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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on personal protective equipment

(Text with EEA relevance)

{SWD(2014) 118 final}
{SWD(2014) 119 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context, reasons for and objectives of this proposal

Directive 89/686/EEC on personal protective equipment[1] was adopted on 21 December 1989 and became fully applicable as from 1 July 1995.

Directive 89/686/EEC (PPE Directive) ensures the free movement of personal protective equipment (PPE). It has contributed considerably to the completion and operation of the Single Market with regard to PPE. It permits the free movement of PPE covered by its scope in Europe while ensuring a high level of protection for its user.

The PPE Directive sets out basic requirements, that PPE must comply with in order to be made available on the EU market. PPE must be designed and manufactured in compliance with the provisions of the Directive. Manufacturers must also affix the CE marking and provide users with instructions for storage, use, cleaning, maintenance, servicing and disinfection of the PPE.

The PPE Directive is based on Article 114 of the Treaty on the Functioning of the European Union and is one of the first harmonisation Directives based on the "New Approach" principles, according to which manufacturers must ensure compliance of their products with the essential health and safety requirements provided for in the legislative instrument. The essential requirements are performance based, without imposing specific technical solutions or specifications.

The PPE Directive applies to PPE that is defined as *"any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards"*. It also covers *"interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment"* and *"any system placed on the market in conjunction with PPE for its connection to another external, additional device"*. Examples of PPE are safety helmets, ear muffs, safety shoes, life jackets but also bicycle helmets, sunglasses and high-visibility vests.

Certain types of PPE are excluded from the scope of the PPE Directive, namely PPE specifically designed and manufactured for use by armed forces or in the maintenance of law and order, PPE for self-defence, PPE designed and manufactured for private use against atmospheric conditions, damp, water and heat, PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time and helmets and visors intended for users of two- or three-wheeled motor vehicles.

While the directive has successfully achieved its objectives in creating a single market and ensuring a high level of protection for users of PPE, certain problems have been encountered in its implementation. These concern products on the market that do not ensure an adequate level of protection, diverging approaches of the notified bodies, the effectiveness of the market surveillance as well as risks related to protective equipment which is currently not covered by the PPE Directive. Furthermore some provisions of the PPE Directive should be made clearer and simpler.

This proposal intends to replace Directive 89/686/EEC on personal protective equipment by a Regulation, in line with the Commission's simplification objectives.

[1] OJEU L 399, 30.12.1989, p.18.

The overall objectives of this initiative are to better protect the health and safety of PPE users, to ensure a level playing field for PPE economic operators within the internal market and simplify the European regulatory environment in the field of PPE. The proposal modifies and clarifies a number of the provisions of the existing Directive and aligns it with the provisions of Decision No 768/2008/EC[2] establishing a common framework for the marketing of products (NLF Decision).

More specifically, it is proposed to slightly enlarge the scope of the current PPE Directive by removing the exclusions of products for private use providing protection against heat, damp and water. Experience with the implementation and enforcement of the PPE Directive showed that these exclusions were no longer justified. In order to improve the health and safety of the users, the requirements of the PPE Directive and hence of this proposal should apply to these products. Clarifications were introduced in order to reduce interpretation, e. g. concerning provisions for made-to-measure and individually adapted PPE. The list of the products subject to the most stringent conformity assessment procedure was revised in order to remove inconsistencies. Documentary requirements were changed in order to improve the work of the market surveillance authorities and minor changes to three essential health and safety requirements were introduced in order to remove sources of confusion.

The proposal also intends to align the PPE Directive to the NLF Decision. Many of the general problems identified at horizontal level have also been observed in the context of implementing the PPE Directive (PPE placed on the market that does not ensure an adequate level of protection, problems with the quality of the services delivered by some notified bodies, different practices in the Member States as regards the evaluation and monitoring of notified bodies). A number of manufacturers are also faced with the problem of the legal framework being complex and sometimes inconsistent. The alignment of the PPE Directive with the NLF responds to the political commitment laid down in Article 2 of the NLF Decision.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc.). These common provisions have been reinforced to ensure that the legislation can be applied and enforced more effectively in practice. New elements, such as obligations of importers, have been introduced, which are crucial for improving the safety of products on the market.

The Commission has already proposed the alignment of nine Directives to the NLF Decision within an NLF implementation package adopted on 21 November 2011.

In view of ensuring consistency across Union harmonisation legislation for industrial products, in accordance with the political commitment resulting from the adoption of the NLF Decision and the legal obligation provided for in Article 2 of the NLF Decision, it is necessary that this proposal is in line with the provisions of the NLF Decision.

The proposal takes into account 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, 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[3].

