annex II – point 3 – point 3.4- – heading

Text proposed by the Commission	*Amendment*
3.4. Protection in ***the water***	3.4. Protection in ***liquid medium***

Amendment 108

Proposal for a regulation
Annex II – point 3 – point 3.4. – point 3.4.2. – paragraph 1

Text proposed by the Commission	*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 ***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 from danger or to rescue other persons.	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 ***a liquid medium***. 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 from danger or to rescue other persons.

Amendment 109

Proposal for a regulation
Annex II – point 3 – point 3.5. – paragraph 2

Text proposed by the Commission	*Amendment*
Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.	Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE; should this not be possible, the labelling must be ***clearly and properly*** fixed to the packaging.

Amendment 110

Proposal for a regulation
Annex II – point 3 – point 3.6. – point 3.6.1. – paragraph 1

Text proposed by the Commission	*Amendment*
Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be ***sufficiently*** incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.	Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be ***adequately*** incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Amendment 111

Proposal for a regulation
Annex II – point 3 – point 3.6. – point 3.6.1. – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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 112

Proposal for a regulation
Annex II – point 3 – point 3.6. – point 3.6.2. – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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 113

Proposal for a regulation
Annex II – point 3 – point 3.7. – point 3.7.2. – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) PPE must ***as far as possible*** prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.	(b) PPE must prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.

Amendment 114

Proposal for a regulation
Annex II – point 3 – point 3.9. – point 3.9.1. – paragraph 1

Text proposed by the Commission	*Amendment*
PPE designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation must be capable of absorbing or reflecting ***the majority of*** the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of	PPE designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation must be capable of absorbing or reflecting ***all*** the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

use.

Amendment 115

Proposal for a regulation
Annex II – point 3 – point 3.9. – point 3.9.1. – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 116

Proposal for a regulation
Annex II – point 3 – point 3.9. – point 3.9.1. – paragraph 3

Text proposed by the Commission	*Amendment*
Furthermore, the ***glasses*** must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.	Furthermore, the ***eye protective equipment*** must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Amendment 117

Proposal for a regulation
Annex II – point 3 – point 3.9. – point 3.9.1. – paragraph 4

Text proposed by the Commission	*Amendment*
Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance	***Eye protective equipment*** suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance

Amendment 118

Proposal for a regulation
Annex II – point 3 – point 3.9. – point 3.9.1. – paragraph 5

Text proposed by the Commission	*Amendment*
The relevant protection factor number must be marked on all specimens of filtering ***glasses*** by the manufacturer.	The relevant protection factor number must be marked on all specimens of filtering ***eye protective equipment*** by the manufacturer.

Amendment 119

Proposal for a regulation
Annex II – point 3 – point 3.10. – point 3.10.2. – paragraph 2

Text proposed by the Commission	*Amendment*
To this end, the constituent materials and other components of these types of PPE must be chosen or designed and incorporated to ensure, ***as far as possible,*** complete leak-tightness, which will allow ***where necessary*** prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.	To this end, the constituent materials and other components of these types of PPE must be chosen or designed and incorporated to ensure, complete leak-tightness, which will ***also*** allow prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Amendment 120

Proposal for a regulation
Annex III – paragraph 2 – point 3

Text proposed by the Commission	*Amendment*
3. a list of ***the*** essential health and safety requirements that are applicable to the PPE;	3. a list of ***all*** essential health and safety requirements that are applicable to the PPE;

Amendment 121

Proposal for a regulation
Annex III – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
10. a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the ***design specifications***;	10. a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the ***specifications defined in the technical documentation***;

Amendment 122

Proposal for a regulation
Annex IV – point 1

Text proposed by the Commission	*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 ***essential health and safety*** requirements ***referred to in Article 5 and set out in Annex II***.	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***.

Amendment 123

Proposal for a regulation
Annex IV – point 4 – point 4.1.

Text proposed by the Commission	*Amendment*
4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable ***essential health and safety requirements***.	4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable ***requirements of this Regulation***.

Amendment 124

Proposal for a regulation
Annex V – point 3 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) for made-to-measure PPE, a description of the range of permissible 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 essential health and safety requirements.

Amendment 125

Proposal for a regulation
Annex V – point 7 – point 7.3.

Text proposed by the Commission	*Amendment*
7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements ***in light of the state of the art***.	7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements.

Amendment 126

Proposal for a regulation
Annex V – point 7 – point 7.4. – point b

Text proposed by the Commission	*Amendment*
(b) in case of a change in the ***state of the art*** referred to in point 7.3;	(b) in case of a change in the ***legal requirements*** referred to in point 7.3;

Amendment 127

Proposal for a regulation
Annex V – point 9

Text proposed by the Commission	*Amendment*
9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been ***placed*** on the market.	9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been ***made available*** on the market.

