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From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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Subject:	Proposal for a Regulation of the European Parliament and of the Council on personal protective equipment - Preparation for the informal trilogue

Delegations will find attached the 4-column document referred to in the note to Coreper reflecting the state-of-play of the negotiations with the European Parliament.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(Text with EEA relevance)			GREEN - EC TEXT
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,			GREEN - EC TEXT
Having regard to the proposal from the European Commission,			GREEN - EC TEXT
After transmission of the draft legislative act to the national Parliaments,			GREEN - EC TEXT
Having regard to the opinion of the European Economic and Social Committee,			GREEN - EC TEXT
Acting in accordance with the ordinary legislative procedure,			GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Whereas:			GREEN - EC TEXT
(1) Council Directive 89/686/EEC13 was adopted in the context of establishing the internal market in order to harmonise health and safety requirements for personal protective equipment (PPE) in all Member States and to remove obstacles to trade in PPE between Member States.			GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(2) Directive 89/686/EEC is based on the New Approach principles, as set out in the Council Resolution on a new approach to technical harmonisation and standards14. Thus, it sets only the essential safety requirements applying to PPE, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council15. Conformity with the harmonised standards so set, the reference number of which is published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 89/686/EEC. Experience has shown that those basic principles have worked well in this sector and should be maintained and even further promoted.			GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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.			GREEN - EC TEXT
	[AM 1] (3a) This Regulation covers PPE which is new to the Union market when it is placed on the market; that is to say it is either new PPE made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.	**(3a) This Regulation covers PPE which are new to the Union market when they are placed on the market; that is to say they are either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.**	***GREEN*** ***(3a) This Regulation covers PPE which is new to the Union market when it is placed on the market; that is to say it is either new PPE made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 2] (3b) This Regulation should apply to all forms of supply, including distance selling.	**(3b) This Regulation should apply to all forms of supply, including distance selling.**	***GREEN*** ***(3b) This Regulation should apply to all forms of supply, including distance selling.***
(4) Since the scope, the essential health and safety requirements and conformity assessment procedures are to be identical in all the Member States there is almost no flexibility in transposing Directives based on the New Approach principles into national law. Directive 89/686/EEC should therefore be replaced by a Regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States.		(4) Since the scope, the essential health and safety requirements and conformity assessment procedures are to be identical in all the Member States there is almost no flexibility in transposing Directives based on the New Approach principles into national law. Directive 89/686/EEC should therefore be replaced by a Regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States.	GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(5) Regulation (EC) No 765/2008 of the European Parliament and of the Council16 lays down horizontal provisions on the accreditation of conformity assessment bodies and on the CE marking.	[AM 3] (5) Regulation (EC) No 765/2008 of the European Parliament and of the Council[16] lays down ***rules*** on the accreditation of conformity assessment bodies***, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of*** the CE marking. [16] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L 218, 13.8.2008, p. 30).	(5) Regulation (EC) No 765/2008 of the European Parliament and of the Council[1] lays down ~~horizontal provisions~~ **rules** on the accreditation of conformity assessment bodies, **provides a framework for the market surveillance of products and for controls on products from third countries**, and **lays down the general principles of** ~~on~~ the CE marking.	GREEN (5) Regulation (EC) No 765/2008 of the European Parliament and of the Council[16] lays down ***rules*** on the accreditation of conformity assessment bodies***, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of*** the CE marking. [16] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L 218, 13.8.2008, p. 30).

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

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(6) Decision No 768/2008/EC of the European Parliament and of the Council17 provides common principles and reference provisions for the purposes of legislation based on the New Approach principles. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution.Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with products presenting a risk should be aligned to that Decision.	[AM 4] (6) Decision No 768/2008/EC of the European Parliament and of the Council[1] ***lays down*** common principles and reference provisions ***intended to apply across sectoral*** legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with products presenting a risk should be aligned to that Decision.	(6) Decision No 768/2008/EC of the European Parliament and of the Council[2] ~~provides~~ **lays down** common principles and reference provisions ~~for the purposes of~~ **intended to apply across sectoral** legislation ~~based on the New Approach principles~~. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with products presenting a risk should be aligned	GREEN (6) Decision No 768/2008/EC of the European Parliament and of the Council[1] ***lays down*** common principles and reference provisions ***intended to apply across sectoral*** legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with products presenting a risk should be aligned to that

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

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		to that Decision.	Decision.
(7) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.		(7) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.	GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(8) Regulation (EU) No xx/xxxx of the European Parliament and of the Council 18 provides detailed rules on market surveillance and on controls of harmonised products, including PPE, entering the Union from third countries. In accordance with that Regulation, Member States are to organise and carry out market surveillance, to appoint market surveillance authorities, to specify their powers and duties, and to set up general and sector-specific market surveillance programmes. That Regulation also sets out a safeguard clause procedure.	[AM 5] ***deleted***	(8) ~~Regulation (EU) No xx/xxxx of the European Parliament and of the Council[3] provides detailed rules on market surveillance and on controls of harmonised products, including PPE, entering the Union from third countries. In accordance with that Regulation, Member States are to organise and carry out market surveillance, to appoint market surveillance authorities, to specify their powers and duties, and to set up general and sector-specific market surveillance programmes. That Regulation also sets out a safeguard clause procedure~~.	GREEN ***deleted***

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

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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.	[AM 6] (9) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. ***Artisanal or decorative products for which the manufacturer does not explicitly claim a protective function are not personal protective equipment; they should therefore not be covered by this Regulation.*** In order to ensure ***a*** high level of protection***, the scope of this Regulation should include*** products ***which are explicitly described and marketed accordingly by their manufacturers*** for private use ***to protect*** against heat. ***In the case of products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including but not limited to seasonal clothing, umbrellas and dishwashing gloves, these should be outside of the scope of this Regulation.*** It is also appropriate to clarify the exclusion list set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore are excluded from the PPE Regulation.	(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, **designed for decorative purposes and not intended to fulfil** ~~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	YELLOW PCY text proposal: (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~~ **high temperature environments** (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, designed for decorative purposes and not intended to fulfil a protective function are not personal protective equipment~~;~~ **and** ~~they are~~ therefore not concerned by this inclusion. **Clothing intended for private use with reflective or fluorescent elements which are**

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		excluded from the PPE Regulation.	**exclusively included for reasons of design or decoration are not personal protective equipment and therefore not covered by this Regulation. In the case of products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including but not limited to seasonal clothing, umbrellas and dishwashing gloves, these should be outside of the scope of this Regulation.** It is also appropriate to clarify the exclusion list set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore are excluded from the PPE Regulation.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(10) In order to facilitate the understanding and uniform application of this Regulation, new definitions for “individually adapted PPE” and “made-to-measure PPE” should be introduced and the conformity assessment procedures for these kinds of PPE should be adapted to the specific conditions of their manufacture.		~~(10) In order to facilitate the understanding and uniform application of this Regulation, new definitions for “individually adapted PPE” and “made-to-measure PPE” should be introduced and the conformity assessment procedures for these kinds of PPE should be adapted to the specific conditions of their manufacture of~~.	GREEN

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 7] ***(10a) During field demonstrations and field tests, adequate measures should be taken to ensure the protection of persons. Field tests should not be designed to test the protection performance of the PPE but to evaluate other non-protective aspects such as comfort, ergonomics and design. All concerned parties, for instance the employer as well as the wearer or the consumer, should be informed in advance concerning the scope and purpose of the test.***		YELLOW PCY text proposal: (10a) **Field test can be carried out on PPE that meets the health and safety requirements set out in this Regulation.** During ~~field demonstrations and~~ field tests, adequate measures should be taken to ensure the protection of persons. Field tests should not be designed to test the protection performance of the PPE but to evaluate**, for a limited period only,** ~~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.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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.	[AM 8] (11) Economic operators should be responsible for the compliance of ***the PPE***, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of users ***and, where appropriate, other persons,*** and to guarantee fair competition on the Union market.	(11) Economic operators should be responsible for the compliance of **the PPE** ~~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 where appropriate, other persons**~~ and to guarantee fair competition on the Union market.	GREEN - CEU TEXT
(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that PPE protects the health and safety of persons and that they make available on the market only products which comply with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution chain.	[AM 9] (12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only ***PPE*** which ***is in conformity*** with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each ***economic*** operator in the supply and distribution chain.	(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~~ **PPE** which **are in conformity** ~~comply~~ with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each **economic** operator in the supply and distribution chain.	GREEN (12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only ***PPE*** which ***is in conformity*** with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each ***economic*** operator in the supply and distribution chain.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 10] ***(12a) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.***	**(12a) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.**	GREEN ***(12a) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.***
(13) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.		(13) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain **solely** the obligation of the manufacturer ~~alone~~.	GREEN -CEU TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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.	[AM 11] (14) It is necessary to ensure that PPE entering the Union market complies with this Regulation and, in particular, that appropriate ***conformity*** assessment procedures have been carried out by manufacturers. Provision should therefore be made ***to the effect that*** importers ***shall*** place on the market ***only PPE which*** complies with the requirements of this Regulation and ***does not*** present a risk**.** Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the market surveillance authorities.	(14) It is necessary to ensure that PPE entering the Union market complies with this Regulation and, in particular, that appropriate **conformity** assessment procedures have been carried out by manufacturers. Provision should therefore be made for importers to make sure that the PPE they place on the market complies with the requirements of this Regulation and that they do not place on the market PPE which does not comply with such requirements or which present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the **competent national** ~~market surveillance~~ authorities.	GREEN It is necessary to ensure that PPE entering the Union market complies with this Regulation and, in particular, that appropriate ***conformity*** assessment procedures have been carried out by manufacturers. Provision should therefore be made ***to the effect that*** importers ***shall*** place on the market ***only PPE which*** complies with the requirements of this Regulation and ***does not*** present a risk**.** Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection **by the competent national authorities**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(15) Distributors make PPE available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that their handling of the PPE does not adversely affect the compliance of the PPE.		(15) Distributors make PPE available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that their handling of the PPE does not adversely affect the compliance of the PPE.	GREEN
(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.	[AM 12] (16) When placing PPE on the market, importers should indicate on the ***PPE*** their name***, registered name or trademark*** and the ***postal*** address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow for ***it***. This includes cases where the importer would have to open the packaging to put his name and address on the ***PPE***.	(16) When placing PPE on the market, importers should indicate on the **PPE** ~~product~~ their name, **registered trade name or registered trade mark** and the **postal** address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow **it** ~~for such an indication~~. This includes cases where the importer would have to open the packaging to put his name and address on the **PPE** ~~product.~~	GREEN – CEU TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 13] ***(16a) Efforts should be made by economic operators to ensure that all relevant documentation, such as the user's instructions, whilst ensuring precise and comprehensible information, are easily understandable, take into account technological developments and changes to end-user behaviour, and are as up to date as possible.***		GREEN
(17) Any economic operator that either places PPE on the market under its own name or trademark or modifies a product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.		(17) Any economic operator that either places PPE on the market under its own name or trademark or modifies a product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.	GREEN

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.		(18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.	GREEN

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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 noncompliant product available on the market.	[AM 14] (19) Ensuring traceability of PPE throughout the ***whole*** supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant product available on the market. ***When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with PPE or to whom they have supplied PPE unless such updated information has been supplied to them.***	(19) Ensuring traceability of PPE throughout the **whole** supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant **PPE** ~~product~~ available on the market. **When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a PPE or to whom they have supplied a PPE.**	GREEN (19) Ensuring traceability of PPE throughout the **whole** supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant **PPE** ~~product~~ available on the market. **When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a PPE or to whom they have supplied a PPE** ***unless such updated information has been supplied to them*****.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(20) In order to simplify and adapt certain essential safety requirements of Directive 89/686/EEC to the current practice the requirement to label PPE protecting against harmful noise with a comfort index should be removed as experience has shown that it is not possible to measure and establish such an index. As regards mechanical vibrations, it is appropriate to remove the requirement not to exceed the limit values set by Union legislation on the exposure of workers to vibrations since the use of PPE alone is not able to achieve this objective. As regards PPE protecting against radiation, it is no longer necessary to require that the instructions for use supplied by the manufacturer indicate transmission curves, since the indication of the protection factor is more useful and is sufficient for the user.		(20) In order to simplify and adapt certain essential safety requirements of Directive 89/686/EEC to the current practice the requirement to label PPE protecting against harmful noise with a comfort index should be removed as experience has shown that it is not possible to measure and establish such an index. As regards mechanical vibrations, it is appropriate to remove the requirement not to exceed the limit values set by Union legislation on the exposure of workers to vibrations since the use of PPE alone is not able to achieve this objective. As regards PPE protecting against radiation, it is no longer necessary to require that the instructions for use supplied by the manufacturer indicate transmission curves, since the indication of the protection factor is more useful and is sufficient for the user.	GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 15] ***(20a) 'Field test' means a trial period by the user of non-compliant PPE, before it is placed on market and for which all the necessary information of tests carried out by accredited or authorised laboratories is available in the technical file to ensure the protection of the user and meets the applicable requirements in Annex II, is made available in a very limited number for a limited time and whose principal purpose is to undertake a final evaluation of its non-protection characteristics.***		YELLOW **WP 29.05. MS did not support articles on field tests. As a compromise a recital can be acceptable, therefore PCY proposes new wording for Recital (10a). Accordingly, text of Recital (20a) should be rejected.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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.	[AM 16] (21) It is necessary to clearly specify the relationship and scope of this Regulation with the entitlement of Member States to lay down requirements for the use of PPE at workplace, in particular pursuant to Council Directive 89/656/EEC[19], in order to avoid any confusion and ambiguity and hence ensure the free movement of compliant PPE. ***Article 4 of that Directive obliges employers to provide PPE which complies with the relevant Union provisions on design and manufacture with respect to safety and health. Pursuant to that Article, manufacturers of PPE who provide that PPE to their employees must ensure that such PPE fulfils the requirements laid down in this Regulation.*** [19] Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (OJ L 393, 30.12.1989, p. 18).	(21) It is necessary to clearly specify the relationship and scope of this Regulation with the entitlement of Member States to lay down requirements for the use of PPE at workplace, in particular pursuant to Council Directive 89/656/EEC[4] , in order to avoid any confusion and ambiguity and hence ensure the free movement of compliant PPE. **Article 4 of Directive 89/656/EEC obliges employers to provide PPE which complies with the relevant Union provisions on design and manufacture with respect to safety and health. Pursuant to this provision, manufacturers of PPE who provide that PPE to their employees must ensure that such PPE fulfils the requirements of this Regulation.**	GREEN – EP TEXT

[4] 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).

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(22) The requirement in other internal market legislation to supply an EU declaration of conformity with the equipment has been found to facilitate and to enhance the efficiency of market surveillance and should therefore also be introduced into this Regulation. It should be possible to provide a simplified EU declaration of conformity in order to reduce the burden associated with this requirement without reduction of its effectiveness. Both possibilities should therefore be provided for in this Regulation.	[AM 17] (22) ***Market surveillance authorities should have easy access to the*** declaration of conformity***. In order to fulfil that requirement, manufacturers should ensure PPE is accompanied either by a full copy of the declaration of conformity or the internet address where the*** EU declaration of conformity ***can be accessed. Alternatively, the manufacturer should be able to choose to provide a simplified declaration of conformity***.	~~(22) The requirement in other internal market legislation to supply an EU declaration of conformity with the equipment has been found to facilitate and to enhance the efficiency of market surveillance and should therefore also be introduced into this Regulation. It should be possible to provide a simplified EU declaration of conformity in order to reduce the burden associated with this requirement without reduction of its effectiveness. Both possibilities should therefore be provided for in this Regulation.~~ **Market surveillance authorities should have easy access to the declaration of conformity. In order to fulfil this requirement, manufacturers should include in the instruction information on the internet address where the EU declaration of conformity can be accessed. Alternatively, the manufacturer may choose to provide the EU declaration of conformity with each product.**	GREEN (22) ***Market surveillance authorities should have easy access to the*** declaration of conformity***. In order to fulfil that requirement, manufacturers should ensure PPE is accompanied either by a full copy of the declaration of conformity or the internet address where the*** EU declaration of conformity ***can be accessed. ~~Alternatively, the manufacturer should be able to choose to provide a simplified declaration of conformity~~.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 18] ***(22a) To ensure effective access to information for market surveillance purposes, in cases where PPE is covered by one or more Union harmonisation legal acts the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.***	**(22a) To ensure effective access to information for market surveillance purposes, in cases where a PPE is covered by several pieces of Union harmonisation legislation, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.**	GREEN – EP TEXT
(23) In order to increase the efficiency of market surveillance it is necessary to extend the obligation to draw up a complete technical documentation to all PPE.		(23) In order to increase the efficiency of market surveillance it is necessary to extend the obligation to draw up a complete technical documentation to all PPE.	GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(24) In order to ensure that PPE is examined on the basis of the state of the art the limit of validity of the EU type-examination certificate should set to a maximum of five years. A process for reviewing the certificate should be provided for. A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.	[AM 19] (24) PPE ***should be*** examined on the basis of the state of the art***. The maximum period*** of validity of the EU type-examination certificate should ***be*** five years ***and a*** process for reviewing the certificate should be provided for. ***Following a positive review, a renewed certificate may continue to be valid for further periods, each of which should be for a maximum of five years.*** A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.	(24) In order to ensure that PPE is examined on the basis of the state of the art the limit of validity of the EU type-examination certificate should set to a maximum of five years. A process for reviewing the certificate should be provided for. A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.	YELLOW **WP 29.05. MS supported the idea of simplified procedure, AM 19 can be accepted.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 20] ***(24a) A simplified procedure should be applied for re-certification of the EU-type examination certificate when the product, applied harmonised standards or other technical solutions applied by the manufacturer have not been changed and continue to meet the essential health and safety requirements in the light of the state of the art, making additional tests or technical examinations unnecessary and thereby keeping the administrative burden and related costs to a minimum.***		RED **WP 29.05. MS supported the idea of simplified procedure, therefore PCY proposes following compromise text:** (24a) A simplified procedure should be applied for ~~re-certification~~ **review** of the EU-type examination certificate when **the manufacturer has not modified the approved type and** the ~~product, applied~~ harmonised standards or other technical ~~solutions~~ **specifications** applied by the manufacturer have not been changed and continue to meet the essential health and safety requirements in the light of the state of the art~~,~~**.** **In such cases** ~~making~~ additional tests or ~~technical~~ examinations **should be** unnecessary and ~~thereby keeping~~ the administrative burden and related costs **should be kept** to a minimum.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 21] ***(24b) The withdrawal of a harmonised standard should not invalidate existing certificates issued by notified bodies; it only concerns the conformity that is conferred onto new conformity assessments that follow the new harmonised standard. Products produced in accordance with the existing certificate should still benefit from the continuing conformity with the essential requirements and it should continue to be possible to place them on the market until the end of the validity of the relevant certificates issued by notified bodies.***		YELLOW **WP 26.05. MS were strongly opposed this AM and corresponding AM.71 (Art.15(1)) , to be rejected.**
(25) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on PPE should be laid down in this Regulation.		(25) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on PPE should be laid down in this Regulation.	GREEN - EC TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(26) It is crucial to make clear to manufacturers and users that by affixing the CE marking to the product, the manufacturer declares that the product is in conformity with this Regulation and takes full responsibility therefor.		(26) ~~It is crucial to make clear to manufacturers and users that by affixing the CE marking to the product, the manufacturer declares that the product is in conformity with this Regulation and takes full responsibility therefor~~.	GREEN **deleted**
(27) The CE marking should be the only marking indicating that PPE is in conformity with Union harmonisation legislation. However, other markings should be allowed as long as they contribute to the improvement of consumer protection and are not covered by Union harmonisation legislation.		(27) ~~The CE marking should be the only marking indicating that PPE is in conformity with Union harmonisation legislation. However, other markings should be allowed as long as they contribute to the improvement of consumer protection and are not covered by Union harmonisation legislation~~.	GREEN **deleted**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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 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.	[AM 22] (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 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.	(28) In order to ensure compliance with the essential **health and** 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 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.	GREEN – EP TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		(~~10~~**28a**) ~~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~~ **defined** ~~introduced and~~ **T**~~t~~he conformity assessment procedures ~~for these kinds of PPE~~ should be adapted to the specific conditions of the~~ir~~ manufacture **of PPE produced in series where each item is adapted to fit an individual user and of PPE produced as a single unit to fit an individual user.**	GREEN – CEU TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(29) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of PPE throughout the Union, and all such bodies should perform their functions at the same level and under conditions of fair competition. Therefore obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services under this Regulation.		(29) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of PPE throughout the Union, and all such bodies should perform their functions at the same level and under conditions of fair competition. Therefore obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services under this Regulation.	GREEN - EC TEXT
	[AM 23] ***(29a) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards it should be presumed to comply with the corresponding requirements set out in this Regulation.***	**(29a) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards it should be presumed to comply with the corresponding requirements set out in this Regulation.**	GREEN ***(29a) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards it should be presumed to comply with the corresponding requirements set out in this Regulation.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(30) In order to ensure a consistent level of quality in the performance of conformity assessment of PPE, it is also necessary to set requirements that notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies must fulfil.		(30) In order to ensure a consistent level of quality in the performance of conformity assessment of PPE, it is also necessary to set requirements **for** ~~that~~ notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies ~~must fulfil~~.	GREEN – CEU TEXT
	[AM 24] ***(30a) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.***	**(30a) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.**	GREEN ***(30a) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 25] ***(30b) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.***	**(30b) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.**	GREEN ***(30b) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 26] ***(30c) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the PPE to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.***	**(30c) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the PPE to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.**	GREEN ***(30c) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the PPE to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 27] ***(30d) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.***	**(30d) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.**	GREEN ***(30d) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 28] ***(30e) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.***	**(30e) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.**	GREEN ***(30e) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.***
		(30ea) Interested parties should have the right to appeal against the result of an assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.	GREEN

