PPE REGULATION GUIDELINES

GUIDE TO APPLICATION OF REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 9 MARCH 2016 ON PERSONAL PROTECTIVE EQUIPMENT AND REPEALING COUNCIL DIRECTIVE 89/686/EEC

4th EDITION – October 2024

FOREWORD

The 4th edition of the PPE Regulation Guidelines has been developed by the European Commission services and the PPE Expert Group. It includes the agreements reached in the PPE Expert Group at the meeting held on 4 May 2024. The updates concern the topics and the sections indicated below:

- *clothing with reflective elements, section 2.2*
- *ergonomic equipment, section 2.3*

The 3rd edition of the PPE Regulation Guidelines published in October 2023 included the agreements reached in the PPE Expert Group at the meetings held on 22 May 2022 and 4 May 2023 and approved by the PPE Expert Group via written procedure in June 2023. The updates concern the topics and the sections indicated below:

- *exoskeletons, section 2.3*
- *module B+C2 - placing on the market, sections 5.2. and 16*
- *conformity assessment of multi-risk PPE, section 11.21*
- *harmful effects of noise, section 11.29*
- *review of the EU-type examination certificate, section 14*
- *blue light, points 2.1 and 2.10 of the categorization guide*
- *laser radiation, points 2.2, 4.2, 5.2, 6.3, 8.3 and 9.3 of the categorization guide*
- *welder's clothing and gloves, points 5.2, 5.4, 6.2, 6.3, 9.2 and 9.3 of the categorization guide.*

In addition, the European Commission services have modified section 11.6. on manufacturer's instructions and information, aiming to align it with the obligations laid down in the PPE Regulation and the recommendation of the EU product rules.

The 2nd edition of PPE Regulation Guidelines published in April 2023 included the agreements reached in the PPE Working Group at the meetings held on 19 November 2018, 26 March 2019, 7 October 2019, 13 November 2020 and in the PPE Expert Group at the meetings held on 27 May 2021 and 20 May 2022, as well as the set of guidance documents on the transition from the PPE Directive issued in 2017 and 2018. The document was approved by the PPE Expert Group via written procedure in June 2022. The updates concerned the topics and the sections indicated below:

- *guidance documents that were available on the PPE Website:*
  - *"Approval decisions based on EC type examination certificates", section 9.3*
  - *"Placing on the market and product in stocks", section 9.3*
  - *"Validity of an EC-type examination certificate and revision of harmonised standards", section 14*
- *protective gloves for hairdressers: sections 11.1, 11.5 and 11.34, and point 9.5 of the categorization guide*
- *baby neck buoys, section 11.28 and point 10.7 of the categorization guide*
- *face masks with integrated snorkel, point 2.5 of the categorization guide*
- *face shields used in the context of covid-19, point 5.1 of the categorization guide*
- *aprons for butcher, point 6.8 of the categorization guide*
- *potholders, point 9.15 of the categorization guide*
- *as well as, the update of some links and a few small editorial comments.*

Brussels, October 2024

PRELIMINARY NOTES

1. *These **PPE Guidelines** are intended to be a manual for all parties directly or indirectly affected by **Regulation (EU) 2016/425**[1], commonly referred to as the PPE (Personal Protective Equipment) Regulation, applicable from 21 April 2018, replacing the previous Directive 89/686/EEC.*

2. *Readers' attention is drawn to the fact that these Guidelines are intended only to facilitate the application of Regulation (EU) 2016/425, directly applicable to the EU Member States and legally binding as such. However, this document does represent a reference for ensuring consistent application of the PPE Regulation. The PPE Guidelines are intended to help ensure the free movement of PPE in the European Union territory[2] as a result of the work carried out by the Commission services, Member States' government experts and other parties concerned.*

3. *These guidelines have been prepared by the relevant services of the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs of the European Commission (DG GROW)[3] in co-operation with representatives and experts from EU/EEA Member States, European standardisation, notified bodies, industry and other relevant sectoral stakeholders in the PPE Working Group (the PPE Expert Group from May 2021). They are based on the last issue (Version 24 August 2017) of the "Guide to application of the PPE Directive 89/686/EEC", as well as other horizontal and vertical guidance documents.*

4. *The European Commission services will undertake to maintain these Guidelines. It is our goal to ensure that the information provided is both timely and accurate. If errors are brought to our attention, we will try to correct them as soon as possible. However, the Commission accepts no responsibility or liability whatsoever with regard to the information in this document.*

   This information is:
   - *of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;*
   - *not necessarily comprehensive, complete, accurate or up-to-date;*
   - *sometimes referring to external information over which the Commission services have no control and for which the Commission assumes no responsibility;*
   - *not professional or legal advice.*

5. *All references to the CE marking and the EU declaration of conformity in these PPE Guidelines relate only to Regulation (EU) 2016/425. To place PPE on the market in the European Union territory, all other relevant legislation must be applied. For wider*

[1] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. OJEU L 81, 31.3.2016, p. 51.

[2] According to the agreement related to the European Economic Area (EEA) (Decision of the Council and the Commission 94/1/EC of 13 December 1993, OJEU L 1, 3.1.1994, p. 1), the territories of Iceland, Liechtenstein and Norway have to be considered, for the implementation of Regulation (EU) 2016/425, in the same right as of the European Union territory. When this term, European Union territory, is used in these Guidelines, the same applies to the EEA territory. Likewise, solely in respect of this Regulation, the responsibilities of the EU Member States can also be taken for the national authorities of these three countries.

[3] The former Directorate-General for Enterprise and Industry; until 31 October 2014.

information on the whole system, see the latest version of "The 'Blue Guide' on the implementation of EU product rules", available in the EU official languages.

6. *Further guidance and information can be found on the European Commission's website on EUROPA regarding Personal Protective Equipment (PPE).*

INTRODUCTION

The objective of these PPE Guidelines is to clarify certain matters and procedures referred to in Regulation (EU) 2016/425 on personal protective equipment. They provide a cross reference from the legal text of the Regulation to explanations by EU sectorial experts. The Guidelines should be used in conjunction with the Regulation itself and with the European Commission's "*The 'Blue Guide' on the implementation of EU product rules*".

These Guidelines are not only for the use of Member States' competent authorities, but also by the main economic operators concerned, such as manufacturers, their trade associations, bodies in charge of the preparation of standards as well as those entrusted with the conformity assessment procedures.

First and foremost, this document must ensure that, when correctly applied, the Regulation leads to the removal of obstacles and difficulties related to the free circulation (free movement) of goods within the European Union (EU) and the European Economic Area (EEA) (*see footnote 2*). It should be noted that the statements in these Guidelines refer only to the application of Regulation (EU) 2016/425 unless otherwise indicated. All parties concerned should be aware of other requirements, which may also apply.

The PPE Regulation (EU) 2016/425 is total harmonisation and a "New Approach" legislation aligned to the "New Legislative Framework". It lays down essential health and safety requirements (EHSRs) and leaves it to standards, primarily European harmonised standards, to give technical expression of the relevant requirements contained in the Regulation.

Regulation (EU) 2016/425 replaces the previous PPE Directive 89/686/EEC as from 21 April 2018. After a transition period, as indicated in Article 47, from 21 April 2019 the PPE Regulation is the sole legal instrument applicable for products in its scope to be placed on the EU/EEA market.

The reader has to be aware that when PPE is intended for use in a workplace, national and Union legislation, intended to ensure the safety of employees, will usually apply. Whereas "New Approach / "New Legislative Framework" legislation set the highest possible requirements given their overall objectives and hence do not allow for additional national provisions within scope, "use" Directives (89/391/EEC[4], 89/656/EEC[5]) set minimum requirements. In effect this means that national authorities, following the agreement of other Member States by means of the notification procedure under Directive (EU) 2015/1535[6], can put in place further requirements relating to "use" and selection so long as these do not constitute a barrier to trade.

[4] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

[5] 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 (third individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18).

[6] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1). It repealed Directive 98/34/EC and its amendments as from 7 October 2015.

TABLE OF CONTENTS

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2016

on personal protective equipment and repealing Council Directive 89/686/EEC

(Text with EEA relevance)

1. PREAMBLE TO THE PPE REGULATION - THE CITATIONS AND THE RECITALS

- **1.1. The citations**

The citations included in the preamble to the PPE Regulation (EU) 2016/425 indicate the legal basis of the PPE Regulation, the opinions expressed by the relevant consultative Committee and the procedure according to which the Regulation was adopted.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the ordinary legislative procedure ([2]),

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([1]) OJ C 451, 16.12.2014, p. 76.

([2]) Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.

- **1.2. The legal basis of the PPE Regulation**

The legal basis of the PPE Regulation (EU) 2016/425 is provided by Article 114 of the Treaty on the Functioning of the European Union (TFEU)[7] that enables the European Union to adopt measures to harmonise the legislation of the Member States in order to ensure the establishment and functioning of the single internal market. Such measures must take as a basis the highest possible level of protection of the health and safety of people and of the environment. The Regulation thus has a dual objective: to permit the free movement of products with the internal market whilst ensuring a high level of protection of health and safety.

Following the proposal by the European Commission, the PPE Regulation was adopted by the European Parliament and the Council of the European Union after consulting the European

[7] OJ C 326, 26.10.2012, p. 47.

Economic and Social Committee, according to the ordinary legislative procedure (formerly known as "co-decision") set out in Article 294 of the TFEU.

The footnotes to the citation give the references and dates of the successive steps of the procedure. The text of the PPE Regulation was published on the Official Journal of the European Union (OJEU) L 81, 31.3.2016, p. 51.

- **1.3. The recitals**

The recitals, also known as *consideranda*, introduce the main provisions of the PPE Regulation (EU) 2016/425 and present the reasons for their adoption. Some of the recitals explain the changes that have been made compared with the previous Directive 89/686/EEC, including also those related to the alignment to the "New Legislative Framework" mainly through the provisions of Decision No 768/2008/EC.

The recitals do not have legal force as such; however, they help to understand the PPE Regulation, in particular, by clarifying the meaning of certain provisions. When interpreting the text of the PPE Regulation, the Courts may take the recitals into consideration in order to ascertain the intention of the legislators.

In the following comments, reference is made to the Articles and Annexes of the PPE Regulation introduced by each of the recitals. For further explanations, please refer to the comments on the Articles and Annexes concerned.

(1) Council Directive 89/686/EEC ([3]) 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.

(2) Directive 89/686/EEC is based on the 'new approach' principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards ([4]). Thus, it sets only the essential 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 Council ([5]). Conformity with the harmonised standards so set, the reference numbers of which are 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 that sector and should be maintained and even further promoted.

(3) Experience with the application of Directive 89/686/EEC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. In order to take account of that experience and to provide clarification in relation to the framework within which products covered by this Regulation may be made available on the market, certain aspects of Directive 89/686/EEC should be revised and enhanced.

(4) Since the scope, the essential health and safety requirements and conformity assessment procedures have to be identical in all the Member States there is almost no flexibility in transposing a directive 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.

(3) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).

(4) OJ C 136, 4.6.1985, p. 1.

(5) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- **1.4. The previous PPE Directive**

The first recitals recall that the new PPE Regulation (EU) 2016/425 is based on the previous PPE Directive 89/686/EEC. This Directive was a total harmonisation directive, i.e. its provisions replaced existing divergent national and European legislation which covered the same subjects.

Directive 89/686/EEC was applicable from 1 July 1992 and remained in force until 20 April 2018, according to Article 46 of the PPE Regulation. However, Article 47 provides for specific transitional provisions, in particular allowing the placing on the market of products in conformity with the Directive until 20 April 2019.

(5) Regulation (EC) No 765/2008 of the European Parliament and of the Council (6) 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.

(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 PPE presenting a risk should be adapted to that 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.

(6) 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 and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

([1]) 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).

- **1.5. The "New Legislative Framework"**

The PPE Regulation (EU) 2016/425 is aligned to the "New Legislative Framework" (NLF), configured as the improvement and update of the regulatory method known as the "New Approach to technical harmonisation and standards". The set of legislative acts of the NLF includes Regulation (EC) No 765/2008 and Decision No 768/2008/EC.

See also § 1.2. "The 'New Legislative Framework'" in "The 'Blue Guide' on the implementation of EU product rules".

In particular, the aligned contents of the PPE Regulation related – among others – to definitions and obligations of economic operators, to notified bodies, to conformity assessment procedures and declaration of conformity, come directly from the NLF Decision, as additions and/or terminology adaptation.

(8) 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 PPE, whether new or second-hand, imported from a third country.

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

- **1.6. The scope and the objective of the PPE Regulation**

The PPE Regulation (EU) 2016/425 provides for harmonised requirements and procedures to establish compliance for products placed on the EU market, to ensure free movement in the EU territory for personal protective equipment in the scope.

The PPE Regulation carries specific obligations for the person (natural or legal) who places products on the market be it the manufacturer, its authorised representative or the importer.

The PPE Regulation is applicable to all forms of making products available on the EU market, regardless of the selling technique. Therefore, it includes distance selling and selling through electronic means (Internet, e-commerce…), as the whole Union harmonisation legislation on products. This is particularly related to the definitions (2) "making available on the market" and (3) "placing on the market" of Article 3 as well as the contents of Article 4 on "Making available on the market".

(10) 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 a level of protection for the user of those products as for the user of PPE covered by Directive 89/686/EEC, the scope of this Regulation should include PPE for private use against heat, in line with similar PPE for professional use which is already covered by Directive 89/686/EEC. Artisanal decorative products do not claim to fulfil a protective function, are by definition not personal protective equipment and

are therefore not concerned by that inclusion. Clothing intended for private use with reflective or fluorescent elements included for reasons of design or decoration is not personal protective equipment and is therefore not covered by this Regulation. As for 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, those should also fall outside of the scope of this Regulation. It is also appropriate to clarify the list of excluded PPE set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore excluded from the scope of this Regulation.

- **1.7. Exclusions from the scope**

Exclusions from the scope of the PPE Regulation (EU) 2016/425 are laid down in Article 2(2).

(11) Economic operators should be responsible for the compliance of PPE with the requirements of this Regulation, 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.

(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.

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

- **1.8. Responsibilities of economic operators**

Union harmonisation legislation defines the manufacturer, the authorised representative, the importer and the distributor as "economic operators". Within the "New Legislative Framework", the responsibilities and obligations of the economic operators are defined more in detail: all of them have to play key roles in the supply chain, in particular in terms of compliance of products, appropriate measures, communication and co-operation.

The inclusion of a website address in addition to the postal address is related to the requirements for manufacturers in Article 8(6) and for importers in Article 10(3). In any case, a website is additional information, but it is not enough as an address.

See also §§ 3. "The actors in the product supply chain and their obligations" and 4.2.2. "Traceability provisions" in "The 'Blue Guide' on the implementation of EU product rules".

(14) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

- **1.9. Responsibilities of manufacturers: conformity assessment**

Conformity assessment according to the conformity assessment procedures applicable to PPE, is the responsibility of the manufacturer only, whether the PPE Regulation (EU) 2016/425 provides for the involvement of a conformity assessment body (notified body) or not.

(15) It is necessary to ensure that PPE from third countries entering the Union market complies with the requirements of 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 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 authorities.

(16) The distributor makes 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 its handling of PPE does not adversely affect the compliance of the PPE.

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

- **1.10. Responsibilities of importers and distributors**

The importer is the economic operator established in the Union who places a product from a third country on the Union market for the first time. The responsibilities and obligations of importers are described in Article 10 of the PPE Regulation.

The distributor is a natural or a legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market. The responsibilities and obligations of distributors are described in Article 11 of the PPE Regulation.

(18) 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. When PPE is made available on the market in packages containing

multiple units, the instructions and information should accompany each smallest commercially available unit.

- **1.11. Documentation to be provided by economic operators**

Requirements on manufacturer's instructions and information are set out in point 1.4. of Annex II to the PPE Regulation (EU) 2016/425, when the technical documentation for PPE is described in Annex III.

(19) Any economic operator who either places PPE on the market under his 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.

- **1.12. Obligations of the manufacturer for economic operators**

If PPE is marketed under another person's name or trademark, this person will be considered as the manufacturer.

The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes or labels ready-made products and places them on the market under his own name or trademark. Further, the responsibility of the manufacturer is placed on any person who changes the intended use of a product in such a way that different essential or other legal requirements will become applicable, or substantially modifies or re-builds a product (thus creating a new product), with a view to placing it on the market.

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

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

- **1.13. Information and traceability of PPE for market surveillance**

Economic operators (manufacturers, authorised representatives, distributors and importers) must co-operate with national authorities to carry out effective market surveillance activities, including provision of information and ensuring the traceability of PPE throughout the whole supply chain.

Article 13 of the PPE Regulation (EU) 2016/425 deals with "Identification of economic operators" (*see point 3.6*).

(22) 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.

- **1.14. Noise, vibrations and radiation**

Specific requirements on protection against the harmful effects of noise are laid down in point 3.5. of Annex II to the PPE Regulation (EU) 2016/425.

(23) It is necessary to clearly specify the relationship with, and the scope of this Regulation as regards, the entitlement of Member States to lay down requirements for the use of PPE at the workplace, in particular pursuant to Council Directive 89/656/EEC ([1]), 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.

([1]) 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 (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18).

- **1.15. Use of PPE at the workplace**

Recital 23 of the PPE Regulation (EU) 2016/425 makes reference to the Occupational Safety and Health Directive 89/656/EEC on use of personal protective equipment, which is the "workplace" legislation related to the "product" legislation on PPE.

(24) Market surveillance authorities should have easy access to the EU declaration of conformity. In order to fulfil that requirement, manufacturers should ensure that PPE is accompanied either by a copy of the EU declaration of conformity or by the internet address at which the EU declaration of conformity can be accessed.

(25) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for PPE 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.

- **1.16. The EU declaration of conformity**

Recitals 24 and 25 of the PPE Regulation (EU) 2016/425 introduce the provisions related to the EU declaration of conformity, to be drawn up by the manufacturer for products to be placed on the EU market. The PPE Regulation includes such provisions in Article 15 (in particular, paragraph 3 on the single EU declaration of conformity) and in Annex IX setting out the model structure.

See also § 4.4 "EU declaration of conformity" in "The 'Blue Guide' on the implementation of EU product rules".

(26) In order to increase the efficiency of market surveillance, it is necessary to extend the obligation to draw up complete technical documentation to all PPE.

- **1.17. Technical documentation**

Technical documentation for PPE is described in Annex III to the PPE Regulation (EU) 2016/425.

(27) 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 be set at 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.

(28) A simplified procedure should be applied in the case of renewal of the EU type-examination certificate where the manufacturer has not modified the approved type and the harmonised standards or other technical 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, additional tests or examinations should not be necessary and the administrative burden and related costs should be kept to a minimum.

- **1.18. The EU type-examination certificate**

Provisions on the EU type-examination certificate are included in Annex V to the PPE Regulation (EU) 2016/425.

(29) 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.

- **1.19. The CE marking**

Recital 29 of the PPE Regulation (EU) 2016/425 introduces the provisions related to the CE marking, making reference to the general principles set out in Article 30 of the "New Legislative Framework" Regulation (EC) No 765/2008. The PPE Regulation includes the reference to those provisions as well as the rules and conditions for affixing the CE marking in Articles 16 and 17.

See also § 4.5.1. "CE marking" in "The 'Blue Guide' on the implementation of EU product rules".

(30) 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 of all PPE, the range 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.

(31) The conformity assessment procedures should be adapted to the specific conditions of the 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.

- **1.20. Conformity assessment procedures**

Among the modules established by the Decision No 768/2008/EC within the "New Legislative Framework", the PPE Regulation (EU) 2016/425 includes five modules for conformity assessment procedures (Annexes IV to VIII) for assessing the conformity of PPE with the applicable essential health and safety requirements laid down in Annex II:

- Annex IV: Internal production control (Module A)
- Annex V: EU type-examination (Module B)
- Annex VI: Conformity to type based on internal production control (Module C)
- Annex VII: Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)
- Annex VIII: Conformity to type based on quality assurance of the production process (Module D)

See also § 5.1. "Modules for conformity assessment" in "The 'Blue Guide' on the implementation of EU product rules".

(32) 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.

(33) 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.

(34) 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 notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(35) 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.

(36) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, 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.

(37) 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.

(38) 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.

(39) 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.

(40) Interested parties should have the right to appeal against the result of a conformity 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.

- **1.21. Conformity assessment bodies: notified bodies**

Conformity assessment bodies, known as notified bodies for being notified by the competent national authorities of the EU Member States to the Commission and to the other Member States, are required to intervene in three conformity assessment procedures of the PPE Regulation (EU) 2016/425, as indicated in:

- Annex V: EU type-examination (Module B)
- Annex VII: Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)
- Annex VIII: Conformity to type based on quality assurance of the production process (Module D)

The PPE Regulation devotes the whole Chapter V – Articles 20 to 36 – to notified bodies, basically reproducing the relevant contents of the Decision No 768/2008/EC. Rules on accreditation for notified bodies are provided in the Regulation (EC) No 765/2008.

See also §§ 5.2 "Conformity assessment bodies" and 5.3 "Notification", as well as § 6 "Accreditation", in "The 'Blue Guide' on the implementation of EU product rules".

(41) Member States should take all appropriate measures to ensure that PPE covered by this Regulation may be placed on the market only if, when properly stored and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons. PPE 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.

(42) 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 PPE covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.

- **1.22. Compliance of products on the market and market surveillance**

The term "market surveillance" designates the activity of the competent national authorities of the Member States, checking the conformity of products subject to the EU harmonisation legislation, after they have been placed on the EU market, and taking the necessary action to deal with non-compliant products.

See also § 7 "Market surveillance" in "The 'Blue Guide' on the implementation of EU product rules".

(43) Directive 89/686/EEC already provides for a safeguard procedure which is necessary to allow for the possibility of 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.

(44) 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 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.

(45) 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.

- **1.23. The safeguard clause procedure**

Article 39 of the PPE Regulation (EU) 2016/425 describes the Union safeguard procedure. It comes from Decision No 768/2008/EC, with the aim to make it more efficient and effective in terms of information, communication, resources and results.

See also § 7.6.2. "The application of the safeguard clause" in "The 'Blue Guide' on the implementation of EU product rules".

(46) In order to take into account technical progress and knowledge 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 in respect of amending the categories of risks against which the PPE is intended to protect users. It is of particular importance that the Commission carry 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 to the Council.

(47) 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) No 182/2011 of the European Parliament and of the Council ([1]).

(48) 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.

(49) 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.

(50) 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.

([1]) Regulation (EU) No 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).

- **1.24. Delegated and implementing powers and procedures**

Delegated and implementing powers are conferred and monitored by the EU legislators (European Parliament and the Council) to the European Commission to ensure that certain measures are uniformly implemented across the EU, in accordance with Article 291 of the Treaty on the Functioning of the European Union (TFEU). Regulation (EU) No 182/2011 (the "Comitology Regulation") establishes the rules and general principles on the exercise of such implementing powers by the Commission.

Within the PPE Regulation (EU) 2016/425, delegated acts can be adopted to adapt the risk categories of PPE laid down in Annex I to the evolution of technical progress).

On the other hand, adoption of an implementing act is required in case of objections raised concerning a notified body and in case of compliant products on the market presenting a risk. According to Article 2(2) and (3) of Regulation (EU) No 182/2011, the examination procedure applies for implementing acts with respect to products, being related to "protection of the health or safety of humans and animals" (b)(iii), when the advisory procedure applies for implementing acts on corrective measures in respect of notified bodies.

(51) 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.

(52) 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.

- **1.25. The PPE Committee**

The PPE Regulation (EU) 2016/425 establishes in Article 44 a Committee to deal with the different questions related to the implementation, application and management of the PPE Regulation.

According to Regulation (EU) No 182/2011 (the "Comitology Regulation"), the Committee has an obligation of provision of information and documentation to the European Parliament, about the issues under discussion, other than those specifically related to the implementation or infringements of the PPE Regulation.

(53) 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 PPE are justified or not.

- **1.26. Implementing acts concerning measures on non-compliant products**

Adoption of an implementing act by the Commission is required not only in cases related to notified bodies or to compliant products presenting a risk, but also when Member States take actions in respect of non-compliant products ("the safeguard clause procedure").

(54) 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.

- **1.27. Transitional provisions**

Specific transitional provisions for products and certificates, from the previous Directive 89/686/EEC to the new PPE Regulation (EU) 2016/425, are provided for in Article 47.

A "Guidance document on the PPE transition from Directive 89/686/EEC to Regulation (EU) 2016/425" is available on the Commission's website on Personal Protective Equipment (PPE). The website also includes a list of "Frequently Asked Questions and Answers", covering both horizontal and sectorial questions, this is to say, those common to all the EU legislation aligned to the "New Legislative Framework" and those specifically related to the PPE Regulation. It was issued in March 2017 and reflects the results of discussions developed during the transition period, notably at the workshop held in Brussels on 16 November 2016.

(55) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

- **1.28. Enforcement: penalties**

Provisions on penalties are laid down in Article 45 of the PPE Regulation (EU) 2016/425.

(56) Since the objective of this Regulation, namely to ensure that PPE on the market fulfils the requirements providing for a high level of protection of health and safety of users, whilst guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, 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.

- **1.29. Subsidiarity and proportionality**

Recital 56 of the PPE Regulation (EU) 2016/425 makes reference to the principles of subsidiarity and proportionality set out in Article 5 of the Treaty on European Union (TEU).

According to these principles, the European Union shall take action only if the same objectives cannot be better achieved by the action of the Member States.

In fact, without any EU harmonised legislation on PPE, manufacturers of PPE would have to apply different rules, requirements and procedures for safety of products in each EU Member State, which would both constitute a serious obstacle to the single internal market (free circulation of goods) and be a less effective means of ensuring and improving safety of PPE.

(57) 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,

- **1.30. Repeal of Directive 89/686/EEC**

The repeal of the previous Directive 89/686/EEC is prescribed in Article 46 of the PPE Regulation (EU) 2016/425, with effect from 21 April 2018. However, Article 47 provides for specific transitional provisions, in particular allowing the placing on the market of products in conformity with the Directive until 20 April 2019.

THE ARTICLES OF THE PPE REGULATION

2. CHAPTER I - GENERAL PROVISIONS

- **2.1. Article 1 - Subject matter**

Article 1

Subject matter

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

The PPE Regulation (EU) 2016/425 applies to personal protective equipment (PPE) intended for use in domestic, leisure and sports activities, as well as for professional use.

The objectives of the PPE Regulation are:
- to provide the Essential Health and Safety Requirements (EHSRs) which the PPE must satisfy to ensure protection of the health and safety of the intended users;
- to ensure free movement of PPE within the internal market of the European Union.

- **2.2. Article 2 - Scope**

Article 2

Scope

1. This Regulation applies to PPE.

. . .

The PPE Regulation (EU) 2016/425 applies to each individual PPE which is placed on the Union market. Consequently, the PPE Regulation applies to new PPE manufactured in the Member States, and to new and used PPE imported from outside of the European Union.

The provisions of the PPE Regulation do not apply to PPE intended to be placed on the market in a country outside the European Union, or imported into the Union for re-export to a country outside the European Union.

Article 2 (continued)

2. This Regulation does not apply to PPE:

. . .