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2 OJEU L 218, 13.8.2009, p.82.

3 OJEU L 316, 14.11.2012, p.12.

The proposal also takes into account the proposal of the Commission of 13 February 2013 for a Regulation on market surveillance of products[4], which intends to set out a single legal instrument on the market surveillance activities in the field of non-food goods, consumer or non-consumer products and products covered or not by Union harmonisation legislation. The proposal merges the rules on market surveillance of Directive 2001/95/EC on general product safety[5], Regulation (EC) 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[6] and of sector-specific harmonisation legislation in order to increase the effectiveness of market surveillance activities within the Union. The proposed Regulation on market surveillance of products contains also the relevant provisions on market surveillance and safeguard clauses. Therefore, provisions in existing sector specific harmonisation legislation that relate to market surveillance and safeguard clauses should be removed from that harmonisation legislation. The overacting objective of the proposed Regulation is to simplify the Union market surveillance framework fundamentally so that it works better for its main users: market surveillance authorities and economic operators. The current PPE Directive provides for a safeguard clause procedure. In line with the framework intended to be established by the proposed Regulation on market surveillance of products, this proposal for a Regulation on PPE does not include the provisions on market surveillance and safeguard clause procedures for PPE provided for in the NLF Decision. However, in order to ensure legal clarity, it makes a reference to the proposed Regulation on market surveillance of products.

Consistency with other policies and objectives of the Union

This initiative is in line with the Single Market Act[7], which stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

This proposal does not change the relationship to the Directive 89/656/EEC[8] 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).

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

Consultation of interested parties

The revision of the PPE Directive has been discussed with all stakeholders, including Member States, manufacturers' federations, notified bodies and representatives from standardisation.

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4 Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council (COM(2013) 75 final).

5 OJEU L 11, 15.1.2002, p.4.

6 OJEU L 218, 13.8.2008, p.30.

7 Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions (COM(2011) 206 final).

8 OJEU L 393, 30.12.1989, p.18.

The consultation included meetings for a selected group of experts as well as consultation of the PPE Working Group as well as the PPE AdCo Group of market surveillance authorities.

While the success of the Directive is generally recognised a broad consensus exists among the Member States and other stakeholders that some improvements can be made, contributing to an even more effective protection of the health of the users and to a more efficient functioning of the PPE legislation including more effective market surveillance. Most of the proposed improvements result from the day to day experience of Member States authorities and other stakeholders with the enforcement and implementation of the PPE legislation and are not directly related to accidents.

From April to June 2011 a public consultation collected views and opinions of relevant stakeholders and citizens on the various issues that the revision of the PPE Directive might address. Overall 77 responses were received, 74 from the 27 Member States (authorities, enterprises, notified bodies, trade associations, individual citizens), 2 from an EFTA country and 1 from overseas. The replies provided the Commission services with a broader view on the identified policy needs and as such confirmed the envisaged approaches[9].

In general all stakeholders expressed support for the initiative. Both authorities and industry consider that the PPE legislation needs to be simplified and clarified. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring notified bodies.

There is also unanimity on the need to align the PPE Directive to the NLF and thus to improve the existing general regulatory framework. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry expects a more level playing field resulting from more effective actions against products that do not comply with the legislation, as well as a simplification effect from the alignment of legislation.

Furthermore Member States and stakeholders expressed their support for:

– The extension of the product coverage of the PPE Directive;

– The addition of some types of PPE to the list of products subject to the most stringent conformity assessment procedure;

– The change of three basic health and safety requirements; and

– The change of the requirements to the technical file, the validity and content of the EC type-examination certificate, and the EC Declaration of Conformity.

Collection and use of expertise - Impact assessment

An impact assessment on the revision of the PPE Directive has been conducted. The impact assessment sets out extensively the different options of revision of the sector related aspects of the PPE Directive.

With regard to the NLF alignment aspects, the impact assessment report for the revision of the PPE Directive refers to the general impact assessment conducted in the framework of the NLF Implementation package of 21 November 2011[10].

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9 A report on the results is available at http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/pc-report_en.pdf.

10 New Legislative Framework (NLF) Alignment Package (Implementation Goods Package), Commission Staff Working Paper – Impact Assessment accompanying document to the 10 Proposals to Align Product Harmonisation Directives to Decision No 768/2008/EC (SEC(2011) 1376 final).

In particular, the modifications due to the alignment to the NLF Decision and their impacts are expected to be the same as for the nine product harmonisation Directives included in the Alignment Package.

The Impact Assessment Report on this Alignment Package has already examined in depth the different options, which are exactly the same with regard to the PPE Directive. The Report contained also an analysis of the impacts resulting from the legislative alignment to the provisions of the NLF Decision.