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 29] ***(30f) Member States should take all appropriate measures to ensure that products covered by this Regulation may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and or safety of users or, where applicable, of other persons. Products covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.***	**(30f) Member States should take all appropriate measures to ensure that products covered by this Regulation may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health ~~and~~ or safety of ~~users or, where applicable, of other~~ persons. Products covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.**	GREEN – CEU TEXT

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

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 31] ***(30h) Directive 89/686/EC already provides for a safeguard procedure which is necessary to allow the possibility for contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.***	**(30h) Directive 89/686/EC already provides for a safeguard procedure which is necessary to allow the possibility for contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.**	GREEN ***(30h) Directive 89/686/EC already provides for a safeguard procedure which is necessary to allow the possibility for contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.***
	[AM 32] ***(30i) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to PPE presenting a risk to the health or safety of users or, where applicable, of other persons. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such PPE.***	**(30i) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to PPE presenting a risk to the health *or* safety of ~~users or, where applicable, of other~~ persons. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such PPE.**	GREEN – CEU TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 33] ***(30j) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.***	**(30j) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.**	GREEN ***(30j) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(31) In order to take into account the progress of technical knowledge and new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to amend the list of PPE included in each category. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.		(31) In order to take into account ~~the~~ **technical** progress ~~of technical~~ **and** knowledge ~~and~~ **or** 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~~ **categories of risks against which the** PPE is ~~designed~~ **intended** to protect **users** ~~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.	GREEN – CEU TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(32) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council20. The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.		(32) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council[5] .	GREEN (32) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council[6] .

[5] Regulation (EU) 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

[6] Regulation (EU) 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		(32a) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.	GREEN - CEU text Alignment: recital 32 is split into two recitals
		(32b) The examination procedure should be used for the adoption of implementing acts with respect to compliant PPE which presents a risk to the health or safety of persons or to other aspects of public interest protection.	RED Joint trilogue
	[AM 34] ***(32a) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant PPE which presents a risk to the health or safety of persons, imperative grounds of urgency so require.***	**(32c) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant PPE which presents a risk to the health or safety of persons, imperative grounds of urgency so require.**	GREEN ***(32a) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant PPE which presents a risk to the health or safety of persons, imperative grounds of urgency so require.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		(32d) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.	RED Joint trilogue
		(32e) When matters relating to this Regulation, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.	RED Joint trilogue

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		(32f) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant products are justified or not.	RED Joint trilogue
(33) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.		(33) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are **enforced** ~~implemented~~. ~~Those~~ **The** penalties **provided for** should be effective, proportionate and dissuasive.	GREEN – CEU TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(34) In order to allow manufacturers and other economic operators sufficient time to adapt to the requirements of this Regulation, it is necessary to provide for a sufficient transitional period after the entry into force of this Regulation during which PPE which complies with Directive 89/686/EEC may still be placed on the market.		(34) In order to allow manufacturers and other economic operators sufficient time to adapt to the requirements of this Regulation, it is necessary to provide for a sufficient transitional period after the entry into force of this Regulation during which PPE which complies with Directive 89/686/EEC may still be placed on the market. **~~Distributors should therefore be able to supply PPE that have been placed on the market, namely stock that is already in the distribution chain, before the end of the transitional period.~~**	GREEN - EC text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(35) Since the objective of this Regulation, namely to ensure a high level of protection of human health and safety whilst guaranteeing the functioning of the internal market by setting harmonised health and safety requirements for PPE and minimum requirements for market surveillance, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.		(35) Since the objective of this Regulation, namely to ensure **that PPE on the market fulfil the requirements providing for** a high level of protection of ~~human~~ health and safety **of users, ~~and where applicable, other persons,~~** whilst guaranteeing the functioning of the internal market ~~by setting harmonised health and safety requirements for PPE and minimum requirements for market surveillance~~, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	GREEN – CEU TEXT

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(36) Directive 89/686/EEC has been amended several times. Since further substantial amendments are to be made and in order to ensure a uniform implementation throughout the Union, Directive 89/686/EEC should be repealed and replaced by a Regulation.		(36) Directive 89/686/EEC has been amended several times. Since further substantial amendments are to be made and in order to ensure a uniform implementation throughout the Union, Directive 89/686/EEC should be repealed and replaced by a Regulation.	GREEN - EC Text
HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
CHAPTER I		CHAPTER I	
GENERAL PROVISIONS		**GENERAL PROVISIONS**	
Article 1 *Subject Matter*		*Article 1* *Subject Matter*	
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.	[AM 35] This Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) ***which is being made available on the market*** in order to ensure the protection of users and rules on its free movement in the Union.	This Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) **~~with a view to it~~ which is to be ~~being~~ made available on the market** in order to ensure **protection of** the health and safety ~~protection~~ of users **~~and where applicable, of other persons,~~** and rules on its free movement in the Union.	GREEN – CEU Text
Article 2 *Scope*	*Article 2* *Scope*	*Article 2* *Scope*	RED
1. This Regulation shall apply to personal protective equipment (PPE), as defined in Article 3.	[AM 36] 1. This Regulation shall apply to personal protective equipment (PPE), as defined in Article 3 ***and classified into the risk categories set out in Annex I***.	1. This Regulation shall apply to personal protective equipment (PPE), ~~as defined in Article 3~~.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. This Regulation shall not apply to PPE:		2. This Regulation shall not apply to PPE:	GREEN - EC Text
(a) specifically designed for use by the armed forces or for the maintenance of law and order;	[AM 37] (a) specifically designed for use by the armed forces or ***in*** the maintenance of law and order;	(a) specifically designed for use by the armed forces or ~~for~~ **in** the maintenance of law and order;	GREEN (a) specifically designed for use by the armed forces or ***in*** the maintenance of law and order;
(b) intended to be used for self-defence;	[AM 38] (b) ***designed*** to be used for self-defence***, with the exception of PPE intended for sporting activities***;	(b) **designed** ~~intended~~ to be used for self-defence **with the exception of PPE intended for sporting activities**;	GREEN - Identical
(c) intended for private use to protect against atmospheric conditions that are not of an extreme nature;	[AM 39] (c) intended for private use to protect against:	(c) **designed** ~~intended~~ for private use to protect against atmospheric conditions that are not of an extreme nature;	YELLOW **PCY compromise text proposal:** (c) designed for private use to protect against ~~**atmospheric conditions that are not of an extreme nature;**~~:
	(i) atmospheric conditions that are not of an extreme nature;		YELLOW **PCY compromise text proposal:** ***(i)*** atmospheric conditions that are not of an extreme nature;

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	(ii) damp and water not of an extreme nature;		RED **PCY compromise text proposal:** **(ii) damp and water not of an extreme nature;**
	(iii) heat, for which the economic operator does not explicitly describe and market the products as having a protective function;		RED **PCY compromise text proposal:** **(iii) heat if the risk involved for the user is not classified higher than risk category I as set in Annex I for which the manufacturer has provided clear information on the product, its packaging or accompanying documents that it can only be used in low temperature environment.**
(d) for use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;		(d) for **exclusive** use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(e) for head, face or eye protection of users, subject to the relevant Regulation of the United Nations Economic Commission for Europe (UNECE), of two- or three-wheeled motor vehicles.	[AM 40] (e) for head, face or eye protection of users, subject to ***Regulation 22*** of the United Nations Economic Commission for Europe (UNECE), ***on uniform provisions concerning the approval of protective helmets and of their visors for drivers and passengers of*** motor ***cycles and mopeds;***	(e) for head, face or eye protection of users, subject to ~~the relevant~~ Regulation **22** of the United Nations Economic Commission for Europe (UNECE) **on uniform provisions concerning the approval of protective helmets and of their visors for drivers and passengers of motor cycles and mopeds**~~, of two- or three-wheeled motor vehicles~~.	GREEN (e) for head, face or eye protection of users, subject to ***Regulation 22*** of the United Nations Economic Commission for Europe (UNECE), ***on uniform provisions concerning the approval of protective helmets and of their visors for drivers and passengers of*** motor ***cycles and mopeds;***
	[AM 41] ***(ea) in the form of clothing intended for private use, with reflective or fluorescent garments which are exclusively included for reasons of design or decoration, and for which the economic operator does not describe and market the products as having a protective function;***		RED WP 29.05.2015. MS were of an opinion that there is no need for this AM since products described there clearly are not PPE. As a compromise MS can accept to include reference to clothing in Recital 9.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 42] ***(eb) designed and placed on the market as artisanal products which are decorative in nature.***		RED WP 29.05.2015. MS were of an opinion that there is no need for this AM since products described there clearly are not PPE. As a compromise MS can accept to include reference to artisanal products in Recital 9 as it was already included in General approach text of CEU.
Article 3 *Definitions*	*Article 3* Definitions	*Article 3* Definitions	GREEN - EC Text
For the purposes of this Regulation, the following definitions shall apply:		For the purposes of this Regulation, the following definitions shall apply:	GREEN - EC Text
1. 'Personal protective equipment' (PPE) means:		1. 'Personal protective equipment' (PPE) means:	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(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;	[AM 43] (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;	(a) equipment **designed and manufactured** ~~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~~ **made available** ~~on the market separately or combined with personal non-protective equipment~~;	GREEN – CEU Text including word “safety”
(b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;		(b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;	GREEN - EC Text
(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;	[AM 44] (c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, ***but which are essential to the equipment's function,*** that are ***designed*** to connect that equipment to an external device or ***to a reliable anchorage point, that are not designed*** to be permanently fixed ***and that do not require fastening works before use***;	(c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are ~~intended~~ **designed** to connect that equipment to an external device or ~~structure~~ **to a reliable anchorage point**, that are ~~removable~~ **not designed** ~~and not intended~~ to be permanently fixed ~~to a structure~~ **and that do not require fastening works before use**;	YELLOW **CEU text is preferable, but as a compromise EP AM 44 can be accepted.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. 'individually adapted PPE' means PPE produced in series where each item is manufactured to f it an individual user;	[AM 45] 2. ***'PPE type' means the series of PPE that is equal to the PPE described in the technical documentation and to the PPE subject to the EU type examination (in the case of category II or III)***;	~~2. 'individually adapted PPE' means PPE produced in series where each item is manufactured **as adjustable** to fit an individual user~~;	GREEN **deleted**
3. 'made-to-measure PPE' means PPE produced as a single unit to accommodate the special needs of an individual user according to a basic model, following the instructions of the designer of that basic model and respecting the range of permissible variations;		~~3. 'made-to-measure PPE' means PPE produced 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~~;	GREEN **deleted**
4. 'making available on the market' means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;		4. 'making available on the market' means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	GREEN - EC Text
5. 'placing on the market' means the first making available of PPE on the Union market;	[AM 46] 5. 'placing on the market' means the first making available of ***the PPE type*** on the Union market;	5. 'placing on the market' means the first making available of PPE on the Union market;	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
6. 'manufacturer' means any natural or legal person who designs or manufactures PPE or has it designed or manufactured, and markets it under his name or trademark; for the purposes of the second subparagraph of Article 8(2), the designer of a basic model of made-to-measure PPE shall be considered as a manufacturer;		6. 'manufacturer' means any natural or legal person who ~~designs or~~ manufactures PPE or has it designed or manufactured, and markets it under his name or trademark; ~~for the purposes of the second subparagraph of Article 8(2), the designer of a basic model of made-to-measure PPE shall be considered as a manufacturer~~;	GREEN – CEU Text
7. 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;		7. 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;	GREEN - EC Text
8. 'importer' means any natural or legal person established within the Union who places PPE from a third country on the Union market;		8. 'importer' means any natural or legal person established within the Union who places PPE from a third country on the Union market;	GREEN - EC Text
9. 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market;		9. 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market;	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
10. 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;		10. 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;	GREEN - EC Text
11. ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by PPE;		11. ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by PPE;	GREEN - EC Text
12. 'harmonised standard' means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;		12. 'harmonised standard' means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;	GREEN - EC Text
13. 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;		13. 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;	GREEN - EC Text
14. 'national accreditation body' means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;		14. 'national accreditation body' means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
15. 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Regulation relating to PPE have been fulfilled;		15. 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Regulation relating to PPE have been fulfilled;	GREEN - EC Text
16. 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;		16. 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;	GREEN - EC Text
17. 'recall' means any measure aimed at achieving the return of PPE that has already been made available to the end user;		17. 'recall' means any measure aimed at achieving the return of PPE that has already been made available to the end user;	GREEN - EC Text
18. 'withdrawal' means any measure aimed at preventing PPE in the supply chain from being made available on the market;		18. 'withdrawal' means any measure aimed at preventing PPE in the supply chain from being made available on the market;	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 47] ***18a. 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;***	**<u>18a. 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products</u>**	GREEN ***18a. 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;***
19. 'CE marking' means a marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;		19. 'CE marking' means a marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;	GREEN - EC Text
20. 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.		~~20. 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.~~	GREEN - moved up
	[AM 48] ***20a. 'Demonstration' means any showing of PPE, not in a hazardous setting, for promotional purposes;***		YELLOW **WP 29.05.2015. No support from MS.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 49] ***20b. 'Field test' means an event in which a non-certified PPE for which all the necessary test documents (tests carried out by accredited or authorised laboratories) supporting the technical file to ensure the protection of the wearer are available and met is made available in a very limited number to carry out a final evaluation. A field test is limited in time, with time and purpose defined and motivated before the start of the test and confirmed by the concerned parties;***		YELLOW **WP 29.05.2015. no support from MS and COMM who suppose there is no need for provisions that are outside of scope of this regulation.** **As a compromise, PCY suggests a modified text of Recital (10a).**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 4 *Making available on the market*	*Article 4* *Making available on the market*	*Article 4* *Making available on the market*	
Member States shall take all appropriate measures to ensure that PPE is made available on the market only if, where properly maintained and used for its intended purpose, it complies with this Regulation.		~~Member States shall take all appropriate measures to ensure that~~ PPE ~~is~~ **shall only be** made available on the market ~~only~~ if, where properly maintained and used for its intended purpose, it complies with this Regulation **and does not endanger the health or safety of ~~users, other~~ persons, domestic animals or property.**	GREEN – CEU Text
Article 5 *Essential health and safety requirements*	Article 5 Essential health and safety requirements	Article 5 Essential health and safety requirements	GREEN - EC Text
PPE shall fulfil the applicable essential health and safety requirements set out in Annex II.		PPE shall fulfil the applicable essential health and safety requirements set out in Annex II.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 6 *Provisions concerning the use of PPE*	*Article 6* *Provisions concerning the use of PPE*	*Article 6* *Provisions concerning the use of PPE*	GREEN - EC Text
This Regulation shall not affect Member States' entitlement, in particular when implementing Directive 89/656/EEC, to lay down requirements concerning the use of PPE provided that these requirements do not affect the design of PPE which is placed on the market in accordance with this Regulation.		This Regulation shall not affect Member States' entitlement, in particular when implementing Directive 89/656/EEC, to lay down requirements concerning the use of PPE provided that these requirements do not affect the design of PPE which is placed on the market in accordance with this Regulation.	GREEN - EC Text
Article 7 *Free movement*	[AM 50] Free movement***, demonstrations and field tests***	*Article 7* *Free movement*	YELLOW **WP 29.05.2015. no support from MS and COMM who suppose there is no need for provisions that are outside of scope of this regulation.** **As a compromise, PCY suggests a modified text of Recital (10a).**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
1. Member States shall not impede, for the aspects covered by this Regulation, the making available of PPE which complies with this Regulation in their territory.		1. Member States shall not impede, for the aspects covered by this Regulation, the making available of PPE which complies with this Regulation in their territory.	GREEN - EC Text
2. 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.	[AM 51] 2. At trade fairs, exhibitions, ***demonstrations or field tests***, Member States shall not prevent the showing of PPE which does not comply with this Regulation ***and is not available on the market. Field tests shall not be designed to test the protection performance of the PPE, but to evaluate other non-protective aspects such as comfort, ergonomics and design***.	2. At trade fairs, exhibitions, and demonstrations **or similar events**, 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.	YELLOW **WP 29.05.2015. no support from MS and COMM who suppose there is no need for provisions that are outside of scope of this regulation.** **As a compromise, PCY suggests a modified text of Recital (10a).**
During demonstrations, adequate measures shall be taken to ensure the protection of persons.	[AM 52] During demonstrations, ***and field tests,*** adequate measures shall be taken to ensure the protection of persons.	During demonstrations, adequate measures shall be taken to ensure the protection of persons.	YELLOW **WP 29.05.2015. no support from MS and COMM who suppose there is no need for provisions that are outside of scope of this regulation.** **As a compromise, PCY suggests a modified text of Recital (10a).**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 53] ***PPE covered by this paragraph may be displayed or field tested provided that a visible sign clearly indicates that the PPE does not comply with this Regulation.***		YELLOW **WP 29.05.2015. no support from MS and COMM who suppose there is no need for provisions that are outside of scope of this regulation.** **As a compromise, PCY suggests a modified text of Recital (10a).**
CHAPTER II	CHAPTER II	CHAPTER II	GREEN - EC Text
OBLIGATIONS OF ECONOMIC OPERATORS	OBLIGATIONS OF ECONOMIC OPERATORS	OBLIGATIONS OF ECONOMIC OPERATORS	GREEN - EC Text
Article 8 Obligations of manufacturers	*Article 8* Obligations of manufacturers	*Article 8* Obligations of manufacturers	GREEN - EC Text
1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and *safety requirements set out in Annex II.*		1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. Manufacturers shall draw up the technical documentation referred to in Annex III and carry out the applicable conformity assessment procedure(s) referred to in Article 18 or have them carried out.		2. Manufacturers shall draw up the technical documentation referred to in Annex III and carry out the applicable conformity assessment procedure(s) referred to in Article 18 or have them carried out.	GREEN - EC Text
The designer of a basic model of made-to-measure PPE shall draw up the technical documentation referred to in Annex III and carry out the EU type-examination set out in Annex V or have them carried out. Manufacturers of made-to-measure PPE shall carry out the conformity assessment procedure set out in Annex VI.		~~**In case of a made-to-measure PPE**~~, T~~the designer of a basic model of made-to-measure PPE shall draw up the technical documentation referred to in Annex III and~~**, if appropriate,** ~~carry out the EU type-examination set out in Annex V or have them carried out. Manufacturers of made-to-measure PPE shall carry out the conformity assessment procedures~~ set out ~~**in Annex IV or**~~ in Annex VI~~**, as appropriate**~~.	GREEN **deleted**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure(s), manufacturers shall draw up an EU declaration of conformity referred to in Article 15 and affix the CE marking referred to in Article 16.		Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure(s), manufacturers shall draw up an EU declaration of conformity referred to in Article 15 and affix the CE marking referred to in Article 16.	GREEN - EC Text
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.	[AM 54] 3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least ***five*** years after the PPE has been placed on the market.	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.	YELLOW