The PPE Regulation does not apply to clothing intended for private use with reflective or fluorescent elements included only for reasons of design or decoration. However, if the

manufacturer claims that the product has a protective function, or if a product is sold and marketed for use as PPE, it shall fulfil the applicable EHSR of the PPE Regulation.

Regardless the intended professional or private use of the product, if the information provided or the appearance of the product gives the impression that the product is meant to be used as visibility PPE, the manufacturer may not be able to derogate from his obligations even with a warning stating that the product is not intended for use as PPE, and the product should therefore fulfil the applicable EHSRs of the PPE Regulation.

See also § 2.8 "Reasonably foreseeable and intended use/misuse" in "The 'Blue Guide' on the implementation of EU product rules".

Barrier creams, as for example creams protecting against natural UV-radiation, are not PPE under the PPE Regulation because the definition of PPE is not fulfilled.

Article 2(2) (continued)

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

. . .

PPE designed and manufactured for military or police purposes means PPE designed and intended to be used exclusively for such purposes. This exclusion applies to all categories of PPE. However, PPE which can be used by armed forces or in the maintenance of law and order that is not specifically designed for their use is covered by the PPE Regulation, for example high-visibility clothing with a logo of the Police force. Equipment used by firefighters is PPE with regard to the PPE Regulation.

Bullet-proof and knife stab protective equipment, for example for security guards, are PPE and are not covered by the exclusion relating to the armed forces or the maintenance of law and order.

It is permitted for a manufacturer to use the EHSRs of the Regulation or relevant harmonised European standards when specifically designing and manufacturing protective equipment exclusively for use by armed forces or in the maintenance of law and order, but this PPE must not be marked with the CE marking, unless other applicable Union harmonisation legislation would require CE marking.

Article 2(2) (continued)

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

. . .

Equipment designed for self-defence is excluded from the PPE Regulation. Examples of such equipment are aerosol canisters and personal deterrent weapons.

PPE intended to protect against injuries in self-defence sporting activities, for example protective equipment for fencing or for martial arts as karate (*see standards series EN 13277*), fall under the PPE Regulation. This specific "exclusion from the exclusion" was introduced in the PPE Regulation in order to ensure that these kinds of PPE for sporting activities remain covered by the PPE Regulation.

Article 2(2) (continued)

(c) designed for private use to protect against:

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

(ii) damp and water during dishwashing;

. . .

PPE designed and manufactured for private use to provide protection against weather (atmospheric) conditions, including but not limited to seasonal clothing e.g. rainwear and clothing protecting against cold that is not extreme, does not fall under the scope of the PPE Regulation. Natural UV-radiation (sunlight) is not an atmospheric condition.

However, PPE for professional use designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme fall under the PPE Regulation. For example, rainwear and protection against cold in normal weather conditions for professional use is included in the scope of the PPE Regulation.

Dishwashing gloves for private use and solely designed and manufactured to provide protection against damp and water, do not fall under the scope of the PPE Regulation.

Protection against heat for private use, for example oven gloves and mitts, was excluded from the previous PPE Directive but is included in the PPE Regulation. Artisanal decorative products which do not claim to protect against heat, for example self-crocheted "potholders" from bazars with decorative function only, are by definition not PPE *(see Recital 10)*.

Article 2(2) (continued)

(d) for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;

. . .

This refers to PPE intended for the protection or rescue of persons on seagoing vessels or aircraft, not worn all the time i.e. only used in case of emergency. The term "seagoing vessels and aircraft" refer exclusively to those carrying passengers and to seagoing vessels subject to the international conventions such as the International Maritime Organisation (IMO) or the International Civil Aviation Organisation (ICAO).

Article 2(2) (continued)

(e) for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning

the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds.

- **2.3. Article 3 - Definitions**

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'personal protective equipment' (PPE) means:
(a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;

. . .

The field of PPE is not limited to equipment used by employees or workers in general, but extends to areas unconnected with work, such as sports and leisure activities. Sunglasses, cycling or riding helmets, gardening gloves, shin-guards for footballers, harnesses for mountaineering, are all PPE.

This definition has proved readily understandable to equipment manufacturers and users alike, although some borderline cases still raise questions. Every term in the definition is important:

– PPE is *"worn"* in the sense that clothing, glasses, hearing protectors or fall arrest harnesses are worn. Indeed much PPE is clothing, be it garments, headgear, gloves or footwear. Other PPE is to be *"held"* in the hand, such as screens to protect the eyes and face during welding. The protection provided by PPE thus depends on an action by the person exposed to the hazard: the donning or holding of the equipment.
Portable equipment which is neither worn nor held during use is not considered as PPE. So, for example, insulating mats or stools used by electricians for live working, or protective screens placed in the work stations are not regarded as PPE.

– PPE is worn or held *"by a person"*. This is what distinguishes personal equipment from collective protective equipment. Significantly, the terms of the definition of PPE place it within the broad field of the protection of persons.

– PPE is used *"for protection"* of the individual. Generally the equipment forms a shield between part of the body and the hazard for the protection of the individual against any type of risk: a shield of leather against rough surfaces which may graze the skin on hands, a shield of filtering glass against radiation which may injure the eyes, a shield of lead against X-rays which can damage body cells, and so on. This role of PPE as a shield is underlined by the pictograms which are sometimes chosen by PPE standards to symbolise protection against different hazards: a symbol representing the hazard is shown within a shield.

On the other hand, equipment warning against risks, but which do not have a protective function, such as stand-alone alarm devices e.g., gas detectors or oxygen depletion detectors, are not classed as PPE. However if these devices are integrated in the PPE then

they are to be considered as integral part of the PPE. (*see also EHSR 2.8 3rd paragraph and EHSR 3.11 b*)

Equipment used to perform physical tasks with less effort or more comfort e.g. by adding extra energy or keeping or improving the posture, but which do not have a protective function (e.g. some types of exoskeletons, back belts or cushioned shoes) are not classed as PPE. However, considering the variety of the products on the market and their quick evolution, an assessment should be made on a case-by-case basis.

– PPE protects against "one or more risks". Risk can be defined as the conjunction of two elements: a hazard, which is a phenomenon which may cause harm, and the probability of a person being exposed to that hazard[8]. Since PPE is designed to protect against risks, its function is to prevent the occurrence of harm to the exposed person. Consequently, when several risks exist simultaneously, the PPE has to protect against all the risks, not just against one of them.

This is what differentiates PPE from equipment used after harm has occurred, such as rescue or first-aid equipment, which also tends to be used by third parties. Equipment used by a rescuer is not classed as PPE, unless used to protect the rescuer himself, for example, respiratory protective devices used by firemen when retrieving people from smoke-filled buildings.

Equipment with non-automatic protective function, i.e. where the protective function has to be manually activated, is considered as PPE subject to the PPE Regulation.

The risks involved are those which may harm the user of the equipment. Equipment used to protect people other than the wearer, such as masks used to protect hospital patients, is not PPE. Nevertheless all equipment worn by health care personnel to protect themselves is PPE. Similar equipment for protecting goods, such as gloves worn to protect foodstuffs or electronic components, is not PPE.

Article 3 (continued)

(b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;

. . .

Interchangeable components are components used exclusively for the equipment referred to in Article 3(a). Items under this category are for example filters for respiratory protective

[8] In the "RAPEX Guidelines" (Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive) (notified under document C(2009) 9843) (2010/15/EU) (OJ L 22, 26.1.2010, p. 1), "risk" is defined as "combination of hazard and probability" and "the combination of the severity of possible damage to the consumer and the probability that this damage should occur" (point 2.1. of the "Risk Assessment Guidelines for Consumer Products"). In the Machinery Directive 2006/42/EC, "risk" is defined as "a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation (Annex I, 1.1.1.(e)).

devices and welding filters for eye protection. They are essential for the protective function and a part of the equipment referred to in Article 3(a).

Items of the PPE to be replaced by original parts or parts according to manufacturer's instructions and information and that has no impact on the protective function of the PPE do not fall under this definition. For example hygiene pads for protective earmuffs and sweat bands for safety helmets.

Article 3 (continued)

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

. . .

Connexion systems are regarded as PPE when tools are not needed to fasten or remove the connexion system. An air line linking respiratory equipment to a compressor is an example of a connexion system.

In contrary, a connexion system is not PPE when permanently fixed and when tools are needed to fasten or remove the connexion system to or from a structure. For example, anchor devices that are a part of the structure or require tools for its installation, for example in building and on machinery, are not regarded as PPE.

Article 3 (continued)

(2) '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;

. . .

A PPE is made available on the market when supplied for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

"Making available" supposes an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of the PPE after the stage of manufacture has taken place, that is, either the transfer of ownership, or the physical hand-over of the PPE by the manufacturer, his authorised representative in the EU or the importer to the person responsible for distributing these onto the EU market or the passing of the PPE to the final consumer, intermediate supplier or user in a commercial transaction, for payment or free of charge, regardless of the legal instrument upon which the transfer is based (sale, loan, hire, leasing, gift, or any other type of commercial legal instrument). The PPE must comply with the PPE Regulation at the moment of the first making available, that is, the placing on the market.

See also § 2.2. "Making available on the market" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(3) 'placing on the market' means the first making available of PPE on the Union market;

. . .

A PPE is placed on the market when it is made available for the first time on the European Union market, against payment or free of charge, for the purpose of distribution in the EU territory. It refers to each individual PPE and not to a type of PPE or series of PPE.

PPE made available on the market must comply with the applicable Union harmonisation legislation at the moment of placing on the market.

See also § 2.3. "Placing on the market" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(4) 'manufacturer' means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark;

. . .

For the obligations of manufacturers, see Article 8.

According to the definition, the manufacturer may design and manufacture the PPE itself, or alternatively may use bought-in items, third-party subcontractor services or components, CE marked or not, to assist in the manufacture of the PPE.

Whoever substantially modifies a PPE already placed on the market resulting in an "as-new" product, such that its health and safety characteristics (and/or performance) are in any way affected, with a view to placing it on the EU market, also becomes a manufacturer.

The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes or labels ready-made PPE and places them on the market under his own name or trademark.

See also § 3.1. "Manufacturer" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(5) '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;

. . .

For the obligations of authorised representatives, see Article 9.

An authorised representative is the person expressly appointed by the manufacturer by a written mandate to act on his behalf in respect of certain manufacturer's obligations within the EU. The extent to which the authorised representative may enter into commitments binding on the manufacturer is restricted by the relevant Articles of the PPE Regulation and determined by the mandate conferred on him by the latter.

When appointed, they must at least keep the EU declaration of conformity and the technical documentation within the EU at the disposal of the competent authorities; provide the competent authorities, upon request, with the information and documentation necessary to demonstrate the conformity of a product; and cooperate with the competent national authorities on any action taken to eliminate the risks posed by products covered by their mandate. They may also be appointed to affix the CE marking or draw up and sign the EU declaration of conformity.

See also § 3.2. "Authorised representative" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(6) 'importer' means any natural or legal person established within the Union who places PPE from a third country on the Union market;

. . .

For the obligations of importers, see Article 10.

The importer is the economic operator established in the EU who places a product from a third country on the Union market.

See also § 3.3. "Importer" and § 2.9. "Geographical application (EEA EFTA States, overseas countries and territories (OCTS), Turkey)" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(7) '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;

. . .

For the obligations of distributors, see Article 11.

The distributor is a natural or a legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

See also § 3.4. "Distributor" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(8) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

. . .

The "New Legislative Framework" as in Decision No 768/2008/EC defines the manufacturer, the authorised representative, the importer and the distributor as "economic operators". Users are not economic operators.

Article 3 (continued)

(9) 'technical specification' means a document that prescribes technical requirements to be fulfilled by PPE;

. . .

This is a very general concept that includes different kinds of technical requirements for PPE or categories of PPE, according to applicable legislation and/or to sectoral provisions. Technical specifications can be provided by standards or any other technical document drafted by authorised experts as well as by public or private organisations. They can establish a "minimum" as "essential requirements" or can be more detailed in terms of specific technical solutions for design and manufacturing of a PPE.

Since the "New Approach" / "New Legislative Framework" calls for common essential requirements to be made mandatory by legislation, this approach is appropriate only where it is possible to distinguish between essential requirements (*see Annex II*) and technical specifications.

Article 3 (continued)

(10) 'harmonised standard' means a harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

. . .

The PPE Regulation provides manufacturers with the option of complying with its requirements by designing and manufacturing either directly in accordance with the essential health and safety requirements of the PPE Regulation, or by using harmonised European standards as defined in the Standardisation Regulation (EU) No 1025/2012, which are developed specifically to cover the essential requirements in order to confer a presumption of conformity with those requirements, when the references of such standards are published in the Official Journal of the European Union (OJEU).

See also Article 14 on presumption of conformity of products, and § 4.1.2.2. "Role of harmonised standards" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(11) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(12) 'national accreditation body' means a national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

. . .

Accreditation is the attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.

It is based on the international standards for conformity assessment bodies that have been harmonised in the "New Legislative Framework" and the references of which have been published in the Official Journal of the European Union (OJEU). With Regulation (EC) No 765/2008, only national accreditation bodies are allowed to provide accreditation of conformity assessment bodies.

Accreditation is to be operated as a public authority activity and is to be provided on a not-for-profit basis.

Each EU Member State may appoint one single national accreditation body. The responsibilities and tasks of the national accreditation body have to be clearly distinguished from those of other national authorities.

Within the EU, accreditation bodies are not allowed to compete with other accreditation bodies. They can only be active on the territory of their own Member State (with the exception of cases of "cross-border accreditation" as per Article 7(1) of Regulation (EC) No 765/2008).

See also § 6. "Accreditation" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(13) 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Regulation relating to PPE have been fulfilled;

(14) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

. . .

As for the other EU legislative acts under the "New Approach" / "New Legislative Framework" covering products in the internal market, two important elements of the PPE Regulation are:

– the legislative requirements governing the characteristics of the PPE covered, and
– the conformity assessment procedures the manufacturer carries out in order to demonstrate that a PPE, before it is placed on the market, conforms to these legislative requirements.

Conformity assessment is the process carried out by the manufacturer of demonstrating whether specified requirements relating to a PPE have been fulfilled.

A PPE is subjected to conformity assessment both during the design and production phase. Conformity assessment is the responsibility of the manufacturer. Should a manufacturer subcontract design or production, he still remains responsible for the execution of conformity assessment.

The essential objective of a conformity assessment procedure is to demonstrate that products placed on the market conform to the requirements expressed in the provisions of the relevant legislation.

Conformity assessment bodies (notified bodies under the PPE Regulation) provide the professional and independent judgements, which consequently enable manufacturers or their authorised representatives to fulfil the procedures in order to presume conformity to the PPE Regulation. Their intervention is required for:
– issuing of EU type-examination certificates, following inspection, verification and testing of PPE against the EHSRs before they can be placed on the market;
– the assessment of conformity of production according to the procedures set out in Annexes VII and VIII for Category III PPE.

See also § 5. "Conformity assessment" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(15) 'recall' means any measure aimed at achieving the return of PPE that has already been made available to the end-user;

(16) 'withdrawal' means any measure aimed at preventing PPE in the supply chain from being made available on the market;

. . .

Competent national authorities must take action to enforce compliance, when they discover that a PPE is not in conformity with the applicable provisions of the PPE Regulation.

Enforcement against non-conformity can be achieved by obliging the manufacturer, the authorised representative, or other responsible persons, to take required measures, including recall and withdrawing of PPE from the market.

In case of formal non-compliance the market surveillance authority should first oblige the manufacturer, or the authorised representative, to make the PPE intended to be placed on the market and if necessary, the PPE already on the market, comply with the provisions and to remedy the infringement.

See also § 7.4.2. "Market surveillance measures" in "The 'Blue Guide' on the implementation of EU product rules".

Article 3 (continued)

(17) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

. . .

Union harmonisation legislation is issued by the European Union, for products in the single internal Union market.

Article 3 (continued)

(18) '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.

As a general rule, the "New Approach" / "New Legislative Framework" legislation, including the PPE Regulation, provides for the affixing of the CE marking as part of the conformity assessment procedures in the perspective of total harmonisation.

Where a PPE is subject to several Union harmonisation legislations, which all provide for the affixing of CE marking, the marking indicates that the PPE is presumed to conform to the provisions of all these Union harmonisation legislations.

The CE marking is mandatory and must be affixed before any PPE is placed on the market.

Articles 16 and 17 of the PPE Regulation set out the general principles of the CE marking (making reference to Regulation (EC) No 765/2008) and the rules and conditions for affixing the CE marking.

- **2.4. Article 4 - Making available on the market**

Article 4

Making available on the market

PPE shall only be made available on the market if, where properly maintained and used for its intended purpose, it complies with this Regulation and does not endanger the health or safety of persons, domestic animals or property.

A PPE is made available on the market when supplied for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. This concept of "making available" refers to each individual PPE.

The concept of "placing on the market" is directly related to "making available" in the sense that a PPE is placed on the market when it is made available for the first time on the Union

market. PPE made available on the market must comply with the applicable Union harmonisation legislation at the moment of placing on the market.

- **2.5. Article 5 - Essential health and safety requirements**

Article 5

Essential health and safety requirements

PPE shall meet the essential health and safety requirements set out in Annex II which apply to it.

Article 5 sets out the obligation of the manufacturer to design and produce PPE which satisfies the requirements of Annex II to the PPE Regulation. The manufacturer must ensure that the EHSRs remain fulfilled during the lifetime of the PPE.

Only PPE complying with these EHSRs may be placed on the Union market. The manufacturer must provide information about the measures he has taken in order to ensure the conformity of the PPE to the EHSRs in his technical documentation which is further referred to in Article 8 and described in detail in Annex III to the PPE Regulation.

EHSRs only deal with product characteristics aimed at ensuring the health and safety of intended users. They do not cover either environmental or social aspects.

These requirements are designed to ensure the optimal level of protection of the user from risks. They:

- arise from certain risks that a user is exposed to, associated with the product, for example physical, mechanical, exposure to heat and flames, chemical, electrical, biological, hygiene or radioactivity;
- refer to the PPE and/or its performance, for example provisions regarding materials, design, construction, manufacturing process, instructions drawn up by the manufacturer;
- lay down the principal protection objective(s) for example by means of an illustrative list;

or a combination of these three aspects.

- **2.6. Article 6 - Provisions concerning the use of PPE**

Article 6

Provisions concerning the use of PPE

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

Member States retain the right to lay down additional national provisions regarding the use of PPE which is intended to ensure the protection of workers or other intended users.

Directives 89/391/EEC and 89/656/EEC lay down minimum requirements for the health and safety of users under Article 153 of the Treaty on the Functioning of the European Union

(TFEU). Member States are allowed to adopt or retain more stringent provisions, so long as they are compatible with the Treaty.

However, such measures must neither lead to the modification of a PPE designed and manufactured in accordance with the provisions of the applicable Union harmonisation legislation, nor influence the conditions for its placing on the Union market. This is evidently the case with the Regulation, which is a total harmonisation Regulation under Article 114 of the TFEU.

National regulations (e.g. national exposure values) can lead to different rules for selection and use of PPE.

The PPE Regulation does not lay down obligations for users. However, it must be remembered that according to Directives based on Article 153 of the TFEU, employers have obligations as regards the use of work equipment at the workplace. An employer is considered to be any natural or legal person who has an employment relationship with a worker (that is any person employed by an employer), and has responsibility for the undertaking or establishment.

- **2.7. Article 7 - Free movement**

Article 7

Free movement

1. Member States shall not impede, for the aspects covered by this Regulation, the making available on the market of PPE which complies with this Regulation.

. . .

The objective of eliminating trade barriers among the EU Member States and of strengthening the free movement of PPE guarantees the free movement of PPE complying with the legislation. Therefore, Member States shall not impede the making available on the market of a PPE which complies with all the provisions of the PPE Regulation.

See also § 8. "Free movement of products within the EU" in "The 'Blue Guide' on the implementation of EU product rules".

Article 7 (continued)

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.

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

The second paragraph of Article 7 concerns the showing at exhibitions of PPE which do not comply with the Regulation. The display of PPE at a trade or retail show does not constitute "placing on the market".

3. CHAPTER II - OBLIGATIONS OF ECONOMIC OPERATORS

Chapter II of the PPE Regulation deals with obligations and identification of manufacturers, authorised representatives, importers and distributors, collectively defined as "economic operators". Those are the active parts in the supply chain when a PPE is placed and made available on the EU market and in this sense, specific obligations and responsibilities are defined. It should be noted that users (consumers, workers…) are not considered as "economic operators" with respect to the PPE Regulation.

See also § 3. "The actors in the product supply chain and their obligations" in "The 'Blue Guide' on the implementation of EU product rules".

- **3.1. Article 8 - Obligations of the manufacturers**

Article 8

Obligations of the manufacturers

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.

2. Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15 and affix the CE marking referred to in Article 16.

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

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 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.

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 in a document accompanying the PPE.

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.

7. Manufacturers shall ensure that the PPE is accompanied by the instructions and 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 and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

8. The manufacturer shall either provide the EU declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the EU declaration of conformity can be accessed.

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 corrective measures necessary to bring that PPE 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 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.

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 with this Regulation, 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.

For the definition of manufacturer, see Article 3(4).

The manufacturer has sole and ultimate responsibility for the conformity of his PPE with the applicable Union harmonisation legislation. He must understand both the design and construction of the PPE to be able to declare such conformity in respect of all applicable provisions and requirements of the relevant Union harmonisation legislation.

The placing on the market referred to in Article 8(3) is the last placing on the market of a single PPE which is in conformity with the model for which the certification has been granted. For example, if the PPE is in production for 5 years, the file must be archived for at least 15 years (counting from the first PPE of the series placed on the market).

The important point in Article 8(5) is that the type, batch or serial number must make a clear link to the relevant documentation that demonstrates the conformity of the specific type of PPE and in particular to the EU declaration of conformity. This is left to the discretion of the manufacturer. But manufacturers should be aware that when public authorities in charge of market surveillance recall products and if it is not possible to distinguish between batches or serial numbers, all products of that type or batch must be removed from the market. The PPE Regulation allows placing the information on the packaging or in a document accompanying the product if the size or nature of the product does not allow it. If the information is not visible at a first sight, it must be easily and safely accessible.

The manufacturers' instructions and information for use according to 8(7) has to be written in the language(s) decided by the Member States where the PPE is intended to be sold, the translation of such information must be provided by the manufacturer and/or his authorized representative established in the Union under his/their responsibility. Manufacturers are advised to check the language requirements with the national authorities concerned.

The manufacturer's instructions and information are one of the fundamental elements of any PPE and as such they have to be clear, concise, understandable and giving the appropriate information for the end users. It should be taken into account that the manufacturer's instructions and information may only be considered effective when they are easily perceived and understood, retained and appropriately used. Since the manufacturer's instructions and information provides the basis on which consumers can make a reasoned selection of appropriate PPE, it is also one of the means to increase the health and safety of the intended end user. High quality information minimises the risk of an incorrect selection and/or misuse. The better the quality of information, the easier the selection and correct use of the PPE will be.

The instructions for use shall accompany each single PPE, or each batch of identical products delivered to the same end user.

In order to enhance the manufacturer's instructions and information, the font size should be as large as possible to aid readers. The readability of text is also influenced by contrast between print colour and support and opacity of support.

For the purposes of market surveillance, among others, the EU declaration of conformity in Article 8(8) must either be accompanied with the instructions for use document or the internet address at which the EU declaration of conformity can be accessed, included in the instructions for use. If the internet option is chosen, manufacturers can use different solutions (e.g. direct web address, generic webpage with search function), but it must be ensured that the EU declaration of conformity is easily accessible via this route.

See also § 4.4. "EU declaration of conformity" in "The 'Blue Guide' on the implementation of EU product rules".

Articles 14-19 and the associated annexes to the PPE Regulation define the obligations of the manufacturer with regards to conformity assessment, CE marking, the EU declaration of conformity as well as the arrangements for holding the EU declaration of conformity and the technical documentation at the disposal of the competent authorities for a period of 10 years after the last single unit PPE has been placed on the market.

See also § 3.1. "Manufacturer" in "The 'Blue Guide' on the implementation of EU product rules".

- **3.2. Article 9 - Authorised representatives**

Article 9

Authorised representatives

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.

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:

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

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

For the definition of authorised representative, see Article 3(5).

Article 9 of the PPE Regulation defines the role and possible tasks of the authorised representative established within the EU, on the basis of the mandate of the manufacturer: such mandate has to cover at least specific activities related to conformity assessment, CE marking, EU declaration of conformity, as well as the arrangements for holding the EU declaration of conformity and the technical documentation at the disposal of the competent authorities for a period of 10 (ten) years after the last single unit of PPE has been placed on the market.

See also § 3.2. "Authorised representative" in "The 'Blue Guide' on the implementation of EU product rules".

- **3.3. Article 10 - Obligations of importers**

Article 10

Obligations of importers

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

2. Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 19 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 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

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.

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.

4. Importers shall ensure that the PPE is accompanied by the instructions and 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.

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.

6. 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.

7. 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 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.

8. Importers shall, for 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.

9. 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.

For the definition of importer, see Article 3(6).

The importer has important and clearly defined responsibilities under the PPE Regulation, to a large extent based on the type of responsibilities which a manufacturer based in the EU is subjected to.

The importer must ensure that the manufacturer has correctly fulfilled his obligations. The importer is not a simple re-seller of products, but has a key role to play in guaranteeing the compliance of imported products.

See also § 3.3. "Importer" in "The 'Blue Guide' on the implementation of EU product rules".

Imported products are required to indicate the name and address of the manufacturer and of the importer, as a basic traceability requirement for market surveillance. But, if both, manufacturer and importer, belong to the same group or company and if the company based in the EU takes the full manufacturer's responsibility, the indication of the branch based in the EU will suffice to comply with the requirements.

See also § 4.2.2. "Traceability provisions" in "The 'Blue Guide' on the implementation of EU product rules".

- **3.4. Article 11 - Obligations of distributors**

Article 11

Obligations of distributors

1. When making PPE available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required documents and by the instructions and 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.

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.

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.

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

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.

For the definition of distributor, see Article 3(7).

Along with manufacturers and importers, distributors are the third category of economic operators who are subject to specific obligations. The distributor is a natural or a legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market. Retailers, wholesalers and other distributors in the supply chain are not required to have a preferential relationship with the manufacturer like the authorised representative. A distributor acquires products for further distribution either from a manufacturer, from an importer, or from another distributor.

Distributors must act with due care in relation to the applicable requirements of the PPE Regulation. Due care refers to the effort made by an ordinarily prudent or reasonable party to avoid harm to another, taking the circumstances into account. It refers to the level of judgement, precaution, prudence, determination and activity that a person would reasonably be expected to do under particular circumstances.

Distributors have to know, for instance, which products must bear the CE marking, what information has to be provided with the product (for example the EU declaration of conformity), what are the language requirements for labelling, user instructions or other accompanying documents, and what is a clear indication of the product being non-compliant. They have an obligation to demonstrate to the national market surveillance authority that they have acted with due care and make sure that the manufacturer, or his authorised representative, or the person who provided him with the product has taken the measures required by the PPE Regulation, as far as can be reasonably expected.