Amendment 128

Proposal for a regulation
Annex VI – point 2 – paragraph 2

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

	necessary so that the adaptation process and its monitoring ensure conformity of the individually adapted PPE with the basic model described in the EU type-examination certificate and with the applicable essential health and safety requirements.

Amendment 129

Proposal for a regulation
Annex VI – paragraph 1 – point 3 – point 3.1.

Text proposed by the Commission	*Amendment*
3.1. The manufacturer shall affix the CE marking 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***.	3.1. The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable ***requirements of this Regulation***.

Amendment 130

Proposal for a regulation
Annex VII – point 1

Text proposed by the Commission	*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 ***essential health and safety*** requirements ***referred to in Article 5 and set out in Annex II***.	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 131

Proposal for a regulation
Annex VIII – point 6 – introductory part

Text proposed by the Commission	*Amendment*
6. The manufacturer shall, for a period ending 10 years after the PPE has been ***placed*** on the market, keep at the disposal of the national authorities:	6. The manufacturer shall, for a period ending 10 years after the PPE has been ***made available*** on the market, keep at the disposal of the national authorities:

Amendment 132

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***. It may, where useful for the identification of the PPE, include an image of sufficient clarity***):

PROCEDURE

Title	Personal protective equipment
References	COM(2014)0186 – C7-0110/2014 – 2014/0108(COD)
Committee responsible Date announced in plenary	IMCO 2.4.2014
Opinion by Date announced in plenary	EMPL 2.4.2014
Rapporteur Date appointed	Laura Agea 30.9.2014
Discussed in committee	26.2.2015 24.3.2015
Date adopted	1.4.2015
Result of final vote	+: 49 –: 0 0: 0
Members present for the final vote	Laura Agea, Guillaume Balas, Brando Benifei, Enrique Calvet Chambon, Martina Dlabajová, Arne Gericke, Marian Harkin, Danuta Jazłowiecka, Agnes Jongerius, Rina Ronja Kari, Jan Keller, Ádám Kósa, Agnieszka Kozłowska-Rajewicz, Zdzisław Krasnodębski, Jean Lambert, Jérôme Lavrilleux, Patrick Le Hyaric, Jeroen Lenaers, Verónica Lope Fontagné, Javi López, Thomas Mann, Anthea McIntyre, Elisabeth Morin-Chartier, Emilian Pavel, Georgi Pirinski, Sofia Ribeiro, Claude Rolin, Anne Sander, Sven Schulze, Siôn Simon, Jutta Steinruck, Romana Tomc, Yana Toom, Ulrike Trebesius, Marita Ulvskog, Renate Weber, Tatjana Ždanoka, Jana Žitňanská, Inês Cristina Zuber
Substitutes present for the final vote	Daniela Aiuto, Maria Arena, Georges Bach, Elmar Brok, Sergio Gutiérrez Prieto, Joachim Schuster, Neoklis Sylikiotis, Claudiu Ciprian Tănăsescu, Ivo Vajgl
Substitutes under Rule 200(2) present for the final vote	Eleonora Evi

PROCEDURE

Title	Personal protective equipment			
References	COM(2014)0186 – C7-0110/2014 – 2014/0108(COD)			
Date submitted to Parliament	27.3.2014			
Committee responsible Date announced in plenary	IMCO 2.4.2014			
Committees asked for opinions Date announced in plenary	EMPL 2.4.2014	ENVI 2.4.2014	ITRE 2.4.2014	
Not delivering opinions Date of decision	ENVI 24.7.2014	ITRE 22.7.2014		
Rapporteurs Date appointed	Vicky Ford 17.7.2014			
Discussed in committee	3.12.2014	24.2.2015	24.3.2015	20.4.2015
Date adopted	23.4.2015			
Result of final vote	+: –: 0:	24 3 10		
Members present for the final vote	Dita Charanzová, Sergio Gaetano Cofferati, Daniel Dalton, Nicola Danti, Pascal Durand, Vicky Ford, Ildikó Gáll-Pelcz, Evelyne Gebhardt, Maria Grapini, Antanas Guoga, Sergio Gutiérrez Prieto, Robert Jarosław Iwaszkiewicz, Liisa Jaakonsaari, Philippe Juvin, Antonio López-Istúriz White, Marlene Mizzi, Eva Paunova, Jiří Pospíšil, Virginie Rozière, Christel Schaldemose, Andreas Schwab, Olga Sehnalová, Ivan Štefanec, Catherine Stihler, Róża Gräfin von Thun und Hohenstein, Mylène Troszczynski, Anneleen Van Bossuyt, Marco Zullo			
Substitutes present for the final vote	Pascal Arimont, Cristian-Silviu Buşoi, Birgit Collin-Langen, Dawid Bohdan Jackiewicz, Franz Obermayr, Julia Reda, Ulrike Trebesius, Ulla Tørnæs			
Substitutes under Rule 200(2) present for the final vote	Andor Deli			
Date tabled	30.4.2015			