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.	[AM 55] 4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. ***When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and*** shall ***keep distributors informed of any such monitoring***.	4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account. **When deemed appropriate with regard to the risks presented by a PPE, manufacturers shall, to protect the health and safety of consumers and other end users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
5. Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or a document accompanying the PPE.	[AM 56] 5. Manufacturers shall ensure that the PPE which they place on the market bears ***either*** a type, batch or serial number or other element allowing its identification or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or a document accompanying the PPE.	5. Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging ~~**and in**~~ or **in** a document accompanying the PPE.	GREEN - CEU text
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.	[AM 57] 6. Manufacturers shall indicate, their name, registered trade name or registered trade mark***,*** the postal ***or e-mail*** address at which they can be contacted ***on the PPE***, its packaging or in a document accompanying the PPE. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in ***the*** language ***or languages of the Member State in which the PPE is to be marketed***.	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 ~~**and**~~ 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.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
7. Manufacturers shall ensure that the PPE is accompanied by the instructions set out in point 1.4 of Annex II in a language which can be easily understood by end-users, as determined by the Member State concerned.	[AM 58] 7. Manufacturers shall ensure that PPE is accompanied by the instructions set out in point 1.4 of Annex II in a language which can be easily understood by ***consumers and*** end-users, as determined by the Member State concerned ***in which the PPE is made available on the market. Such instructions, as well as any labelling, shall be clear, understandable and intelligible. Where PPE is available in packages containing multiple units, such instructions shall accompany each smallest commercially available unit.***	7. Manufacturers shall ensure that the PPE is accompanied by the instructions **and other information** set out in point 1.4 of Annex II in a language which can be easily understood by **consumers and other** end-users, as determined by the Member State concerned. **Such instructions, as well as any labelling, shall be clear, understandable, intelligible and legible.**	YELLOW CEU text remains, EP will consider whether they want to keep the final sentence of AM.58. MS did not support this AM (WP 26.05.). PCY nevertheless asks the Committee to receive a mandate for flexibility regarding the last sentence of IMCO amendments.
	[AM 59] ***7a. Manufacturers shall ensure that performance as recorded during relevant technical tests to check the levels of classes of protection provided by the PPE is available electronically or upon request.***		GREEN – CEU text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
8. Manufacturers shall ensure that the PPE is accompanied by a copy of the EU declaration of conformity referred to in Article (15)(2). Manufacturers may choose to fulfil this requirement by accompanying the PPE with the simplified EU declaration of conformity referred to in Article (15)(3). Where only the simplified EU declaration of conformity is provided, it shall be immediately followed by the exact internet address where the full text of the EU declaration of conformity can be obtained.	[AM 60] 8. Manufacturers shall ensure that the PPE is accompanied by a copy of the EU declaration of conformity referred to in Article (15)(2). Manufacturers may choose to fulfil this requirement by accompanying the PPE with the simplified EU declaration of conformity referred to in Article (15)(3) ***or include in the instructions and information the internet address where the EU declaration of conformity can be accessed***. Where only the simplified EU declaration of conformity is provided, it shall ***contain*** the exact internet address where the full text of the EU declaration of conformity can be obtained.	8. ~~Manufacturers shall ensure that the PPE is accompanied by a copy of the EU declaration of conformity referred to in Article (15)(2). Manufacturers may choose to fulfil this requirement by accompanying the PPE with the simplified EU declaration of conformity referred to in Article (15)(3). Where only the simplified EU declaration of conformity is provided, it shall be immediately followed by~~ **contain** ~~the exact internet address where the full text of the EU declaration of conformity can be obtained.~~ **The manufacturer shall either provide the EU declaration of conformity with the PPE or include in the instructions and information the internet address where the EU declaration of conformity can be accessed.**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
9. Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective measures to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the market surveillance authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in *particular, of the non-conformity and of any corrective measures taken.*		9.Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective measures to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the **competent national** ~~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.	GREEN - CEU text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the PPE, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.	[AM 61] 10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the PPE, in ***paper or electronic form, in*** a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.	10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation**, in paper or electronic form,** necessary to demonstrate the conformity of the PPE, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.	GREEN - CEU text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 9 *Authorised representatives*	*Article 9* *Authorised representatives*	*Article 9* *Authorised representatives*	GREEN - EC Text
1. A manufacturer may, by a written mandate, appoint an authorised representative. The obligations laid down in Article 8(1) and the obligation to draw up the technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.		1. A manufacturer may, by a written mandate, appoint an authorised representative. The obligations laid down in Article 8(1) and the obligation to draw up the technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.	GREEN - EC Text
2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:		2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:	GREEN - EC Text
(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;	[AM 62] *(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;*	(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;	YELLOW

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(b) further to a reasoned request from a national market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;		(b) further to a reasoned request from a **competent** national ~~market surveillance~~ authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;	GREEN – CEU Text
(c) cooperate with the national market surveillance authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised *representative's mandate.*		(c) cooperate with the **competent** national ~~market surveillance~~ authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.	GREEN - CEU Text
Article 10 *Obligations of importers*	*Article 10* *Obligations of importers*	*Article 10* *Obligations of importers*	GREEN - EC Text
1. Importers shall place only compliant PPE on the market.		1. Importers *shall place only compliant PPE on the market.*	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. 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).*		2. Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure~~(s)~~ referred to in Article 18 ~~have~~ **has** 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 **a copy of** ~~the EU declaration of conformity or a simplified EU declaration of conformity, and that it is accompanied by instructions **and other information** referred to in **point 1. 4 of Annex II** Article 8(7)~~ **the required documents**and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).	GREEN 2. Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure~~(s)~~ referred to in Article 18 ~~have~~ **has** 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 **a copy of** ~~the EU declaration of conformity or a simplified EU declaration of conformity, and that it is accompanied by instructions **and other information** referred to in **point 1. 4 of Annex II** Article 8(7)~~ **the required documents** and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Where an importer 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 place it on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.		Where an importer 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 place it on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.	GREEN - EC Text
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.	[AM 63] 3. Importers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted on its packaging or in a document accompanying the PPE. The contact details shall be in ***the official*** language ***or languages of the Member State(s) in which the PPE is to be marketed***.	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 ~~**and**~~ in a document accompanying the PPE. The contact details shall be in a language easily understood by end-users and market surveillance authorities.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.	[AM 64] 4. Importers shall ensure that PPE is accompanied by the instructions ***and safety information as set out*** in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned***. Where PPE is available in packages containing multiple units, such instructions shall accompany each smallest commercially available unit***.	4. Importers shall ensure that the PPE is accompanied by the instructions **and other information** 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.	YELLOW CEU text remains, EP will consider whether they want to keep the final sentence of AM.64. MS did not support this AM (WP 26.05.). PCY nevertheless asks the Committee to receive a mandate for flexibility regarding the last sentence of IMCO amendments.
5. Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.		5. Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 65] ***5a. When deemed appropriate with regard to the risks presented by PPE, importers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.***	**5a. When deemed appropriate with regard to the risks presented by a PPE, importers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.**	GREEN ***5a. When deemed appropriate with regard to the risks presented by PPE, importers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.	[AM 66] 6. Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the ***manufacturer and the competent national*** authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.	6. Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the **competent national** ~~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.	YELLOW **WP 29.05.2015. MS did not support AM as additional burden on business and not aligned with NLF.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
7. Importers shall, for at least 10 years after the PPE has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.	[AM 67] 7. Importers shall, for at least 10 years after the PPE has been placed on the market, ***ensure that*** a copy of the EU declaration of conformity ***and*** the technical documentation can be made available to ***the market surveillance*** authorities upon request.	7. Importers shall, for ~~at least~~ 10 years after the PPE has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.	YELLOW
8. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.		8. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.	GREEN - EC Text
Article 11 *Obligations of distributors*	*Article 11* *Obligations of distributors*	*Article 11* *Obligations of distributors*	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
1. When making PPE available on the market, distributors shall act with due care in *relation to the requirements of this Regulation.*		1. When making PPE available on the market, distributors shall act with due care in relation to the requirements of this Regulation.	GREEN - EC Text
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).	[AM 68] 2. Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the ***required documents,*** by the instructions ***and other information*** set out in point 1.4 of Annex II in a language which can be easily understood by ***consumers and other*** end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3).	2. Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied ~~by a copy of the EU declaration of conformity or a simplified EU declaration of conformity~~, **by the required documents** ~~that it is accompanied~~ **and** by the instructions **and other information** set out in point 1.4 of Annex II in a language which can be easily understood by **consumers and other** end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) **respectively**.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.		Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.	GREEN - EC Text
3. Distributors shall ensure that, while PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.		3. Distributors shall ensure that, while PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
4. Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with the requirements of this Regulation shall make sure that the necessary corrective measures are taken to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, distributors shall immediately inform the market surveillance authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.	[AM 69] 4. Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with the requirements of this Regulation shall make sure that the necessary corrective measures are taken to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, distributors shall immediately inform the ***manufacturer or importer and the competent national*** authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.	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 **competent national** ~~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.	YELLOW **WP 29.05.2015. MS did not support AM as additional burden on business and not aligned with NLF.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the PPE. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have made available on the market.		5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the PPE. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have made available on the market.	GREEN – EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 12 *Cases in which obligations of manufacturers apply to importers and distributors*	*Article 12* *Cases in which obligations of manufacturers apply to importers and distributors*	*Article 12* *Cases in which obligations of manufacturers apply to importers and distributors*	GREEN - EC Text
An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that the conformity with the applicable essential health and safety requirements set out in Annex II may be affected.	[AM 70] 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.	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** ~~the conformity~~ with **this Regulation** ~~the applicable essential health and safety requirements set out in Annex II~~ may be affected.	GREEN 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.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 13 *Identification of economic operators*	*Article 13* *Identification of economic operators*	*Article 13* *Identification of economic operators*	GREEN - EC Text
Economic operators shall, on request, identify the following to the market surveillance authorities:		Economic operators shall, on request, identify the following to the market surveillance authorities:	GREEN - EC Text
(a) any economic operator who has supplied them with PPE;		(a) any economic operator who has supplied them with PPE;	GREEN - EC Text
(b) any economic operator to whom they have supplied PPE.		(b) any economic operator to whom they have supplied PPE.	GREEN - EC Text
Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the PPE and for a period of 10 years after they have supplied the PPE.		Economic operators shall be able to present the information referred to in the first paragraph for ~~a period of~~ 10 years after they have been supplied with the PPE and for ~~a period of~~ 10 years after they have supplied the PPE.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
CHAPTER III	CHAPTER III	CHAPTER III	GREEN - EC Text
CONFORMITY OF THE PPE	CONFORMITY OF THE PPE	CONFORMITY OF THE PPE	GREEN - EC Text
Article 14 *Presumption of conformity*	*Article 14* *Presumption of conformity*	*Article 14* *Presumption of conformity*	GREEN - EC Text
PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof.		PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 15 *EU declaration of conformity*	*Article 15* *EU declaration of conformity*	*Article 15* *EU declaration of conformity*	GREEN - EC Text
1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.		1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 71] ***Unless otherwise provided for by Union harmonisation legislation, the withdrawal of a harmonised standard shall not invalidate existing certificates issued by notified bodies. Such withdrawal shall only concern the conformity that is conferred onto new conformity assessments that follow the new harmonised standard. Products produced in accordance with the existing certificate shall still benefit from continuing conformity with the essential requirements and may continue to be placed on the market until the end of the validity of the relevant certificates issued by notified bodies.***		YELLOW MS were strongly opposed to this AM (WP 26.05.)

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. The EU declaration of conformity shall have the structure and shall contain the elements set out in Annex IX and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is made available on the market.	[AM 72] 2. The EU declaration of conformity shall ***be based on the model*** structure ***set out in Annex IX,*** shall contain the elements ***specified in the relevant modules*** set out in ***Annexes IV, VI, VII and VIII*** and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is ***placed or*** made available on the market.	2. The EU declaration of conformity shall have the **model** structure ~~and shall contain the elements~~ set out in Annex IX**, shall contain the elements specified in the relevant modules set out in Annexes IV, VI, VII and VIII** and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is **placed or** made available on the market.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
3. A simplified EU declaration of conformity shall contain the elements set out in Annex X and it shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is made available on the market. The EU declaration of conformity accessible through internet address shall be available in the language or languages required by the Member State in which the PPE is made available on the market.	[AM 73] 3. A simplified EU declaration of conformity shall ***be based on the model structure*** set out in Annex X and it shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is made available on the market. The EU declaration of conformity accessible through internet address shall be available in the language or languages required by the Member State in which the PPE is ***placed or*** made available on the market.	3. ~~A simplified EU declaration of conformity shall contain the elements set out in Annex X and it shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is made available on the market. The EU declaration of conformity accessible through internet address shall be available in the language or languages required by the Member State in which the PPE is **placed or** made available on the market~~.	GREEN **deleted**
4. Where PPE is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.		4. Where PPE is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
5. By drawing up the EU declaration of conformity, the manufacturer shall assume the full responsibility for the conformity of the PPE with the requirements of this Regulation.	[AM 74] 5. By drawing up the EU declaration of conformity, the manufacturer shall assume the full responsibility for the ***compliance*** of the PPE with the requirements ***laid down in*** this Regulation.	5. By drawing up the EU declaration of conformity, the manufacturer shall assume ~~the full~~ responsibility for the **compliance** ~~conformity~~ of the PPE with the requirements **laid down in** ~~of~~ this Regulation.	GREEN – CEU Text 5. By drawing up the EU declaration of conformity, the manufacturer shall assume ~~the full~~ responsibility for the ***compliance*** of the PPE with the requirements ***laid down in*** this Regulation.
Article 16 *CE marking*	*Article 16* CE marking	*Article 16* **General principles of the CE marking**	
1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.		~~1.~~ The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	GREEN – CEU text
		Article 16 a **Rules and conditions for affixing the CE marking**	GREEN – CEU text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.		**1**.~~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.	GREEN – CEU text
3. The CE marking shall be affixed before the PPE is placed on the market. It may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.	[AM 75] 3. The CE marking shall be affixed before the PPE is placed on the market.	**2**. ~~3.~~ The CE marking shall be affixed before the PPE is placed on the market. ~~It may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.~~	GREEN - identical