Conformity assessment, drawing up and keeping the EU declaration of conformity and the technical documentation remain the responsibility of the manufacturer. It is not part of the distributor's obligations to check whether a product already placed on the market is still in conformity with the legal obligations that are currently applicable in case these have changed. The obligations of the distributor refer to the legislation applicable when the product was placed on the market by the manufacturer or the importer.

The distributor must be able to identify the manufacturer, his authorised representative, the importer or the person who has provided him with the product in order to assist the market surveillance authority in its efforts to obtain the EU declaration of conformity and the necessary parts of the technical documentation. Market surveillance authorities have the possibility to address their request for the technical documentation directly to the distributor. The latter is however not expected to be in possession of the relevant documentation.

See also § 3.4. "Distributor" in "The 'Blue Guide' on the implementation of EU product rules".

- **3.5. 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

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.

The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes or labels ready-made PPE and places them on the market under his own name or trademark. Further, the responsibility of the manufacturer is placed on any person who changes the intended use of a PPE in such a way that different essential or other legal requirements will become applicable, or substantially modifies or re-builds a PPE (thus creating a new PPE), with a view to placing it on the market.

See also § 3.1. "Manufacturer" in "The 'Blue Guide' on the implementation of EU product rules".

- **3.6. Article 13 - Identification of economic operators**

Article 13

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with PPE;

(b) any economic operator to whom they have supplied PPE.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the PPE and for 10 years after they have supplied the PPE.

Economic operators are obliged to keep track of the economic operators they supplied their PPE to or from whom they bought their PPE for a period of 10 years. End-users are not covered by this requirement as they are not considered to be economic operators.

The way to comply with this requirement by economic operators is not prescribed by the PPE Regulation, but it must be noted that market surveillance authorities can ask for relevant documents, including invoices, allowing the origin of the product to be traced. Hence, it could be useful to keep invoices for a longer period than envisaged in accounting legislation to comply with the requirements on traceability.

See also § 4.2.2.6. "Identification of economic operators" in "The 'Blue Guide' on the implementation of EU product rules".

4. CHAPTER III - CONFORMITY OF THE PPE

Chapter III of the PPE Regulation (EU) 2016/425 deals with presumption of conformity of PPE and the EU declaration of conformity.

- **4.1. Article 14 - Presumption of conformity of PPE**

Article 14

Presumption of conformity of PPE

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.

The presumption of conformity of PPE is confirmed by the use of harmonised European standards (hENs) of which the reference is published in all official EU languages in the Official Journal of the European Union (OJEU).

The European Standardisation Organisations (ESOs: CEN and CENELEC for the PPE sector) and their specific Technical Committees, as well as other sectoral interested parties (national experts, notified bodies, industry, etc.) are involved in the development of European standards. These standards are usually the preferred option by manufacturers to demonstrate compliance once they become available as harmonised standards and their references are published in the OJEU.

Harmonised European standards are the only documents that can be applied to provide presumption of conformity with the essential health and safety requirements of the PPE Regulation covered by the standards. However, their use is voluntary: manufacturers may also decide to use other existing European, international or national standards and/or technical specifications regarded as important, relevant or useful to cover the applicable essential health and safety requirements of the PPE Regulation, together with additional controls addressing those other requirements not already covered. These alternative means do not benefit from the presumption of conformity; when used by the manufacturer, he must demonstrate that by applying these alternative means the PPE complies with the relevant EHSRs.

European standards are reviewed and updated on a regular basis and in response to new technical knowledge, to reflect the “state of the art”. During the process of updating of a standard, a manufacturer may continue to use a current harmonised standard for the assessment procedure of compliance with the PPE Regulation, until a new harmonised standard replaces (supersedes) the previous one after a set transition period.

For Category II and III PPE, when an applied harmonised European standard does not cover all EHSRs, the EU type-examination procedure carried out by the notified body must assess compliance with the EHSRs directly, in order to issue the relevant the EU type-examination certificate. If this is the case for Category I PPE, the manufacturer must be able to demonstrate how the compliance to the EHSRs has been assured.

See also § 4.1.2. "Conformity with the essential requirements: harmonised standards" in "The 'Blue Guide' on the implementation of EU product rules".

Harmonised European standards, specifying technical requirements to the EHSRs in Annex II of the PPE Regulation, are developed by the following European Standardisation Organisations (ESOs):
– European Committee for Standardisation (CEN)
– European Committee for Electrotechnical Standardisation (CENELEC)

Detailed information on the EU standardisation policy is available at:
http://ec.europa.eu/growth/single-market/european-standards/policy/.

The list of references of harmonised European standards in the OJEU under the PPE Regulation is regularly updated and is available at the following European Commission Internet address:
http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment/.

Information on harmonised European standards is also available on the CEN and CENELEC websites:
– http://www.cen.eu
– http://www.cenelec.eu

A list of the national standardisation organizations is provided at:
– CEN - http://standards.cen.eu/dyn/www/f?p=CENWEB:5
– CENELEC - http://www.cenelec.eu/dyn/www/f?p=WEB:5

National transpositions of harmonised European standards are available from the national standardisation bodies which are members of CEN and CENELEC.

- **4.2. Article 15 - EU declaration of conformity**

Article 15

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.

. . .

The EU declaration of conformity is the legal statement by the manufacturer or his authorised representative established in the Union, attesting that the PPE being placed on the market complies with all relevant provisions of the PPE Regulation.

Once the manufacturer has undertaken the appropriate procedures to assure conformity with the essential health and safety requirements of the PPE Regulation, it is the responsibility of the manufacturer or his authorised representative established in the EU to draw up a written EU declaration of conformity according to Annex IX and affix the CE marking.

The manufacturer, his authorised representative established in the EU or the importer shall keep a copy of the EU declaration of conformity for a period of 10 years after the last single unit of PPE has been placed on the market (*see Articles 8, 9 and 10*). When the manufacturer is not established within the EU, the obligation to keep the copy of the EU declaration of conformity available, during the same period of 10 years, is the responsibility of the importer who places the product on the EU market or the manufacturer's authorised representative.

> *Article 15 (continued)*
>
> 2. The EU declaration of conformity shall have 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.
>
> . . .

The EU declaration of conformity must be written taking into account the category of the PPE according to Article 18.

For Category II and III PPE, when notified bodies are involved in the conformity assessment procedure, the EU declaration of conformity must contain the name and the identification number of the notified body, as well as the number of the EU type-examination certificate. For Category III PPE, the declaration of conformity must also contain the name and the identification number of the notified body involved in the production assessment.

> *Article 15 (continued)*
>
> 3. 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.
>
> . . .

Union harmonisation legislation sometime covers a wide range of products, phenomena and/or risks.

As a result several Union harmonisation legislations may have to be taken into consideration for PPE, since the placing on the market can only take place when the PPE complies with the provisions of all legislation applicable to it.

Manufacturers of PPE may need to consider the following Union harmonisation legislations[9]:

- **Pressure Equipment Directive** (PED) 2014/68/EU

  The PED applies to a limited range of PPE equipment for holding gasses under pressure, for example breathing devices.

[9] Please note that this list of examples is not exhaustive.

- **Electromagnetic Compatibility** (EMC) **Directive** 2014/30/EU

  The EMCD must also be applied to ensure that PPE with electrical or electronic devices does not cause electromagnetic disturbance and that its normal operation is not affected by such disturbances.

- **Radio Equipment Directive** (RED) 2014/53/EU

  The RED must also be applied to ensure that PPE incorporating such device(s) is safe and does not disturb radio services or other equipment. The RED also covers EMC and safety aspects of such equipment.

- **General Product Safety Directive** (GPSD) 2001/95/EC

  The GPSD requires that producers only place on the market safe products destined for the consumer and entrusts Member States with the obligation to ensure that both producers and distributors comply with their obligations.
  For more information, see the "Guidance document on the relationship between the General Product Safety Directive (GPSD) and certain sectorial Directives with provisions on safety of products"[10].

There are also a number of products which, whilst they may appear to fall within the scope of the PPE Regulation, are dealt with by other Union harmonisation legislations because of their "specificity", as follows:

- **Toys Directive** 2009/48/EC

  Equipment designed to be worn by children to protect them against one or more risks falls within the scope of the PPE Regulation e.g. bicycle or ski helmets, ski goggles etc. However, imitations of PPE (such as imitations of firemen's helmets, doctor's protective clothing) fall under the Toys Directive. Where there may be doubt as to the real intended use of such a product, it has been agreed with the Member States that such products should be supplied with a warning to the effect that they are toys and not PPE. Care does need to be taken by the manufacturer if it appears that imitation PPE might be reasonably assumed to protect against hazards. In such cases the manufacturer may not be able to derogate from his liability even with such a warning.
  Without prejudice to the above, on 5 November 2008 the PPE WG further clarified the borderline between the two legislations by agreeing distinguishing two categories of products:
  a) Toys which imitate PPE but are toys are only acceptable if it is clear that no protection be expected from them. For example: products imitating a fireman's or motorcyclist's helmet in a fancy dress outfit.
  b) Products for children which have a protection function are considered to be PPE. For example a child's cycle helmet, irrespective of its appearance, is a PPE because of its intended use and expected protection.

[10] For more information please visit "Product safety rules": http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/general_product_safety_directive/index_en.htm.

- **Medical Devices Directive** (MDD) 93/42/EEC

  The MDD applies to devices, other than medicines, used in health care. It aims to protect the health and safety of patients, users of medical devices and other exposed persons. Furthermore a subsequent modification to the MDD makes it possible that "Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and the MDD, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled" (Article 2 (l) (f) of Directive 2007/47/EC).
  On the consequences of this amendment please refer to the following interpretative document:
  http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/interpretative_ppe_2009_en.pdf.
  On 5 April 2017, two new Regulations on medical devices were adopted: Regulation (EU) 2017/745 and Regulation (EU) 2017/746. These replace the existing Directives and will apply after a transitional period: see
  http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en.

- **Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres** (ATEX) **Directive** 2014/34/EU

  Equipment covered by the PPE Regulation is specifically excluded from the ATEX Directive and shall not be marked with the specific marking of explosion protection. However, the manufacturer of PPE for use in potentially explosive atmospheres is required to consider EHSR 2.6. PPE intended for use in 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. Following the Essential Health and Safety Requirements in the ATEX Directive would be one way to demonstrate compliance.

- **Marine Equipment Directive** (MED) 2014/90/EU

  Equipment covered by the MED is not designed to fulfil the role of PPE. Such safety equipment is subject to specific standards listed in Annex I of the MED and is for use only in emergency situations or during training.

Article 15 (continued)

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

The completion of the EU declaration of conformity and its signature, together with the affixing of the CE marking prescribed by Article 16 and 17, is one of the last actions in any of the conformity assessment procedures. Once affixed to a PPE, the manufacturer or his authorised representative attests that the appropriate conformity assessment procedures have been completed in accordance with all the provisions of this Regulation, and the manufacturer assumes full responsibility for the compliance of the product.

- **4.3. Article 16 - General principles of the CE marking**

Article 16

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Regulation (EC) No 765/2008 lays down the general principles governing the CE marking, while Decision No 768/2008/EC provides for the rules governing its affixing. The PPE Regulation (EC) 2016/425, as the other sectoral Union harmonisation legislation providing for CE marking, is based on the Regulations mentioned above.

See also § 4.5. "Marking requirements" in "The 'Blue Guide' on the implementation of EU product rules".

- **4.4. Article 17 - Rules and conditions for affixing the CE marking**

Article 17

Rules and conditions for affixing the CE marking

1. 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 documents accompanying the PPE.

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

3. For Category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure 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.

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.

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.

PPE must, when placed on the market, bear the CE marking on the PPE, or on the packaging in certain conditions as required. In case of Category III PPE, listed in Annex I of the PPE Regulation, the identification number of the notified body involved in one of the procedures set out in Annex VII and VIII, must follow the CE marking.

The CE marking shall, as a rule, be affixed to the PPE. However, in exceptional circumstances, the CE marking may not be placed on the PPE itself, if the conditions do not permit its affixing. This would be justified where affixing it to the PPE is:

- virtually impossible,
- not achievable under reasonable technical and economic conditions,

- where the minimum dimensions of the CE marking cannot be respected, or
- when it cannot be ensured that the CE marking is visibly, legibly and indelibly affixed.

In such cases, the CE marking has to be affixed to the smallest commercially available packaging intended for the end user and to the documents accompanying the PPE.

The CE marking symbolises conformity to all applicable provisions of the Union harmonisation legislation which provide for its affixing. Therefore the affixing of other marks, except for a pictogram or other marking indicating the risk against which the PPE is intended to protect, such as the manufacturer's logo or a voluntary quality mark overlapping with or which may be confused with the CE marking, is prohibited.

5. CHAPTER IV - CONFORMITY ASSESSMENT

Chapter IV of the PPE Regulation (EU) 2016/425 deals with the risk categories of PPE and conformity assessment procedures.

- **5.1. Article 18 - Risk categories of PPE**

Article 18

Risk categories of PPE

The PPE shall be classified according to the risk categories set out in Annex I.

Article 18 gives the classification of PPE covered by the PPE Regulation into risk categories, Category I, II and III, as listed in Annex I.

The Appendix to these Guidelines in the Appendix provides information on borderline cases and exclusions of different types of PPE. The information in the Appendix reflects the outcome of the discussions in the PPE Working Group with the Commission, Member States and other interested parties.

- **5.2. Article 19 - Conformity assessment procedures**

Article 19

Conformity assessment procedures

The conformity assessment procedures to be followed for each of the risk categories set out in Annex I are as follows:

(a) Category I: internal production control (module A) set out in Annex IV;

(b) Category II: EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C) set out in Annex VI;

(c) Category III: EU type-examination (module B) set out in Annex V, and either of the following:

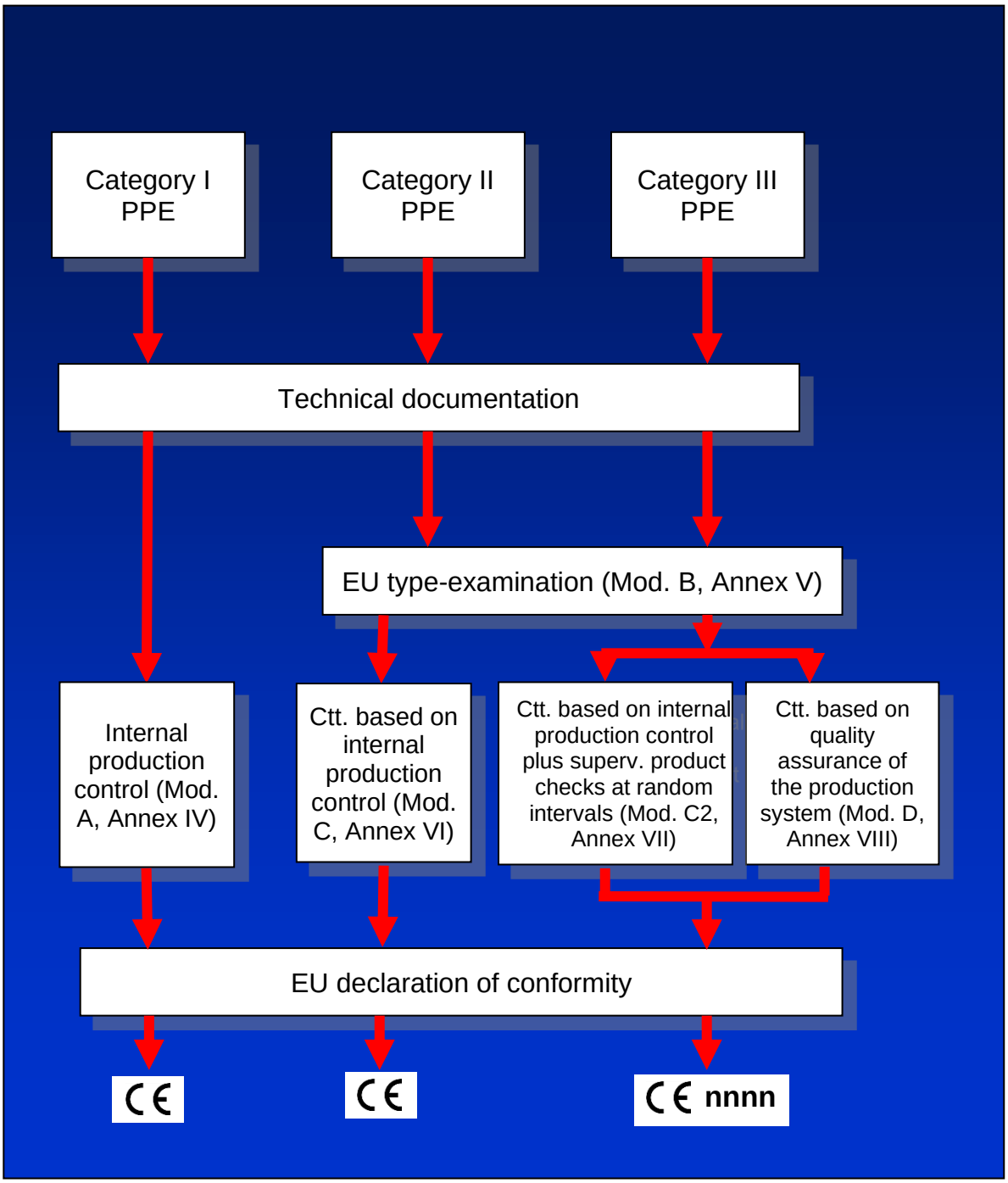
(i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII;

(ii) 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 referred to in point (b) may be followed.

Article 19 specifies the relevant conformity assessment procedures for the different risk categories as defined in Annex I.

The scheme below gives an overview of the conformity assessment procedures for the different categories of PPE. (Ctt. = Conformity to type)



For Category II and III PPE, before serial production starts, the model (type) of the PPE has to be submitted for an EU type-examination. Exceptions are pre-prototypes and research prototypes.

For Category III PPE, before placing on the market, the manufacturer shall lodge an application for supervised product checks at random intervals as set in Annex VII or for assessment of his quality system as set in Annex VIII to a single notified body, and fulfil, respectively, the obligations there indicated.

PPE produced as a single unit to fit an individual user have to be adapted to a specific intended user to ensure perfect fit and functionality. This means that such PPE are unique pieces. Examples of PPE produced as a single unit to fit an individual user are, e.g. custom-made orthopaedic footwear, where a single product is produced for the specific medical needs of the user. Because of the fact that there is only one single product, production control measures are not feasible (the single product would have to be destroyed in the testing and is not possible to perform product quality assessment according to Annexes VII and VIII as they are produced in single units and not in series). Therefore, the conformity assessment procedure in Article 19(b) may be followed for these PPE. In this case is not possible for the identification number of the notified body involved in one of the procedures, set out in Annex VII and VIII, to follow the CE marking.

Other products, PPE produced in series which need to be adapted to individual users, for example custom-moulded earplugs, safety footwear with inserted orthopaedic inlay soles and protective glasses with corrective lenses, can be subject to production control, since the tests would be carried out on the basic model subject to the EU type-examination, and a range for adaptation would be defined.

6. CHAPTER V - NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Chapter V of the PPE Regulation (EU) 2016/425 deals with the requirements and notification procedures for notifying authorities in the EU Member States and for notified conformity assessment bodies – in short, "notified bodies". The Regulation includes the related contents of Decision No 768/2008/EC.

Notified bodies must provide the professional and independent judgements, which consequently enable manufacturers or their authorised representatives to fulfil the procedures in order to presume conformity to the PPE Regulation. Their intervention is required:

- for the type-examination assessment and the issuing of EU type-examination certificates for Category II and III PPE before they can be placed on the market;
- for the production control assessment measures set out in Annexes VII and VIII to the PPE Regulation.

See also §§ 5.2. "Conformity assessment bodies" and 5.3 "Notification" in "The 'Blue Guide' on the implementation of EU product rules".

• 6.1. Article 20 - Notification

Article 20

Notification

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.

The bodies authorised to undertake the tasks referred to in Article 19 in relation to the conformity assessment procedures of the PPE Regulation must be notified by the Member State under whose jurisdiction they fall, on their own responsibility, to the European Commission and the other Member States of the EU. This notification also includes the relevant scope of competence for which that body has been assessed as technically competent to certify against the essential health and safety requirements as shown in the PPE Regulation. For the EU Member States, this responsibility of notification involves the obligation to ensure that the notified bodies permanently maintain the technical competence required by the PPE Regulation and that they keep their notifying authorities informed on the performance of their tasks.

Therefore, an EU Member State, which does not have a technically competent body under its jurisdiction to notify, is not required to make such a notification. A manufacturer always has the choice of contacting any notified body with the appropriate scope of technical competence, which has been notified by any Member State.

On their own responsibility, Member States reserve the right not to notify a body and to remove an appointment, should there be reason to do so. In the latter circumstance the relevant Member State shall inform the Commission and all the other Member States.

- **6.2. Article 21 - Notifying authorities**

Article 21

Notifying authorities

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 26.

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.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article 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 22. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

A notifying authority is the governmental or public body with the task to designate and notify conformity assessment bodies under the PPE Regulation. Most often it is the national administration responsible for the implementation and management of the Union harmonisation legislation under which the body is notified. Each Member State must designate a notifying authority to be responsible for the assessment, notification and monitoring of conformity assessment bodies. The notifying authority assumes full responsibility for the competence of the bodies it notifies.

- **6.3. Article 22 - Requirements relating to notifying authorities**

Article 22

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

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.

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.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its

disposal for the proper performance of its tasks.

Each Member State must establish its notifying authorities in such a way that there is no conflict of interest with conformity assessment bodies. They must be organised and operated so as to safeguard the objectivity and impartiality of their activities. Each decision relating to notification of a conformity assessment body must be taken by competent persons different from those who carried out the assessment.

Further requirements on a notifying authority are that it must not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis. It must safeguard the confidentiality of the information it obtains, and it must have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

- **6.4. Article 23 - Information obligation on notifying authorities**

Article 23

Information obligation on notifying authorities

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.

The Commission shall make that information publicly available.

Member States must inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies. The Commission makes that information publicly available on its NANDO website.

- **6.5. Article 24 - Requirements relating to notified bodies**

Article 24

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the 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.

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 the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

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 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.

A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

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.

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.

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.

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:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(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;

(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.

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.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and

adequate authority to carry out those assessments;

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

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

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.

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 their tasks under Annexes V, VII and VIII or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

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 36 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 24 of the PPE Regulation defines the criteria that notified bodies must fulfil. Bodies which are able to provide proof of their conformity with such criteria by presenting to their notifying authorities a certificate of accreditation, or other sufficient means of documentary proof, are considered notifiable and in this respect they conform to Article 24 of the Regulation.

Notified bodies are designated to assess conformity with the essential health and safety requirements of the PPE Regulation, and to ensure consistent technical application of these requirements according to the relevant procedures in the PPE Regulation. The notified bodies must have appropriate facilities and technical staff that enable them to carry out technical and administrative tasks related to conformity assessment. They must also apply appropriate procedures of quality control in relation to such services provided.

A notified body wishing to offer services according to one or more of the conformity assessment procedures, specified in Annexes V, VII and VIII, must fulfil the relevant requirements for each different procedure in question, and this has to be assessed according to these requirements. A notified body may be notified for a defined range of products only and does not need to be qualified to cover all products falling within the scope of the PPE Regulation.

Notified bodies must have appropriate structures and procedures to ensure that the conduct of conformity assessment and the issuing of certificates are subject to a review process. Relevant procedures must, in particular, cover obligations and responsibilities in relation to suspension and withdrawal of certificates, requests addressed to the manufacturer to take corrective measures, and reporting to the competent authority.

There is no guidance document at the European level which indicates the financial value of liability insurance. It should generally correspond to the level of activities of the notified body in the field of PPE. The insurance should in particular cover cases where the notified body may be obliged to withdraw certificates.

To provide for technical competence, notified bodies are obliged to either participate directly or be represented in European standardisation or otherwise ensure that they keep themselves informed of the standardisation and its development.

- **6.6. Article 25 - Presumption of conformity of notified bodies**

Article 25

Presumption of conformity of notified bodies

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 out in Article 24 in so far as the applicable harmonised standards cover those requirements.

Relevant harmonised European standards, i.e. the EN ISO/IEC 17000 series of standards, provide useful and appropriate mechanisms towards presumption of conformity of notified bodies to some criteria set out in Article 24 of the PPE Regulation (the referred standards do not cover all those criteria). However, this does not rule out the possibility of bodies not conforming to the harmonised standards to be notified, on the grounds that compliance is obligatory only with respect to the criteria set out in Article 24 of the Regulation.

- **6.7. Article 26 - Subsidiaries of and subcontracting by notified bodies**

Article 26

Subsidiaries of and subcontracting by notified bodies

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 24 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant

documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes V, VII and VIII.

In order to comply with the provisions of Article 26 of the PPE Regulation, notified bodies are to keep a register of any subcontracting or subsidiarity to allow effective monitoring by the responsible Member State in order to ensure activities are being conducted properly. The register is to be updated systematically. The register should contain information about the name and location of the subcontractor or the subsidiary, the nature and scope of work undertaken, the results of regular evaluations of the subcontractor, or the subsidiary including evidence that details of tasks are monitored as well as evidence that the subcontractor or the subsidiary is competent and maintains competence for the tasks specified and evidence that a direct private law contract exists.

A notified body may engage experts in support of its assessment activities but the experts' activities are to be controlled as if the expert were directly employed by the notified body under the same contractual obligations and operate within the notified body's own quality system.

Although assessment activity can be sub-contracted including assessment against the relevant essential health and safety requirements, the notified body remains entirely responsible for the whole operation and shall safeguard impartiality and operational integrity.

Procedures for reviewing and accepting the work of any subcontractor or subsidiary will ensure that the subcontractor or the subsidiary has not offered or provided consultancy or advice to the manufacturer, supplier, authorised representative or their commercial competitor with respect to the design, construction, marketing or maintenance of the products which are the subject of the subcontracted task.

- **6.8. Articles 27 and 28- Application and procedures for notification**

Article 27

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

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 24.

Article 28

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have

satisfied the requirements laid down in Article 24.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate referred to in Article 27(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 24.

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 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.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

These articles reflect the principles of the "New Legislative Framework" contained in Decision No 768/2008/EC, which establish detailed requirements for notified bodies and national authorities concerning the application for notification and the notification procedure.

See also § 5.3. "Notification" in "The 'Blue Guide' on the implementation of EU product rules".

- **6.9. Article 29 - Identification numbers and lists of notified bodies**

Article 29

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

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.

The Commission shall ensure that the list is kept up to date.

When a body is notified for the first time under Union harmonisation legislation, the European Commission assign to it an identification number, in the format "NB xxxx" (4-digits correlative number).

For information purposes, the lists of notified bodies are made publicly available by the Commission on a specific database on its EUROPA server, called NANDO ("New Approach Notified and Designated Organisations" information system), available on http://ec.europa.eu/growth/tools-databases/nando/index.cfm.

The lists are updated as and when the notifications are published, and the website is refreshed daily to keep it up-to-date.

See also § 5.3.3. "Publication by the Commission - the NANDO web site" in "The 'Blue Guide' on the implementation of EU product rules".

- **6.10. Article 30 - Changes to notifications**

Article 30

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the 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.

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.

