

2014 - 2019

Committee on Employment and Social Affairs

2014/0108(COD)

7.4.2015

OPINION

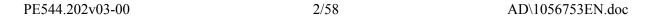
of the Committee on Employment and Social Affairs

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

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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.

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Proposal for a regulation Recital 3

Text proposed by the Commission

(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.

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 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

(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

Amendment

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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.

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

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

Amendment

(9) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC 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, selfcertification should be encouraged for those products. Many manufacturers are already doing this today.

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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

(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.

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 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

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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

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

Amendment

(11) Economic operators should be responsible for the compliance of *the PPE*, in relation to their respective roles in the *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

(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

Amendment

(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure 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

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distribution of obligations which correspond to the role of each operator in the supply and distribution chain. 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

(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

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.

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

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

Amendment

(16) When placing PPE on the market, importers should indicate on the 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

(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

Amendment

(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

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requirements of this Regulation may be affected *should be* considered to be the manufacturer and should assume the obligations of the manufacturer.

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

(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.

Amendment

(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

(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.

Amendment

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

Proposal for a regulation Recital 21

Text proposed by the Commission

(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/EEC¹⁹, 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/EEC¹⁹, 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.

Amendment 19

Proposal for a regulation Recital 24

Text proposed by the Commission

(24) In order to ensure that PPE is examined on the basis of the state of the art the limit of validity of the EU type-

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-

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Amendment

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).

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

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

(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.

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 *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

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

Amendment

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

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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

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

(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.

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 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

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Text proposed by the Commission

(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.

Amendment

(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.

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)

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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

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essential.

Amendment 32

Proposal for a regulation Article 1 – paragraph 1

Text proposed by the Commission

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.

Amendment

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

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

Amendment

(c) intended for private use to protect against:

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.);

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

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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

(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;

Amendment

(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;

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

Text proposed by the Commission

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

Amendment

(c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, *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

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

Amendment

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;

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

Text proposed by the Commission

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;

Amendment

3. 'made-to-measure PPE' means PPE produced to accommodate the special needs of *a specific individual 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

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

Amendment

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

Amendment 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;

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

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Text proposed by the Commission

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.

Amendment

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

PPE shall fulfil the applicable essential health and safety requirements set out in Annex II.

Amendment

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

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.

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 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

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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

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.

Amendment

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

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

Amendment

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 enduser) 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

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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

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.

Amendment

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

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

Amendment

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least 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

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

Amendment

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

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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

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

Amendment

6. Manufacturers shall indicate, 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

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* endusers, as *determined* by the Member State concerned

Amendment

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.

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Proposal for a regulation Article 8 – paragraph 9

Text proposed by the Commission

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.

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 nonconformity 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

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

Amendment

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

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

Amendment

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

Amendment 62

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

Text proposed by the Commission

(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;

Amendment

(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

(c) cooperate with the national *market surveillance* authorities, at their request, on any action taken to eliminate the risks

Amendment

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

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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

1. Importers shall place *only compliant PPE on the market*.

Amendment

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

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).

Amendment

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).

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

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

Amendment

3. Importers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted, 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

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

Amendment

4. Importers shall ensure that 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

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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

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

Amendment

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

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Article 11 – paragraph 2 – subparagraph 1

Text proposed by the Commission

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).

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 *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

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.

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. 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.

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Proposal for a regulation Article 11 – paragraph 4

Text proposed by the Commission

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

Amendment

4. Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with the requirements of this Regulation shall make sure that the necessary corrective measures are taken to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, distributors shall immediately inform the manufacturer 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

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

Amendment

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

affected.

Amendment 74

Proposal for a regulation Article 15 – paragraph 1

Text proposed by the Commission

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.

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. 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

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.

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 *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

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

Amendment

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

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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

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

Amendment

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

A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses.

Amendment

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

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,

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,

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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

(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;

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;

Amendment 81

Proposal for a regulation Article 23 – paragraph 9

Text proposed by the Commission

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

Amendment

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

Amendment 82

Proposal for a regulation Article 23 – paragraph 11

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Text proposed by the Commission

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

Amendment

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under 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

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.

Amendment

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

Penalties

Amendment

Surveillance, control and penalties

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Proposal for a regulation Article 39 – paragraph 1

Text proposed by the Commission

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.

Amendment

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

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

Amendment

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

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

Text proposed by the Commission

(e) low-temperature environments the effects of which are *comparable* to those of an air temperature of -50°C or less;

Amendment

(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

PPE must provide adequate protection against the risks *against which it is intended to protect*.

Amendment

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

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

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 or result in the PPE no longer complying with the essential health and safety requirements laid down in this Regulation.

Amendment 91

users.

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

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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;

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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

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

Text proposed by the Commission

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*

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 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

2.8. PPE for intervention in *very dangerous* situations

Amendment

2.8. PPE for intervention in *high-risk* situations

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

Text proposed by the Commission

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.

Amendment

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

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.

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 *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

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

Amendment

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

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

Text proposed by the Commission

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

Amendment

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

Amendment 105

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

Text proposed by the Commission

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.

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 *clearly and properly mentioned* in the manufacturer's instructions.

Amendment 106

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

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Text proposed by the Commission

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

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 *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

3.4. Protection in *the water*

Amendment

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

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.

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 *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

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Text proposed by the Commission

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.

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 *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

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.

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 *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

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

Amendment

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

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

Text proposed by the Commission

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

Amendment

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

Amendment 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

(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.

Amendment

(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

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

Amendment

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.

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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

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

Amendment

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

Justification

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

Amendment 116

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

Text proposed by the Commission

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.

Amendment

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.

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

Text proposed by the Commission

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

Amendment

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 leaktightness, which will *also* allow prolonged daily use or, failing this, limited leaktightness necessitating a restriction of the period of wear.

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

Text proposed by the Commission

3. a list of *the* essential health and safety requirements that are applicable to the PPE;

Amendment

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

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*;

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 *specifications defined in the technical documentation*;

Amendment 122

Proposal for a regulation Annex IV – point 1

Text proposed by the Commission

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

Amendment

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

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

Text proposed by the Commission

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

Amendment

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

Amendment 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

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*.

Amendment

7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements.

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

Text proposed by the Commission

(b) in case of a change in the *state of the art* referred to in point 7.3;

Amendment

(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

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.

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 *made available* on the market

Amendment 128

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

Text proposed by the Commission

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

Amendment

For made-to-measure PPE the manufacturer shall take all measures necessary so that the *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

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necessary so that the adaptation process and its monitoring ensure conformity of the individually adapted PPE with the basic model described in the EU typeexamination 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

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.

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 *requirements of this Regulation*.

Amendment 130

Proposal for a regulation Annex VII – point 1

Text proposed by the Commission

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

Amendment

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

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

Text proposed by the Commission

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:

Amendment

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

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

Amendment

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