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
4. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure for ensuring conformity to type based on product verification or the procedure for ensuring conformity to type based on quality assurance of the production process.	[AM 76] 4. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure for ensuring conformity to type based on product verification or the procedure for ensuring conformity to type based on quality assurance of the production process. ***The identification number of the notified body shall be affixed under its instructions, by the manufacturer or his authorised representative.***	**3.** ~~4.~~ For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure ~~for ensuring conformity to type based on product verification or the procedure for ensuring conformity to type based on quality assurance of the production process~~ **set out in Annex VII or VIII**. **The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	[AM 77] ***4a. The CE marking and, where applicable, the identification number of the notified body may be accompanied by a pictogram or other marking indicating the risk against which the PPE is intended to protect.***	**4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.**	GREEN – EP Text
	[AM 78] ***4b. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.***	**5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.**	GREEN
CHAPTER IV	CHAPTER IV	CHAPTER IV	GREEN - EC Text
CONFORMITY ASSESSMENT	CONFORMITY ASSESSMENT	CONFORMITY ASSESSMENT	GREEN - EC Text
Article 17 *Risk categories of PPE*	[AM 79] ***Deleted***	*Article 17* *Risk categories of PPE*	GREEN
The PPE shall be classified into the risk categories set out in Annex I.	***deleted***	The PPE shall be classified ~~into~~ **according to** the risk categories set out in Annex I.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 18 *Conformity assessment procedures*	*Article 18* *Conformity assessment procedures*	*Article 18* *Conformity assessment procedures*	GREEN - EC Text
The procedures to be followed, for each of the risk categories set out in Annex I, are as follows:		The procedures to be followed, for each of the risk categories set out in Annex I, are as follows:	GREEN - EC Text
(a) Category I: internal production control (module A) set out in Annex IV;		(a) Category I: internal production control (module A) set out in Annex IV;	GREEN - EC Text
(b) Category II: EU type-examination (module B) set out in Annex V that is followed by conformity to type based on internal production control (module C) set out in Annex VI;		(b) Category II: EU type-examination (module B) set out in Annex V that is followed by conformity to type based on internal production control (module C) set out in Annex VI;	GREEN - EC Text
(c) Category III: EU type-examination (module B) set out in Annex V and either of the following:		(c) Category III: EU type-examination (module B) set out in Annex V and either of the following:	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(1) conformity to type based on product verification (module F) set out in Annex VII;		(1) conformity to type based on **internal production control plus supervised product checks at random intervals** ~~product verification~~ (~~module F~~ **module C2**) set out in Annex VII;	GREEN – CEU Text
(2) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.		(2) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII. **By way of derogation, for PPE produced as a single unit to fit an individual user and classified according to Category III, the procedure mentioned under (b) may be followed.**	GREEN – CEU Text
CHAPTER V	CHAPTER V	CHAPTER V	GREEN - EC Text
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES	NOTIFICATION OF CONFORMITY ASSESSMENT BODIES	NOTIFICATION OF CONFORMITY ASSESSMENT BODIES	GREEN - EC Text
Article 19 *Notification*	*Article 19* *Notification*	*Article 19* *Notification*	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.		Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.	GREEN - EC Text
Article 20 *Notifying authorities*	*Article 20* *Notifying authorities*	*Article 20* *Notifying authorities*	GREEN - EC Text
1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 25.		1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 25.	GREEN - EC Text
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.		2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 21. In addition that body shall have arrangements to cover liabilities arising out of its activities.		3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 21. In addition that body shall have arrangements to cover liabilities arising out of its activities.	GREEN - EC Text
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.		4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.	GREEN - EC Text
Article 21 *Requirements relating to notifying authorities*	*Article 21* *Requirements relating to notifying authorities*	*Article 21* *Requirements relating to notifying authorities*	GREEN - EC Text
1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.		1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.		2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.	GREEN - EC Text
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.		3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.	GREEN - EC Text
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.		4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.	GREEN - EC Text
5. A notifying authority shall safeguard the confidentiality of the information it obtains.		5. A notifying authority shall safeguard the confidentiality of the information it obtains.	GREEN - EC Text
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.		6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 22 *Information obligation on notifying authorities*	*Article 22* *Information obligation on notifying authorities*	*Article 22* *Information obligation on notifying authorities*	GREEN - EC Text
Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.		Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.	GREEN - EC Text
The Commission shall make that information publicly available.		The Commission shall make that information publicly available.	GREEN - EC Text
Article 23 *Requirements relating to notified bodies*	*Article 23* *Requirements relating to notified bodies*	*Article 23* *Requirements relating to notified bodies*	GREEN - EC Text
1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.		1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. A conformity assessment body shall be established under national law and have legal personality.	[AM 80] 2. A conformity assessment body shall be established under national law ***of a Member State*** and have legal personality.	2. A conformity assessment body shall be established under national law **<u>of a Member State</u>** and have legal personality.	GREEN 2. A conformity assessment body shall be established under national law ***of a Member State*** and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses.		3. A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses.	GREEN - EC Text
A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of PPE which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.		A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of PPE which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, purchaser, owner, user or maintainer of the PPE which they assess, nor the authorised representative of any of those parties. This does not preclude the use of assessed PPE that are necessary for the operations of the conformity assessment body or the use of such PPE for personal purposes.		4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, purchaser, owner, user or maintainer of the PPE which they assess, nor the ~~authorised~~ representative of any of those parties. This does not preclude the use of assessed PPE that are necessary for the operations of the conformity assessment body or the use of such PPE for personal purposes.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly or indirectly involved in the design, manufacture, making available, use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.		A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly ~~or indirectly~~ involved in the design, manufacture, **marketing** ~~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.	GREEN – CEU Text
Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.		Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.		5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes V, VII and VIII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.		6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes V, VII and VIII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.	GREEN - EC Text
At all times and for each conformity assessment procedure and each kind of PPE for which it has been notified, a conformity assessment body shall have at its disposal the necessary:		At all times and for each conformity assessment procedure and each kind of PPE for which it has been notified, a conformity assessment body shall have at its disposal the necessary:	GREEN - EC Text
(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;		(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;		(b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;	GREEN - EC Text
(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.		(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.	GREEN - EC Text
A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.		A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
7. The personnel responsible for carrying out conformity assessment activities shall have the following:		7. The personnel responsible for carrying out conformity assessment activities shall have the following:	GREEN - EC Text
(a) sound technical and vocational training covering all the conformity assessment tasks for which the conformity assessment body has been notified;		(a) sound technical and vocational training covering all the conformity assessment tasks for which the conformity assessment body has been notified;	GREEN - EC Text
(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;		(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;	GREEN - EC Text
(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;	[AM 81] (c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the corresponding harmonised standards and of the relevant provisions of Union harmonisation legislation ***and of relevant national legislation***;	(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the corresponding harmonised standards and of the relevant provisions of Union harmonisation legislation **and of relevant national legislation**;	GREEN (c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the corresponding harmonised standards and of the relevant provisions of Union harmonisation legislation ***and of relevant national legislation***;

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.		(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.	GREEN - EC Text
8. The impartiality of the conformity assessment bodies, their management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.		8. The impartiality of the conformity assessment bodies, their management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.	GREEN - EC Text
The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.		The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.	[AM 82] 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.	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.	GREEN 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.
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the tasks under Annexes V, VII and VIII or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.		10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the tasks under Annexes V, VII and VIII ~~or any provision of national law giving effect to them~~, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.	[AM 83] 11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under ***Article 35 of*** this Regulation and shall apply ***the*** decisions and documents produced as a result of the work of that group.	11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established **under Article 35** ~~this Regulation~~ and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.	YELLOW **WP 29.05.2015.** **No support from MS to this AM**
Article 24 *Presumption of conformity of notified bodies*	*Article 24* *Presumption of conformity of notified bodies*	*Article 24* *Presumption of conformity of notified bodies*	GREEN - EC Text
Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set		Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set	GREEN - EC Text

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out in Article 23 in so far as the applicable harmonised standards cover those requirements.		out in Article 23 in so far as the applicable harmonised standards cover those requirements.	
Article 25 *Subsidiaries of and subcontracting by notified bodies*	*Article 25* *Subsidiaries of and subcontracting by notified bodies*	*Article 25* *Subsidiaries of and subcontracting by notified bodies*	GREEN - EC Text
1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 23 and shall inform the notifying authority accordingly.		1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 23 and shall inform the notifying authority accordingly.	GREEN - EC Text
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.		2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.	GREEN - EC Text
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.		3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.	GREEN - EC Text
4. Notified bodies shall keep at the		4. Notified bodies shall keep at the	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the tasks carried out by them under Annexes V, VII and VIII.		disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the **work** ~~tasks~~ carried out by them under Annexes V, VII and VIII.	
Article 26 *Application for notification*	*Article 26* *Application for notification*	*Article 26* *Application for notification*	GREEN - EC Text
1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.		1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.	GREEN - EC Text
2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment procedure(s) and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils	[AM 84] 2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment ***module or modules*** and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils	2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment **module or modules** ~~procedure(s)~~ and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity	GREEN 2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment ***module or modules*** and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
the requirements laid down in Article 23.	the requirements laid down in Article 23.	assessment body fulfils the requirements laid down in Article 23.	accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 23.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 23.		3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 23.	GREEN - EC Text
Article 27 *Notification procedure*	*Article 27* *Notification procedure*	*Article 27* *Notification procedure*	GREEN - EC Text
1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 23.		1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 23.	GREEN - EC Text
2. They shall notify the Commission and the other Member States using the electronic notification tool developed and		2. They shall notify the Commission and the other Member States using the electronic notification tool developed and	GREEN - EC Text

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managed by the Commission.		managed by the Commission.	
3. The notification shall include full details of the conformity assessment activities, the conformity assessment procedure(s) and the kinds of PPE concerned and the relevant attestation of competence.		3. The notification shall include full details of the conformity assessment activities, the conformity assessment **module or modules** ~~procedure(s)~~ and the kinds of PPE concerned and the relevant attestation of competence.	GREEN – CEU Text
4. Where a notification is not based on an accreditation certificate referred to in Article 26(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 23.	[AM 85] ***deleted***	4. Where a notification is not based on an accreditation certificate referred to in Article 26(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 23.	YELLOW
5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two		5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two	GREEN - EC Text

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weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.		weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.	
Only such a body shall be considered a notified body for the purposes of this Regulation.		Only such a body shall be considered a notified body for the purposes of this Regulation.	GREEN - EC Text
6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.		6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.	GREEN - EC Text
Article 28 *Identification numbers and lists of notified bodies*	*Article 28* *Identification numbers and lists of notified bodies*	*Article 28* *Identification numbers and lists of notified bodies*	GREEN - EC Text
1. The Commission shall assign an identification number to a notified body.		1. The Commission shall assign an identification number to a notified body.	GREEN - EC Text
It shall assign a single identification number even where the body is notified under several Union acts.		It shall assign a single identification number even where the body is notified under several Union acts.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.		2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.	GREEN - EC Text
The Commission shall ensure that the list is kept up to date.		The Commission shall ensure that the list is kept up to date.	GREEN - EC Text
Article 29 *Changes to notifications*	*Article 29* *Changes to notifications*	*Article 29* *Changes to notifications*	GREEN - EC Text
1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 23, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.		1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 23, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.	[AM 86] 2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request. ***The notifying Member State shall inform the manufacturers concerned and give them the possibility to select another notified body of their choice.***	2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.	YELLOW MS did not support the last sentence of EP AM 86. There is a publicly available data base where this info is accessible (NANDO), or this should be done by NB, not MS (WP 26.05.).
Article 30 *Challenge to the competence of notified bodies*	*Article 30* *Challenge to the competence of notified bodies*	*Article 30* *Challenge to the competence of notified bodies*	GREEN - EC Text
1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding the competence of a notified body or the continued fulfilment by a notified body of the		1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding the competence of a notified body or the continued fulfilment by a	GREEN - CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
requirements and responsibilities to which it is subject. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.		notified body of the requirements and responsibilities to which it is subject.	
	[AM 87] ***1a. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.***	**1a.** The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.	GREEN ***1a. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.***
2. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.		2. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.	GREEN - EC Text
3. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act		3. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an	GREEN - EC Text

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requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.		implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.	
4. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 38(2).		~~4.~~ That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 38(2).	GREEN - EC Text
Article 31 *Operational obligations of notified bodies*	*Article 31* *Operational obligations of notified bodies*	*Article 31* *Operational obligations of notified bodies*	GREEN - EC Text
1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII.		1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII.	GREEN - EC Text
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it		2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it	GREEN - EC Text

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operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.		operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.	
In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the PPE with the requirements of this Regulation.		In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the PPE with the requirements of this Regulation.	GREEN - EC Text
3. Where a notified body finds that the applicable essential health and safety requirements set out in Annex II or the corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.		3. Where a notified body finds that the ~~applicable~~ essential health and safety requirements set out in Annex II or the corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a conformity certificate **or approval decision**.	GREEN – CEU Text
4. Where, in the course of the monitoring of conformity following the issue of a certificate,		4. Where, in the course of the monitoring of conformity following the issue of a certificate	GREEN – CEU Text

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a notified body finds that a PPE no longer complies with the requirements laid down in this Regulation, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.		**or approval decision**, a notified body finds that a PPE no longer complies ~~with the requirements laid down in this Regulation~~, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.	
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw the certificate, as appropriate.		5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw the certificate **or approval decision**, as appropriate.	GREEN – CEU Text
Article 32 *Appeal against decisions of notified bodies*	*Article 32* *Appeal against decisions of notified bodies*	*Article 32* *Appeal against decisions of notified bodies*	GREEN - EC Text
Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.	[AM 88] Member States shall ensure that ***a transparent and accessible*** appeal procedure against decisions of the notified bodies is available.	~~Member States~~ **Notified bodies** shall ensure that an appeal procedure against **their** decisions ~~of the notified bodies~~ is available.	YELLOW ~~Member States~~ **Notified bodies** shall ensure that ~~**an**~~ ***a transparent and accessible*** appeal procedure against **their** decisions ~~of the notified bodies~~ is available.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Article 33 *Information obligation on notified bodies*	*Article 33* *Information obligation on notified bodies*	*Article 33* *Information obligation on notified bodies*	GREEN - EC Text
1. Notified bodies shall inform the notifying authority of the following:		1. Notified bodies shall inform the notifying authority of the following:	GREEN - EC Text
(a) any refusal, restriction, suspension or withdrawal of a certificate;		(a) any refusal, restriction, suspension or withdrawal of a certificate **or approval decision**;	GREEN – CEU Text
(b) any circumstances affecting the scope of and conditions for notification;		(b) any circumstances affecting the scope of **or** ~~and~~ conditions for notification;	GREEN – CEU Text
(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;		(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;	GREEN - EC Text
(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.		(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.	GREEN - EC Text

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2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to negative and, on request, positive conformity assessment results.		2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to negative and, on request, positive conformity assessment results.	GREEN – EC Text
Article 34 *Exchange of experience*	*Article 34* *Exchange of experience*	*Article 34* *Exchange of experience*	GREEN - EC Text
The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.		The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.	GREEN - EC Text
Article 35 *Coordination of notified bodies*	*Article 35* *Coordination of notified bodies*	*Article 35* *Coordination of notified bodies*	GREEN - EC Text
The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group of		The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group of	GREEN - EC Text

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notified bodies.		notified bodies.	
Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	[AM 89] 2. Notified ***bodies shall*** participate in the work of that group, directly or by means of designated representatives. ***In the event that a notified body does not comply with this requirement, the notification shall be suspended or withdrawn.***	**Notified bodies shall** ~~Member States shall ensure that the bodies notified by them~~ participate in the work of that group, directly or by means of designated representatives.	YELLOW
	[AM 90] ***CHAPTER VA***	**CHAPTER V A**	GREEN ***CHAPTER VA***
	UNION MARKET SURVEILLANCE, CONTROL OF PPE ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE	**UNION MARKET SURVEILLANCE, CONTROL OF PPE ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE**	GREEN ***UNION MARKET SURVEILLANCE, CONTROL OF PPE ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE***
	[AM 91] ***Article 35a***	**Article 35 a**	GREEN ***Article 35a***
	Union market surveillance and control of PPE entering the Union market	**Union market surveillance and control of PPE entering the Union market**	***Union market surveillance and control of PPE entering the Union market***

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	Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to PPE covered by Article 2(1) of this Regulation.	**Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to PPE covered by Article 2 (1) of this Regulation.**	***Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to PPE covered by Article 2(1) of this Regulation.***
	[AM 92] ***Article 35b*** ***Procedure for dealing with PPE presenting a risk at national level***	**Article 35 b** **Procedure for dealing with PPE presenting a risk at national level**	GREEN ***Article 35b*** ***Procedure for dealing with PPE presenting a risk at national level***
	1. Where the market surveillance authorities of one Member State have sufficient reason to believe that PPE covered by this Regulation presents a risk to the health or safety of users or, where applicable, of other persons, they shall carry out an evaluation in relation to the PPE concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.	**1. Where the market surveillance authorities of one Member State have sufficient reason to believe that PPE covered by this Regulation presents a risk to the health or safety of ~~users or, where applicable, of other~~ persons, they shall carry out an evaluation in relation to the PPE concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose**.	GREEN **1. Where the market surveillance authorities of one Member State have sufficient reason to believe that PPE covered by this Regulation presents a risk to the health or safety of ~~users or, where applicable, of other~~ persons, they shall carry out an evaluation in relation to the PPE concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities**

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			for that purpose.
	Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the PPE does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the PPE into compliance with those requirements, to withdraw the PPE from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.	**Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the PPE does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the PPE into compliance with those requirements, to withdraw the PPE from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.**	***Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the PPE does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the PPE into compliance with those requirements, to withdraw the PPE from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.***
	The market surveillance authorities shall inform the relevant notified body accordingly.	**The market surveillance authorities shall inform the relevant notified body accordingly.**	***The market surveillance authorities shall inform the relevant notified body accordingly.***
	Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.	**Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this**	***Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		paragraph.	
	2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.	**2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.**	***2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.***
	3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE concerned that it has made available on the market throughout the Union.	**3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE concerned that it has made available on the market throughout the Union.**	***3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE concerned that it has made available on the market throughout the Union.***
	4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the PPE's being made available on their national market, to withdraw the	**4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the PPE's being made available**	***4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the PPE's being made available on their national market, to withdraw the PPE***

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	PPE from that market or to recall it.	**on their national market, to withdraw the PPE from that market or to recall it.**	***from that market or to recall it.***
	The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.	**The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.**	***The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.***
	5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, the origin of the PPE, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:	**5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, the origin of the PPE, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:**	***5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, the origin of the PPE, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:***

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	(a) failure of the PPE to meet requirements relating to the health or safety of persons; or	**(a) failure of the PPE to meet requirements relating to the health or safety of persons; or**	***(a) failure of the PPE to meet requirements relating to the health or safety of persons; or***
	(b) shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.	**(b) shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.**	***(b) shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.***
	6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned, and, in the event of disagreement with the adopted national measure, of their objections.	**6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned, and, in the event of disagreement with the adopted national measure, of their objections.**	***6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned, and, in the event of disagreement with the adopted national measure, of their objections.***
	7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a	**7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the**	***7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a***

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	Member State, that measure shall be deemed justified.	**Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.**	***Member State, that measure shall be deemed justified.***
	8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the PPE from the market, are taken in respect of the PPE concerned without delay.	**8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the PPE from the market, are taken in respect of the PPE concerned without delay**.	***8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the PPE from the market, are taken in respect of the PPE concerned without delay.***
	[AM 93] ***Article 35c*** ***Union safeguard procedure***	**Article 35 c** **Union safeguard procedure**	GREEN ***Article 35c*** ***Union safeguard procedure***
	1. Where, on completion of the procedure set out in Article 35b(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the	**1. Where, on completion of the procedure set out in Article 35b (3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall**	***1. Where, on completion of the procedure set out in Article 35b(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the***

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	Commission shall adopt an implementing act determining whether the national measure is justified or not.	**evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.**	***Commission shall adopt an implementing act determining whether the national measure is justified or not.***
	The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.	**The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators**.	***The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.***
	2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant PPE is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.	**2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant PPE is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.**	***2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant PPE is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.***
	3. Where the national measure is considered justified and the non-	**3. Where the national measure is considered justified and the non-**	***3. Where the national measure is considered justified and the non-***

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	compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35b(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.	**compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35b (5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.**	***compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35b(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.***
	[AM 94] ***Article 35d*** ***Compliant PPE which presents a risk***	**Article 35 d** **Compliant PPE which presents a risk**	GREEN ***Article 35d*** ***Compliant PPE which presents a risk***
	1. Where, having carried out an evaluation under Article 35b(1), a Member State finds that although a PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to withdraw the PPE from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may	**1. Where, having carried out an evaluation under Article 35b (1), a Member State finds that although a PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to withdraw the PPE from the market or to recall it within a**	***1. Where, having carried out an evaluation under Article 35b(1), a Member State finds that although a PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to withdraw the PPE from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.***

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	prescribe.	**reasonable period, commensurate with the nature of the risk, as it may prescribe.**	
	2. The economic operator shall ensure that corrective action is taken in respect of all the PPE concerned that he has made available on the market throughout the Union.	**2. The economic operator shall ensure that corrective action is taken in respect of all the PPE concerned that he has made available on the market throughout the Union.**	***2. The economic operator shall ensure that corrective action is taken in respect of all the PPE concerned that he has made available on the market throughout the Union.***
	3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.	**3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.**	***3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.***
	4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures	**4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the**	***4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures***

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	taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.	**national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.**	***taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.***
	The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 38(2a).	**The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 38(3).**	***The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 38(2a).***
	On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 38(2b).	**On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 38(4).**	***On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 38(2b).***
	5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic	**5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the**	***5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic***

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	operator or operators.	**relevant economic operator or operators.**	***operator or operators.***
	[AM 95] ***Article 35e*** ***Formal non-compliance***	**Article 35 e** **Formal non-compliance**	YELLOW ***Article 35e*** ***Formal non-compliance***
	1. Without prejudice to Article 35b, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:	**1. Without prejudice to Article 35b, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:**	***1. Without prejudice to Article 35b, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:***
	(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Regulation or has not been affixed;	**(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Regulation or has not been affixed;**	***(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Regulation or has not been affixed;***
	(b) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 16 or has not been affixed;	**~~(b) the CE marking has not been affixed;~~**	PCY: Corresponds to (c) in CEU text, should be green as identical.