In case of changes to notifications, the relevant national authority must use the same notification procedure for informing the Commission and the other EU Member States, in order to keep the list of notified bodies duly updated.

See also § 5.3.4. "Monitoring of the competence of notified bodies - suspension - withdrawal - appeal" in "The 'Blue Guide' on the implementation of EU product rules".

- **6.11. Article 31 - Challenge of the competence of notified bodies**

Article 31

Challenge of the competence of notified bodies

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 requirements and responsibilities to which it is subject.

2. 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.

3. The Commission shall ensure that all sensitive information obtained in the course of

its investigations is treated confidentially.

4. 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 requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

This article lays down the procedure to deal with any challenge against the competence of any notified body, according to the "New Legislative Framework" as in Decision No 768/2008/EC which provides for the possibility to raise objections concerning a notified body, its competence and its activities. In such cases, the Commission is required to carry out an investigation and, when the conclusions reveal that a notified body does not meet or no longer meets the requirements for its notification, the Commission adopts an implementing act ("Implementing Commission Decision") requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

- **6.12. Article 32 - Operational obligations of notified bodies**

Article 32

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII.

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 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.

3. Where a notified body finds that the 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 certificate or approval decision.

4. Where, in the course of the monitoring of conformity following the issue of a certificate or approval decision, a notified body finds that a PPE no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.

The operational obligations of notified bodies when performing their activities are listed in detail in Decision No 768/2008/EC of the "New Legislative Framework".

A body notified under PPE Regulation issues the following documents according to the provisions of the relevant conformity assessment procedures:

- EU type-examination certificates.
- Product and production quality assurance approval decisions.

These documents are not required to accompany the PPE.

Although being a separate document, the report by a notified body describing how the PPE fulfils the essential health and safety requirements of the PPE Regulation is considered to be integral to the provision of a certificate. Evaluation and test results supporting its decision to issue an EU type-examination certificate should accompany the certificate from the notified body to the manufacturer.

- **6.13. Article 33 - Appeal against decisions of notified bodies**

Article 33

Appeal against decisions of notified bodies

Notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

Notified bodies must set up an adequate appeal procedure against the decisions taken by them with respect to their activities, in particular issuing or refusing of certificates, accessible to manufacturers or any other interested party, through appropriate legal procedures set out by the Member States. This should take into consideration the specific private/civil legal framework in which contractual agreements are stipulated between notified bodies and their customers (manufacturers or their authorised representatives).

- **6.14. Article 34 - Information obligation on notified bodies**

Article 34

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

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.

Notified bodies have specific obligations with regard to providing information to their notifying authorities about the actions as listed in this article, and when requested by the authorities or other notified bodies.

Also a notified body which gets knowledge of non-conforming PPE, but is neither engaged in the module for EU type-examination or in a module for surveillance of the manufacturer, should take some action, i.e. inform the national market surveillance authorities.

If there is no immediate danger and, after contact with the responsible notified body for EU type examination and with the notified body responsible for surveillance of the production of the non-compliant PPE, no satisfactory solution is reached after appropriate time the notified body should inform its own authorities in charge of market surveillance to initiate the adequate measures.

In the case of immediate danger, the notified body should inform its own authority in charge of market surveillance, the notified body for EU type-examination and the notified body for surveillance of the production without delay.

- **6.15. Article 35 - Exchange of experience**

Article 35

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

The IMP-ACA (Internal Market Policy - Accreditation and Conformity Assessment) is the transversal group, established by the Commission, for the exchange of experience between the Member States' national authorities responsible for notification policy.

- **6.16. Article 36 - Coordination of notified bodies**

Article 36

Coordination of notified bodies

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 notified bodies.

Notified bodies shall participate in the work of that group, directly or by means of designated representatives.

Since 1992, the Horizontal Committee of the European Co-ordination and Co-operation of Notified Bodies in the field of PPE (HCNB) and its Vertical Groups (VGs) dealing with the different types of PPE has been in existence for co-ordination and cooperation of notified

bodies. The contact address of HCNB is available on the Commission's sectoral website on Personal Protective Equipment (PPE):
http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment/.

The HCNB and its VGs are run by notified bodies in order to assist in achieving a uniform application of the PPE Regulation. While it is independent of the PPE Committee and Working Group, it works closely with those working parties and with the European Commission services, all of which have a responsibility for the effective and uniform application of the PPE Regulation.

The HCNB plays an important role as coordinator of notified bodies, as well as technical reference and feedback to the standardisers. The HCNB normally meets every nine months and consists of representatives of the notified bodies. In order to achieve a higher degree of efficiency in their work, the groups can set up subgroups with a restricted number of participants to discuss specific technical questions. The Commission is represented in the HCNB. Governmental experts and representatives of the authorities directly responsible for the effective implementation of Union harmonisation legislation can participate as observers in the HCNB. The European standardisation organisations are invited to participate in the groups when issues related to standards arise. The groups may also invite other relevant European federation's interested parties. Where the HCNB have to treat subjects of a confidential nature, the participation in meetings is restricted when deemed necessary.

The VGs are responsible for discussing issues of a technical nature that affect specific types of PPE (head protection, respiratory protection etc.) to ensure that the technical provisions of the PPE Regulation and harmonised standards are applied in a uniform way.

Where ambiguities exist in administrative or technical procedures, the HCNB and its VGs can issue specific guidance documents called "Recommendation for Use sheets" (RfUs). Recommendations for Use sheets should only deal with technical interpretations and practical implementation on essential requirements and conformity assessments and on standards.

The content of Recommendation for Use sheets dealing with technical interpretations on essential requirements and conformity assessments are forwarded to the PPE Committee or Working Group: they can be endorsed by the PPE Committee or Working Group as guidance documents, as useful in providing expert interpretation, not only to notified bodies, but also to manufacturers and other interested parties. Endorsed RfUs are made publicly available on the Commission website:
http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment/.

After having been endorsed, RfUs can be incorporated into the PPE Guidelines. After incorporation of the content into the PPE Guidelines, the RfUs are withdrawn. If the HCNB and its VGs have identified a legal question that cannot be solved in consultation with the national authorities, they can forward such question to the PPE WG for consultation. If a decision or recommendation is reached by PPE WG, it may be incorporated into the PPE Guidelines.

The content of Recommendations for Use sheets regarding interpretation or clarification of requirements of harmonised European standards to the PPE Regulation are forwarded to the relevant standardisation committee for their consideration and incorporation into standards as

appropriate. After incorporation of the content into the standard the Recommendations for use sheets are withdrawn.

The Recommendation for Use sheets are guidance documents and as such do not provide presumption of conformity with the essential health and safety requirements of the PPE Regulation in a manner which the harmonised European standards provide: in fact, the use of RfUs cannot be considered as an evidence of compliance of such requirements.

The Recommendation for Use sheets of the HCNB and its Vertical Groups shall be applied by all notified bodies. (*see also Article 24(11) regarding requirements relating to notified bodies*)

See also § 5.2.4. "Coordination between notified bodies" in "The 'Blue Guide' on the implementation of EU product rules".

7. CHAPTER VI - UNION MARKET SURVEILLANCE, CONTROL OF PPE ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Chapter VI of the PPE Regulation (EU) 2016/425 deals with EU market surveillance, control of products entering the EU market and the EU safeguard procedure.

See also § 7. "Market surveillance" in "The 'Blue Guide' on the implementation of EU product rules".

A useful document for the market surveillance authorities in the Member States is "Good practice for the market surveillance" which has been developed by market surveillance experts, who are members or Chairpersons of various Administrative Cooperation (AdCo) groups. The purpose of this document is to provide guidance to Market Surveillance Authorities in the EU/EEA responsible for market surveillance in sectors within the scope of Regulation (EC) No 765/2008. It is intended to be a working tool which will help to facilitate effective cross border market surveillance and provide a common understanding of the procedures laid down in applicable EU legislation ensuring a consistent approach to market surveillance.

The document covers:

- the procedural steps described in Regulation (EC) No 765/2008 on market surveillance for products covered by Union harmonisation legislation. This Regulation directly applies to Member States and national authorities;
- where applicable, the market surveillance provisions described in Decision No 768/2008/EC on a common framework for the marketing of products and incorporated in sectoral legislation aligned to it.

In addition, the document provides, in the annexes, checklists and other tools for carrying out market surveillance activities.

• 7.1. Article 37 - Union market surveillance and control of PPE entering the Union market

Article 37

Union market surveillance and control of PPE entering the Union market

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

The referred articles of Regulation (EC) No 765/2008, setting out requirements for accreditation and market surveillance relating to the marketing of products, are included into Chapter VI of the PPE Regulation and apply to PPE falling into its scope.

See also § 7.5. "Control on products from third countries" in "The 'Blue Guide' on the implementation of EU product rules".

- **7.2. Article 38 - Procedure at national level for dealing with PPE presenting a risk**

Article 38

Procedure at national level for dealing with PPE presenting a risk

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 persons, they shall carry out an evaluation in relation to the PPE concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

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

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

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

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

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

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

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

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

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

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

6. Member States other than the Member State initiating the procedure under this

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

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

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

When a product presents a risk at national level, a detailed procedure is set up for Member States authorities in charge of market surveillance in their territory, with specific obligations for the concerned economic operators, to deal with the risk.

See also § 7.4 "Checks by Market Surveillance authorities", in "The 'Blue Guide' on the implementation of EU product rules".

- **7.3. Article 39 - Union safeguard procedure**

Article 39

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

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

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

3. Where the national measure is considered justified and the non-compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

The safeguard clause referred to in Article 39 of the PPE Regulation is the EU procedure whereby any measure taken by a Member State, on the grounds of non-compliance with the essential health and safety requirements and when it is deemed that PPE is liable to endanger persons, animals or property, with the purpose to withdraw from the market, prohibit the placing on the market or restrict the free movement of PPE accompanied by one of the means

of attestation provided for in the PPE Regulation and therefore bearing the CE marking, must be immediately notified to the Commission by the Member State which has taken the measure.

In considering whether the safeguard clause should be triggered, Member States and the respective enforcement authorities will need to consider whether the non-compliance is substantial to warrant formal measures or non-substantial, that can be resolved without recourse to the safeguard procedures. For example, a non-substantial non-compliance could be illegible CE marking. In such cases, the Member State could issue a compliance notice to the manufacturer or authorised representative or take other actions allowed by national legislation to encourage the responsible person(s) to take appropriate corrective action.

Member States will need to consider in each case whether the non-compliance is liable to endanger persons, animals or property and if the safeguard clause is the most effective means of ensuring their safety, which remains paramount under this section of the PPE Regulation.

Where objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union harmonisation legislation, the Commission must carry out a process of consultation with the parties concerned, i.e. the Member States, the manufacturer or his authorised representative established within the EU or, failing this, the person who placed the PPE on the EU market.

The consultation procedure enables the Commission to assess whether the restrictive measure is justified or not, based on the information provided by the notifying Member State, as well as the positions of all the parties concerned, in particular regarding the reasons why the essential health and safety requirements of the PPE Regulation have not been complied with.

Where the Commission finds, following such consultation, that the measures are justified, it informs all the parties concerned. All the Member States must take appropriate measures to ensure that the non-compliant PPE is withdrawn from their market. On the contrary, if the national measure is considered unjustified, the Member State concerned must withdraw that measure and immediately take the appropriate action to re-establish the free movement of the PPE in question on its territory.

See also § 7.6.2. "The application of the safeguard clause" in "The 'Blue Guide' on the implementation of EU product rules".

- **7.4. Article 40 - Compliant PPE which presents a risk**

Article 40

Compliant PPE which presents a risk

1. Where, having carried out an evaluation under Article 38(1), a Member State finds that although PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to withdraw the PPE from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the

PPE concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).

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 44(4).

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

A specific procedure is provided for PPE that is compliant with the requirements of the PPE Regulation but nevertheless presents a health and safety risk. The relevant national authority is required to take appropriate action, involving the concerned economic operators, and must inform the Commission and the other Member States. The Commission has to duly analyse the case and issue an implementing decision on whether the national measure adopted is justified or not.

- **7.5. Article 41 - Formal non-compliance**

Article 41

Formal non-compliance

1. Without prejudice to Article 38, 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 17 of this Regulation;

(b) the CE marking has not been affixed;

(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 17 or has not been affixed;

(d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;

(e) the technical documentation is either not available or not complete;

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

(g) 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.

A formal non-compliance of a PPE is when it is not directly related to a health and safety risk, but could be an indicator of possible risks.

The cases listed in Article 41(1) include defects in markings, documents and other information to be provided with the PPE.

For example, the affixing of marking and marks in addition to the CE marking is subject to certain restrictions. The market surveillance authority needs to ensure that these principles are respected and, where necessary, take appropriate action. Such action must evidently be taken with due respect to the principle of proportionality.

8. CHAPTER VII - DELEGATED AND IMPLEMENTING ACTS

Chapter VII of the PPE Regulation (EU) 2016/425 deals with delegated and implementing acts for the Commission, including the provisions on the PPE Committee.

- **8.1. Article 42 - Delegated power**

Article 42

Delegated power

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 43 in order to amend Annex I by reclassifying the risk from one category to another.

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

3. Prior to adopting a delegated act, the Commission shall carry out a thorough assessment of the risks that require reclassification and the impact of such reclassification.

- **8.2. Article 43 - Exercise of the delegation**

Article 43

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 42 shall be conferred on the Commission for a period of five years from 21 April 2018. 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.

It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The delegation of powers referred to in Article 42 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 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.

5. A delegated act adopted pursuant to Article 42 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 of the Council.

- **8.3. Article 44 - Committee procedure**

Article 44

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 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.

4. 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) 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.

As indicated in Recitals 46 to 54, the PPE Committee has a specific role in examining different questions related to the implementation, application and management of the PPE Regulation. Regulation (EU) No 182/2011 (the "Comitology Regulation") establishes the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. In its Article 3 "Common provisions" it defines the role and composition of committees; when Article 4 deals with the "Advisory procedure" and Article 5 with the "Examination procedure", also in conjunction with Article 8 on "Immediately applicable implementing acts". Reference to Regulation (EU) No 1025/2012 on European standardisation recalls consultation of sectoral experts on matters regarding requests for European standards or objections to harmonised standards.

The PPE Committee is integrated by the representatives of the EU Member States (and restricted to them only), and it is chaired by the Commission. The PPE Committee has its own Rules of Procedure (based on the "Standard Rules of Procedure" adopted by the Commission) and creates the PPE Working Group which extends participation of representatives of all sectorial stakeholders[11].

[11] Member States, standardisation and conformity assessment bodies, industry, trade unions and consumers associations.

9. CHAPTER VIII - TRANSITIONAL AND FINAL PROVISIONS

Chapter VIII of the PPE Regulation (EU) 2016/425 deals with transitional and final provisions.

- **9.1. Article 45 - Penalties**

Article 45

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those rules to the Commission by 21 March 2018, 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.

As indicated in Recital 56, national authorities of EU Member States in charge of enforcement of the provisions of the PPE Regulation (the market surveillance authorities) must be able to impose appropriate penalties if those provisions are not correctly applied by economic operators (manufacturers, authorised representatives, importers, distributors). Such penalties must be foreseen in the national legislative acts issued in accordance to the PPE Regulation and notified in due time.

- **9.2. Article 46 - Repeal**

Article 46

Repeal

Directive 89/686/EEC is repealed with effect from 21 April 2018.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex X.

The PPE Regulation (EU) 2016/425 repeals the previous Directive 89/686/EEC on 21 April 2018. Taking into consideration that the new act is the result of the alignment and recast of the previous one, references to Directive 89/686/EEC remaining after the repeal date have to be considered as references to Regulation (EU) 2016/425, according to the correlation table in Annex X.

- **9.3. Article 47 - Transitional provisions**

Article 47

Transitional provisions

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 21 April 2019.

2. EC type-examination certificates and approval decisions issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date.

The PPE Regulation (EU) 2016/425 foresees a specific transitional regime for PPE: a transitional period of 1 year (from 21 April 2018 to 20 April 2019) where both, the PPE Directive and the PPE Regulation, are applicable. Thus, in accordance with Article 47(1), PPE designed and manufactured in accordance with the PPE Directive 89/686/EEC can still be placed on the market until 20 April 2019 and in principle EC type-examination certificates in accordance with the PPE Directive can be issued until the end of the transitional period, i.e. 20 April 2019. For those products in accordance with the PPE Directive until 20 April 2019, it is not required to update the accompanying documents (e.g. the EC declaration of conformity). As the PPE Regulation is applicable from 21 April 2018, from that date manufacturers can start placing on the market PPE in accordance with the PPE Regulation.

As from 21 April 2019, all PPE newly placed on the market shall comply with the requirements of the PPE Regulation, being accompanied by the EU declaration of conformity (Article 15, Annex IX) and instructions for use as foreseen under Annex II, point 1.4, based, for Category II and III PPE, on the EU type-examination certificate (Annex V) and for Category III PPE on quality assurance approval decisions in accordance with the relevant conformity assessment procedures (Article 19, Annexes VII and VIII).

Article 47(2) provides that EC type-examination certificates and approval decisions issued under the PPE Directive, before 21 April 2019, remain valid until 21 April 2023 unless they expire before that date.

Some practical cases:

- Approval decisions issued before the applicability of the Regulation (21 April 2019):

  Approval decisions issued on the basis of Article 11A of Directive 89/686/EEC (module C2) are normally valid for one year, i.e. issued after each supervised product checks which are performed at least once a year.

  On the other hand, approval decisions based on Article 11B of Directive 89/686/EEC (module D) are normally valid up to three years, i.e. corresponding to the approval of the Quality Management System according to EN ISO 9000 or other similar systems. The approval decision remains valid if no serious non-conformities are found in the audits performed at least once a year.

Those approval decisions issued under Directive 89/686/EEC (Article 11A and Article 11B) can be valid for 1 or 3 years after the end of the transitional period, e.g. after 20 April 2019. On the basis of Article 47(2) of the Regulation, it is considered that approval decisions are valid until the end of the validity of the underlying EC type-examination certificate, it is to say, until 21 April 2023 unless they expire before that date.

- Approval decisions issued during the transition period under Directive 89/686/EEC:

  According to the interpretation of Article 47(1) of the Regulation referred above, approval decisions under Directive 89/686/EEC can be issued during the transition period, i.e. between 21 April 2018 and 20 April 2019, and remain valid until 21 April 2023, unless they expire before.

  This is in line with the wording of Article 47(2) which extends the validity of both the EC type-examination certificates and the approval decisions.

- Approval decisions issued during the transitional period under Regulation (EU) 2016/425 and based on an EU type-examination:

  A notified body can issue an approval decision under Regulation (EU) 2016/425 which is based on an EC type-examination under Directive 89/686/EEC.

  According to Article 47(2), there is a link between the EC type-examination and the approval decisions. An EC type-examination certificate is, therefore, regarded as a basis for issuing new approval decisions, which meanwhile have expired, until the end of the validity of the correspondent EU type-examination certificate. (See also the 'Guidance document on the implementation of Article 47 on transitional provisions' with respect to validity of certificates in case of changes in the essential health and safety requirements, in the design and/or manufacture of the PPE and in the state of the art)

- Approval decisions expired during the transitional period and the responsible notified body is not re-notified under the Regulation:

  The conformity assessment body, notified under the Directive but not under the Regulation, can renew the approval decision under Directive 89/686/EEC, as during the transitional period and before 21 April 2019, products in conformity with Directive 89/686/EEC can be still placed on the market, so the Directive is practically still applicable and notified bodies can still perform their activities during this period, according to the interpretation of Article 47(1) of the Regulation. Certificates and approval decisions issued by those notified bodies under Directive 89/686/EEC remain valid until 21 April 2023 unless they expire before that date. However, if the approval decisions expire after 20 April 2019, the approval decisions can be renewed only by a body notified under the Regulation. Therefore, after 20 April 2019, the bodies which were notified under Directive 89/686/EEC and which were not subsequently re-notified under the Regulation, can no longer issue or renew approval decisions.

As a general rule, PPE may be placed on the market after the full applicability of the PPE Regulation (21 April 2019), on the basis of an EC type-examination certificate and/or an approval decision in accordance with the PPE Directive, until 21 April 2023. After that date the validity of the EC type-examination certificate and approval decision expires (if not

already expired before that date) and a new EU type-examination certificate and approval decision in accordance with the PPE Regulation is needed.

This approach is not applicable in the following cases:

- one or several applicable essential health and safety requirement(s) in the PPE Regulation has/have changed on substance to the extent that a higher level of protection than the PPE Directive is required. In this case a certificate issued under the PPE Directive cannot be used to demonstrate compliance with the Regulation and an EU type-examination certificate under the PPE Regulation must be issued;
- the design and/or manufacture of the PPE has changed since the last EC type-examination;
- the generally acknowledged state of the art, which is reflected by harmonised European standards, has changed (updated versions with significant changes on safety clauses, withdrawal of current versions, etc.) and therefore it may imply that the PPE may not be compliant. When a standard is revised, information on the changes in relation to the previous version is given in the annexes of the standard.

Instructions for use are part of the essential safety requirements and these requirements have been slightly changed from the PPE Directive to the PPE Regulation. However the changes are minor and cannot be seen as affecting the safety level of the PPE. It would be disproportionate to require that all PPE should be subject to recertification or reissue of the EC type-examination certificates only because of these minor changes.

Nevertheless, since the PPE shall in any case to be in conformity with the Regulation, at least technical documentation, marking, user information and the declaration of conformity should be updated by the manufacturer.

Taking into account the definitions in Article 3 of the PPE Regulation and the explanations in sections 2.2. and 2.3. of "The 'Blue Guide' on the implementation of EU product rules" of "making available on the market" and of "placing on the market", despite being in the stock of the manufacturer, individual product items of PPE can be considered as "placed on the market" when they are effectively offered for distribution, consumption or use. While the physical handover of these products is not necessary to consider that they have been placed on the market, the offer or the transaction must refer to a quantifiable lot of product items which have been already manufactured.

According to that, products in compliance with the PPE Directive which are in the warehouse of the manufacturer, can be considered as already placed on the market before 21 April 2019 in the case that these products have been offered for sale in product catalogues, or on websites, or in the manufacturer's own store(s) and/or online store. Therefore, these products in compliance with the PPE Directive already placed on the market before 21 April 2019 can continue to be made available on the market after 20 April 2019.

In the case of a central warehouse delivering PPE to subsidiary company's warehouse in another EU Country, or a parent company sells PPE to a subsidiary company as business operations within a corporate group, these activities can be considered as "placing on the market", provided that the central warehouse or parent company, and the subsidiary company, are separate juridical entities (legal or natural persons), and assuming that there is at least a verbal contract. If, after that, the parent company buy the products from the subsidiary company and continue selling them after 20 April 2019, the products can be considered to be

in the distribution chain and therefore they can continue to be made available after 20 April 2019.

The manufacturer must be able to provide, on a case-by-case basis, the adequate proofs (documentation, justification, traceability) to demonstrate that products that have been designed and manufactured according to the PPE Directive have been legally placed on the market before 21 April 2019, because after that date, only products in conformity with the PPE Regulation can be placed on the market. In case of central warehouse or parent company and subsidiary company, it is necessary to prove that the concerned products were intended to be marketed before the circulation between the different entities of the group.

In any case, after 20 April 2019, only products in conformity with the PPE Regulation can be placed on the market (made available for the first time).

- **9.4. Article 48 - Entry into force and application**

Article 48

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. This Regulation shall apply from 21 April 2018, with the exception of:

(a) Articles 20 to 36 and Article 44, which shall apply from 21 October 2016;

(b) Article 45(1), which shall apply from 21 March 2018.

Article 48 set out the key dates of the PPE Regulation (EU) 2016/425: publication, entry into force and applicability. The date of publication is the date when the legal text is published in the Official Journal of the European Union (OJEU), it is to say, 31 March 2016. The date of entry into force is expressed as the 20th day following publication: it means that the EU rules have been adopted and published, thus producing legal effects, in this case, 20 April 2016.

The date when these rules become mandatory is the date of applicability, established on 21 April 2018, from which Member States have to apply the provisions of the PPE Regulation, according to Article 48(2). However, some of the provisions of the PPE Regulation became applicable earlier, namely Articles 20 to 36 on notification of conformity assessment bodies ("notified bodies"); Article 44 on the Committee procedure; and Article 45(1) on penalties.

See also the "Guidance document on the PPE transition from Directive 89/686/EEC to Regulation (EU) 2016/425".

- **9.5. Legal value, direct applicability and signatories of the Regulation**

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 March 2016.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	J.A. HENNIS-PLASSCHAERT

The PPE Regulation (EU) 2016/425 as such is legally binding and directly applicable in all the Member States.

The Regulation is signed by the Presidents of the European Parliament and of the Council at the date, since it was adopted by these EU Institutions according to the ordinary legislative procedure (formerly known as "co-decision") set out in Article 294 of the TFEU.

10. ANNEX I - RISK CATEGORIES OF PPE

ANNEX I

RISK CATEGORIES OF PPE

This Annex lays down the categories of risk against which PPE is intended to protect users.

. . .

Annex I deal with the categorisation of personal protective equipment (PPE) based on the type of risk. If the PPE are intended to provide protection against more than one risk, they shall be placed in the category corresponding to the risk(s) of highest category.

In the Appendix to these PPE Guidelines, a "Guide for the categorisation of personal protective equipment (PPE)" is provided. The guide is based on the results of the discussions and common agreements reached in the PPE Working Group.

- **10.1. Category I**

ANNEX I (continued)

Category I

Category I includes exclusively the following minimal risks:

(a) superficial mechanical injury;

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

(c) contact with hot surfaces not exceeding 50 °C;

(d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);

(e) atmospheric conditions that are not of an extreme nature.

Superficial mechanical injuries are for example bruises, pricks from plants and scratches resulting from bumping into fixed obstacles and gardening and that do not need medical attention.

Weak cleaning materials are for example surfactants diluted in water used for dishwashing, where the main risk could be atopic eczema due to prolonged exposure to water and weak aqueous solutions, i.e. when water tightness is required only.

PPE for direct observation of the sun (e.g. sun eclipses) or against radiation from artificial light sources such as those used in solaria are Category II PPE.

Atmospheric conditions that are not of an extreme nature are normal weather conditions, i.e. rainfall, splashes of water and cold temperatures in wintertime, which can be expected when performing outdoor activities, for example snow shovelling, sport activities, sailing and construction work.

- **10.2. Category II**

ANNEX I (continued)

Category II

Category II includes risks other those listed in Categories I and III;

- **10.3. Category III**

ANNEX I (continued)

Category III

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following:

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

(b) atmospheres with oxygen deficiency;

(c) harmful biological agents;

(d) ionising radiation;

(e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;

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

(g) falling from a height;

(h) electric shock and live working;

(i) drowning;

(j) cuts by hand-held chainsaws;

(k) high-pressure jets;

(l) bullet wounds or knife stabs;

(m) harmful noise.

In (a) substances and mixtures which are hazardous to health (carcinogenic, mutagenic, reprotoxic, toxic, irritant or sensitizing) is any liquid, gas or solid (including industrial dusts) that poses a risk to health and safety of humans. For the classification of substances and mixtures, Regulation (EC) 1272/2008[12] should be considered.