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	(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;	**(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 16 or has not been affixed;**	PCY: Corresponds to (e) in CEU text, should be green as identical
	(d) the technical documentation is either not available or not complete.	~~**(d) the EU declaration of conformity or the simplified declaration of conformity does not accompany the product**~~	PCY: Corresponds to (g) in CEU text, should be green as identical
	(e) the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;	**(e) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;**	PCY: Corresponds to (h) in CEU text, should be green as identical
	(f) any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.	~~**(f) the EU declaration of conformity has not been drawn up correctly;**~~	PCY: Corresponds to (i) in CEU text, should be green as identical
		(g) the technical documentation is either not available or not complete.	
		(h) the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;	

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		(i) any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.	
	2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.	**2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.**	GREEN ***2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.***
CHAPTER VI	CHAPTER VI	CHAPTER VI	GREEN
DELEGATED AND IMPLEMENTING ACTS	DELEGATED AND IMPLEMENTING ACTS	DELEGATED AND IMPLEMENTING ACTS	GREEN
Article 36 *Delegating power*	*Article 36* *Delegating power*	*Article 36* *Delegating power*	GREEN
The Commission shall be empowered to adopt delegated acts in accordance with Article 37 to amend Annex I with respect to the category of a specific risk, in response to technical progress and	[AM 96] ***In order to take into account technical progress and knowledge or new scientific evidence with respect to the category of a specific risk,*** the Commission shall be empowered	~~The Commission shall be empowered to adopt delegated acts in accordance with Article 37 to amend Annex I with respect to the category of a specific risk, in response to technical progress and~~	GREEN

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knowledge or new scientific evidence and by taking into account the conformity assessment procedure that need to be followed for each category, in accordance with Article 18.	to adopt delegated acts in accordance with Article 37 to amend Annex I ***by reclassifying the risk from one category to another.*** ***A Member State which has concerns about the classification of a risk into a*** specific risk ***category referred to in Article 17 shall immediately inform the Commission of its concerns and provide reasons in support.*** ***Prior to adopting a delegated act the Commission shall carry out a thorough assessment of the risks that require reclassification and of its impacts***.	~~knowledge or new scientific evidence and by taking into account the conformity assessment procedure that need to be followed for each category, in accordance with Article 18.~~	
		1. In order to take into account technical progress and knowledge or new scientific evidence with respect to the category of a specific risk, the Commission shall be empowered to adopt delegated acts in accordance with Article 37 in order to amend Annex I by reclassifying the risk from a	GREEN

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		category to another.	
		2. A Member State having concerns about the classification of a risk into a specific risk category referred to in Article 17 shall immediately inform the Commission of its concerns and provide reasons in support.	GREEN
		3. Prior to adopting a delegated act the Commission shall carry out a thorough assessment of the risks that require reclassification and its impacts.	GREEN
Article 37 *Exercise of the delegation*	*Article 37* *Exercise of the delegation*	*Article 37* *Exercise of the delegation*	GREEN - EC Text
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	GREEN - EC Text
2. The power to adopt delegated acts referred to in Article 36 shall		2. The power to adopt delegated acts referred to in Article 36 shall	GREEN - EC Text

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be conferred on the Commission for a period of five years from *[the date specified in Article 42(2)]*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period		be conferred on the Commission for a period of five years from *[7] ~~[the date specified in Article 42(2)]~~. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period,	
3. The delegation of powers referred to in Article 36 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect		3. The delegation of powers referred to in Article 36 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not	GREEN - EC Text

[7] ***) OJ, please insert the date of application of this Regulation.**

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the validity of any delegated acts already in force.		affect the validity of any delegated acts already in force.	
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	GREEN - EC Text
5. A delegated act adopted pursuant to Article 36 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.		5. A delegated act adopted pursuant to Article 36 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.	GREEN - EC Text
Article 38 *Committee procedure*	*Article 38* *Committee procedure*	*Article 38* *Committee procedure*	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	GREEN - EC Text
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) 182/2011 shall apply.		2. Where reference is made to this paragraph, Article 4 of Regulation (EU) 182/2011 shall apply.	GREEN - EC Text
	[AM 97] ***2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.***	**3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.**	GREEN ***2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.***
	[AM 98] ***2b. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.***	**4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.**	GREEN ***2b. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.***
		5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU)	RED

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		No 1025/2012 or by any other Union legislation.	
		The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.	RED
CHAPTER VII	CHAPTER VII	CHAPTER VII	
FINAL AND TRANSITIONAL PROVISIONS	FINAL AND TRANSITIONAL PROVISIONS	FINAL AND TRANSITIONAL PROVISIONS	
Article 39 *Penalties*	*Article 39* *Penalties*	*Article 39* *Penalties*	
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	[AM 99] Member States shall lay down the rules on penalties applicable to infringements ***by economic operators*** of the provisions of this Regulation and shall take all measures necessary to ensure that they are ***enforced. Such rules may include criminal penalties for serious***	Member States shall lay down the rules on penalties applicable to infringements **by economic operators** of the provisions of this Regulation and shall take all measures necessary to ensure that they are **enforced** ~~implemented.~~ **Such rules may include criminal penalties for serious**	GREEN – CEU Text **Text suggestion from PCY based on input from legal services:** (1) Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation ~~and shall take all measures necessary~~

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.	***infringements***. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them.	**infringements.** The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by [~~3~~**one** month~~s~~ prior to the date of application of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them.	~~to ensure that they are enforced~~. Such rules may include criminal penalties for serious infringements. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by [one month prior to the date of application of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them. (2) Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.
Article 40 *Repeal*	*Article 40* *Repeal*	*Article 40* *Repeal*	*Article 40* *Repeal*
Directive 89/686/EEC is repealed.		Directive 89/686/EEC is repealed **from**[*] [8].	GREEN – CEU Text
References to the repealed Directive shall be construed as		References to the repealed Directive shall be construed as	GREEN – EC Text

[8] **OJ: Please insert date of application of this Regulation.**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
references to this Regulation and shall be read in accordance with the correlation table in Annex XI.		references to this Regulation and shall be read in accordance with the correlation table in Annex XI.	
Article 41 *Transitional period*	*Article 41* *Transitional period*	*Article 41* *Transitional period*	
1. Without prejudice to paragraph 2, Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before *[1 year after the date of application]*		1. Without prejudice to paragraph 2, Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before [1 year after the date of application]	GREEN - EC Text
2. EC type-examination certificates issued under Directive 89/686/EEC shall remain valid until *[6 years after the date of application]* unless they expire before that date.		2. EC type-examination certificates **and approval decisions** issued under Directive 89/686/EEC shall remain valid until [~~6~~ **5** years after the date of application] unless they expire before that date.	GREEN – CEU Text
Article 42 *Entry into force and application*	*Article 42* *Entry into force and application*	*Article 42* *Entry into force and application*	
This Regulation shall enter into		*Article 42*	YELLOW

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
force on the twentieth day following its publication in the *Official Journal of the European Union*.		*Entry into force and application* This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.	**Text suggestion from PCY based on input from legal services:** **(1)** This Regulation shall enter into force on the twentieth day following its publication in the Official Journal of the European Union.
It shall apply from [*two years after entry into force*].		It shall apply from [two years after entry into force].	**(2)** It shall apply from [two years after entry into force].
However, Articles 19 to 35 shall apply from *[six months after entry into force]*.	[AM 100] However, Articles 19 to 35 ***and Articles 38 and 39*** shall apply from [six months after entry into force].	However, Articles 19 to **32** ~~35~~ **and Article 38** shall apply from [six months after entry into force].	**Text suggestion from PCY based on input from legal services:** **(3) By way of derogation from paragraph 2:** **(a)** Articles 19 to **35** and Article 38 shall apply from [six months after entry into force]. **(b) Paragraph 1 of Article 39 shall apply from [1 year and 11 months after entry into force].**
This Regulation shall be binding in		This Regulation shall be binding in	

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
its entirety and directly applicable in all Member States.		its entirety and directly applicable in all Member States.	
Done at Brussels,		Done at Brussels,	
ANNEX I	**ANNEX I**	**ANNEX I**	**ANNEX I**
Risk Categories of PPE	**Risk Categories of PPE**	**Risk Categories of PPE**	GREEN - EC Text
Category I			
PPE intended to protect users against minimal risks. Category I includes exclusively PPE intended to protect users against the following risks:		~~PPE intended to protect users against minimal risks~~. Category I includes exclusively ~~PPE intended to protect users against~~ the following **minimal** risks:	GREEN – CEU Text
(a) superficial mechanical injury;		(a) superficial mechanical injury;	GREEN - EC Text
(b) contact with water or cleaning materials of weak action;	[AM 101] (b) contact with water or cleaning materials of weak action ***or prolonged contact with water***;	(b) **contact with** cleaning materials of weak action or **prolonged** contact with water;	GREEN – CEU Text
(c) contact with hot surfaces not exceeding 50°C;		(c) contact with hot surfaces not exceeding 50°C;	GREEN - EC Text
(d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);		(d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(e) atmospheric conditions that are not of an extreme nature.		(e) atmospheric conditions that are not of an extreme nature.	GREEN - EC Text
Category II	*Category II*	*Category II*	GREEN - EC Text
Category II includes:	Category II includes:	Category II includes:	GREEN - EC Text
(a) PPE intended to protect users against risks other than those listed in Categories I and III;		~~(a)~~ ~~PPE~~ ~~intended to protect users against~~ risks other than those listed in Categories I and III;	GREEN – CEU Text
(b) made-to-measure PPE except where such PPE is intended to protect users against risks listed in Category I.	[AM 102] ***deleted***	~~(b) made-to-measure PPE except where such PPE is intended to protect users against risks listed in Category I~~.	GREEN ***deleted***
Category III	*Category III*	*Category III*	GREEN - EC Text
PPE intended to protect users against very serious risks. Category III includes exclusively PPE intended to protect users against the following risks:	[AM 103] PPE intended to protect users against very serious risks**,** ***such as death or irreversible damage to health***. Category III includes exclusively PPE intended to protect users against the following risks:	~~PPE intended to protect users against very serious risks~~ Category III includes exclusively ~~PPE intended to protect users against~~ the following risks ~~the following risks~~ **~~provided~~ that ~~they~~ may cause very serious consequences such as death or irreversible damage to health**:	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(a) inhalation of harmful substances;	[AM 104] (a) substances ***and mixtures which are hazardous to health***;	(a) ~~inhalation of harmful substances~~ **health hazardous substances and mixtures**;	GREEN – EP Text (a) substances ***and mixtures which are hazardous to health***;
	[AM 105] ***(aa) atmospheres with oxygen deficiency;***	**(a1) atmospheres with oxygen deficiency;**	GREEN
(b) aggressive chemicals;	[AM 106] (b) ***harmful biological agents***;	(b) ~~aggressive chemicals~~; **biological agents**	GREEN – EP Text (b) ***harmful biological agents***;
(c) ionising radiation;	[AM 108] (c) ionising radiation**,** ***laser radiation and radioactive contamination***;	(c) ionising radiation;	GREEN – CEU Text
(d) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100°C;		(d) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100°C;	GREEN - EC Text
(e) low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less;		(e) low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less;	GREEN - EC Text
(f) falling from a height;		(f) falling from a height;	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(g) electric shock and live working;		(g) electric shock and live working;	GREEN - EC Text
(h) drowning;		(h) drowning;	GREEN - EC Text
(i) cuts by hand-held chain-saws;		(i) cuts by hand-held chain-saws;	GREEN - EC Text
(j) high-pressure cutting;		(j) high-pressure ~~cutting~~ **jets**;	GREEN – CEU text
(k) bullet wounds or knife stabs;	[AM 109] (k) bullet wounds**,** ***explosive fragments*** or knife stabs;	(k) bullet wounds or knife stabs;	GREEN – CEU Text
(l) harmful noise.		(l) harmful noise	GREEN - EC Text
	[AM 107] ***(la) occupational risk of severe impact to the head.***		YELLOW **WP 29.05.2015. no support from MS to this AM, as there is no impact assessment on the consequences of this change.**
ANNEX II		**ANNEX II**	
Essential health and safety requirements		**Essential health and safety requirements**	GREEN
		PRELIMINARY REMARKS	GREEN
		1. The essential health and safety requirements laid down in this	GREEN

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		Regulation are compulsory.	
		2. Obligations under essential health and safety requirements apply only where the corresponding risk exists for the PPE in question	GREEN
		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.	GREEN
		4. The manufacturer is under an obligation to carry out a risk assessment in order to identify all the risks which apply to his PPE. He shall then design and manufacture it taking into account of the assessment.	YELLOW PCY: Question of “all the risks”, EP suggests “foreseeable” or “reasonable”. The concept "foreseeable"/"reasonable" is about the use of the product. The manufacturer has to assess the risks. Therefore PCY suggests to stick to the CEU text.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
			If there is a need to compromise, then the word "all" can be cut and the text refers to "identify the risks", but not "foreseeable" or "reasonable".
		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 foreseen uses. Where applicable, the health and safety of persons other than the user shall be ensured.	GREEN
1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE	1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE	1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE	GREEN - EC Text
PPE must provide adequate protection against the risks against which it is intended to protect.		PPE must provide adequate protection against the risks against which it is intended to protect.	GREEN - EC Text
1.1. Design principles	**1.1. Design principles**	**1.1. Design principles**	GREEN - EC Text
1.1.1. Ergonomics	*1.1.1. Ergonomics*	*1.1.1. Ergonomics*	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.		PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.	GREEN - EC Text
1.1.2. Levels and classes of protection		*1.1.2. Levels and classes of protection*	GREEN - EC Text
1.1.2.1. Optimum level of protection		1.1.2.1. Optimum level of protection	GREEN - EC Text
The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.		The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.	GREEN - EC Text
1.1.2.2. Classes of protection appropriate to different levels of		1.1.2.2. Classes of protection appropriate to different levels of	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
risk		risk	
Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.		Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.	GREEN - EC Text
1.2. Innocuousness of PPE		**1.2. Innocuousness of PPE**	GREEN - EC Text
1.2.1. Absence of inherent risks and other nuisance factors		*1.2.1. Absence of inherent risks and other nuisance factors*	GREEN - EC Text
PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.		PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.	GREEN - EC Text
1.2.1.1. Suitable constituent materials		1.2.1.1. Suitable constituent materials	GREEN - EC Text
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.	[AM 110] 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***	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.	YELLOW PCY: ANNEX II sets out exact essential health and safety requirements, that is why general

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	complying with the essential health and safety requirements laid down in this Regulation.		wordings should be deleted
1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user		1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user	GREEN - EC Text
Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.		Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.	GREEN - EC Text
1.2.1.3. Maximum permissible user impediment		1.2.1.3. Maximum permissible user impediment	GREEN - EC Text
PPE shall hinder as little as possible the actions to be carried out, the postures to be adopted and sensory perceptions; furthermore, use of the PPE must not engender actions which might endanger the user or other persons.		**Any impediment caused by** PPE ~~shall hinder as little as possible~~ **to** the actions to be carried out, the postures to be adopted and sensory perceptions **shall be minimised**; furthermore, use of the PPE must not engender actions which might endanger the user ~~or other persons~~.	GREEN – CEU Text
1.3. Comfort and effectiveness		**1.3. Comfort and effectiveness**	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
1.3.1. Adaptation of PPE to user morphology		*1.3.1. Adaptation of PPE to user morphology*	GREEN - EC Text
PPE must be designed and manufactured to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.		PPE must be designed and manufactured to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.	GREEN - EC Text
1.3.2. Lightness and strength		*1.3.2. Lightness and strength*	GREEN - EC Text
PPE must be as light as possible without prejudicing its strength and effectiveness.		PPE must be as light as possible without prejudicing its strength and effectiveness.	GREEN - EC Text
As well as the specific additional requirements which they must satisfy in order to provide adequate		As well as the specific additional requirements which they must satisfy in order to provide adequate	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
protection against the risks for which they are intended, PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.		protection against the risks for which they are intended, PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.	
1.3.3. Compatibility of types of PPE intended for simultaneous use		*1.3.3. Compatibility of **different** types of PPE intended for simultaneous use*	GREEN – CEU Text
If the same manufacturer places on the market several models of PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	[AM 111] If the same manufacturer places on the market several models of PPE of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	If the same manufacturer places on the market several ~~models of~~ PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	GREEN – CEU Text
	[AM 112] ***1.3.3a. Protective clothing containing removable protectors Protective clothing containing removable protectors constitute PPE and should be assessed as a combination during conformity assessment procedures.***	***1.3.4. Protective clothing containing removable protectors*** **Protective clothing containing removable protectors constitute a PPE and should be assessed as a combination during conformity assessment procedures.**	GREEN ***1.3.3a. Protective clothing containing removable protectors*** **Protective clothing containing removable protectors constitute PPE and should be assessed as a combination during conformity assessment procedures.**
1.4. Manufacturer's instructions	[AM 113] 1.4. Manufacturer's instructions ***and information***	**1.4. Manufacturer's instructions and information**	GREEN 1.4. Manufacturer's instructions

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
			and information
In addition to the name and address of the manufacturer or his authorized representative, or both, the instructions that must be drawn up by the manufacturer and supplied with the PPE when it is placed on the market must contain all relevant information on:		In addition to the name and address of the manufacturer ~~or his authorized representative, or both,~~ the instructions that must be ~~drawn up by the manufacturer and~~ supplied with the PPE ~~when it is placed on the market~~ must contain all relevant information on:	GREEN – CEU Text
(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 recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;	GREEN - EC Text
(b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE;	[AM 114] ***deleted***	(b) performance as recorded during **relevant** technical tests to check the levels or classes of protection provided by the PPE;	GREEN – CEU Text
(c) accessories that may be used with the PPE and the characteristics of appropriate spare parts;	[AM 115] (c) ***where applicable,*** accessories that may be used with the PPE and the characteristics of appropriate spare parts;	(c) accessories that may be used with the PPE and the characteristics of appropriate spare parts;	GREEN – EP Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;	[AM 116] (d) ***where applicable,*** the classes of protection appropriate to different levels of risk and the corresponding limits of use;	(d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;	GREEN – EP Text
(e) the date or period of obsolescence of the PPE or of certain of its components;	[AM 117] (e) ***where applicable,*** the date or period of obsolescence of the PPE or of certain of its components;	(e) **if applicable**, the **month/year** ~~date~~ or period of obsolescence of the PPE or of certain of its components;	GREEN – CEU Text
(f) the type of packaging suitable for transport;	[AM 118] (f) ***where applicable,*** the type of packaging suitable for transport;	(f) the type of packaging suitable for transport;	GREEN – EP Text
(g) the significance of any markings (see 2.12);		(g) the significance of any markings (see 2.12);	GREEN - EC Text
		(ga) information on the risk against which the PPE is designed to protect	GREEN – EP Text (Am.119)
(h) where applicable, the references of other Union harmonisation legislation;		(h) **the reference to this Regulation,** and where applicable, the references **to** ~~of~~ other Union harmonisation legislation;	GREEN – CEU Text
	[AM 119] ***(ha) risks against which the PPE is designed to protect;***		PCY: Should be moved up and green as identical to CEU (ga) point