[12] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Biological agents in (c) are considered as defined in Directive 2000/54/EC on exposure to biological agents at work[13] which are micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity. Biological agents belonging to group 3 and 4 (as classified in the Directive) as well as multi-resistant bacteria are considered to be able cause very serious consequences such as death or irreversible damage to health.

In (e) the risk of exposure to high-temperature environments are related to effects comparable with air temperature of 100 °C. Scientific literature describes that exposure to an air temperature of more than 100 °C, in combination with other aspects or risks, would result in second degree burn injuries in less than fifteen seconds. This means that the heat flux transmitted to the skin will cause second degree burn within fifteen seconds. This criteria for second degree burn injuries should be regarded as the criteria when deciding if a PPE protecting against heat is Category III PPE or not. This criterion should also be applied where a risk of splashes of hot material and contact with hot surfaces might exist.

The risk related to exposure to low-temperature environments in (f) are related to effects comparable with air temperature of –50 °C, the effects of –50 °C are to be seen in calm air with a wind speed of max. 5 km/h. These conditions can result in frostbite of the exposed surface in less than two minutes. In conditions with higher wind speeds this effect can be reached at less extreme temperatures. Conditions that can result in frostbite of the exposed surface in less than two minutes should be regarded as the criteria when deciding if a PPE protecting against cold is Category III PPE or not.

PPE protecting against falls from a height in (g) shall be designed to prevent or arrest a fall as well as to support the wearer in case of a fall. Examples are equipment used in work on roofs where there is a risk of a fall to a lower level or climbing equipment used in rock climbing.

For PPE providing protection against electric shock and live working in (h), voltages of more than 50 V AC or 75 V DC are normally considered dangerous and to have very serious consequences, including cardiac arrest. It also include conductive PPE intended to be worn by skilled persons during live working at a nominal power system voltage up to 800 kV AC and 600 kV DC.

PPE designed to prevent drowning in (i) must be capable of returning the user to the surface as quickly as possible and without danger to health and a user, who may be exhausted or unconscious after falling into a liquid medium, must be kept afloat in a position which permits breathing while awaiting help.

High pressure jets in (k) require PPE designed and manufactured to protect when the work pressure is 200 bar or more. The limit for skin penetration according to the literature is 80 bar, but up to 200 bar normal work clothing provide protection against high pressure jets. Equipment with high pressure jets up to 3000 bar can be found on the market for professional use. Equipment for use by consumers, for example high pressure washers, have a work pressure of less than 200 bar.

[13] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 262, 17.10.2000, p. 21).

PPE protecting against injuries caused by bullets and knife stabs in (l) are for example vests, protecting against bullet wounds and knife stab, for security guards.

11. ANNEX II - ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

ANNEX II

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

. . .

Essential Health and Safety Requirements (EHSRs) at Annex II to the PPE Regulation (EU) 2016/425 are drafted to ensure the highest possible level of protection. In practice this means the best compromise between efficiency of protection, usability and comfort according to the generally acknowledged state of the art. These requirements are to be applied in accordance with the foreseeable conditions of use for which the PPE is intended. They either lay down the possible protection objectives and/or refer to the performance of the PPE itself.

Although no detailed manufacturing specifications are included in the EHSRs, their wording is aimed at being precise enough to create legally enforceable obligations, and at facilitating the drafting of mandates by the Commission to the European Standardisation Organisations in order to produce European harmonised standards.

EHSRs define the results to be attained, or the risks to be dealt with, but do not specify or predict the technical solutions for doing so. They are also formulated so as to enable the assessment of conformity with those requirements, in the absence of European harmonised standards or in case the manufacturer chooses not to apply them.

This flexibility allows manufacturers to choose the most suitable way to meet the requirements. It also allows, for example, the materials and product design to be adapted to technological progress. Accordingly, Union harmonisation legislation such as the PPE Regulation do not need regular adaptation to technical progress, since assessment of whether requirements have been met or not are based on the state of technical know-how at a given moment.

Annex II is divided into four sections:
- Preliminary remarks
- General requirements applicable to all PPE;
- Additional requirements common to several classes or types of PPE;
- Additional requirements specific to particular risks.

Therefore, in addition to the application of the general requirements, manufacturers need to clearly identify:
- the risk the PPE is intended to protect against in order to determine the additional EHSRs to be applied to the PPE;
- the foreseeable conditions of use for which the PPE is intended.

If the manufacturer chooses to use European harmonised standards to assess the conformity of the PPE Regulation, he shall make sure that these standards cover all EHSRs applicable to his PPE under the foreseeable conditions of use for which the PPE is intended. If the existing European harmonised standards do not cover all applicable EHSRs he has, in addition to the

application of these standards, to assess the conformity to the EHSRs not covered by using other relevant technical specifications and test methods.

EHSRs set out in Annex II include all that is necessary to achieve the objective of the PPE Regulation. PPE may be placed on the market only if they are in compliance with all applicable EHSRs. The guidance provided on this part of the PPE Regulation has been carefully drafted to give the best possible advice to stakeholders. However, it should always be kept in mind that in Union harmonisation legislation all technical solutions are available to the manufacturer in order to meet the relevant EHSRs to be applied to his PPE.

- **11.1. Preliminary remarks**

ANNEX II (continued)

PRELIMINARY REMARKS

1. The essential health and safety requirements laid down in this Regulation are compulsory.
2. Obligations related to essential health and safety requirements apply only where the corresponding risk exists for the PPE in question.
3. The essential health and safety 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 technical and economic considerations which are consistent with a high degree of health and safety protection.
4. The manufacturer shall carry out a risk assessment in order to identify the risks which apply to his PPE. He shall then design and manufacture it taking into account that assessment.
5. When designing and manufacturing the PPE, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the PPE, but also the reasonably foreseeable uses. Where applicable, the health and safety of persons other than the user shall be ensured.

To make sure that the protection offered by PPE is adequate against the risks encountered, the manufacturer should carry out a risk assessment of the PPE in order to identify the intended use and required level of protection under reasonably foreseeable use.

Preliminary Remark 1 – EHSRs are compulsory

Preliminary Remark 1 recalls that the EHSRs, when they are applicable to a given type of PPE, are legally binding. This is clear from the terms of Article 8(1) setting out the obligations of manufacturers. In this respect, it is important to distinguish the EHSRs of Annex II from the specifications of harmonised European standards, the application of which is voluntary.

Preliminary Remark 2 – applicable EHSRs

Preliminary Remark 2 must be borne in mind when reading each of the EHSRs set out in Annex II. The EHSRs are usually expressed without qualification. However, they are only applicable when they are relevant and necessary.

Preliminary Remark 3 – "state of the art"

The notion of "state of the art" is not defined as such in the PPE Regulation. However, it is clear from Preliminary Remark 3 that the notion of the "state of the art" includes both technical and economic aspects. In order to correspond to the "state of the art", the technical solutions adopted to fulfil the EHSRs must employ the most effective technical means that are available at the time for a cost which is reasonable taking account of the seriousness of the harm the risk reduction is required to address.

It may not always be possible to satisfy certain EHSRs fully, given the current "state of the art". In such cases, the PPE manufacturer must strive to fulfil the objectives set out in the EHSRs to the greatest extent possible.

Manufacturers of PPE cannot be expected to use solutions that are still at the research stage or technical means that are not generally available on the market. On the other hand, they must take account of technical progress and adopt the most effective technical solutions that are appropriate to the PPE concerned when they become available for a reasonable cost.

The "state of the art" is thus a dynamic concept: the "state of the art" evolves when more effective technical means become available or when their relative cost diminishes. Thus a technical solution that is considered to satisfy the EHSRs of the Regulation at a given time may be considered inadequate at a later time, if the state of the art has evolved. Usually, harmonised European standards are taken as a reference to define the "state of the art" at a done moment.

A PPE manufacturer can only take account of the "state of the art" at the time the PPE is manufactured. If an evolution of the "state of the art" makes it possible to approach the objectives set out in the EHSRs more closely, a manufacturer producing a series of PPE according to the same design must upgrade his design accordingly (while taking account of the time necessary for the redesign and the corresponding changes in the production).

A revision of a harmonised standard does not necessary reflect a change in the "state of the art". Thus a revised version of a harmonised standard does not automatically invalidate existing EU type-examination certificates. (*see also § 4.1.2.6. "Revision of harmonised standards" in "The 'Blue Guide' on the implementation of EU product rules".*) The information on technical changes given in the standard can be used to judge if the revision of the standard should to be considered as a change in the "state of the art".

Preliminary Remark 4 – risk assessment

The term risk assessment is used for assessment of different risks. The risk assessment in the PPE Regulation is not to be confused with the risk assessment an employer is obliged to make in relation to the legislation on Occupational Health and Safety (*see the OSH "Framework Directive" 89/391/EEC*). For example, the OiRA tool for hairdressers in certain countries stresses among other things the importance of the right gloves as PPE against the risks of water and chemical products, to prevent hairdresser's eczema.

The risk assessment in the PPE Regulation is only related to the PPE and not to the working or use conditions. On one hand, the manufacturer has to assess against which risks the PPE he

designs intends to protect. On the other hand, the manufacturer must assess the risks related to the use of his PPE in the foreseeable conditions of use.

The results of the risk assessment should be reflected in the technical documentation and also in the manufacturer's instructions and information so the user is able to estimate the risk reduction when using the PPE (in a quantitative or qualitative manner) under the foreseeable conditions of use. The manufacturer's instructions and information should include: maximum exposure values for harmful agents to which the PPE provides protection (if applicable), maximum time of protection (if applicable), environmental conditions affecting the effectiveness of the PPE (e.g. humidity, temperature, severity of work), limitations of use, identification of signs of loss of protective function of PPE.

According to Preliminary Remark 4, the EHSRs are only applicable when the corresponding risk exists for the PPE in question. In order to identify against what risks the PPE will protect, taking into account all phases of the foreseeable lifetime of the PPE, the manufacturer or his authorised representative must ensure that a risk assessment is carried out. The manufacturer is responsible for the risk assessment.

The second sentence states that the PPE must then be designed and manufactured taking into account the results of the risk assessment.

Preliminary Remark 5 – reasonably foreseeable uses

According to Preliminary Remark 5, the manufacturer has to take account of the reasonably foreseeable uses of the PPE. The PPE manufacturer cannot be expected to take account of all possible uses of the PPE. However, certain kinds of uses, whether intentional or unintentional, are predictable on the basis of experience of past use, without prejudice of the preliminary remarks, of the same type of PPE or of similar PPE, accident investigations and knowledge about human behaviour.

- **11.2. 1. General requirements applicable to all PPE**

ANNEX II (continued)

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

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

In the previous PPE Directive, personal protective equipment was expected to provide "protection against all risks encountered", where the PPE Regulation focuses on "protection against the risks which the PPE is intended to protect".

- **11.3. 1.1. Design principles**

ANNEX II (continued)

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured 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 possible level.

At the design stage of the PPE, ergonomic principles need to be applied to make PPE suited to its protection function under the foreseeable conditions of use.

The operating requirements of PPE have to be evaluated simultaneously on the basis of the level of:

- protection which must be highest possible according to the current state of the art;
- maximum reasonably "usability" to fit to the characteristics and to the environment where the tasks are performed by possible different users.

ANNEX II (continued)

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

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 normal performance of the activity.

This requirement introduces the principle of the best possible balance between as high a level of protection as possible and the lowest possible level of constraint. (*see also point 1.1.1. of Annex II*) Nevertheless, for very specific applications, the safety of the wearer takes precedence. This is particularly the case, where according to the general recognised state of the art it is not possible to simultaneously ensure comfort and protection against high hazard levels (e.g. self-rescue during an emergency situation, protection against ionising radiations, land mines removal…).

Practical performance tests using test subjects can be performed to evaluate the acceptability of PPE and the feasibility of carrying out the intended activity.

ANNEX II (continued)

1.1.2.2. Classes of protection appropriate to different levels of 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.

It is easier to indicate the nature of a risk than to quantify its level. Therefore it is difficult to define classes of protection appropriate to the levels of risks against which the PPE is intended to protect. This is why, in practice, classes of protection are generally defined by the levels of performance of one or several characteristics. These levels of performance are determined by conventional testing methods simulating the situations of risks as close as possible to the reality.

The number of classes should be kept to a minimum in order to avoid difficulties and errors during the selection phase of the appropriate PPE by users and purchasers. In fact, the creation of several classes of protection can only be justified by the corresponding existence of a number of various fields of application, in terms of both risk levels and ergonomic factors, which cannot be covered by a single class of PPE.

On the other hand, different classes of protection can be useful to offer, where appropriate, the possibility to use more comfortable PPE instead of PPE having an unnecessarily high level of protection.

In any case, if several classes of protection and/or performance levels are used, the corresponding levels of risks and/or fields of application are to be clearly identified and given in the manufacturer's instructions and information.

Furthermore, when defining classes of protection, for instance in standards or other specifications, the uncertainty of measurements attached to the test results need to be taken into account to avoid difficulties of interpretation.

- **11.4. 1.2. Innocuousness of PPE**

ANNEX II (continued)

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other 'inherent' nuisance factors

PPE must be so designed and manufactured as to not to create risks and other nuisance factors under foreseeable conditions of use.

Even if during the design of the PPE, possible causes of nuisance are eliminated as far as possible, the use of PPE can sometimes cause some nuisance to the wearer. Especially that is the case if the PPE selected is not the optimal choice or it is used wrongly or in unsuitable work situations. Therefore the requirements and guidance for the proper selection and use should be carefully taken into account. The ergonomic, physiological and other factors should be considered.

Those additional risks are not related to the risks against which they protect.

The following examples illustrate the inherent risks which can be generated by PPE:

- tight PPE preventing the evaporation of sweat and causing risk of, for example, hyperthermia, skin irritations and discomfort;
- pockets allowing hot or cold products to be caught;
- PPE leading to difficulties in identifying optical or acoustical warning signals;
- psycho-physiological constraints such as the increase of metabolic rate or fatigue.

ANNEX II (continued)

1.2.1.1. Suitable constituent materials

PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.

The constituent materials cannot, in the foreseeable conditions of normal use, release or degrade to release substances known to be toxic, carcinogenic, mutagenic, allergenic, teratogenic or otherwise harmful.

The following are examples of possible documents that can be used to demonstrate conformity to this requirement:
a) A declaration supplied by the manufacturer confirming that the PPE does not contain any substances at levels that are known or suspected to adversely affect user hygiene or health;
b) Materials specifications;
c) Safety data sheets relating to the materials;
d) Information relating to the suitability of materials for use with food, in medical devices, or other relevant applications;
e) Test reports or other information relating to toxicological, allergenic, carcinogenic, toxic to reproduction or mutagenic investigations and measurements on the materials;
f) Information relating to eco-toxicological and other environmental investigations on the materials.

Particular attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes.

The exposure limit values of harmful substances, such as for example Cr (VI), Ni and Azo colorants are often laid down in European or national regulations. In particular, the manufacturer should consider:

- Directives on the protection of workers from risks related to exposure to chemical, biological agents at work within the meaning of Article 16 of Directive 89/391/EEC;

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation). Annex VI of this Regulation contains an index of around 4500 dangerous substances for which harmonised classification and labelling have been agreed at Union level There are currently twenty-four classes of danger such as: toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, toxic for reproduction, etc. considered in this Regulation;

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This Regulation is also applicable to PPE, which may contain chemicals hazardous to health coming into direct and prolonged contact with the skin.

ANNEX II (continued)

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any PPE part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.

The assessment of the characteristics of roughness, sharp edges etc. likely to cause injury can be based on objective tests (e.g. visual or tactile) and/or practical experience. As an example

there shall be no attachment elements for the accessories in the helmet which goes through the shell of the helmet in a way which causes a risk to the user.

Injuries may originate not only from the characteristics of the PPE but also from the activity of the user.

ANNEX II (continued)

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to the actions to be carried out, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

Impediment to movement depends in particular on the PPE weight and design sizes which have to take into account not only the morphology of intended users but also the dynamic movement required by their activity, the adjustment possibilities and on the characteristics of constituent materials. For example, the more the constituent materials are thick and rigid, the more likely they will be an impediment to movements.

Impediment to sensory perception by the intended user can take many different forms. E.g. hearing protectors are intended to ensure the attenuation of noise which arrives at the intended user's ear but this requirement needs also to be considered alongside the need of the intended user to communicate with other operators and/or to hear warning signals.

Another example is fire-fighter clothing that needs to ensure protection against heat and flame. The protection may be of a lower level for minor part of the body in order for the intended user to be more quickly become aware of the danger and to escape more quickly.

With respect to sensory perception, it is necessary to seek the best possible compromise between safety and usability. For example, a glove needs to preserve the dexterity and tactile sensitivity of the intended wearer yet nevertheless ensure protection against risks which can be mechanical, chemical and/or thermal.

In order to assess the conformity of the PPE to this EHSR, objective test methods can be used to measure physical characteristics of the PPE having an effect of impediment on user such as: sizes, rigidity, weight, field of vision, etc. When no objective method for the measurement of the level of impediment to movement exists, subjective trials can be performed, consisting in practical tests on a panel of test persons carrying out tasks simulating the possible foreseeable conditions of use.

- **11.5. 1.3. Comfort and effectiveness**

ANNEX II (continued)

1.3. Comfort and effectiveness

PPE must be designed and manufactured in order to provide the highest possible comfort as well as effectiveness for each wearer, thus for different morphology types and for all genders.

ANNEX II (continued)

1.3.1. Adaptation of PPE to the user morphology

PPE must be so designed and manufactured as to facilitate 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 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 size range.

Many variables are necessary to describe morphology i.e. to define the shapes of the human body. Moreover, sizes of people and ethnical composition of the European population are likely to evolve (rapidly) in time. This should be carefully considered by referring to updated anthropometric databases while designing PPE. Where possible, systems of adjustment are useful to adapt the PPE to each wearer to avoid custom-made products, which are not economically viable.

PPE needs to be equipped with elements capable of ensuring it remains in place, taking into account all possible foreseeable factors, such as forces affecting the PPE's stability, movements to be made and postures to be adopted during the tasks, etc.

For example:

- Protective helmets need to be stable on the head of the wearer: a balanced weight distribution, an appropriate location of the centre of gravity and a nape strap are a few ways to do this. When necessary, and acceptable from a safety point of view, the helmet could also be equipped with a chin strap.
- Lifejackets need to remain in place when the user falls into water.
- Hairdressing gloves should not be too tight for optimal protection. They should touch the skin between the fingers, there shouldn't be too much space above the fingertips and they should not be too loose around the wrist. The glove should be designed in a way that prevents liquids from running into the glove.

PPE must be so designed and manufactured as to facilitate correct positioning on the user. This could be evaluated by subjective tests, e.g. considering the opinion of wearers executing a conventional task. In certain cases, this facility of correct positioning can be evaluated by measuring technical properties specific to the risk to prevent. For example test subjects performing dynamic tasks to evaluate the degree of tightness of the face piece of a respiratory protective device.

Trials with test subjects or laboratory measurements could also be used to assess objective criteria:

- Adjustability, the stability of adjustments;
- Consequences of displacement of the PPE, and the maximum tolerable displacement;
- Static and dynamic forces that might be exerted on the PPE in normal use, and in circumstances in which it is intended to provide protection.

ANNEX II (continued)

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

The manufacturer should design the PPE so that the best compromise between the weight and protection efficiency is realised. PPE can have adverse effects on the body by increasing muscle strain or energy consumption through increased or altered passive or dynamic loading. The weight (and its distribution) of PPE has to be considered in relation to the specific body part or parts likely to be affected. For example, additional mass on the head produces forces in the neck that have to be countered by the neck muscles and thus might have a negative influence on the wearer's health and safety. Heavy weights on the body or body parts increase energy consumption, especially when walking or running.

The efficiency of PPE can be affected by any number of environmental factors. These factors can lower the protection efficiency in time. The manufacturer should give enough information how environmental factors affect the protection level so that the user can assess the service life of the PPE. The manufacturer needs to include in the instructions for use the foreseeable environment and working conditions he has taken into account when designing the PPE in order to allow correct use and selection in any given situation.

For example, PPE integrating electronic components the behaviour in an EMC "disturbed" environment must be thoroughly checked. The PPE needs to remain safe and not lead to dangerous situations in cases of failure of or damage to the circuit or errors in the circuit logic.

ANNEX II (continued)

1.3.3. Compatibility of different classes or types of PPE intended for simultaneous use

If the same manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, these must be compatible.

When different types of PPE from a manufacturer are intended to be worn simultaneously, the manufacturer will need to ensure that the safety function and comfort of each PPE are not compromised by the wearing of another PPE. For example an earmuff or a face shield is considered as compatible with a safety helmet, if the protective characteristics and the comfort of the hearing protector and of the face shield are not impaired by the simultaneous wearing of these PPE.

In all cases, the manufacturer will also need to draw the attention of intended users on any limitation of use or possible incompatibility.

(See also the EHSR 2.14.)

ANNEX II (continued)

1.3.4. Protective clothing containing removable protectors

Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.

This new requirement was added to the PPE Regulation. Any protective clothing with explicit means to incorporate a removable protector is meant to provide a protective function: therefore, such clothing is PPE. The protective clothing with explicit means to incorporate a removable protector shall, at conformity assessment procedures, be assessed in combination with the removable protectors they are designed to incorporate. These protective clothing shall be accompanied by explicit information for the final end users about the characteristics of the appropriate removable protectors in combination of which they have been assessed.

In case removable protectors are placed on the market, they are required to be certified as PPE on their own, as these must fulfil all the applicable requirements of the PPE Regulation (EU declaration of conformity, CE marking, etc.).

- **11.6. 1.4. Manufacturer's instructions and information**

ANNEX II (continued)

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer and/or his authorized representative established in the Community, the notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

. . .

The manufacturer's instructions and information constitute a fundamental element of a PPE and are considered as integral part of the PPE. They have to be clear, concise, understandable giving the appropriate information for the intended user.

The manufacturer's instructions and information provides a basis on which the user can make a reasoned selection of the correct PPE for their intended activity.

The manufacturer's instructions and information shall be checked, in terms of content and understanding, by the notified body when undertaking an EU type-examination. The notified body shall check that the claims of the manufacturer on the area and limits of protection of the product are in line with the technical specification used and with the relevant essential safety requirements in order to verify that the PPE can be used safely for its intended purpose.

The manufacturer's instructions and information shall be established in conformity with this EHSR, but also, where relevant, with other applicable EHSRs.

The manufacturer has the obligation to provide his instructions and information to the users with each unit of PPE placed on the market (*see also section 3.1. "Article 8 on Obligations of*

manufacturers" and section § 3.1. "Manufacturers" of "The 'Blue Guide' on the implementation of EU product rules").

For some types of PPE, such as earplugs or specific protective gloves which are sometimes sold in dispenser boxes, the instructions for use can be affixed to the boxes or be provided with each unit.

ANNEX II 1.4. (continued)

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

. . .

The storage instructions must specify the conditions, for example how to store, maximum temperature of use, cleaning procedures, etc.

The manufacturer's instructions and information must give necessary information for putting on or taking off the PPE as well as how to make the necessary adjustments to the wearer's morphology.

The manufacturer cannot deviate from the obligation to define cleaning (including decontamination when necessary), maintenance and, if applicable, disinfection processes, since these are necessary to ensure the hygiene of the intended user of the PPE.

The instructions for cleaning, maintenance and disinfection must specify the products or at least the criteria necessary to select them and also the procedures to be applied. These procedures should specify:

- the preliminary operations such as the disassembling of sensitive components, the type of and concentrations of cleaning products
- the laundering conditions, i.e. domestic and/or industrial laundry process and temperature
- the drying conditions, i.e. method and temperature
- the maximum number of cleaning cycles that can be performed, i.e. after how many cleaning cycles the PPE has been tested
- the operations necessary to apply after cleaning or maintenance, to ensure that the PPE retain the optimum level of effectiveness. For example, the cleaning procedures include the conditions of drying for a PPE intended for heat and flame protection or the precautions to be taken with respect to electric shock if the PPE has electric or electronic components.

The conditions of disinfection depend on the type of PPE and the way in which it is carried or worn by the user. They can be less constraining if there is no direct contact of the PPE with the skin of the wearer, for example, the harnesses of fall arrest systems. On the other hand, they should be very prescriptive if there is direct and prolonged contact with the skin, for example, as is the case with respiratory protective devices or safety gloves.

The maintenance instructions must specify which operations the user can carry out himself and how to do so and which spare parts to use, for example which filters can be used in a facemask and how to replace it; or about reparations of holes, seams and replacement of zippers, etc. It shall also specify when the intervention of the manufacturer or a specialised person is required.

Any product specified by the manufacturer for the cleaning, maintenance or disinfection of the PPE should not be harmful for the PPE or its user. For instance, products that are recommended should be tested for carcinogenic or allergic reactions and should not destroy the integrity of the material used in the PPE. The harmful effects on a potential user can be verified using safety data sheets of the products while the effects on the integrity of PPE can be checked by applying the cleaning procedure according to manufacturer's instruction before carrying out the test to determine the performance of the PPE.

ANNEX II 1.4. (continued)

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

. . .

The information shall mention the levels or classes of protection, determined by the manufacturer according to European harmonised standards or other relevant specifications and shall not duplicate the content of the test report. The information shall be based on the risk assessment according to Annex II included in the technical documentation described in Annex III to the PPE Regulation.

ANNEX II 1.4. (continued)

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

. . .

The manufacturer needs to indicate the accessories and spare parts compatible with the PPE in his instructions and information. The manufacturer is responsible for the design of these accessories and of their compatibility with the PPE. As a consequence he cannot assume any responsibility if a person uses accessories other than those envisaged by him.

The manufacturer's instructions and information must give the necessary information how to replace the accessories and spare parts and the limits of their use.

ANNEX II 1.4. (continued)

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

. . .

For a class of protection claimed by the manufacturer, the instructions must specify the level of the risk covered and the corresponding limits of use. These are generally expressed by:
- the nature of the covered risk;
- the limitation of the parameters defining the risk (temperature, pressure, acoustic level, list of chemicals etc.);
- the time limit of the exposure to the risk.

These levels of the risk covered are sometimes difficult to know beforehand. In such cases they can be indicated by reference to the test conditions in which the EU type-examination was undertaken.

ANNEX II 1.4. (continued)

(e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;

. . .

Information on obsolescence can be expressed in different ways to indicate that the PPE is no longer fit for purpose, for example:
- an expiry date irrespective of time of use;
- time of use: e.g. hours after opening of the packaging, maximum number times the PPE can be reprocessed, single or limited use etc.;
- in function of an incident: impact (harness after fall, helmet after impact), when contaminated:
- deficiencies such as holes, breaks etc. which should require the PPE to be repaired.

Information on obsolescence is when the PPE becomes unusable for its intended use or is no longer fit for its purpose due to either a change in its protective properties or to loss in functionality over its intended period or number of times so that the user has information on whether to discard or repair it as appropriate.

The manufacturer must provide all information necessary so that the user can determine a reasonable period of obsolescence. However the manufacturer is not obliged to affix the date of manufacture on the product or in his instructions and information as the obsolescence of PPE may not be dependent on date of manufacture but other factors such as number of times it can be used or effectiveness after certain cleaning cycles, etc.