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(i) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE.		(i) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE.,	GREEN - EC Text
	[AM 120] ***(ia) reference to the relevant harmonised standard(s) used, including the date of the standard(s) or references to the other technical specification used:***	**(ia) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used,**	GREEN **(ia) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used,**
	[AM 121] ***(ib) the internet address where the EU declaration of conformity can be accessed.***	**(ib) the internet address where the EU declaration of conformity can be accessed.**	GREEN ***(ib) the internet address where the EU declaration of conformity can be accessed.***
		The information referred to ~~under~~ in points (h), (i), (ia) and (ib) need not be contained in the instructions supplied by the manufacturer, if the EU declaration of conformity is accompanying the ~~product~~ PPE.	GREEN

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
These instructions, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.	[AM 122] These instructions, which must be precise and comprehensible ***and clearly legible***, must be provided at least in the official language(s) of the Member State of destination. ***Any additional relevant instructions for selection, use, care and maintenance of the PPE must be made available in a way that is easily accessible to any person concerned.***	~~These instructions, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination~~.	YELLOW PCY: Requirements on languages are stated in Article 8(7) (for manufacturers) in Article 10 (4) (for importers), in Article 11 (2) (for distributors), that is why it is deleted here.
2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE		2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE	GREEN - EC Text
2.1. PPE incorporating adjustment systems		**2.1. PPE incorporating adjustment systems**	GREEN - EC Text
If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do no become undone unintentionally in the foreseeable conditions of use.		If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do no**t** become undone unintentionally in the foreseeable conditions of use.	GREEN If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do no**t** become undone unintentionally in the foreseeable conditions of use.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2.2. PPE enclosing the parts of the body to be protected		**2.2. PPE enclosing the parts of the body to be protected**	GREEN - EC Text
As far as possible, PPE enclosing the parts of the body to be protected must be sufficiently ventilated to limit perspiration resulting from use; otherwise, it must be equipped with means of absorbing perspiration.	[AM 124] As far as possible, PPE enclosing the parts of the body to be protected must be ***designed*** to limit perspiration resulting from use; otherwise, means of absorbing perspiration ***must be incorporated***.	~~As far as possible,~~ PPE ~~enclosing the parts of the body to be protected~~ must be ~~sufficiently ventilated~~ **designed and manufactured in a way that** ~~to limit~~ perspiration resulting from use **is minimized**~~; otherwise, it must be equipped with means of absorbing perspiration~~.	YELLOW PCY: EP agreed on CEU text if the last part starting with "otherwise" would be restored in text. ~~As far as possible,~~ PPE ~~enclosing the parts of the body to be protected~~ must be ~~sufficiently ventilated~~ **designed and manufactured in a way that** ~~to limit~~ perspiration resulting from use **is minimized**; otherwise, it must be equipped with means of absorbing perspiration.
2.3. PPE for the face, eyes and respiratory system		**2.3. PPE for the face, eyes and respiratory system**	GREEN - EC Text
PPE for the face, eyes or respiratory system shall restrict the user's field of vision and sight as little as possible.		**Any restriction of the user's** ~~PPE for the~~ face, eyes**, field of vision** or respiratory system **by the PPE** shall ~~restrict the user's field of vision and sight as little as possible~~ **be minimised**.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
The screens for these types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.		The screens for these types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.	GREEN - EC Text
If necessary, they must be treated or provided with means to prevent misting up.		If necessary, they must be treated or provided with means to prevent misting up.	GREEN - EC Text
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.		Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.	GREEN - EC Text
2.4. PPE subject to ageing		**2.4. PPE subject to ageing**	GREEN - EC Text
If it is known that the design performance of new PPE may be significantly affected by ageing, the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly and unambiguously marked on each item of PPE or each interchangeable component for PPE placed on the market and on their packaging.		If it is known that the design performance of new PPE may be significantly affected by ageing, the ~~date~~ **month and year** of manufacture and/or, if possible, the ~~date~~ **month and year** of obsolescence, must be indelibly and unambiguously marked on each item of PPE ~~or each interchangeable component for PPE~~ placed on the market and on	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		their packaging.	
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.		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~~ **month and year**, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.	GREEN – CEU Text
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		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	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
instructions.		instructions.	
2.5. PPE which may be caught up during use		**2.5. PPE which may be caught up during use**	GREEN - EC Text
Where the foreseeable conditions of use include in particular the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must possess an appropriate resistance threshold above which a constituent part will break and eliminate the danger.		Where the foreseeable conditions of use include in particular the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must ~~possess an appropriate resistance threshold above~~ **be designed and manufactured in a way that** ~~which~~ a constituent part will break **or tear** and so eliminate~~e~~**ing** the danger.	GREEN – CEU Text
2.6. PPE for use in potentially explosive atmospheres		**2.6. PPE for use in potentially explosive atmospheres**	GREEN - EC Text
PPE intended for use in potentially explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.		PPE intended for use in potentially explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.	GREEN - EC Text
2.7. PPE intended for rapid intervention or to be put on or		**2.7. PPE intended for rapid intervention or to be put on or**	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
removed rapidly		**removed rapidly**	
These types of PPE must be designed and manufactured to minimize the time required for putting on and removing the equipment.		These types of PPE must be designed and manufactured to minimize the time required for putting on and removing the equipment.	GREEN - EC Text
Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate them quickly and easily.		Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate them quickly and easily.	GREEN - EC Text
2.8. PPE for intervention in very dangerous situations		**2.8. PPE for intervention in very dangerous situations**	GREEN - EC Text
The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.		The instructions supplied by the manufacturer with PPE for intervention in 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.	GREEN - EC Text
They must also describe the procedure to be adopted in order to verify that PPE is correctly		They must also describe the procedure to be adopted in order to verify that PPE is correctly	GREEN - EC Text

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adjusted and functional when worn by the user.		adjusted and functional when worn by the user.	
Where the PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.		Where the PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.	GREEN - EC Text
2.9. PPE incorporating components which can be adjusted or removed by the user		**2.9. PPE incorporating components which can be adjusted or removed by the user**	GREEN - EC Text
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.	[AM 125] 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.	Where PPE incorporates components which can be adjusted or removed by the user for replacement purposes, they must be designed and manufactured so that they can be easily attached**,** **adjusted** and removed without tools.	GREEN 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.
2.10. PPE for connection to complementary equipment external to the PPE		**2.10. PPE for connection to complementary equipment external to the PPE**	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Where PPE incorporates a connexion system permitting its connection to other, complementary equipment, the means of attachment must be designed and manufactured to enable it to be mounted only on appropriate equipment.		Where PPE incorporates a connexion system permitting its connection to other, complementary equipment, the means of attachment must be designed and manufactured to enable it to be mounted only on appropriate equipment.	GREEN - EC Text
2.11. PPE incorporating a fluid circulation system		**2.11. PPE incorporating a fluid circulation system**	GREEN - EC Text
Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.		Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.	GREEN - EC Text
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety		**2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety**	GREEN - EC Text
The identification markings or indicators directly or indirectly	[AM 126] The identification markings or indicators directly or	The identification markings or indicators directly or indirectly	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.	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***.	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 end-users, as determined by the Member State where the equipment is made available on the market.** ~~the official language(s) of the Member State where the equipment is to be used~~.	
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		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	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
manufacturer's instructions.		manufacturer's instructions.	
2.13. PPE capable of signalling the user's presence visually		**2.13. PPE capable of signalling the user's presence visually**	GREEN - EC Text
PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.		PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.	GREEN - EC Text
2.14. Multi-risk PPE		**2.14. Multi-risk PPE**	GREEN - EC Text
PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured to satisfy, in particular, the essential health and safety requirements specific to each of those risks.		PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured to satisfy, in particular, the essential health and safety requirements specific to each of those risks.	GREEN - EC Text
3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS		3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
3.1. Protection against mechanical impact		**3.1. Protection against mechanical impact**	GREEN - EC Text
3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle		*3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle*	GREEN - EC Text
PPE intended for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.		PPE intended for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.	GREEN - EC Text
3.1.2. Falls		*3.1.2. Falls*	GREEN - EC Text
3.1.2.1. Prevention of falls due to slipping		3.1.2.1. Prevention of falls due to slipping	GREEN - EC Text
The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means to		The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means to	GREEN – CEU Text

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ensure adequate grip by friction, studs or spikes, having regard to the nature or state of the ground surface.		ensure adequate grip ~~by friction, studs or spikes~~, having regard to the nature or state of the ~~ground~~ surface.	
3.1.2.2. Prevention of falls from a height		3.1.2.2. Prevention of falls from a height	GREEN - EC Text
PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimized to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.		PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimized to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.	GREEN - EC Text
It must also ensure that, after braking, the user is maintained in a correct position in which he may		It must also ensure that, after braking, the user is maintained in a correct position in which he may	GREEN - EC Text

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await help if necessary.		await help if necessary.	
The manufacturer's instructions must specify, in particular, all relevant information relating to:		The manufacturer's instructions must specify, in particular, all relevant information relating to:	GREEN - EC Text
(a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;		(a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;	GREEN - EC Text
(b) the proper way of putting on the body harness and of attaching the connexion system to the reliable anchorage point.		(b) the proper way of putting on the body harness and of attaching the connexion system to the reliable **external** anchorage point.	GREEN – CEU Text
3.1.3. Mechanical vibration		*3.1.3. Mechanical vibration*	GREEN - EC Text
PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.		PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.	GREEN - EC Text
3.2. Protection against static compression of part of the body		**3.2. Protection against static compression of part of the body**	GREEN - EC Text
PPE designed to protect part of the body against static compressive		PPE designed to protect part of the body against static compressive	GREEN - EC Text

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stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints.		stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints.	
3.3. Protection against mechanical injuries		**3.3. Protection against mechanical injuries**	GREEN - EC Text
PPE constituent materials and other components designed to protect all or part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also 3. 1) under the foreseeable conditions of use.		PPE constituent materials and other components designed to protect all or part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also 3. 1) under the foreseeable conditions of use.	GREEN - EC Text
3.4. Protection in the water	[AM 127] 3.4. Protection in ***liquids***	**3.4. Protection in ~~the water~~ liquids**	GREEN 3.4. Protection in ***liquids***
3.4.1. Prevention of drowning		*3.4.1. Prevention of drowning*	GREEN - EC Text
PPE designed to prevent drowning must be capable of returning to the		PPE designed to prevent drowning must be capable of returning to the	GREEN - EC Text

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surface as quickly as possible, without danger to his health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping him afloat in a position which permits breathing while awaiting help.		surface as quickly as possible, without danger to his health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping him afloat in a position which permits breathing while awaiting help.	
PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or orally.		PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or orally.	GREEN - EC Text
Under the foreseeable conditions of use:		Under the foreseeable conditions of use:	GREEN - EC Text
(a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;		(a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;	GREEN - EC Text
(b) inflatable PPE must be capable of inflating rapidly and fully.		(b) inflatable PPE must be capable of inflating rapidly and fully.	GREEN - EC Text
Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one		Where particular foreseeable conditions of use so require, certain types of PPE must also	GREEN - EC Text

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or more of the following additional requirements:		satisfy one or more of the following additional requirements:	
(a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;		(a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;	GREEN - EC Text
(b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;		(b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;	GREEN - EC Text
(c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring his immersion in it.		(c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring his immersion in it.	GREEN - EC Text
3.4.2. Buoyancy aids		*3.4.2. Buoyancy aids*	GREEN - EC Text
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	[AM 128] Clothing which will ensure an effective degree of buoyancy, depending on its foreseeable use, which is safe when worn and which affords positive support in ***liquids***. In foreseeable conditions of use, this PPE must not restrict the user's freedom of	Clothing ~~which will~~ **intended to** ensure an effective degree of buoyancy, depending on its foreseeable use, **shall be** ~~which is~~ safe when worn and **afford** ~~which affords~~ positive support in ~~water~~ **the liquid medium**. In foreseeable conditions of use, this PPE must	GREEN – CEU Text

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must enable him, in particular, to swim or take action to escape from danger or to rescue other persons.	movement but must enable him, in particular, to swim or take action to escape from danger or to rescue other persons.	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.	
3.5. Protection against the harmful effects of noise		**3.5. Protection against the harmful effects of noise**	GREEN - EC Text
PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not under any circumstances exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council1.		PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not ~~under any circumstances~~ exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council.	GREEN – CEU Text
Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.		Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.	GREEN - EC Text
3.6. Protection against heat and/or fire		**3.6. Protection against heat and/or fire**	GREEN - EC Text

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PPE designed to protect all or part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.		PPE designed to protect all or part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.	GREEN - EC Text
3.6.1. PPE constituent materials and other components		*3.6.1. PPE constituent materials and other components*	GREEN - EC Text
Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.		Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.	GREEN - EC Text
Where the outside of these materials and components must be reflective, its reflective power , must be appropriate to the intensity of the heat flux due to radiation in the infra-red range.		Where the outside of these materials and components must be reflective, its reflective power must be appropriate to the intensity of the heat flux due to radiation in the infra-red range.	GREEN – EC Text
Materials and other components of equipment intended for brief use in	[AM 129] Materials and other components of equipment intended	Materials and other components of equipment intended for brief use in	GREEN – CEU Text

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high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his PPE.	for brief use in high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material must also possess sufficient thermal capacity to ***protect from burns*** until after the user has left the danger area and removed his PPE.	high-temperature environments and of PPE which may be splashed by hot products such as ~~large quantities of~~ molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his PPE.	
PPE materials and other components which may be splashed by large amounts of hot products must also possess sufficient mechanical-impact absorbency (see 3.1).		PPE materials and other components which may be splashed by ~~large amounts of~~ hot products must also possess sufficient mechanical-impact absorbency (see 3.1).	GREEN – CEU Text
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.	[AM 130] 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	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.	GREEN – EP Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	propagation.		
3.6.2. Complete PPE ready for use		*3.6.2. Complete PPE ready for use*	GREEN - EC Text
Under the foreseeable conditions of use:		Under the foreseeable conditions of use:	GREEN - EC Text
(a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;		(a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;	GREEN - EC Text
(b) the PPE must if necessary prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.		(b) the PPE must if necessary prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.	GREEN - EC Text
If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not		If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not	GREEN - EC Text

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towards the user.		towards the user.	
If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.		If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	GREEN - EC Text
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.	[AM 131] 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.	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.	GREEN – CEU Text
3.7. Protection against cold		**3.7. Protection against cold**	GREEN - EC Text
PPE designed to protect all or part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.		PPE designed to protect all or part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
3.7.1. PPE constituent materials and other components		*3.7.1. PPE constituent materials and other components*	GREEN - EC Text
Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.		Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.	GREEN - EC Text
PPE materials and other components which may be splashed by large amounts of cold products must also possess sufficient mechanical-impact absorbency (see 3.1).		PPE materials and other components which may be splashed by ~~large amounts of~~ cold products must also possess sufficient mechanical-impact absorbency (see 3.1).	GREEN – CEU Text
3.7.2. Complete PPE ready for use		*3.7.2. Complete PPE ready for use*	GREEN - EC Text
Under the foreseeable conditions of use the following requirements apply:		Under the foreseeable conditions of use the following requirements apply:	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health-impairment threshold;		(a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health-impairment threshold;	GREEN - EC Text
(b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.		(b) PPE must 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.	GREEN - EC Text
If PPE incorporates a breathing device, this must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.		If PPE incorporates a breathing device, this must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.	GREEN - EC Text
The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the		The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
maximum permissible user exposure to the cold transmitted by the equipment.		maximum permissible user exposure to the cold transmitted by the equipment.	
3.8. Protection against electric shock		**3.8. Protection against electric shock**	GREEN - EC Text
3.8.1. Insulating equipment		*3.8.1. Insulating equipment*	GREEN - EC Text
PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.		PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.	GREEN - EC Text
To this end, the constituent materials and other components of these types of PPE must be so chosen or designed and incorporated as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimized and, at all events, below a		To this end, the constituent materials and other components of these types of PPE must be so chosen or designed and incorporated as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimized and, at all events, below a	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
maximum conventional permissible value which correlates with the tolerance threshold.		maximum conventional permissible value which correlates with the tolerance threshold.	
Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture; a space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.		Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture; a space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.	GREEN - EC Text
The manufacturer's instructions must indicate, in particular, the exclusive use for which these PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.		The manufacturer's instructions must indicate, in particular, the exclusive use for which these PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
3.8.2. Conductive equipment		*3.8.2. Conductive equipment*	GREEN - EC Text
Conductive PPE intended for live working at high voltages shall be designed and manufactured to ensure that there is no difference of potential between the user and the installations on which he is intervening.		Conductive PPE intended for live working at high voltages shall be designed and manufactured to ensure that there is no difference of potential between the user and the installations on which he is intervening.	GREEN - EC Text
3.9. Radiation protection		**3.9. Radiation protection**	GREEN - EC Text
3.9.1. Non-ionizing radiation		*3.9.1. Non-ionizing radiation*	GREEN - EC Text
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 use.		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 use.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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.	[AM 132] 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.***	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. **PPE designed to protect the skin against non-ionizing radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.**	GREEN – EP Text
Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.		Furthermore, the 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.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
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		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.	GREEN - EC Text
The relevant protection factor number must be marked on all specimens of filtering glasses by the manufacturer.	[AM 133] The relevant protection factor number must be marked on all specimens of filtering ***eye protective equipment*** by the manufacturer.	The relevant protection factor number must be marked on all specimens of filtering glasses by the manufacturer.	GREEN – EP Text
3.9.2. Ionizing radiation		*3.9.2. Ionizing radiation*	GREEN - EC Text
3.9.2.1. Protection against external radioactive contamination		3.9.2.1. Protection against external radioactive contamination	GREEN - EC Text
PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to		PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.		ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.	
Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurization systems designed to prevent the back-scattering of these contaminants.		Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurization systems designed to prevent the back-scattering of these contaminants.	GREEN - EC Text
Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these types of equipment.		Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these types of equipment.	GREEN - EC Text
3.9.2.2. Protection against external irradiation		3.9.2.2. Protection against external irradiation	GREEN - EC Text
PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak		PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak	GREEN - EC Text

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electron (e. g. beta) or weak photon (e. g. X, gamma) radiation.		electron (e. g. beta) or weak photon (e. g. X, gamma) radiation.	
The constituent materials and other components of these types of PPE must be so chosen or designed and incorporated as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see 1.3.2).		The constituent materials and other components of these types of PPE must be so chosen or designed and incorporated as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see 1.3.2).	GREEN - EC Text
PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.		PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.	GREEN - EC Text
3.10. Protection against dangerous substances and infectious agents	[AM 134] 3.10. Protection against substances and ***mixtures which are hazardous to health and against biological*** agents	**3.10. Protection against health hazardous ~~dangerous~~ substances and mixtures and biological ~~infectious~~ agents**	GREEN 3.10. Protection against substances and ***mixtures which are hazardous to health and against harmful biological*** agents
3.10.1. Respiratory protection		*3.10.1. Respiratory protection*	