This can be expressed by relevant information on how to identify the “end of life”, for example a limiting date of use or a maximum service time.

The service life of PPE depends on many factors such as the conditions of storage, use, cleaning, revision, maintenance where a manufacturer does not have control. The manufacturer has to provide any useful information so that the intended user can determine a reasonable time limitation. It can be a question of the evolution of a characteristic of use (for example, an increase in respiratory resistance making the use difficult or of a characteristic of aspect and/or integrity (for example, striped or split eyepiece). It could also refer to the ageing of materials. For example, the appearance of cracks or discolouration on the surface of some types of thermoplastic safety helmet may be an objective sign of ageing.

ANNEX II 1.4. (continued)

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

. . .

This is related to the description of packaging to be used by the user for transport, for example original packaging or special packing, to keep the safety and usability characteristics of the PPE or to the protection of the PPE when not in use.

ANNEX II 1.4. (continued)

(g) the significance of any markings (see 2.12).

. . .

Requirement 2.12 is related to the markings affixed on PPE concerning directly or indirectly the health or the safety of the intended user. There are other provisions of the Regulation which mention the affixing of markings with particular significance, for example requirements in EHSRs 2.4 (relating to the PPE subject to ageing), 3.5 (relating to hearing protectors), 3.9 (relating to eye protectors against the ionizing radiations), 3.10 (relating to respiratory protective devices).

In addition to these markings whose affixing is mandatory, other markings or pictograms can exist, providing useful information on field of use of the PPE and its level of performance. This shall be clearly explained in the instructions for use and cannot lead to confusion with respect to mandatory marking requirements, i.e. CE marking.

ANNEX II 1.4. (continued)

(h) the risk against which the PPE is designed to protect;

. . .

The manufacturer shall clearly inform, in his instructions and information, the user about the intended use of the PPE and the risks which it is designed to protect against, based on the risk assessment performed according to Annex II “Preliminary Remarks” and included in the technical documentation in Annex III to the PPE Regulation.

ANNEX II 1.4. (continued)

(i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;

. . .

This requirement concerns only the application of Union harmonisation legislation for which the CE marking is foreseen. The references detailed here is only other Union harmonisation legislation, for example medical devices or gas appliances, which have been applied to the PPE by the manufacturer.

ANNEX II 1.4. (continued)

(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE.

. . .

This requirement relates only to Category II and III PPE. For Category III PPE also the name, address and identification number of the notified body involved in the conformity assessment according to module C2 or module D. This can be the same notified body or two different ones.

Using a notified body in the conformity assessment does not discharge the manufacturer from his responsibilities as defined in the relevant articles of the PPE Regulation.

ANNEX II 1.4. (continued)

(k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;

. . .

This means the reference (title) and the year of publication of a harmonised European standard (hEN) as published in the Official Journal of the European Union (OJEU) to confer presumption of conformity, not the year of publication on national level in the Member States. This is necessary to provide clear and non-ambiguous information to the users on the version of the harmonised standard effectively used.

ANNEX II 1.4. (continued)

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

. . .

In case the internet option is chosen, different solutions can be used (e.g. direct web address, generic webpage with search function), but it must be clearly explained how to obtain the EU declaration of conformity relating to the specific PPE via this route and the internet link shall be maintained during the lifetime of the PPE.

ANNEX II 1.4. (continued)

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

As this information is a part of the EU declaration of conformity it is not necessary to repeat the information if the EU declaration of conformity accompanies the PPE.

- **11.7. 2. Additional requirements common to several types of PPE**

ANNEX II (continued)

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

- **11.8. 2.1. PPE incorporating adjustment systems**

2.1 PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be so designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

The manufacturer shall ensure by proper design that no unintentional changes of adjustment can influence the protection level of the PPE. For example the adjustments of strap length of a full body harness must not change during use when the tension in the straps and buckles varies.

This condition is generally met for attachment units if they are inaccessible when conducting a task. When the attachment units are accessible an accidental release shall not be possible, e.g. when two simultaneous voluntary executions of distinct movements is required.

- **11.9. 2.2. PPE enclosing the parts of the body to be protected**

ANNEX II (continued)

2.2. PPE enclosing the parts of the body to be protected

PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.

The main method that the body uses to keep a suitable temperature is sweat evaporation. Evidently, PPE has an influence on the conditions applying to the wearer affecting this physiological phenomenon.

As a result, the PPE must be designed so ensure perspiration from its use is minimised, as to allow a sufficient level of ventilation according to the task and foreseeable use conditions, or the manufacture has to use breathable materials. In order to increase comfort, for example where protection against a toxic environment is required and where the PPE has to be impermeable, sweat absorbing materials can evidently be chosen.

Where this EHSR is to be applied, the manufacturer's instructions and information needs to specify the necessary ventilation rate if the PPE is to be supplied with air ventilation. Useful information, in respect of maintenance, also has to be given by specifying the cleaning and drying operations to be carried out after use.

This information has to be sufficient to make it possible for the employer to determine the maximum physiologically acceptable duration use of the PPE in accordance with Directive 89/656/EEC on the use by workers of personal protective equipment at the workplace.

Different solutions may satisfy the basic requirements to keep the body in a thermal balance.

- **11.10. 2.3. PPE for the face, eyes and respiratory system**

ANNEX II (continued)

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those 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.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

Any restriction to the natural field of vision of the intended user must be minimised in order to minimise risks or discomfort associated with either the intended tasks or environment.

PPE for eye protection should not impair the field of vision in order to ensure the comfort of a user and it shall have a refractive power as low as possible to be optically neutral. PPE for eye protection with low refractive powers are recommended for permanent use or for meticulous work.

Lenses provided with "anti-fogging" coating need to be designed to be so that this characteristics prevent moisture formation remains in all foreseeable conditions of use for which the PPE is intended. For these lenses, information on how to clean the anti-fogging lenses to avoid degradation of the coating shall be described in the instruction for use.

Devices integrated into PPE to reduce moisture have to be designed to prevent fogging whilst not downgrading the PPE protection level, e.g. ventilation holes in goggles.

The air flow in integrated air ventilation shall not create adverse health effects or nuisance (noise, comfort disturbing draught…).

To determine the dimensions of PPE intended to be put over corrective spectacles, the manufacturer needs take into account the normal dimensions of spectacles.

If possible, it is advisable to integrate the optical correction to PPE or to provide a suitable mounting to support the corrective spectacles.

- **11.11. 2.4. PPE subject to ageing**

ANNEX II (continued)

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its 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 month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

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. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

The ageing factors, time, environment and use influence the performance of PPE. The manufacturer should define in his technical documentation the ambient conditions as well as the foreseen use conditions taken into account when evaluating the effects of ageing on PPE. It is understood that the date of expiry of the PPE corresponds with the decrease of the protective performance to a level that is not adequate against the risk.

The manufacturer needs to ensure that the PPE characteristics do not change significantly during storage.

The expiry date of PPE, i.e. the lifetime of PPE, is influenced by the conditions of use for PPE and its interchangeable components. The lifetime can be expressed in terms of time or as number of exposures. It is not possible for the manufacturer to have full control over the conditions of use, therefore the manufacturer shall provide the user of the PPE with all relevant information on the foreseen use conditions and all other factors influencing the lifetime so the user is able to determine when to dispose of the PPE.

If the prescribed cleaning process leads to a rapid and significant deterioration in the performance of PPE, the maximum number of cleaning cycles that can be performed should be indicated in the markings and instructions for use.

For example:

- Certain protective clothing has a finish that will resist only a few wash cycles, but can be restored following manufacturer’s instruction for use. In this case, the maximum number indicated is the number of cleaning cycles between restoring of the finishing or the maximum amount of re-treatments.

- Certain materials used in protective clothing or gloves do not resist cleaning. In that case an indication that the product is only intended for a single use shall be fixed to the PPE.

- **11.12. 2.5. PPE which may be caught up during use**

ANNEX II (continued)

2.5. PPE which may be caught up during use

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 be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.

The design of PPE shall be such that no risk of being caught up exists. If the risk of PPE being caught cannot be prevented, the PPE shall be so designed that that component has a suitable breaking resistance to avoid injuries. The breaking resistance depends on the characteristics of the components of PPE and their assembly. PPE must be designed taking into account the characteristics of the part of the body possible to be injured and the severity of the injury. For example chin straps for helmets for young children shall be self-releasing in order to prevent strangulation if the helmet is caught during playing.

The risk of PPE being caught up can be avoided by design requirements, e.g. for clothing. If the risk of PPE being caught up by a moving object cannot be prevented, the manufacturer's instructions and information shall clearly give warning not to use these PPE in situations where this risk exists.

- **11.13. 2.6. PPE for use in potentially explosive atmospheres**

ANNEX II (continued)

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way 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 to be used in potentially explosive atmospheres, should:

- have anti-static properties which remain effective during all its service life when used and maintained correctly in accordance with the manufacturer's instructions and information;
- be made of materials which are known not to cause sparks e.g. by impact;
- strictly avoid the use of PPE components that are likely to initiate sparks by shock or friction;
- not include unprotected electric components or parts which do not comply (where relevant) to Directive 2014/34/EU of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (ATEX);

- give adequate warning in the instruction for use;
- take into account other relevant factors in foreseeable use.

Equipment covered by the PPE Regulation is specifically excluded from the ATEX Directive 2014/34/EU and shall not be marked with the specific marking of explosion protection defined in that Directive or wording to this effect.

- **11.14. 2.7. PPE intended for rapid intervention or to be put on or removed rapidly**

ANNEX II (continued)

2.7. PPE intended for rapid intervention or to be put on or removed rapidly

Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment.

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 such systems quickly and easily.

The ease of donning and doffing of PPE intended for emergency use shall be as good as possible, taking into account the foreseeable emergency situations and the duration of the tasks. The verification of the required time can only be made by using test subjects in realistic simulated conditions.

In some cases it is important to be able to remove the PPE quickly to avoid or limit severe injuries: e.g. when hot or cold particles or liquids accidentally enter the PPE. In other cases, also other criteria should be taken into consideration, as for protection against chemical or biological contamination.

Instructions for use shall contain the information on quick donning and doffing of the PPE and advice for proper training of the users.

- **11.15. 2.8. PPE for intervention in very dangerous situations**

ANNEX II (continued)

2.8. PPE for intervention in very dangerous situations

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 must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

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

PPE intended for this type of task is Category III.

Where the manufacturer considers that the PPE can only be used by trained persons, further information needs to be provided, as follows:

- the details of the training of the "trainers" of the intended users;
- the correct donning and adjustment of the PPE to maximise its effectiveness;
- the correct procedure to verify the functionality of the PPE (e.g. content and periodicity of controls).

A warning device integrated in PPE needs to be designed so that it remains effective, e.g. visible and/or audible, in all foreseeable conditions of use and irrespective of the intended environmental variations (e.g. heat, cold, moisture, electromagnetic radiation, shocks…). This alarm device may, amongst other relevant factors, need to take into account the following:

- the sound environment;
- the wearing of hearing protectors (*see requirement 3.5*);
- the ambient illumination;
- the use of coloured optical filters against radiation.

Where the manufacturer considers that the required level of protection cannot be assured, even with a warning device, a warning should be included in the instructions for use, e.g. by adding information on environments where the PPE should not be used.

- **11.16. 2.9. PPE incorporating components which can be adjusted or removed by the user**

ANNEX II (continued)

2.9. PPE incorporating components which can be adjusted or removed by the user

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

The instructions given by the manufacturer need to specify the adjustments and replacements that can be made by the user himself without tools (e.g. change of the filters with standard thread for respiratory protective device) and those which are to be done only by competent trained persons (e.g. maintenance of fall arresters). In the first case the procedures to be followed to make the adjustments and replacements safely and easily without tools are to be included in the instructions for use.

The adjustments which can be made without tools shall be limited to safe area. E.g. it shall not be possible to fully close the air flow of the constant flow valve of a compressed air breathing apparatus.

- **11.17. 2.10. PPE for connection to complementary equipment external to the PPE**

ANNEX II (continued)

2.10. PPE for connection to complementary equipment external to the PPE

Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.

As far as possible the design of PPE needs to prevent incorrect connection. The information given by the manufacturer therefore must describe how to ensure safe connection and where appropriate give adequate warnings to ensure that this is the case.

If PPE is designed so that complementary equipment external to the PPE can be connected, for example in different conditions of use, the information given by the manufacturer has to provide an exhaustive list of these complementary equipment external to the PPE and guidance on how to use them correctly.

For example, if the PPE is to be connected with breathable gas mixtures supply, the connector should be designed so that it is impossible to connect it to non-breathable gas supply, such as a nitrogen circuit.

- **11.18. 2.11. PPE incorporating a fluid circulation system**

ANNEX II (continued)

2.11. PPE incorporating a fluid circulation system

Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as 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.

The most frequent use of these systems is in hot or cold environments or in situations when the user must be totally insulated from polluted atmospheres and it is necessary to maintain the body temperature within acceptable limits.

The tubes used should have mechanical resistance high enough against collapsing under mechanical pressure. The efficiency of the circulation system should be designed according to environmental conditions and metabolic rate of the user in order to ensure the thermal comfort or to prevent excessive thermal load on the user.

- **11.19. 2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety**

ANNEX II (continued)

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or

indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

The markings shall not create confusion in respect of the risk covered or the category of PPE. Information given by the manufacturer has to specify the correct meaning of any pictogram (*see requirement 1.4 g)*). These markings need to be designed to remain legible during the service life of the PPE, that means that the marking affixed on the PPE shall not be easily removable and/or damaged by e.g. scratching, cleaning or sun exposure.

The markings can only be considered as effective, when complete, precise and comprehensible and when they are properly perceived, understood, retained by the intended end user.

For the use of harmonised pictograms or ideograms the manufacturer may refer in particular to ISO 7000 "Graphical symbols for use on equipment".

- **11.20. 2.13. PPE capable of signalling the user's presence visually**

ANNEX II (continued)

2.13. PPE capable of signalling the user's presence visually

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.

The intention of this requirement is to make the intended user of PPE visible especially when moving in an area where motor vehicles or other mobile machines are moving, in particular when the illumination is poor. Respect of this requirement allows for a better identification of the users of these PPE by the drivers but does not protect these users of PPE against the risk of collision. The form of direct signalling or reflective material affixed to PPE should make it possible for the driver to recognize that it is a person and not a fixed obstacle. Signalling devices or materials have to be so positioned that in the foreseeable conditions of use for which the PPE is intended, the signalling surfaces are not obstructed.

- **11.21. 2.14. Multi-risk PPE**

ANNEX II (continued)

2.14. Multi-risk PPE

PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.

The full face piece of a respiratory protective device protects simultaneously against inhalation of substances and mixtures which are hazardous to health and the face and eyes against the splashes of chemicals. In addition it shall not limit unnecessarily the field of vision and the optical quality of the visor shall be such that it is not distorting the vision.

Certain types of protective clothing protect simultaneously against several risks. E.g. protective clothing for welders working in traffic environment outside in darkness and cold shall give protection against welding sparks, be visible and give protection against harmful environmental factors.

Conformity assessment of certain multi-risk PPE

Where the intervention of a notified body is required, it could happen that for certain kind of multi-risk PPE there is not a single notified body that has the competence to perform the conformity assessment procedures for all the risks for which the PPE is intended to provide protection.

As indicated in section 5.2.5 *"Subcontracting by notified bodies"* of *"The 'Blue Guide' on the implementation of EU product rules*", notified bodies cannot subcontract tasks that are out of the scope of its notification.

The conformity assessment of multi-risk PPE that requires to have different competences and there is not a single notified body that has them all, should therefore be carried out by different notified bodies.

As indicated in point 3(b) of Annex V, point 3(b) of Annex VII, and point 3.1(c) of Annex VIII of the PPER, the manufacturer is not allowed to lodge the same application with more than one notified body. However, applications for the conformity assessment of a product in different areas of competence are also different.

Therefore, if various notified bodies are involved in the conformity assessment of a product, the manufacturer should lodge an application with each of those notified bodies for the assessment of the product under their respective scope of competence, and, when applicable, affix the identification number of all the notified bodies involved in Module C2 or Module D activities. Similarly as when the product is subject to more than one piece of Union harmonisation legislation.

Coordination between the notified bodies involved in the assessment of multi-risk PPE would be necessary, particularly to ensure that potential existing interactions between different parts of the PPE protecting against different risks have been considered in the assessment.

In accordance with Annex IX of the PPE Regulation, the EU declaration of conformity of the product should include the information of all notified bodies involved in the conformity

assessment procedure and the references of the corresponding EU-type examination certificates.

- **11.22. 3. Additional requirements specific to particular risks**

ANNEX II (continued)

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

- **11.23. 3.1. Protection against mechanical impact**

ANNEX II (continued)

3.1. Protection against mechanical impact

3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle

PPE intended to protect against 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.

Impact tolerance criteria for different body regions are derived from a combination of accident and casualty data.

The influence of impact is not only related to its energy level but also to other parameters such as the direction of impact. Optimum level of protection should be taken into account at the design stage.

- **11.24. 3.1.2. Falls**

ANNEX II (continued)

3.1.2. Falls

3.1.2.1. Prevention of falls due to slipping

The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.

There are several factors affecting the risk of slipping. One of most important influencing factors is the friction of the outsole of the footwear. The friction of the sole on the walking surface shall be in a suitable range of friction values. The properties of the walking surfaces corresponding to the foreseeable conditions of use for which the PPE is intended shall be taken into account during the design. The friction properties of outsoles made from certain materials can also vary with temperature or during lifetime by wear and tear of the sole.

For footwear intended to be used on slippery ice surfaces, the manufacturer may design footwear with spikes or similar additional elements. The manufacturer can also design specific removable PPE which shall be able to be attached easily, firmly and securely onto the footwear.

ANNEX II (continued)

3.1.2.2. Prevention of falls from a height

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 minimised 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.

Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.

The manufacturer's instructions must specify, in particular, all relevant information relating to:

(a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;

(b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.

PPE for the prevention against falls from a height shall be designed so that:

- the user is prevented from reaching any dangerous area where the risk of free fall exists (restraint equipment); or
- if the risk of free fall cannot be prevented, the PPE shall prevent collision with obstacles or the ground and have a braking force which is not harmful to the user to minimise the risk of injury, e.g. by leading-in the forces into the strong parts of the body or by the use of energy absorbing devices.

All the components of a fall arrest system and the assemblies shall be in conformity with the PPE Regulation. The manufacturer has the responsibility to indicate in the instructions for use which components can be used together and how to assemble them properly.

The design must be so that in case of an accident, the victim can wait for rescue in a correct position without excessive harmful effects.

- **11.25. 3.1.3. Mechanical vibration**

ANNEX II (continued)

3.1.3. Mechanical vibration

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.

Directive 2002/44/EC regarding the exposure of workers to the risks arising from physical agents, contains provisions aimed at avoiding or reducing risks arising from vibration. PPE against vibration can be used but can it be difficult, therefore the Directive recommends other prevention means, for example by providing suitable clothing to workers working in cold and damp conditions to minimise the effect of mechanical vibration.

- **11.26. 3.2. Protection against static compression of a part of the body**

ANNEX II (continued)

3.2. Protection against static compression of a part of the body

PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.

- **11.27. 3.3. Protection against mechanical injuries**

ANNEX II (continued)

3.3. Protection against mechanical injuries

PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.

Resistance to abrasion, perforation and cuts are important properties for many PPE as these risks are present in most of the tasks. In most cases, they are caused by:
- Abrasion: contact with abrasive surfaces or abrasive products, sandblasting.
- Perforation: contact with sharp pointed objects.
- Cut: contact with sharp or toothed edges.

- **11.28. 3.4. Protection in liquids**

ANNEX II (continued)

3.4. Protection in liquids

3.4.1. Prevention of drowning

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user 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 inflated orally.

Under the foreseeable conditions of use:

(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;

(b) inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also 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;

(b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;

(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 the user's immersion in it.

PPE which meets this requirement protects the user against a risk of drowning and are Category III PPE. In general, it is considered that "liquid medium" refers to water.

Buoys and life jackets not carried permanently by people on board of aircrafts and ships are not subject to the PPE Regulation (*see Article 2*) but to other specific Directives (e.g. the Marine Equipment Directive 2014/90/EU).

This type of PPE needs to protect against drowning even if the user is unconscious. Hence, the inflation time of inflatable devices needs to be as short as possible to be able to save (in particular) an injured or unconscious person.

The luminous or sound signal device referred to in the requirement must be able to be perceived by the rescuers in all foreseeable conditions of use for which the PPE is intended. Evidently, the reflective materials should be effective when wet.

For prolonged use where the risk of a fall into water might exist, ergonomics requirements, such as be comfort and usability during activities, must be considered.

ANNEX II (continued)

3.4.2. Buoyancy aids

Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.

Over the years there have been discussions regarding the borderline between different types of buoyancy aids. The general understanding is as follows:

- swimming armbands are Category II PPE which provide only an aid to buoyancy;

- floating seats and baby neck buoys are covered by the General Product Safety Directive 2001/95/EC (GPSD);
- inflatable buoys are toys, in terms of the Toys Directive, when they are used in shallow waters by children less than 14 years of age. In other cases, they are covered by the GPSD.

Buoyancy aids allow an unconscious user to stay afloat but do not necessarily keep the head out of the liquid medium. PPE intended for the prevention of drowning maintains the head out of the liquid medium but may offer reduced mobility.

- **11.29. 3.5. Protection against the harmful effects of noise**

ANNEX II (continued)

3.5. Protection against the harmful effects of noise

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 exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council ([1]).

Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.

_____

([1]) Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 42, 15.2.2003, p. 38).

The foreseen necessary attenuation can be obtained by using passive (earmuffs, earplugs or a combination of both) or non-passive (level dependent, active reduction or communication facilities) hearing protectors.

Hearing protectors that include sound generating systems such as entertainment audio, must be designed or additional measures must be specified in manufacturer's instructions and information that accompany them, in order to fulfil the requirements of Directive 2003/10/EC. This takes into account the external sound attenuated by the hearing protection and the sound generated by the system when assessing suitability of the product for the intended application.

The ability to understand speech or to hear warning signals may be taken into account in the design of hearing protectors for certain applications.

For production of custom moulded earplugs individual imprints of the user's ear canal and concha are prepared by the manufacturer or by a person authorised by the manufacturer. Based on this imprint the final PPE is produced by the manufacturer.

Because of the bespoke production process (PPE produced in series where each item is adapted to fit an individual user), specific measures in the quality assurance scheme must be implemented by the manufacturer. The aim is that every user is protected.

To guarantee the protective function as specified the only solution is to perform a final check of the functionality at the user's ear canal by the manufacturer or by a person authorised by the manufacturer.

The protective values of the hearing protection must accompany packaging and user information.

NOTE: There are three separate sets of protective values (SNR, HML, Octave Band), which must not be discriminated against. There is a lack of available printing space on the product to make provision of all three sets of attenuation values this information is supplied with packaging and/or user information.

- **11.30. 3.6. Protection against heat and/or fire**

ANNEX II (continued)

3.6. Protection against heat and/or fire

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.

. . .

This type of PPE consists of several protective material layers or a sufficient thick single layer, with a thermal insulation capacity to achieve the necessary protection. The protection efficiency depends not only on the insulation capacity, but also on the proper coverage of the insulation. The PPE must be designed so that heat or flame is not able to harm the user through possible openings and the protection against heat and flame is not lowered during the exposure. Therefore a sufficient mechanical strength, e.g. against abrasion, cuts and tearing, is needed.

ANNEX II 3.6. (continued)

3.6.1. PPE constituent materials and other components

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.

Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as 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 the PPE.

PPE materials and other components which may be splashed by hot products

must also possess sufficient mechanical-impact absorbency (see point 3.1).

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

. . .

The requirement applies to constituent materials and components and not to a complete PPE.

The mechanical resistance of PPE, materials and other components, must provide sufficient protection to the user against impact energy, nature and temperature of hot splashes.

The manufacturer needs to select materials, components or combinations of them so that in the foreseeable conditions of use:

- the heat flux transmitted to the skin of the user will not cause burn injuries;
- the flammability and/or melting do not create an additional risk of burns for the user.

The reflective capacity of materials used in the design of the PPE should be as high as possible without increasing other harmful factors like heat stress due to non-permeability of the clothing materials.

The thermal capacity of materials, material combinations or components, to be used in high temperature environments, must be designed so the user after exposure have enough time to leave the danger area and remove the PPE before the accumulated heat in the materials causes any harm.

If, in the foreseeable and intended use, there is a risk that the user of the PPE might encounter an electric arc, protection against the heat resulting from such incident must be provided.

ANNEX II 3.6. (continued)

3.6.2. Complete PPE ready for use

Under the foreseeable conditions of use:

(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;

(b) PPE must if necessary prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

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 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.

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.

For the intended use, the manufacturer has to design the PPE so that:

- the accumulation of heat by the PPE does not cause thermal stress, pain or harmful effects to the user;
- it prevents any penetration of liquid or steam liable to cause burns, e.g. by proper coverage of body parts to be protected;
- the parts of the PPE which may reach a harmful temperature will not be in direct contact with the user.

PPE, incorporating refrigeration devices for the absorption of incident heat, must be designed so that volatile substances released are discharged away from the user in order not to cause any additional harmful effect in the foreseeable conditions of use.

PPE protecting against heat and incorporating a breathing device must be designed to fulfil the EHSR applicable to respiratory protective devices: e.g. the air flow in ventilated suits must be high enough to protect against excessive heat load and contaminant inhalation.

For PPE for brief use in high temperatures, the manufacturer must provide information on the maximum effective protection time and/or the maximum acceptable use time from the physiological point of view so the user can determine the protection during his intended actions.

- **11.31. 3.7. Protection against cold**

ANNEX II (continued)

3.7. Protection against cold

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 against cold is designed according to the foreseen risks and usually consists of several protective material layers. The protection efficiency of this type of PPE depends on the insulation capacity as well as proper coverage. The size and model of the PPE needs to be such that cold does not directly harm the user through possible openings in the PPE.

PPE of this type also needs to have adequate mechanical strength against abrasion, cuts and tearing.

ANNEX II 3.7. (continued)

3.7.1. PPE constituent materials and other components

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.

PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).

. . .

This requirement applies to constituent materials and components and not to complete PPE.

The manufacturer needs to select materials, components or a combination of them so that in the foreseeable conditions of use:

- the thermal flux transmitted through the PPE shall be as low as possible;
- the flexibility remains acceptable to insure comfort, usability and integrity of the products.

The mechanical resistance of materials of components needs to be, where necessary, appropriate to the impact energy, nature and temperature of the splashes of cold products.

ANNEX II 3.7. (continued)

3.7.2. Complete PPE ready for use

Under the foreseeable conditions of use, the following requirements apply:

(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;

(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.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

The manufacturer must design the PPE so, that in the foreseeable conditions of use, for which the PPE is intended:

- the loss of body heat does not cause hypothermia, pain or harmful effects, in particular to the user's extremities (e.g. tips of fingers and toes);
- it prevents the penetration of liquids, such as rain water, likely to cause injuries, e.g. by proper coverage of body parts to be protected;
- The parts of the PPE which might reach harmful cold temperatures must not be in direct contact with the user.

PPE protecting against cold, incorporating a breathing device, must be designed to fulfil the EHSR applicable to respiratory protective devices: e.g. that the temperature of breathable air flow is physiologically acceptable.

With regard to PPE for brief use in cold environments, the manufacturer must provide information on the maximum effective protection time and/or the maximum acceptable use time from the physiological point of view so the user can determine the protection during his intended actions.

- **11.32. 3.8. Protection against electric shock**

ANNEX II (continued)

3.8. Protection against electric shock

3.8.1. Insulating equipment

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.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so 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 minimised and, in any event, below a 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.

The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

. . .

To identify the "most unfavourable foreseeable conditions", the manufacturer will need to consider:

- the risk of direct contact to a live conductor;
- the possible harmful electrical parameters and threshold limit values;

- moistness of the skin;
- the effect of contact with chemicals used such as solvents, of mechanical degradation/ageing and of climatic environmental factors during normal use of the PPE.

Marking of a protection class on PPE for professional use, intended for protection against electric shock, is required to ensure the traceability, information on the scope of use and necessary periodic checking.

In addition to the electric shock, other risks related to short-circuiting, such as thermal and mechanical risks, also needs to be taken into account.

The manufacturer needs to clearly indicate in the instructions for use the following:

- maximum voltage for the class considered;
- storage conditions;
- controls to be carried out, visual examination and inflation of gloves, and their periodicity, normally before each use;
- maintenance of the PPE.

Moreover, precautions of use, in particular aimed at preserving the electrical insulation properties of the PPE or against the risks of deterioration need to be indicated, e.g. use of over-gloves to reduce the risk of punctures, cuts, abrasion, chemical attacks.

ANNEX II 3.8. (continued)

3.8.2. Conductive equipment

Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.

The requirement concerns only conductive PPE intended to be worn by (electrically) skilled persons during live working at a nominal power system voltage up to 800 kV AC and 600 kV DC.

Conductive clothing has a very low electrical resistance and is used to create an electrical shielding of the user during work with very high voltage elements. Information that continuity among different garments cannot be broken and information to guarantee the same resistance along the whole body should be included in the manufacturers' instructions and information.

Conductive equipment, i.e. electrostatic dissipative protective equipment with a surface resistivity of up to 10^3 Ohm, is used as part of a total earthed system to avoid incendiary discharges (antistatic) and is covered by Annex II 2.6 in the PPE Regulation.

- **11.33. 3.9. Radiation protection**

ANNEX II (continued)

3.9. Radiation protection

3.9.1. Non-ionizing radiation

PPE designed to prevent acute or chronic eye damage from sources of non-ionising 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.

To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised 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.

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.

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.

The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.

. . .

When designing PPE for eye and skin protection against non-ionising radiation, the manufacturer will, in particular, need to consider the following:

- spectral and additional characteristics of the radiation sources;
- for eye protection, illumination of the environment;
- distance of the wearer from the source(s);
- for eye protection, the need to allow colour recognition (e.g. warning signals or identification of materials at elevated temperatures);
- the effect of radiation and ageing on the efficiency of the exposed PPE, e.g. to sun, UV, IR radiations or laser sources. The transmission characteristics of the PPE shall remain at the requested level during the lifetime of the PPE;
- updated exposure limit values.

The exposure limit values to the non-ionising radiations are laid down in scientific publications and national regulations to which the manufacturer can refer. In particular in:

- Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC;

- the guideline of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) who regularly publishes updated limiting exposure and recommends exposure limits values;
- Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). It covers the exposure of workers to the risks arising from exposure to artificial optical radiation to eyes and skin.

Where this requirement refers to "radiation sources of the same type" it relates, for example, to those of the same nature (e.g. infra-red radiations) or of the same type of operations (e.g. radiations produced by arc and gas welding stations and associated processes).

The manufacturer should give information on the scale or shade numbers of PPE and replaceable spare parts and of the corresponding field of use by means of informative markings on the PPE and in the instructions for use. When the PPE forms a single unit with non-replaceable filters (e.g. laser eye protectors), the marking(s) can be placed on the frame.

Equipment protecting the skin against non-ionising radiation is considered as PPE if protection against erythema is claimed by the manufacturer.

Equipment protecting against natural UV radiation is considered as PPE if it is designed and manufactured to have specific UV-protective properties.

Creams protecting against natural UV radiation, i.e. sun protection creams, are not PPE under the PPE Regulation.

ANNEX II 3.9. (continued)

3.9.2. Ionizing radiation

3.9.2.1. Protection against external radioactive contamination

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 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.

Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these classes of equipment.

. . .

The manufacturers' instructions and information shall specify the procedure of decontamination, only applicable for re-usable PPE, which the PPE can withstand without significant degradation of the level of protection.

ANNEX II 3.9.2. (continued)

3.9.2.2. Protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak 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 chosen or designed and incorporated so 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 point 1.3.2).

PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.

PPE protecting against external radiation is the ultimate resort in the event of deterioration of characteristics of the collective protection enclosures. The lead equivalent thickness is given according to this limiting energy so that the intended user is not exposed beyond the exposure limit values.

Lead and heavy metals are only used to attenuate X- or gamma-rays. In the case of beta radiation, use of this type of protection should be avoided as the heavy metal will stop the beta radiation but also cause a breaking X-ray called "Bremsstrahlung". There is no specific protection against beta radiation other than equipment made of elastomers or polymers which help to stop some of the radiation. The level of protection will depend on the material, its thickness and the energy of the radiation emitted.

The level of protection offered by a PPE is characterised by the determination of equivalent lead thickness of a lead sheet with the same rate of attenuation of the ionizing radiation. If the PPE comprises several components, each component and their assembly shall offer the requested level of protection whatever the posture taken by the user.

The thickness considered here can be expressed in term of lead equivalent thickness. The aim is to supply useful information to the user on the attenuation of the ionizing radiations offered by the PPE.

The lead equivalent thickness always has to be given with the energy of the radiation at which it has been verified.

- **11.34. 3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents**

ANNEX II (continued)

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

against harmful biological agents

3.10.1. Respiratory protection

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.

The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

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 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.

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.

. . .

It is advisable to design the PPE so that exposure to substances and mixtures which are hazardous to health and against harmful biological agents is clearly under the necessary limit values. Air supplied needs to have a suitable temperature and humidity so that the comfort of the intended user is not affected, does not cause harmful effects or endanger the safe operation of the PPE.

Minimum oxygen concentration of the inhaled air has to be sufficient taking into account the demands of the tasks of the user. The amount of re-breathed exhalation air needs to be minimised to avoid the accumulation of carbon dioxide inside the face-piece. For very short periods of use, for example for escape apparatus, higher carbon dioxide concentrations may be accepted.

The filtration efficiency of the substances and mixtures which are hazardous to health and against harmful biological agents is dependent on the size, distribution and nature of the aerosols, particles, gases and vapours as well as of the characteristics of the filtering element. Filtration efficiency changes have to be considered in the design of the device and adequate instructions given.

The breathable gas supply in compressed air or oxygen breathing apparatus is to be ensured by proper design of the mechanical, operational strength and function. The risks caused by wrong combination of air supply systems of the breathing apparatus have to be eliminated as

far as possible by design. If not possible, adequate information on safe combinations shall be given by the manufacturer.

The respiratory protective device cannot contain or release any substances which are known to be harmful. All of the materials used should be listed in the information to the user. The release of harmful filtering material from the filter has to be eliminated.

The design, adjustments and size range or overpressure inside the face-piece has to prevent face seal leakage as far as possible. The maximum breathing rate needs to be considered in the foreseeable use conditions and the device designed so the breathing resistance is not too high. The foreseeable work load can also cause face-piece leakage due to higher under-pressure inside the mask. Moreover, the effect of the increase of the breathing resistance of particle filters during normal use of filtering face piece respirators should also be carefully considered. The magnitude of the penetration between the body of the mask and the face of the user is proportional to the square root of the resistance. Therefore, the higher the resistance of the filter is the greater is the face penetration. This needs to be clearly explained in instructions for use accompanying particle filters and face masks.

The manufacturer is required to mark all respiratory protective devices, their components and important spare parts so that it is clear to which device these belong to. These markings also have to be described in the instructions for use.

All filters have to be marked with relevant pictograms and information on the deadline for the storage of the filters when kept sealed in their original packaging.

The essential requirement 2.3 applies to all respiratory protective devices. This requirement foresees the use of anti-fogging products or lenses when necessary. This is essential for full face masks intended for use in very polluted and foggy atmospheres where it is not possible to remove the apparatus in order to clean it.

ANNEX II 3.10. (continued)

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with 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 those types of PPE must be chosen or designed and incorporated so as 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.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are 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, in the absence of the names, 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 protective part of this PPE will prevent adequately direct contact with the skin or eyes with substances and mixtures which are hazardous to health and against harmful biological agents.

PPE protecting against substances and mixtures which are hazardous to health and against harmful biological agents needs to have penetration and permeation properties suitable according to the risk and tasks for which they are designed. This will be the case at least during the time of use indicated in the instruction for use. In practice all materials have limited protection over time and thus relevant information and warnings are needed in the instructions for use.

It is not possible to test the protection efficiency against all substances and mixtures in all ambient conditions. Tests with representative substances will give an indication to the user of the protection efficiency. In the instructions for use the test substances are to be clearly mentioned so that the end user can select a suitable PPE for his tasks. The meaning of these results, e.g. breakthrough time, needs to be explained to make them clear to the user. On that basis the user will be able to evaluate the protection and time of protection in his/her own working situation. For example, hairdressing gloves protect against harmful ingredients in colouring dyes, bleaching agents, curling and perming products. This context of various substances with different concentrations requires using single use gloves to prevent damage from chemical degradation.

- **11.35. 3.11. Diving equipment**

ANNEX II (continued)

3.11. Diving equipment

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.

Where the foreseeable conditions of use so require, the diving equipment must comprise the following:

(a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);

(b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);

(c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).

The term “diving equipment” is restricted to equipment used for the diving in a sub-aqueous (i.e. water) medium.

Respiratory tracts are subjected to the effect of the pressure. Breathing apparatus must therefore be provided with an automatically regulation system of the feeding system of a breathable gas mixture.

In a sub aqueous medium, the user is always exposed to pressure. Only one type of the diving suits protects the user against the pressure, an atmospheric diving suit (ADS) which is a small one-man articulated submersible of anthropomorphic form which resembles a suit of armour, with elaborate pressure joints to allow articulation. The flexible combinations used in practice cannot ensure a protection against the pressure within the meaning of requirement 3.2. This requirement, with regard to the pressure, imposes only that the combinations will not induce new risks arising from the equipment itself. The warning device forms integral part of the breathing apparatus aimed to requirement 3.11., first subparagraph.

The lifesaving suit, which allows for the rapid escape of the diver, should not be confused with the diving suit. This rescue equipment (called a “buoyancy compensator”), which provides the diver with means for controlling buoyancy and for holding him in a head-up position at the surface even if he is unconscious and in cases of emergency for returning at the surface, is worn independently and over the diving suit.

12. ANNEX III - TECHNICAL DOCUMENTATION FOR PPE

ANNEX III

TECHNICAL DOCUMENTATION FOR PPE

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 include at least the following elements:

(a) a complete description of the PPE and of its intended use;

(b) an assessment of the risks against which the PPE is intended to protect;

(c) a list of the essential health and safety requirements that are applicable to the PPE;

(d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;

(e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;

(f) the references of the harmonised standards 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 umentation shall specify the parts which have been applied;

(g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;

(h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;

(i) 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;

(j) 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;

(k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;

(l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;

(m) 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.

When establishing the technical documentation, the manufacturer must take into account the category of PPE.

The risk assessment in (b) refers to the risk assessment performed by the manufacturer according to Annex II "Preliminary Remarks" in the PPE Regulation.

PPE produced as a single unit to fit an individual user in (l) are PPE placed on the market as a single unit which cannot be tested in a series production because each individual item is unique and would be destroyed in testing, for example custom-made orthopaedic protective footwear. Information on the process followed for manufacturing the single unit shall be included so to guarantee the conformity with the type.

PPE produced in series where each item is adapted to fit an individual user in (m) is PPE produced in series and where general testing of the PPE is possible, for example custom moulded earplugs.

According to (j) information on conformity with Module C (Annex VI) should be included in the technical documentation.

The notified body should check that the information according to point (j) of Annex III is included in the technical documentation, as prescribed in point 4(a) of Annex V.

13. ANNEX IV - INTERNAL PRODUCTION CONTROL (Module A)

ANNEX IV

INTERNAL PRODUCTION CONTROL

(Module A)

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.
2. Technical documentation

   The manufacturer shall establish the technical documentation described in Annex III.
3. Manufacturing

   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 in point 2 and with the applicable requirements of this Regulation.
4. CE marking and EU declaration of conformity

   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. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
5. Authorised representative

   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.

If third parties are involved in the conformity assessment process the manufacturer still has the full responsibility for the compliance of the PPE.

14. ANNEX V - EU TYPE-EXAMINATION (Module B)

ANNEX V

EU TYPE-EXAMINATION

(Module B)

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 requirements of this Regulation that apply to it.

2. EU type-examination shall be carried out 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).

3. Application for EU type-examination

   The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice.

   The application shall include:

   (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

   (b) a written declaration that the same application has not been lodged with any other notified body;

   (c) the technical documentation described in Annex III;

   (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 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, and for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.

4. EU type-examination

   The notified body shall:

   (a) examine the technical documentation to assess the adequacy of the technical design of the PPE. In conducting such an examination, point (j) of Annex III need not be taken into account;

   (b) for PPE produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;

   (c) for PPE produced as a single unit to fit an individual user, examine the instructions for manufacturing such PPE on the basis of the approved basic model to assess their adequacy;

   (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;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen 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.

5. Evaluation report

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.

6. EU type-examination certificate

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.

The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.

6.2. The EU type-examination certificate shall contain at least the following information:

(a) the name and identification number of the notified body;

(b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the latter's name and address;

(c) identification of the PPE covered by the certificate (type number);

(d) a statement that the PPE type complies with the applicable essential health and safety requirements;

(e) where harmonised standards have been fully or partially applied, the references of those standards or parts thereof;

(f) where other technical specifications have been applied, their references;

(g) where applicable, the performance level(s) or protection class of the PPE;

(h) for PPE produced as a single unit to fit an individual user, the range of permissible variations of relevant parameters based on the approved basic model;

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

(j) any conditions attached to the issue of the certificate;

(k) 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 point (c) of Article 19.

6.3. The EU type-examination certificate may have one or more annexes attached.

6.4. 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.

7. Review of the EU type-examination certificate

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

7.2. 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.

7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.

7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate either:

(a) in the case of a modification to the approved type referred to in point 7.2;

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

(c) at the latest, before the date of expiry of the certificate.

In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate.

7.5. The notified body shall examine the PPE type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable health and safety requirements, 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.

7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following:

(a) his name and address and data identifying the EU type-examination certificate concerned;

(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or other technical

specifications applied;

(c) confirmation that there has been no change in the state of the art as referred to in point 7.3;

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

(e) for Category III products, where not already available to the notified body, information on the results of the supervised product checks at random intervals carried out in accordance with Annex VII, or on the results of audits of his quality system carried out in accordance with Annex VIII.

Where the notified body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In such cases, the notified body shall renew the EU type-examination certificate.

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

If the notified body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.

7.7. If, following the review, the notified body concludes that the 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. 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.

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.

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 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, for a period of five years after the expiry of the validity of that certificate.

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.

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.

It is important that the notified body has access to the manufacturers' instructions and information in order to verify that the specifications indicated by the manufacturer really cover the EHSRs applicable to the PPE concerned. Manufacturers' instructions and information must specify the intended use of the PPE and the risks covered.

Verification by the notified body of the effectiveness of the protection offered by the PPE assumes concrete knowledge of the dangerous situations inherent in its intended use as declared in the manufacturers' instructions and information and of the acknowledged state of the art at that moment. Thus, the EU type-examination carried out by the notified body goes beyond simply applying the test resources specified in the relevant European harmonised standards and noting that the test results are in conformity with the levels of performance required by those standards. The fact that the transposed European harmonised standard is regarded as supporting the presumption of conformity does not relieve the manufacturer of his responsibility to design and manufacture PPE which meets the current state of the art, nor does it authorise the notified body to refuse to carry out an EU type-examination of a PPE which meets the current state of the art on the grounds that it would be different from the state of the art considered by the transposed European harmonised standard.

The EHSRs referred to are those relevant requirements of the PPE Regulation which are applicable to the PPE in accordance with the foreseeable use. This allows the manufacturer to innovate by offering a PPE of radically new design, or having characteristics and levels of performance which offer a greater degree of safety than those envisioned in the European harmonised standards. It requires the notified body to demonstrate flexibility whilst at the same time, through its competence and expertise, ensuring that the PPE conforms to the PPE Regulation. The EU type examination of the PPE is the procedure which enables the notified body to verify the conformity of the PPE with the provisions of the PPE Regulation.

It is the responsibility of the manufacturer to supply the information requested in 7.6 to the notified body. If the notified body has reasonable doubts that the manufacturers' instructions and information are not correct, further checks might be necessary. For Category III PPE, the results of the assessments according to module C2 or D should be taken into account.

Validity of an EU type-examination certificate and revision of harmonised standards

As a general principle, the removal of the reference of a superseded harmonised standard from the OJEU after its revision by a superseding harmonised standard does not automatically invalidate existing certificates issued by notified bodies making reference to such superseded harmonised standard.

The necessary information should be included in the revised standard itself, and the relevant European Standardisation Organisation (CEN, CENELEC) in charge of the development and publication of a new harmonised standard, should indicate, in the foreword or in an annex, the nature of the changes made with respect to the superseded version. Such given information may not affect all the products covered by the standards, but it would be necessary to apply it to the specifically concerned products.

Manufacturers must carry out a specific assessment on the extent of the changes to the superseded version of the standard they used as indicated in the EU type-examination certificate, in particular whether these changes are substantial with regard to the coverage of the essential health and safety requirements the product in question must comply with. They should share and discuss their assessment with the relevant notified body with a view to reach agreement about the impacts of the change in the standard. Such agreement should be documented.

If the specific design (type) was concerned by the changes introduced by the revised harmonised standard, then a further assessment, as well the revision of the certificate and of the corresponding documentation are needed, to ensure compliance with the applicable essential requirements.

On the contrary, where a revision of a harmonised standard is limited, for instance, to a 'formal' or an 'administrative exercise' and it seems unlikely that such revision would have impacts on the product's compliance with the essential requirements, such certificates could continue to be considered valid until their expiry date.

In any case, an assessment on a case by case basis is needed to be carried out by the manufacturer who is under an obligation to ensure that the PPE has been designed and manufactured in accordance with the essential health and safety requirements of the applicable PPE legislation. The documentation of the assessment carried out should be added to the relevant technical documentation of the product, in order to clearly explain that while the superseded version of the standard no longer provides presumption of conformity, compliance with the essential requirements is nevertheless still ensured.

Review of the EU type-examination certificate

In the case of a modification to the approved type (point 7.2) or a change in the state of the art (point 7.3.) the manufacturer should ask the notified body to review the EU-type examination certificate as soon as any of these conditions are met. The upper time limit of 12 months prior to the expiry date of the certificate is applicable only when the request to the review of the EU-type examination certificate is made only in view of the date of the expiry of the certificate (7.4.(c)). In all cases, the request to review the EU-type examination certificate should be made at the latest 6 months prior to the expiry date of the certificate.

When the request to review the EU type-examination certificate is made as a consequence of a modification to the approved type (point 7.2) or a change in the state of the art (point 7.3.) before the 12 months limit prior to the expiry date of the certificate, the manufacturer should ask the notified body for an addition to the original EU type-examination certificate, which should be issued, after the relevant examination and tests (point 7.5.) have been carried out. In this case:

- the end date of the validity of the EU type-examination certificate shall remain unchanged;

- the evolution of the EU type-examination certificate should be traced and the date when the additional approval took place should be included.

If, for the case indicated above, the modifications to the approved type (point 7.2) or the changes in the state of the art (point 7.3.) are significant and require almost a complete re-

evaluation of the product, the notified body could issue a new EU type-examination certificate with a new expiry date, instead of an addition to the original EU type examination certificate.

When the request to review the EU type-examination certificate is made between 12 months and 6 months before the expiry date of the certificate:

– the new EU type examination should be issued after the relevant examinations and tests (point 7.5) have been carried out, if there is a modification to the approved type (point 7.2) or a change in the state of the art (point 7.3);

– the new EU type examination should be issued without the need to perform the relevant examinations and tests (point 7.5) by simplified procedure (point 7.6.), if the notified body has confirmed that no modification to the approved type (point 7.2) and no change in the state of the art (point 7.3) has occurred;

– the new EU type-examination certificate should indicate the date of renewal;

– the period of validity of the new EU type-examination certificate should not exceed 5 years.

15. ANNEX VI - CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (Module C)

ANNEX VI

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

(Module C)

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 requirements of this Regulation.
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 requirements of this Regulation.
3. CE marking and EU declaration of conformity

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

   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. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
4. Authorised representative

   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.

16. ANNEX VII - CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (Module C2)

ANNEX VII

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS

(Module C2)

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

2. Manufacturing

   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 requirements of this Regulation.

3. Application for supervised product checks at random intervals

   Before placing PPE on the market, the manufacturer shall lodge an application for supervised product checks at random intervals with a single notified body of his choice.

   The application include the following:

   (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;

   (b) a written declaration that the same application has not been lodged with any other notified body;

   (c) the identification of the PPE concerned.

   Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

   (a) the technical documentation described in Annex III;

   (b) a copy of the EU type-examination certificate.

4. Product checks

   4.1. The notified body shall carry out product checks in order to 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.

   4.2. The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The first product checks shall be carried out no

more than one year after the date of issue of the EU type- examination certificate.

4.3. An adequate statistical 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) 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.

4.5. 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.

4.6. 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.

5. Test report

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

5.2. The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.

5.3. 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

6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this 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.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

7. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised 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.

It should be highlighted that the EU type-examination certificate must be issued to the manufacturer that has applied for the quality control system laid down in this Annex VII. This also applies to manufacturers that have own-brand label EU type-examination certificates.

It would be sensible for the notified body to assess the manufacturer's control procedures before agreeing to its identification number being marked on the product.

In order to place PPE subject to module C2 on the market, manufacturers should have fulfilled the obligations laid down in Annex VII in relation to module C2 (see point 1). In particular the notified body should have performed the first product check (point 4) and provided the manufacturer with a test report (point 5.1.) so that the manufacturer has it at the moment of placing the product on the market and is in the position to provide it to the national authorities when required (point 5.2). Both, the EU-type examination certificate from module B plus the test reports from module C2 should be available before placing the product on the market (see also § 5.1.5 "One- and two-module procedures – Procedures based on type (EU-type examination)" in "The 'Blue Guide' on the implementation of EU product rules").

Sharing of information between the notified bodies used by a manufacturer is confidential, and arises where there is difficulty in assessing the conformity of samples.

17. ANNEX VIII - CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (Module D)

ANNEX VIII

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

(Module D)

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 requirements of this Regulation.

2. Manufacturing

   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.

3. Quality system

   3.1. The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice.

   The application shall include:

   (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

   (b) the address of the manufacturer's premises where the audits can be carried out;

   (c) a written declaration that the same application has not been lodged with any other notified body;

   (d) the identification of the PPE concerned;

   (e) the documentation concerning the quality system.

   Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

   (a) the technical documentation of the PPE described in Annex III;

   (b) a copy of the EU type-examination certificate.

   3.2. The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination certificate and complies with the applicable 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.

The quality system documentation shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions 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;

(d) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned; and

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

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 harmonised standard.

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.

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.

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.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. The notified body shall authorise the manufacturer to affix the notified body's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. 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:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data and qualification 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.

4.4. 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.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable 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 PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information related to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

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.

The notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of such quality system approvals which it has issued.

8. Authorised representative

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 quality assessment system of the authorised representative/responsible person shall not be subject to assessment by a notified body, but the quality assessment system of the actual manufacturer. It would not be reasonable to assess a quality assessment system of a facility that is not producing the product. However, if the authorised representative is carrying out tests and/or verifications required by the PPE Regulation to determine conformity with the essential health and safety requirements, he shall be subject to the quality assurance assessment.

Any assessment following changes to a previously approved system must be limited to the relevant modifications.

18. ANNEX IX - EU DECLARATION OF CONFORMITY

ANNEX IX

EU DECLARATION OF CONFORMITY No … ([1])

1. PPE (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):
5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: …
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:
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).
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 (Module C2) or conformity to type based on quality assurance of the production process (Module D)) … under surveillance of the notified body … (name, number).
9. Additional information:

Signed for and on behalf of: …

(place and date of issue):

(name, function) (signature):

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

The EU declaration of conformity, to be drafted and signed by the manufacturer, is required by Article 15 of the PPE Regulation (EU) 2016/425. Annex IX includes a model structure for the EU declaration of conformity, based on Annex III to Decision No 768/2008/EC.

19. ANNEX X - CORRELATION TABLE

ANNEX X

CORRELATION TABLE

Directive 89/686/EEC	This Regulation
Article 1(1)	Articles 1 and 2(1)
Article 1(2) and (3)	Article 3 point (1)
Article 1(4)	Article 2(2)
Article 2(1)	Article 4
Article 2(2)	Article 6
Article 2(3)	Article 7(2)
Article 3	Article 5
Article 4(1)	Article 7(1)
Article 4(2)	—
Article 5(1), (4), (5)	—
Article 5(2)	Article 14
Article 6	Article 44
Article 7	Articles 37-41
Article 8(1)	Article 8(2) first subparagraph
Article 8(2)-(4)	Articles 18 and 19 and Annex I
Article 9	Articles 20, 24(1), 25, and 30(1)
Article 10	Annex V
Article 11(A)	Annex VII
Article 11(B)	Annex VIII
Article 12(1)	Article 15
Articles 12(2) and 13	Articles 16 and 17
Article 14	—
Article 15	—
Article 16(1) first subparagraph and (2)	—
Article 16(1) second subparagraph	Article 48(2)
Annex I	Article 2(2)
Annex II	Annex II
Annex III	Annex III
Annex IV	Article 16
Annex V	Article 24(2)-(11)
Annex VI	Annex IX

20. APPENDIX: GUIDE FOR THE CATEGORISATION OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

Summary of the provisions of Regulation (EU) 2016/425 (the "PPE Regulation") concerning categorisation of PPE, according to the level of risk the intended user is protected against.

1. Definition of PPE (Article 3(1))

Personal protective equipment (PPE) means:

1.1. equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety (Article 3(1)(a));

1.2. interchangeable components for equipment referred to in point (a) which are essential for its protective function (Article 3(1)(b));

1.3. connexion systems for equipment referred to in point (a) that are not held or worn by a person, 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 (Article 3(1)(c)).