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PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.		PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.	GREEN - EC Text
The breathable air supplied to the user by the PPE must be obtained by appropriate means, for example after filtration of the polluted air through the protective equipment or by supply from an external unpolluted source.		The breathable air supplied to the user by the PPE must be obtained by appropriate means, for example after filtration of the polluted air through the protective equipment or by supply from an external unpolluted source.	GREEN - EC Text
The constituent materials and other components of these types of PPE must be chosen or designed and incorporated to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.		The constituent materials and other components of these types of PPE must be chosen or designed and incorporated to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.	GREEN - EC Text
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification		The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification	GREEN - EC Text

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capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.		capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.	
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.		The PPE must bear ~~the manufacturer's identification mark and~~ details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.	GREEN – CEU Text
In the case of filtering equipment, the manufacturer's instructions must also, indicate the time limit for the storage of new filters kept in their original packaging.		In the case of filtering equipment, the manufacturer's instructions must also, indicate the time limit for the storage of new filters kept in their original packaging.	GREEN - EC Text
3.10.2. Protection against cutaneous and ocular contact		*3.10.2. Protection against cutaneous and ocular contact*	GREEN - EC Text
PPE intended to prevent the surface contact of all or part of the body with dangerous substances and infective agents must be capable of preventing the	[AM 135] PPE intended to prevent the surface contact of all or part of the body with substances and ***mixtures which are hazardous to health or biological agents*** must	PPE intended to prevent the surface contact of all or part of the body with **health hazardous** ~~dangerous~~ substances **and mixtures** and **biological** ~~infective~~ agents must be	GREEN PPE intended to prevent the surface contact of all or part of the body with substances and ***mixtures***

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penetration or permeation of such substances and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.	be capable of preventing the penetration or permeation of such substances ***and mixtures*** and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.	capable of preventing the penetration or permeation of such substances **and mixtures** and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.	***which are hazardous to health or harmful biological agents*** must be capable of preventing the penetration or permeation of such substances ***and mixtures*** and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.
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, 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.	GREEN - EC Text
Where, by virtue of their nature and the foreseeable conditions of their use, certain dangerous substances or infectious agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a	[AM 136] Where, by virtue of their nature and the foreseeable conditions of their use, certain ***health hazardous*** substances ***and mixtures which are hazardous to health or biological*** agents possess high penetrative power which limits the duration of the protection provided by the PPE in question,	Where, by virtue of their nature and the foreseeable conditions of their use, certain **health hazardous** ~~dangerous~~ substances **and mixtures** or **biological** ~~infectious~~ agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be	YELLOW PCY: One of references to „hazardous” should be deleted. Where, by virtue of their nature and the foreseeable conditions of their use, certain ***health hazardous*** substances ***and mixtures which are***

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view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	***hazardous to health or harmful biological*** agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.
3.11. Diving equipment		**3.11. Diving equipment**	GREEN - EC Text

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The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.		The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.	GREEN - EC Text
Where the foreseeable conditions of use so require, the diving equipment must comprise the following:		Where the foreseeable conditions of use so require, the diving equipment must comprise the following:	GREEN - EC Text
(a) a suit which protects the user against cold (see 3.7);		(a) a suit which protects the user against cold (see 3.7) **and/or pressure resulting from the depth of immersion (see 3.2.)**;	GREEN – CEU Text
(b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see 2.8);		(b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see 2.8);	GREEN - EC Text
(c) a life-saving device enabling the user to return to the surface.		(c) a life-saving device enabling the user to return to the surface **(see 3.4.1.).**	GREEN – CEU Text
ANNEX III		**ANNEX III**	

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
Technical documentation for PPE		**Technical documentation for PPE**	GREEN - EC Text
The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.		The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.	GREEN - EC Text
The technical documentation shall include at least the following elements:		The technical documentation shall include at least the following elements:	GREEN - EC Text
1. a complete description of the PPE and of its intended use;		1. a complete description of the PPE and of its intended use;	GREEN - EC Text
2. an assessment of the risk(s) against which the PPE is intended to protect;		2. an assessment of the risk(s) against which the PPE is intended to protect;	GREEN - EC Text
3. a list of the essential health and safety requirements that are applicable to the PPE;		3. a list of the essential health and safety requirements that are applicable to the PPE;	GREEN - EC Text
4. design and manufacturing drawings and schemes of the PPE and of its components, sub-		4. design and manufacturing drawings and schemes of the PPE and of its components, sub-	GREEN - EC Text

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assemblies, and circuits;		assemblies, and circuits;	
5. the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point 4 and of the operation of the PPE;		5. the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point 4 and of the operation of the PPE;	GREEN - EC Text
6. the reference(s) of the harmonised standard(s) referred to in Article 14 that have been applied for the design and manufacture of the PPE; in the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;		6. the reference(s) of the harmonised standard(s) referred to in Article 14 that have been applied for the design and manufacture of the PPE; in the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;	GREEN - EC Text
7. where harmonised standards have not been applied or only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;		7. where harmonised standards have not been applied or only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;	GREEN - EC Text
8. the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the		8. the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
applicable essential health and safety requirements;		applicable essential health and safety requirements;	
9. reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;		9. reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;	GREEN - EC Text
10. a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;		10. a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;	GREEN - EC Text
11. a copy of the manufacturer's instructions referred to in point 1.4 of Annex II;		11. a copy of the manufacturer's instructions **and information** ~~referred to~~ **set out** in point 1.4 of Annex II;	GREEN – CEU Text
12. for made-to-measure PPE, all the necessary instructions of the designer of the basic model for manufacturing made-to-measure PPE on the basis of the approved basic model.		12. for ~~made-to-measure PPE~~ **PPE produced as a single unit to fit an individual user**, all the necessary instructions ~~of the designer of the basic model~~ for manufacturing ~~made-to-measure~~ **such** PPE on the basis of the approved basic model.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		12a. **for PPE produced in series where each item is adapted to fit an individual user a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.**	GREEN
ANNEX IV		**ANNEX IV**	
Internal production control		**Internal production control**	GREEN - EC Text
(Module A)		**(Module A)**	GREEN - EC Text
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.	[AM 137] 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***.	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 **of this Regulation** ~~referred to in Article 5 and set out in Annex II~~.	GREEN 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***.

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. Technical documentation		2. Technical documentation	GREEN - EC Text
The manufacturer shall establish the technical documentation described in Annex III. The documentation shall make it possible to assess the conformity of the PPE to the applicable requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the PPE.	[AM 138] The manufacturer shall establish the technical documentation described in Annex III.	The manufacturer shall establish the technical documentation described in Annex III. ~~The documentation shall make it possible to assess the conformity of the PPE to the applicable requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the PPE.~~	GREEN The manufacturer shall establish the technical documentation described in Annex III.
3. Manufacturing		3. Manufacturing	GREEN - EC Text
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured PPE with the technical documentation referred to		The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured PPE with the technical documentation referred to	GREEN – CEU Text

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in point 2 and with the applicable essential health and safety requirements.		in point 2 and with the applicable ~~essential health and safety~~ **requirements of this Regulation**.	
4. CE marking and EU declaration of conformity		4. CE marking and EU declaration of conformity	GREEN - EC Text
4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable essential health and safety requirements.	[AM 139] 4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable ***requirements of this Regulation***.	4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable ~~essential health and safety~~ requirements **of this Regulation**.	GREEN 4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable ***requirements of this Regulation***.
4.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.		4.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.	GREEN - EC Text
A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.		A copy of the EU declaration of conformity ~~or a simplified EU declaration of conformity~~ shall ~~accompany every PPE~~ **be made available to the relevant**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		authorities upon request.	
5. Authorised representative		5. Authorised representative	GREEN - EC Text
The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.		The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.	GREEN - EC Text
ANNEX V		**ANNEX V**	
EU type-examination		**EU type-examination**	GREEN - EC Text
(Module B)		**(Module B)**	GREEN - EC Text
1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.		1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the ~~applicable essential health and safety~~ requirements ~~referred to in Article 5 and set out in Annex II~~ **of this Regulation**.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. EU type-examination shall be carried out with the examination of a specimen, representative of the production envisaged, of the complete PPE (production type).		2. EU type-examination shall be carried out ~~with the~~ **by assessment of the adequacy of the technical design of the PPE through examination of the technical documentation, plus** examination of a specimen, representative of the production envisaged, of the complete PPE (production type).	GREEN – CEU Text
3. Application for EU type-examination		3. Application for EU type-examination	GREEN - EC Text
The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice.		The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice	GREEN - EC Text
The application shall include:		The application shall include:	GREEN - EC Text
(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;		(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;	GREEN - EC Text
(b) a written declaration that the same application has not been lodged with any other notified		(b) a written declaration that the same application has not been lodged with any other notified	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
body;		body;	
(c) the technical documentation described in Annex III. The documentation shall make it possible to assess the conformity of the PPE to the applicable requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the PPE;		(c) the technical documentation described in Annex III. ~~The documentation shall make it possible to assess the conformity of the PPE to the applicable requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the PPE~~;	GREEN – CEU Text
(d) the specimen(s) of the PPE representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme. For individually adapted PPE, specimens shall be provided that are representative of the range of different users;		(d) the specimen(s) of the PPE representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme. For ~~individually adapted~~ PPE **produced in series where each item is adapted to fit an individual user,** specimens shall be provided that are representative of the range of different users, **for PPE produced as a single unit to accommodate**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		the special needs of an individual user, a basic model shall be provided;	
(e) for individually adapted PPE, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.	[AM 140] (e) for ***made-to-measure*** PPE, a description of the ***possible variations and the*** measures to be taken by the ***economic operator*** during the production process to ensure that each item of PPE complies with the approved ***PPE*** type and with the applicable health and safety requirements ***laid down in Annex II***.	~~(e) for individually adapted PPE~~ **~~produced in series where each item is manufactured to fit an individual user~~** ~~a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements~~.	GREEN – CEU Text
4. EU type-examination		4. EU type-examination	GREEN - EC Text
The notified body shall:		The notified body shall:	GREEN - EC Text
(a) examine the technical documentation to assess the adequacy of the technical design of the PPE;		(a) examine the technical documentation to assess the adequacy of the technical design of the PPE; **in doing so, point 10 of Annex III need not to be taken into account.**	GREEN – CEU Text
(b) for individually adapted PPE, examine the description of the		(b) for ~~individually adapted~~ PPE **produced in series where each**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
measures referred to in point 3 to assess their adequacy;		**item is adapted to fit an individual user**, examine the description of the measures ~~referred to in point 3~~ to assess their adequacy;	
(c) for made-to-measure PPE, examine the instructions of the designer of the basic model for manufacturing made-to-measure PPE on the basis of the approved basic model to assess their adequacy;		(c) for ~~made-to-measure~~ PPE **produced as a single unit to fit an individual user**, examine the instructions ~~of the designer of the basic model~~ for manufacturing **such** ~~made-to-measure~~ PPE on the basis of the approved basic model to assess their adequacy;	GREEN – CEU Tex
(d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed in accordance with other technical specifications;		(d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed in accordance with other technical specifications;	GREEN - EC Text
(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen		(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
to apply the solutions in the relevant harmonised standards, these have been applied correctly;		to apply the solutions in the relevant harmonised standards, these have been applied correctly;	
(f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.		(f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.	GREEN - EC Text
5. Evaluation report		5. Evaluation report	GREEN - EC Text
The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.		The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
6. EU type-examination certificate		6. EU type-examination certificate	GREEN - EC Text
6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.		6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.	GREEN - EC Text
	[AM 141] ***The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall be not more than five years.***		YELLOW **PCY: MS flexible, EP AM 141 can be accepted.**
6.2. That certificate shall contain at least the following information:		6.2. That certificate shall contain at least the following information:	GREEN - EC Text
(a) the name and identification number of the notified body;		(a) the name and identification number of the notified body;	GREEN - EC Text
(b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;		(b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;	GREEN - EC Text
(c) identification of the PPE covered by the certificate (type,		(c) identification of the PPE covered by the certificate **(** type	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
model, manufacturer's reference);		**number** ~~model, manufacturer's reference~~);	
(d) a statement that the PPE complies with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II;		(d) a statement that the PPE **type** complies with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II;	GREEN – CEU Text
(e) where harmonised standards have been fully or partially applied, the references of those standards or parts thereof;		(e) where harmonised standards have been fully or partially applied, the references of those standards or parts thereof;	GREEN - EC Text
(f) where other technical specifications have been applied, their references;		(f) where other technical specifications have been applied, their references;	GREEN - EC Text
(g) where applicable, the performance level(s) or protection class of the PPE;		(g) where applicable, the performance level(s) or protection class of the PPE;	GREEN - EC Text
(h) for made-to-measure PPE, the range of permissible variations of relevant parameters for made-to-measure PPE based on the approved basic model;		(h) for ~~made-to-measure~~ PPE **produced as a single unit to fit an individual user**, the range of permissible variations of relevant parameters ~~for made-to-measure PPE~~ based on the approved basic model;	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(i) the date of issue and, where appropriate, the date(s) of renewal;	[AM 142] (i) the date of issue***, the date of expiry*** and, where appropriate, the date(s) of renewal;	(i) the date of issue and, where appropriate, the date(s) of renewal;	YELLOW **PCY: MS flexible, EP AM 142 can be accepted.**
(j) the date of expiry (a maximum of five years after the date of issue or the date of the last renewal);	[AM 143] ***deleted***	(j) the date of expiry (a maximum of five years after the date of issue or the date of the last renewal);	YELLOW **PCY: MS flexible, EP AM 143 can be accepted.**
(k) any conditions attached to the issue of the certificate;		(k) any conditions attached to the issue of the certificate;	GREEN - EC Text
(l) for category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in Article 18.		(l) for category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in Article 18 **point (c).**	GREEN – CEU Text
6.3. The EU type-examination certificate may have one or more annexes attached.		6.3. The EU type-examination certificate may have one or more annexes attached.	GREEN - EC Text
6.4. For made-to-measure PPE, if the person to whom the EU type-examination certificate was issued is not the manufacturer of the made-to-measure PPE:		~~6.4. For made-to-measure PPE, if the person to whom the EU type-examination certificate was issued is not the manufacturer of the made-to-measure PPE:~~	GREEN **deleted**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
(a) the manufacturer of the made-to-measure PPE shall have the written authorisation of the certificate holder to use that certificate;		~~(a) the manufacturer of the made-to-measure PPE shall have the written authorisation of the certificate holder to use that certificate;~~	GREEN **deleted**
(b) the certificate holder shall provide the manufacturer of the made-to-measure PPE with the instructions referred to in point 12 of Annex III.		~~(b) the certificate holder shall provide the manufacturer of the made-to-measure PPE with the instructions referred to in point 12 of Annex III.~~	GREEN **deleted**
6.5. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.		6.5. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.	GREEN - EC Text
7. Review of the EU type-examination certificate		7. Review of the EU type-examination certificate	GREEN - EC Text
7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable	[AM 144] 7.1 The notified body shall keep itself ***appraised*** of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with	7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable	YELLOW PCY: EP text agreed, but **reference to Annex 5 seems incorrect, to be checked**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.	the applicable essential health and safety requirements, and ***without prejudice to paragraph 1a of point 6.1 of Annex V*** shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.	essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.	
7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.		7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type **and of all modifications of the technical documentation** that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.	GREEN – CEU Text
7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the		7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
state of the art.		state of the art.	
7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate:		7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate:	GREEN - EC Text
(a) in case of a modification to the PPE referred to in point 7.2;		(a) in case of a modification to the PPE referred to in point 7.2;	GREEN - EC Text PCY: To take on board EP AM 145, PCY suggests following amendment to the text: (a) in case of a modification to the ~~PPE~~ **approved type** referred to in point 7.2;
(b) in case of a change in the state of the art referred to in point 7.3;		(b) in case of a change in the state of the art referred to in point 7.3;	GREEN - EC Text
(c) at the latest, before the date of expiry of the certificate.		(c) at the latest, before the date of expiry of the certificate.	GREEN - EC Text PCY: To take on board EP AM 145, PCY suggests following amendment to the text: (c) at the latest, before the date of expiry of the certificate. **The manufacturer shall ensure**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
			that his application is submitted on time in order to allow the notified body to fulfil its tasks before the expiry date of the EU type-examination certificate, but not more than 12 months before that date.
7.5. The notified body shall examine the PPE and carry out any tests necessary to ensure that the PPE continues to fulfil the applicable essential health and safety requirements. In that case, it shall renew the EU type-examination certificate.		7.5. The notified body shall examine the PPE **type** and carry out any tests necessary to ensure that the PPE continues to fulfil the applicable essential health and safety requirements. In that case, it shall renew the EU type-examination certificate.	GREEN – CEU Text PCY: To take on board EP AM 145, PCY suggests following amendment to the text: 7.5. The notified body shall examine the PPE type and carry out any tests necessary to ensure that the ~~PPE~~ **approved type** continues to fulfil the applicable essential health and safety requirements. In that case, it shall renew the EU type-examination certificate. **The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.**
	[AM 145] ***7.5a At the earliest 12 months and at the latest 6 months prior to the expiry date, the***		YELLOW **PCY: MS flexible, however, text**

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	manufacturer may inform the notified body that a simplified procedure shall apply for the review, as no modification to the PPE referred to in point 7.2 has occurred. The manufacturer shall supply the notified body with the following information: ***(a) confirmation of the current company name and address;*** ***(b) confirmation that there has been no modification to the product, including materials, sub-components or sub-assemblies, nor to the solutions applied in the relevant harmonised standards or in other technical specifications;*** ***(c) where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer; and*** ***(d) for category III products, information on the status of the product verification or quality assurance of the production***		**needs to be more precise (with current text no support). To take on board EP AM 145, PCY suggests following amendment to the text:** 7.5a ~~At the earliest 12 months and at the latest 6 months prior to the expiry date~~ **Where the conditions of points (a) and (b) of point 7.4 are not met**, the manufacturer may ~~inform~~ **ask** the notified body ~~that a~~ **to apply a** simplified **review** procedure~~ shall apply for the review, as no modification to the PPE referred to in point 7.2 has occurred~~. The manufacturer shall supply the notified body with the following ~~information~~: (a) ~~confirmation of the current company~~ **his** name and address **and data identifying the EU type-examination certificate concerned**; (b) confirmation that there has been no modification to the ~~product~~ **approved type as referred to in point 7.2**, including materials, sub-

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
	process. ***When the notified body has confirmed that no change in the state of the art referred to in point 7.3 has occurred, the EU type-examination laid down in point 4 of Annex V shall not be carried out and the notified body shall renew the EU-type examination certificate. The notified body shall ensure that the simplified procedure for renewal is finalised before the expiry date of the EU type-examination certificate. The reference of the certificate will remain unchanged.*** ***The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.*** ***If any of the information is missing or if a change in the state of the art referred to in point 7.3 has occurred, the procedure in point 7.5 shall apply.***		components or sub-assemblies, nor to the ~~solutions applied in the~~ relevant harmonised standards or ~~in~~ other technical specifications **applied**; (c) ~~where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer~~ **confirmation that there has been no change in the state of the art and no modification to the approved type as referred to in point 7.3**; and (d) for category III products, information on the ~~status~~ **results** of the **supervised** product ~~verification~~ **checks at random intervals carried out in accordance with Annex VII** or **on the results of audits of his** quality ~~assurance of the production process~~ **system carried out in accordance with Annex VIII**. When the notified body has confirmed that no change in the

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
			state of the art **and no modification to the approved type** referred to in point 7.3 has occurred, the ~~EU type-examination laid down~~ **examinations and tests referred to** in point ~~4~~ **7.5** ~~of Annex V~~ shall not be carried out and the notified body shall renew the EU-type examination certificate. ~~The notified body shall ensure that the simplified procedure for renewal is finalised before the expiry date of the EU type-examination certificate. The reference of the certificate will remain unchanged.~~ ~~The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.~~ If ~~any of the information is missing or if~~ **the notified body finds that** a change in the state of the art referred to in point 7.3 has occurred, the procedure in point 7.5 shall apply.
7.6. If, following the review, the notified body concludes that the		7.6. If, following the review, the notified body concludes that the	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.		EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.	
8. The notified body shall inform its notifying authority concerning the EU typeexamination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.		8. ~~The~~ **Each** notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.	GREEN – CEU Text
The notified body shall inform the other notified bodies concerning the EU typeexamination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.		~~The~~ **Each** notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On a reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.		The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On a reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.	GREEN - EC Text
The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until 5 years after the expiry of the validity of that certificate.		The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until 5 years after the expiry of the validity of that certificate.	GREEN - EC Text
9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been placed on the market.		9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been placed on the market.	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.		10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7**.2, 7.4** and 9, provided that they are specified in the mandate.	GREEN – CEU Text
ANNEX VI		**ANNEX VI**	
Conformity to type based on internal production control (Module C)		**Conformity to type based on internal production control(Module C)**	GREEN - EC Text
1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.		1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable ~~essential health and safety~~ requirements **of this Regulation** ~~referred to in Article 5 and set out in Annex II.~~	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
2. Manufacturing		2. Manufacturing	
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.		The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable ~~essential health and safety~~ requirements **of this Regulation**.	GREEN – CEU Text
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.	[AM 146] For made-to-measure PPE the manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured made-to-measure PPE with the basic model described in the EU type-examination certificate and with the applicable ***requirements of this Regulation***.	~~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 **of this Regulation**.~~	GREEN **deleted**
3. CE marking and EU declaration of conformity		3. CE marking and EU declaration of conformity	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
3.1. The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements.		3.1. The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable ~~essential health and safety~~ requirements **of this Regulation**.	GREEN – CEU Text
3.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.		3.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.	YELLOW
A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.		A copy of the EU declaration of conformity ~~or a simplified EU declaration of conformity~~ shall **be made available to the relevant authorities upon request** ~~accompany every PPE~~.	GREEN – CEU Text
4. Authorised representative		4. Authorised representative	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.		The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.	GREEN - EC Text
ANNEX VII		**ANNEX VII**	
Conformity to type based on product verification **(Module F)**		**Conformity to type based on internal production control plus supervised product checks at random intervals ~~product verification~~ (Module ~~F~~ C 2)**	YELLOW
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	[AM 147] 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***	1. Conformity to type based on **internal production control plus supervised product checks at random intervals** ~~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-	YELLOW

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
referred to in Article 5 and set out in AnnexII.	***Regulation***.	examination certificate and satisfies the applicable ~~essential health and safety~~ requirements ~~referred to in Article 5 and set out in Annex II~~ **of this Regulation**.	
2. Manufacturing		2. Manufacturing	GREEN - EC Text
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.		The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable ~~essential health and safety~~ requirements **of this Regulation**.	YELLOW
3. Application for product verification		3. Application for **supervised product checks at random intervals** ~~product verification~~	YELLOW
Before placing PPE on the market, the manufacturer shall lodge an application for product verification with a single notified body of his choice.		Before placing PPE on the market, the manufacturer shall lodge an application for **supervised product checks at random intervals** ~~product verification~~ with a single notified body of his choice.	YELLOW

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
The application shall include the following:		The application shall include the following:	GREEN - EC Text
(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;		(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;	GREEN - EC Text
(b) a written declaration that the same application has not been lodged with any other notified body;		(b) a written declaration that the same application has not been lodged with any other notified body;	GREEN - EC Text
(c) the identification of the PPE concerned.		(c) the identification of the PPE concerned.	GREEN - EC Text
Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:		Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:	GREEN - EC Text
(a) the technical documentation described in Annex III;		(a) the technical documentation described in Annex III;	GREEN - EC Text
(b) a copy of the EU type-examination certificate.		(b) a copy of the EU type-examination certificate.	GREEN - EC Text
4. Verification of conformity		4. Verification ~~of conformity~~	YELLOW

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		Product checks	
4.1. The notified body shall carry out appropriate examinations and tests in order to check the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.		4.1. The notified body shall carry out **product checks** ~~appropriate examinations and tests~~ in order to ~~check~~ **verify** the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.	YELLOW
4.2. The examinations and tests shall be carried out at least once a year, at random intervals determined by the notified body. The first examinations and tests shall be carried out no more than one year after the date of issue of the EU type-examination certificate.		4.2. The ~~examinations and tests~~ **product checks** shall be carried out at least once a year, at random intervals determined by the notified body. The first **product checks** ~~examinations and tests~~ shall be carried out no more than one year after the date of issue of the EU type-examination certificate.	YELLOW
4.3. An adequate random sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined and appropriate tests set out in the relevant harmonised standard(s)		4.3. An adequate **statistical** ~~random~~ sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined and appropriate tests set out in the	YELLOW

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.		relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.	
4.4. Where the notified body referred to in point 3 is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.		4.4. Where the notified body referred to in point 3 is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.	GREEN - EC Text
	[AM 148] ***4.4a. The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.***	**4.4.a. The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.**	GREEN ***4.4a. The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.***

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
4.5. If the examination and testing reveal that the production is not homogeneous or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.		4.5. If the examination and testing reveal that the production is not homogeneous or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.	GREEN - EC Text
5. Test report		5. Test report **~~Certificate of conformity~~**	GREEN
5.1. The notified body shall provide the manufacturer with a test report, and shall authorise the manufacturer to affix the notified body's identification number to each individual PPE that is in conformity with the type described in the EU typeexamination certificate and satisfies the applicable essential health and safety requirements.	[AM 149] 5.1. The notified body shall provide the manufacturer with a test report.	5.1. The notified body shall provide the manufacturer with a test report **~~certificate of conformity~~**, ~~and shall authorise the manufacturer to affix the notified body's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements.~~	GREEN 5.1. The notified body shall provide the manufacturer with a test report.
5.2. The manufacturer shall keep		5.2. The manufacturer shall keep	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.		the test report **~~certificate of conformity~~** at the disposal of the national authorities for 10 years after the PPE has been placed on the market.	
	[AM 150] ***5.2a. The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.***	**5.2.a. ~~If the notified body referred to in point 3 agrees~~ The manufacturer shall under the responsibility of the notified body affix the notified body's identification number during the manufacturing process.**	GREEN ***5.2a. The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.***
6. CE marking and EU declaration of conformity		6. CE marking and EU declaration of conformity	GREEN - EC Text
6.1. The manufacturer shall affix the CE marking, and, with the authorisation of the notified body referred to in point 3, the latter's identification number to each individual PPE that is in conformity with the type described in the EU typeexamination certificate and satisfy the applicable essential health and safety requirements.		6.1. The manufacturer shall affix the CE marking, and, ~~with the authorisation~~ **under the responsibility** of the notified body referred to in point 3, the latter's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfy the applicable ~~essential health and safety~~ requirements **of this**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		Regulation.	
6.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.		6.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.	GREEN - EC Text
A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.		A copy of the EU declaration of conformity ~~or a simplified EU declaration of conformity~~ shall **be made available to the relevant authorities upon request** ~~accompany every PPE~~.	GREEN – CEU Text
7. If the notified body referred to in point 3 agrees, the manufacturer may affix the notified body's identification number to the PPE during the manufacturing process.		~~7. If the notified body referred to in point 3 agrees the manufacturer may affix the notified body's identification number to the PPE during the manufacturing process~~.	GREEN **deleted**
8. Authorised representative		8. Authorised representative	GREEN - EC Text
The manufacturer's obligations may be fulfilled by his authorised		The manufacturer's obligations may be fulfilled by his authorised	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2.		representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2.	
ANNEX VIII		**<u>ANNEX VIII</u>**	
Conformity to type based on quality assurance of the production process		**Conformity to type based on quality assurance of the production process**	GREEN - EC Text
(Module D)		**(Module D)**	GREEN - EC Text
1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5 and 6, and ensures and declares on his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements		1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5 and 6, and ensures and declares on his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable **<u>requirements of this Regulation</u>**	GREEN – CEU Text

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referred to in Article 5 and set out in Annex II.		~~essential health and safety requirements referred to in Article 5 and set out in Annex II~~.	
2. Manufacturing		2. Manufacturing	GREEN - EC Text
The manufacturer shall operate an approved quality system for production, final product inspection and testing of the PPE concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.		The manufacturer shall operate an approved quality system for production, final product inspection and testing of the PPE concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.	GREEN - EC Text
3. Quality system		3. Quality system	GREEN - EC Text
3.1. The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice.		3.1. The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice.	GREEN - EC Text
The application shall include:		The application shall include:	GREEN - EC Text
(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;		(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address **as well**;	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
		(a1) the address of the manufacturer's premises, where the audits can be carried out	GREEN – CEU Text
(b) a written declaration that the same application has not been lodged with any other notified body;		(b) a written declaration that the same application has not been lodged with any other notified body;	GREEN - EC Text
(c) the identification of the PPE concerned;		(c) the identification of the PPE concerned;	GREEN - EC Text
(d) the documentation concerning the quality system.		(d) the documentation concerning the quality system.	GREEN - EC Text
Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:		Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:	GREEN - EC Text
(a) the technical documentation of the PPE described in Annex III;		(a) he technical documentation of the PPE described in Annex III;	GREEN - EC Text
(b) a copy of the EU type-examination certificate.		(b) a copy of the EU type-examination certificate.	GREEN - EC Text
3.2. The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination		3.2. The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination	GREEN – CEU Text

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certificate and fulfils the applicable essential health and safety requirements.		certificate and **complies with the** ~~fulfils the~~ applicable ~~essential health and safety~~ requirements **of this Regulation**.	
All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.		All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.	GREEN - EC Text
It shall, in particular, contain an adequate description of:		It shall, in particular, contain an adequate description of:	GREEN - EC Text
(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;		(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;	GREEN - EC Text
(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions		(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions	GREEN - EC Text

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that will be used;		that will be used;	
(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;		(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;	GREEN - EC Text
(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and		(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and	GREEN - EC Text
(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.		(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	GREEN - EC Text
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.		3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.	GREEN - EC Text
It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant		It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant	GREEN - EC Text

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harmonised standards.		harmonised standards.	
In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the field of PPE and technology concerned, and knowledge of the applicable essential health and safety requirements. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation of the PPE referred to in point 3.1 to verify the manufacturer's ability to identify the applicable essential health and safety requirements and to carry out the necessary examinations with a view to ensuring conformity of the PPE with those requirements.		In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the field of PPE and technology concerned, and knowledge of the applicable essential health and safety requirements. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation of the PPE referred to in point 3.1 to verify the manufacturer's ability to identify the applicable essential health and safety requirements and to carry out the necessary examinations with a view to ensuring conformity of the PPE with those requirements.	GREEN - EC Text
The result of that assessment shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.		The result of that assessment shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.	GREEN - EC Text

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3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.		3.4. he manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.	GREEN - EC Text
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.		3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.	GREEN - EC Text
The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.		The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.	GREEN - EC Text
It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.		It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	GREEN - EC Text
3.6. The notified body shall authorise the manufacturer to affix the notified body's identification number to each individual PPE that		3.6. The notified body shall authorise the manufacturer to affix the notified body's identification number to each individual PPE	GREEN – CEU Text

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is in conformity with the type described in the EU type-examination certificate and satisfy the applicable essential health and safety requirements.		that is in conformity with the type described in the EU type-examination certificate and satisfy the applicable ~~essential health and safety~~ requirements **of this Regulation**.	
4. Surveillance under the responsibility of the notified body		4. Surveillance under the responsibility of the notified body	GREEN - EC Text
4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.		4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	GREEN - EC Text
4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:		4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:	GREEN - EC Text
(a) the quality system documentation;		(a) the quality system documentation;	GREEN - EC Text
(b) the quality records, such as inspection reports and test data, calibration data, qualification		(b) the quality records, such as inspection reports and test data, calibration data, qualification	GREEN - EC Text

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reports on the personnel concerned.		reports on the personnel concerned.	
4.3. The notified body shall carry out periodic audits, at least once a year, to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.		4.3. The notified body shall carry out periodic audits, at least once a year, to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.	GREEN - EC Text
4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out examinations or tests of the PPE, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.		4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out examinations or tests of the PPE, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	GREEN - EC Text
5. CE marking and EU declaration of conformity		5. CE marking and EU declaration of conformity	GREEN - EC Text
5.1. The manufacturer shall affix the CE marking, and, with the authorisation of the notified body		5.1. The manufacturer shall affix the CE marking, and, ~~with the authorisation~~ **under the**	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
referred to in point 3.1, the latter's identification number to each individual PPE that is in conformity with the type described in the EU typeexamination certificate and satisfy the applicable essential health and safety requirements.		**responsibility** of the notified body referred to in point 3.1, the latter's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfy the applicable ~~essential health and safety~~ requirements **of this Regulation**.	
5.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.		5.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.	GREEN - EC Text
A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.		A copy of the EU declaration of conformity ~~or a simplified EU declaration of conformity~~ shall **be made available to the relevant authorities upon request** ~~accompany every PPE~~.	GREEN – CEU Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
6. The manufacturer shall, for a period ending 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:		6. The manufacturer shall, for a period ending 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:	GREEN - EC Text
(a) the documentation referred to in point 3.1;		(a) the documentation referred to in point 3.1;	GREEN - EC Text
(b) the information related to the change referred to in point 3.5, as approved;		(b) the information related to the change referred to in point 3.5, as approved;	GREEN - EC Text
(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.		(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.	GREEN - EC Text
7. The notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such quality system approvals refused, suspended or otherwise restricted.		7. The notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such quality system approvals refused, suspended or otherwise restricted.	GREEN - EC Text
The notified body shall inform the other notified bodies of quality system approvals which it has		The notified body shall inform the other notified bodies of quality system approvals which it has	GREEN - EC Text

COMMISSION PROPOSAL	EP AMENDMENTS	COUNCIL AMENDMENTS	COMPROMISE
refused, suspended, withdrawn or otherwise restricted, and, upon request, of such quality system approvals which it has issued.		refused, suspended, withdrawn or otherwise restricted, and, upon request, of such quality system approvals which it has issued.	
8. If the notified body referred to in point 3.1 agrees, the manufacturer may affix the notified body's identification number to the PPE during the manufacturing process.	[AM 151] ***deleted***	~~8. If the notified body referred to in point 3.1 agrees, the manufacturer may affix the notified body's identification number to the PPE during the manufacturing process~~.	GREEN ***deleted***
9. Authorised representative		9. Authorised representative	GREEN - EC Text
The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.		The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.	GREEN - EC Text
ANNEX IX		**ANNEX IX**	
EU declaration of conformity	[AM 152] EU declaration of conformity ***The EU declaration of conformity***	EU declaration of conformity ***No XXXX*)***[9]	GREEN – CEU Text

[9] *) It is optional for the manufacturer to assign a number to the declaration of conformity.

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	shall contain the following elements:		
1. PPE (product, batch, type or serial number):	[AM 153] 1. ***Identification of the*** PPE (product, batch, type or serial number)***, including, where useful for the identification of the PPE, an image of sufficient clarity***:	1. PPE (product, **type,** batch, ~~type~~ or serial number):	GREEN – CEU Text
2. Name and address of the manufacturer or his authorised representative [The authorised representative must also give the business name and address of the manufacturer]:	[AM 154] 2. Name and address of the manufacturer or***, where applicable, his*** authorised representative**.**	2. Name and address of the manufacturer ~~or~~ **and, where applicable**, his authorised representative ~~[The authorised representative must also give the business name and address of the manufacturer]:~~	GREEN – CEU Text
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:		3. This declaration of conformity is issued under the sole responsibility of the manufacturer:	GREEN - EC Text
4. Object of the declaration (identification of PPE allowing traceability; it may, where necessary for the identification of the PPE, include a colour image of sufficient clarity):	[AM 155] ***deleted***	4. Object of the declaration (identification of PPE allowing traceability; it may, where necessary for the identification of the PPE, include a colour image of sufficient clarity):	GREEN – EC Text
5. The object of the declaration described in point 4 is in		5. The object of the declaration described in point 4 is in	GREEN - EC Text

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conformity with the relevant Union harmonisation legislation:		conformity with the relevant Union harmonisation legislation:	
6. References to the relevant harmonised standards, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:	[AM 156] 6. References to the ***applied*** harmonised standards, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:	6. References to the relevant harmonised standards **used**, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:	GREEN – CEU Text
7. Where applicable, the notified body ... (name, number)… performed the EU type-examination (Module B) and issued the EU type-examination certificate … (reference to that certificate).		7. Where applicable, the notified body ... (name, number)… performed the EU type-examination (Module B) and issued the EU type-examination certificate … (reference to that certificate).	GREEN - EC Text
8. Where applicable, the PPE is subject to the conformity assessment procedure … (either (Conformity to type based on product verification (Module F)) or (Conformity to type based on quality assurance of the production process (Module D)) … under surveillance of the notified body ... (name, number).		8. Where applicable, the PPE is subject to the conformity assessment procedure … (either (Conformity to type based on **internal production control plus supervised product checks at random intervals** ~~product verification~~ (Module **C 2** ~~F~~)) or (Conformity to type based on quality assurance of the production process (Module D)) … under	GREEN – CEU Text

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		surveillance of the notified body ... (name, number).	
9. Additional Information:	9. Additional Information:	9. Additional Information:	GREEN - EC Text
Signed for and on behalf of:	Signed for and on behalf of:	Signed for and on behalf of:	GREEN - EC Text
(place and date of issue):	(place and date of issue):	(place and date of issue):	GREEN - EC Text
(name, function) (signature):	(name, function) (signature):	(name, function) (signature):	GREEN - EC Text
ANNEX X			
Simplified EU declaration of conformity	[AM 157] ***The full text of the EU declaration of conformity is available at the following internet address:***		GREEN – CEU Text
The simplified EU declaration of conformity shall be provided as follows:			GREEN – CEU Text
Hereby, [Name of manufacturer] declares that the PPE type [designation of type of PPE] is in compliance with the PPE Regulation (EU) No *[XXXX/YYYY]*.			GREEN – CEU Text