2. Equipment excluded from the scope of the PPE Regulation, referred to in this document as "Not PPE" (Article 2(2)):

2.1. PPE specifically designed for use by the armed forces or in the maintenance of law and order (Article 2(2)(a))
(for example: helmets, shields, etc.);

2.2. PPE designed to be used for self-defence, with the exception of PPE intended for sporting activities (Article 2(2)(b))
(for example: aerosol canisters, personal deterrent weapons, etc.);

2.3. PPE designed for private use to protect against:

- atmospheric conditions that are not of an extreme nature (Article 2(2)(c)(i)),
(for example: headgear, seasonal clothing, footwear, umbrellas, etc.)
- damp and water during dishwashing (Article 2(2)(c)(ii))
(for example: dish-washing gloves, etc.);

2.4. PPE for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States (Article 2(2)(d));

2.5. PPE for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds (Article 2(2)(e)).

3. Risk categories of PPE

The risk categories are defined in Annex I of the PPE Regulation.

3.1. Category I includes exclusively the following minimal risks:
(a) superficial mechanical injury;
(b) contact with cleaning materials of weak action or prolonged contact with water;
(c) contact with hot surfaces not exceeding 50 °C;
(d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);
(e) atmospheric conditions that are not of an extreme nature.

3.2. Category II includes risks other than those listed in Categories I and III

3.3. Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following:
(a) substances and mixtures which are hazardous to health;
(b) atmospheres with oxygen deficiency;
(c) harmful biological agents;
(d) ionising radiation;
(e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;
(f) low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less;
(g) falling from a height;
(h) electric shock and live working;
(i) drowning;
(j) cuts by hand-held chainsaws;
(k) high-pressure jets;
(l) bullet wounds or knife stabs;
(m) harmful noise.

PART 1: per type of PPE

Type of PPE		Certification category	Reason
1.	**Equipment for hearing protection**		
1.1	All equipment protecting hearing (whether worn in or over the ear)	III	3.3. (m)
Except:			
1.2	Earplugs intended for swimmers to prevent water entering the ears	Not PPE	Definition of PPE
1.3	Earplugs not designed to protect against hazards, e.g. earplugs for sleeping and earplugs for flying	Not PPE	Definition of PPE

Type of PPE		Certification category	Reason
2.	**Equipment for eye protection**		
2.1	All eye protectors and filters, including eye protectors against artificial UV radiation (e.g. in sunbeds), against high intensity blue light and protective glasses for phototherapy on babies.	II	3.2.
Except:			
2.2	Eye protectors and filters designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, some types of lasers, flames, hot splashes or the projection of large amounts of molten materials	III	3.3. (e)
2.3	Eye protectors and filters designed and manufactured to provide protection against ionising radiation	III	3.3. (d)
2.4	Eye protectors and filters designed and manufactured to provide protection against electric shock	III	3.3. (h)
2.5	Swimming and/or diving goggles and masks, including face masks with integrated snorkel	I	3.1. (a)
2.6	Eye protectors and filters designed and manufactured exclusively to provide protection against sunlight, sun glasses (not corrective) for private and professional use. This includes cases where glasses are tinted after manufacturing or any other assembly after manufacturing (e.g. assembly of sunlight protective lenses in a non CE marked frame)	I	3.1. (d)
2.7	Ski goggles of all types, except corrective spectacles	I	3.1. (d)
2.8	Corrective spectacles including corrective sunglasses *Note: Where corrective spectacles provide protection other than protection against sunlight (e.g. against impact, abrasive projections, etc.), they are classified as personal protective equipment of the category corresponding to the risk in question solely in respect of their protective features*	Depends on which risk protection is given against	*See also the interpretative document between the PPED and MDD*[14]
2.9	Visors incorporated into helmets designed and manufactured for use with two- or three-wheeled motor vehicles	Not PPE	2.5.

[14] http://ec.europa.eu/DocsRoom/documents/10262/attachments/1/translations/en/renditions/pdf.

2.10	Glasses filtering the blue light that comes from screens of electronic devices (*)	Not PPE	Definition of PPE

(*) the intensity of the blue light that comes from screens of electronic devices is low, and according to the literature it seems unlikely that it poses a physical hazard to the retina.

Type of PPE		Certification category	Reason
3.	**Equipment for protection against falls from a height**		
3.1	All protective equipment designed and manufactured to provide protection against falls from a height, for private or professional use (working at heights, falling off boats, mountaineering, rock climbing, speleology, etc.). This category also includes equipment for working at a height and with support (harnesses, thigh straps, belts, etc.) and descenders fitted with a built-in speed-regulating system *Note: This equipment includes harnesses (thigh straps, shoulder belts, etc.) and all accessories intended for attaching a person to a structure, with the exception of anchorage points forming an integral part of the structure or rock face.* ○ *For example: for professional use: lanyards, mobile fall arresters, karabiners, energy absorbers, connectors, anchor points, etc.* ○ *For mountaineering, rock climbing, and speleology: dynamic mountaineering ropes, slings, connectors (climbing karabiners), rope clamps, chocks, rock anchors (pitons), ice anchors, ice tools that can serve as an anchor point (e.g. for climbing), etc.* *Note: The categorisation is not influenced by the fact that the equipment is factory made/assembled or produced/assembled by the (employer) user himself (e.g. double lanyards)*	III	3.3. (g)
Except:			
3.2	Anchorage points forming an integral part of the structure or rock face, or require tools for its installation *Example: Anchor devices of classes A, C and D according to EN 795:2012*[15]	Not PPE	Definition of PPE
3.3	Equipment for accessing or leaving positions at a height (winch seats, descenders not fitted with a built-in speed-regulating system, etc.)	Not PPE	Definition of PPE
3.4	Equipment for climbing, rock climbing, speleology etc. (hammers, descenders not fitted with a built-in speed-regulating system, rope-climbing equipment, etc.)	Not PPE	Definition of PPE
3.5	Support equipment (harnesses, etc.) designed and manufactured for use with parachutes, paragliders, hang-gliders, etc. and which cannot be used for purposes other than those for which they were designed	Not PPE	Definition of PPE
3.6	Emergency parachutes	Not PPE	2.4.

[15] The reader's attention is drawn to the warning published in the OJEU regarding EN 795:2012, see: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment_en.

Type of PPE		Certification category	Reason
4.	**Equipment for head protection** *Note: Equipment protecting against several risks of different categories is subject to the most stringent conformity assessment procedure*		
4.1	Head protection equipment including head protection for sports against mechanical impact	II	3.2.
Except:			
4.2	Head protection equipment designed and manufactured to provide protection, including thermal protection, for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, some types of lasers, flames, hot splashes or the projection of large amounts of molten materials	III	3.3. (e)
4.3	Head protection equipment designed and manufactured to provide protection, including thermal protection, for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less	III	3.3. (f)
4.4	Head protection equipment designed and manufactured to provide protection against electric shock	III	3.3. (h)
4.5	Light headgear designed and manufactured to provide scalp protection against minor impacts whose effects cannot cause irreversible lesions	I	3.1. (a)
4.6	Helmets designed and manufactured for riders of 2- or 3- wheeled motor vehicles, including racing helmets *Note: Car racing helmets are not excluded from the PPE Regulation and are thus Category II PPE*	Not PPE	2.5.
4.7	Helmets designed and manufactured specifically for use by the armed forces or in the maintenance of law and order	Not PPE	2.1.

Type of PPE		Certification category	Reason
5.	**Equipment for part or whole face protection**		
5.1	All equipment *Note: This equipment includes face shields used in the context of COVID-19*	II	3.2.
Except:			
5.2	Equipment designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, some types of lasers, flames, hot splashes or the projection of large amounts of molten materials *Example: some types of face shields for welders*	III	3.3. (e)
5.3	Equipment designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less	III	3.3. (f)
5.4	Equipment designed and manufactured to provide protection against electric shock *Example: some types of face shields for welders*	III	3.3. (h)
5.5	Visors designed and manufactured for incorporation into helmets used by riders of 2- or 3-wheeled motor vehicles, including racing visors	Not PPE	2.5.

Type of PPE		Certification category	Reason
6.	**Protective clothing**		
6.1	All items of clothing and/or accessories (whether or not detachable) designed and manufactured to provide specific protection *Remark: This category includes also:* ○ *protective clothing used for sports activities, such as diving and immersion suits providing thermal protection, protective clothes for waterskiing, etc.;* ○ *protective clothing, such as coveralls and two-piece suits, providing thermal protection in case of accidental fall into the water* ○ *Garments providing additional protection against tick bites* ○ *Beekeeper equipment, in particular beekeeper veils and beekeeper garments which provide protection from bee stings, with the exception of garments that only protect from dirt, and of bee smokers*	II	3.2.
Except:			
6.2	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against electric shock e.g. some types of protective clothing for welders.	III	3.3. (h)
6.3	Clothing and/or accessories (whether or not detachable), designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, some types of lasers, flames, hot splashes or the projection of large amounts of molten materials *Example: protective clothing for wildland firefighters, some types of protective clothing for welders.*	III	3.3. (e)
6.4	Clothing and/or accessories (whether or not detachable), designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less	III	3.3. (f)
6.5	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against substances and mixtures which are hazardous to health, harmful biological agents or ionising radiation *Note: The manufacturer shall indicate the products against which protection is provided, and the time for which such protection lasts*	III	3.3. (a) and (c)-(d)

6.6	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide complete insulation of the respiratory tract from the atmosphere, including those for use in diving	III	3.3. (a)-(d)
6.7	Clothing and/or accessories (whether or not detachable) designed and manufactured to protect against liquid chemicals *Note: The manufacturer shall indicate the products against which protection is provided, and the time for which such protection lasts*	III	3.3. (a)
6.8	Clothing protecting against bullet wound and/or knife stabs used by other than the armed forces (for instance security guards), including apron for butcher	III	3.3. (l)
6.9	Clothing and/or accessories (whether or not detachable) for professional use designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, such as rain, ocean spray and water splash	I	3.1. (e)
6.10	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial	I	3.1. (a)
6.11	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against risks arising from handling hot components which do not expose the user to a temperature of over 50 °C or to dangerous impacts	I	3.1. (c)
6.12	Clothing and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including bullet-proof clothing or jackets, clothing protecting against biological contamination or ionising radiation *Remark: The given examples of garments used by others than armed forces or maintenance of law and order, are PPE and to be categorised depending on the type of risk they provide protection against*	Not PPE	2.1.
6.13	Clothing and/or accessories for private use (whether or not detachable) designed and manufactured to provide protection against adverse atmospheric conditions	Not PPE	2.3.
6.14	Ordinary clothing and/or accessories (whether or not detachable) or sports clothing and/or accessories (not providing specific protection), including uniforms	Not PPE	2.3.
6.15	Motorcyclists' garments and additional protection *See point 14*		

Type of PPE		Certification category	Reason
7.	**Respiratory protective equipment**		
7.1	All respiratory protective equipment (however described) designed and manufactured to provide protection against solid aerosols, liquid aerosols or gases All respiratory protective equipment designed and manufactured to provide full insulation from the atmosphere; all respiratory protective equipment designed and manufactured for use in diving	III	3.3. (a)-(d)
Except:			
7.2	All respiratory protective equipment designed and manufactured specifically for use by the armed forces or in the maintenance of law and order	Not PPE	2.1.
7.3	Surgical masks *Note: Where such masks are also intended to protect the wearer against microbial and viral infections, etc. they are also Category III PPE (personal protection and medical use)*	Not PPE	*See also the interpretative document between the PPED and MDD*[16]
7.4	Nose plugs intended for swimmers to prevent water entering the nose	Not PPE	Definition of PPE
7.5	Nose filters to prevent mainly the nasal inhalation of pollen and other allergens	Not PPE	Definition of PPE

[16] http://ec.europa.eu/DocsRoom/documents/10262/attachments/1/translations/en/renditions/pdf.

Type of PPE		Certification category	Reason
8.	**Equipment for leg and/or foot and anti-slip protection**		
8.1	All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the foot and/or the leg and to provide anti-slip protection, e.g. snow- and ice-spikes *Note: Protection against static electricity is included in this category since this equipment is used in environments with potential risk of explosion*	II	3.2.
Except:			
8.2	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electric shock for work involving dangerous voltages, or used to provide insulation against high voltages	III	3.3. (h)
8.3	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, some types of lasers, flames, hot splashes or the projection of large amounts of molten materials	III	3.3. (e)
8.4	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less	III	3.3. (f)
8.5	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against substances and mixtures which are hazardous to health, harmful biological agents or ionising radiation *Note: The manufacturer shall indicate the products against which protection is provided, and the time for which such protection lasts*	III	3.3 (a), (c) and (d)
8.6	Sports equipment (in particular sport shoes) and/or accessories (whether or not detachable) designed and manufactured to protect against superficial mechanical injury *Note: Sport shin-guards (e.g. for football, hockey) and protective equipment are generally Category II PPE unless designed only for protection against superficial mechanical injury*	I	3.1. (a)

8.7	Equipment and/or accessories for professional use (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme	I	3.1. (e)
8.8	Equipment and/or accessories for private use (whether or not detachable) designed and manufactured to provide protection against atmospheric conditions	Not PPE	2.3.
8.9	Equipment and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including equipment protecting against biological contamination or ionising radiation	Not PPE	2.1.
8.10	Some shoes, in particular sports shoes, contain components intended to absorb shock when walking, running, etc. or to ensure a good grip or stability. These components are to be regarded as being intended to increase comfort *Note: This category includes in particular football and spiked running shoes*	Not PPE	Definition of PPE

Type of PPE		Certification category	Reason
9	**Equipment for hand and arm protection**		
9.1	All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the arm and/or the hand *Note: This includes all equipment or garments protecting the hand or part of the hand, including gloves, fingerless gloves, mittens, garments protecting the fingers only or the palm only, etc.*	II	3.2.
Except:			
9.2	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electric shock for work involving dangerous voltages, or used to provide insulation against high voltages, e.g. some types of gloves for welders	III	3.3. (h)
9.3	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, some types of lasers, flames, hot splashes or the projection of large amounts of molten materials, including fire-fighters' equipment, some types of gloves for welders, etc.	III	3.3. (e)
9.4	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less	III	3.3. (f)
9.5	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against substances and mixtures which are hazardous to health, harmful biological agents or ionising radiation, including single use gloves for hairdressers *Note: The manufacturer shall indicate the products against which protection is provided and the time for which such protection lasts*	III	3.3. (a), (c) and (d)
9.6	Equipment and/or accessories for professional use (whether or not detachable) designed and manufactured to protect against cleaning materials of weak action (for dishwashing, cleaning etc.)	I	3.1. (b)

9.7	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial (pricks due to sewing, gardening, dirty work, sports – including bag gloves for boxing –, etc.)	I	3.1. (a)
9.8	Equipment and/or accessories (whether or not detachable) designed and manufactured to protect against heat and risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50 °C or to dangerous impacts and against and for professional use against unexceptional cold weather,	I	3.1. (c). and (d)
9.9	Gloves and finger guards for medical use in the patient's environment	Depending on the type of protection	*See also the interpretative document between the PPED and MDD*[17]
9.10	Gloves designed and manufactured to provide protection against adverse atmospheric conditions, damp and water or cold for private use	Not PPE	2.3.
9.11	Equipment and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including equipment protecting against biological contamination or ionising radiation	Not PPE	2.1.
9.12	Boxing gloves *Note: Bag gloves are Category I PPE*	Not PPE	Definition of PPE
9.13	Dry gloves for divers	II	3.2.
9.14	Protective gloves against harmful biological agents (e.g. micro-organisms)	III	3.3. (c)
9.15	Protective gloves against heat for private use, including potholders and similar products used for the same purpose as oven gloves and mittens	II	3.2.

[17] http://ec.europa.eu/DocsRoom/documents/10262/attachments/1/translations/en/renditions/pdf.

PART 2: per type of risk

Remark: the tables in this part contain all type of PPE and are not in contradiction with the tables in part 1. These are only given for further clarification.

Type of PPE		Certification category	Reason
10.	**Equipment designed to prevent drowning or for use as buoyancy aids**		
10.1	All equipment designed and manufactured for use as buoyancy aids, including swimming aids and inflatable buoys which are not regarded as toys (for use exclusively in shallow water) *Note:* ○ *Includes crampons and other equipment used to get out of water after falling through ice* ○ *Also included: swimming suits with incorporated floats* ○ *Also included: swimming armbands*	II	3.2.
10.2	Life-buoys and life-jackets to prevent drowning	III	3.3. (i)
Except:			
10.3	Life-buoys and life-jackets for emergency use by ship and aircraft passengers *Note: The terms "ship" and "aircraft" refer exclusively to those carrying passengers and to seagoing vessels subject to the international conventions of the IMO. Pleasure craft (motor boats and sailing boats), fishing boats, working boats, etc. are not included in this category*	Not PPE	2.4.
10.4	Buoyancy aids that are not worn but held by the user (such as foam boards, etc.)	Not PPE	Definition of PPE
10.5	Buoyancy aids that are not designed to be kept in place while worn or assure the upright position of the wearer (such as "tyre type" buoys, floating belts, etc.)	Not PPE	Definition of PPE
10.6	Ropes to exit water after a fall through ice	Not PPE	Definition of PPE
10.7	Babyneck buoys	Not PPE	Definition of PPE

Type of PPE		Certification category	Reason
11.	**Equipment for protection against electric shock**		
11.1	Equipment for protection against electric shock *Note: Dangerous voltages means a voltage equal to or exceeding 50 V alternating current (AC) or 75 V direct current (DC)*	III	3.3. (h)
Except:			
11.2	Hand-held insulating tools	Not PPE	Definition of PPE
11.3	Protective equipment (such as shoes, garments, etc.) against static electricity *Note: This equipment is used in environments with potential risk of explosion due to sparks*	II	3.2.

Type of PPE		Certification category	Reason
12.	**Equipment designed and manufactured to protect against the result of mechanical action**		
12.1	All PPE designed and manufactured to protect the wearer against vibrations	II	3.2.
12.2	PPE designed and manufactured to protect the skin of the user against friction (e.g. patches)	I	3.1. (a)
12.3	PPE designed and manufactured to protect the wearer against increased risk levels arising from impacts with other persons or from falling while performing sports (e.g. back protectors for mountain bikers, football shin-guards, ice hockey protectors, …)	II	3.2.
12.4	PPE designed and manufactured to protect the wearer against impacts resulting from g-forces (e.g. karting collar, racing neck braces, …)	II	3.2.
12.5	PPE designed and manufactured to protect the wearer against high pressure jets with a work pressure of more 200 bars	III	3.3. (k)
Except:			
12.6	Equipment protecting against superficial mechanical injury (such as light anti-scalping helmets, gloves, light footwear, etc.)	I	3.1. (a)
12.7	Sports equipment protecting against minor impacts from falling (protection against bruises, abrasion, light burns, …), such as volleyball knee pads, …	I	3.1. (a)
12.8	Some equipment designed and manufactured to enhance comfort and performance such as footwear and gloves, e.g. running shoes and sport gloves containing components intended to absorb shock when walking, running etc. or to ensure a good grip or stability	Not PPE	Definition of PPE
12.9	Needle caps	Not PPE	Definition of PPE

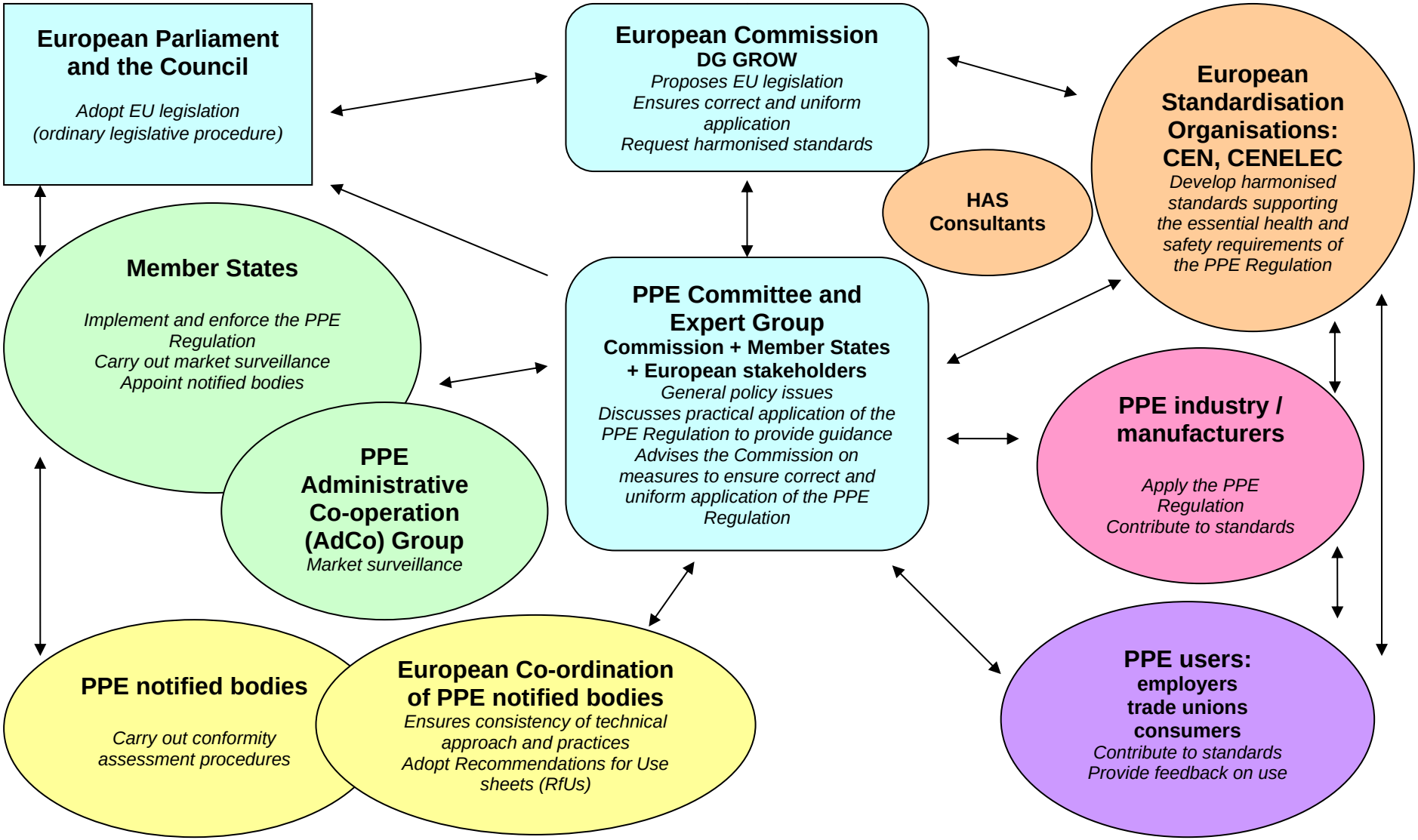
Type of PPE		Certification category	Reason
13.	**Rescue equipment**		
13.1	Resuscitation masks: if the mask has, apart from allowing adequate artificial breathing, also a protective function for the rescuer (protection against contagion by contact with the mouth of the victim for instance) then they are PPE	Depending on the type of protection	
13.2	If the rescue equipment is worn before the accident which prompts the rescue, then it is PPE *Example: A wet suit worn continuously to prevent hypothermia in the event of falling into water is PPE*	Depending on the type of protection	
13.3	Equipment used by a rescuer to protect the rescuer himself *Example: respiratory protective devices used by firemen when retrieving people from smoke-filled buildings*	Depending on the type of protection	
13.4	Anti-avalanche airbags	II	3.2.
Except:			
13.5	If the rescue equipment is placed on the person after the accident occurs, it is not a PPE *Example: A sling used to rescue an unconscious person from an inaccessible point*	Not PPE	Definition of PPE

Type of PPE		Certification category	Reason
14.	**Motorcyclists' equipment**		
14.1	Motorcyclists' helmets	Not PPE	2.5.
14.2	Motorcyclists' garments and additional protection such as gloves for private use as long as only protection against climatic conditions are provided	Not PPE	2.3.
Except:			
14.3	Motorcyclists' garments and additional protection (e.g. gloves, boots) only protecting against climatic conditions for professional use	I	3.1. (e)
14.4	Motorcyclists' garments and additional protection (e.g. gloves, footwear) for which additional protection is provided (e.g. airbag, impact protectors for limb or back, pads for elbow or shoulders, protection against cuts and abrasion, …)	II	3.2.

Type of PPE		Certification category	Reason
15.	**High visibility clothing and accessories**		
15.1	High visibility clothing	II	3.2.
15.2	High visibility accessories (e.g. reflective stickers, free hanging accessories such as dangling tags)	II	3.2.
15.3	Hunters' jacket made of fluorescent material to signal the presence of the users	II	3.2.
Except:			
15.4	High visibility gadgets (e.g. reflective keyrings, backpacks with reflective and/or fluorescent material, etc.)	Not PPE	Definition of PPE

Type of PPE		Certification category	Reason
16.	**Protection against UV radiation**		
16.1	Eyes protection against natural UV radiation (normal level) *Example: sunglasses*	I	3.1. (d)
16.2	Eyes protection against natural UV radiation (higher level) *Example: solar eclipse glasses*	II	3.2.
16.3	Eyes protection against artificial UV radiation *Safety glasses having specific UV-protective properties* (e.g. welding goggles)	II	3.2.
16.4	Eyes and skin protection against artificial UV radiation *Example: face shields with specific UV-protective properties*	II	3.2.
16.5	Skin protection against artificial UV radiation *All garments, including partial or whole body clothing, caps and helmets, gloves, and shoes, designed and manufactured to have specific UV-protective properties against artificial UV radiation (e.g. some types of welder's clothing)*	II	3.2.
16.6	Skin protection against natural UV radiation *All garments, including partial or whole body clothing, caps and helmets, gloves, and shoes, designed and manufactured to have specific UV-protective properties against natural UV radiation*	I	3.1. (e)

ORGANISATIONAL SCHEME FOR THE PPE REGULATION (EU) 2016/425



USEFUL WEBSITES AND LINKS

- Regulation (EU) 2016/425 (multi-lingual texts):
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425

- European Commission's website on Personal Protective Equipment (PPE):
  https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/personal-protective-equipment-ppe_en
  - Minutes of the PPE Working and Expert Group meetings:
    https://ec.europa.eu/docsroom/documents/46591
  - Standardisation for PPE:
    https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment_en
  - PPE notified bodies:
    http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501
  - Market Surveillance Authorities:
    https://ec.europa.eu/docsroom/documents/53315

- New Legislative Framework:
  https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en

- The 'Blue Guide' on the implementation of EU product rules 2022:
  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

- CE marking: https://single-market-economy.ec.europa.eu/single-market/ce-marking_en

- CEN-CENELEC Personal Protective Equipment (PPE):
  https://www.cencenelec.eu/areas-of-work/cen-cenelec-topics/personal-protective-equipment/

- Register of Expert Groups:
  https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3678

- PPE Interest Groups on CIRCABC:
  - PPE Committee:
    https://circabc.europa.eu/w/browse/a875ce58-fbf0-4552-8d45-8afc507389d7
  - PPE Expert Group:
    https://circabc.europa.eu/ui/group/1c9905b3-ca3f-4146-b8c0-e8c84d3d7728
  - PPE Administrative Cooperation Group:
    https://circabc.europa.eu/ui/group/df8a6089-da45-47fe-8087-f40efaf87ffe
  - Personal Protective Equipment Notified Bodies group:
    https://circabc.europa.eu/ui/group/9add5dfd-7495-46d4-a5aa-fce7604bce39