Therefore, the Impact Assessment Report on the revision of the PPE Directive did not examine those aspects and it focussed on specific issues relating to the PPE Directive as well as on the ways to address them.

An external study launched and completed in 2010[11] to complement he results of the consultation .The study provides an overview of the structure of the PPE market as well as it assesses the impacts of the proposed measures.

In 2012 another complementary study was carried out. It focused on analysing the competitiveness impacts of the envisaged changes[12].

Based on the information collected, the impact assessment carried out by the Commission examined and compared three options with regard to problems and issues relating to the PPE Directive.

Option 1 – "Do nothing" - No changes to the existing situation

This option proposes no changes to the PPE Directive.

Option 2 – Intervention by non-legislative measures

Option 2 considers voluntary measures to resolve the identified issues, e.g., guidance documents containing a commonly agreed interpretation of the PPE Directive.

Option 3 – Intervention by legislative measures

This option consists in modifying the PPE Directive.

Option 3 was found to be the preferred option because:

– it is considered more effective than option 2: due to the lack of enforceability of option 2 it is questionable that the positive impacts would materialise under that option;

– it leads to an improved level of protection of the health and safety of the users in a framework of legal certainty;

– it ensures a more effective work of the market surveillance authorities and consequently reduces the non-compliant products and creates a more level playing field;

– it does not entail significant costs for economic operators and notified bodies; for manufacturers of products that are not yet covered by the PPE Directive the cost will be higher but only affect those manufacturers that do not meet the basic requirements at the moment; however, those products are manufactured in mass production resulting in a low impact on cost per unit;

[11] See http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-assess-part1_en.pdf (part 1 on market assessment) and http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-assess-part2_en.pdf (part2 on impact assessment).

[12] See http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-competitiveness_en.pdf.

– it will strengthen the competitiveness of European enterprises as a result of guaranteeing a level playing field for the economic operators and will lead to a better protection of the users of PPE;

– options 1 and 2 do not provide answers to legal inconsistencies or ambiguities and therefore will not lead to a better implementation of the PPE Directive.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Scope and definitions

The scope of the proposed Regulation is enlarged compared to the scope of Directive 89/686/EEC. The exclusions of PPE designed and manufactured for private use against heat, damp and water, set out in Annex I of 89/686/EEC, are removed. These products are included in the scope of the proposed Regulation.

The proposal keeps the other existing exclusions and clarifies that it does not apply to PPE for head, face or eye protection, subject to the relevant UNECE Regulation, of users of two- or three-wheeled motor vehicles.

Two PPE specific definitions have been added in order to clarify the applicable conformity assessment procedures: *"Individually adapted PPE"* and *"Made-to-measure PPE"*.

Additionally, the general definitions of the NLF Decision have been inserted.

3.2. Making available on the market, free movement, obligations of economic operators, CE marking

The proposal contains the typical provisions for product-related Union harmonisation legislation and sets out the obligations of the relevant economic operators (manufacturers, authorised representatives, importers and distributors), in accordance with the NLF Decision.

The proposal obliges the manufacturer of PPE to draw up a technical documentation and to ensure that the PPE is accompanied by a copy of the EU declaration of conformity or a simplified EU declaration of conformity.

3.3. Notified bodies

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and for the confidence of all interested parties in the New Approach system.

Therefore, in line with the NLF Decision, the proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the individual Member State.

3.4. Categories and Conformity assessment

The proposal simplifies the definition of the categories of PPE. The category only depends on the risk against which the PPE is intended to protect. The risks belonging to each category are set out in Annex I. Made-to-measure PPE is defined as category II.

The conformity assessment procedures to be followed depend on the category of the PPE.

The proposed Regulation changes the category of a few types of PPE compared to Directive 89/686/EEC. PPE intended to protect the user against *drowning, cuts by hand-held chain-saws, high-pressure cutting, bullet wounds or knife stabs, and harmful noise* is listed under category III and subject to the most stringent conformity assessment procedure.

The proposal keeps the applicable conformity assessment procedures provided for under Directive 89/686/EEC. It however updates the corresponding modules in line with the NLF Decision.

In module B, EU type-examination, additional requirements are introduced concerning the minimum content and the length of validity of the EU type-examination certificates. The module provides for a procedure for a review of the certificate.

Module B also requires particular steps for individually adapted PPE and made-to-measure PPE.

3.5. Essential health and safety requirements

The proposed Regulation changes marginally three essential health and safety requirements (EHSR) set out in Annex II. EHSR 3.1.3, 3.5, and 3.9.1 are changed in order to remove requirements shown to be impracticable or that create confusion.

3.6. Implementing acts

The proposal empowers the Commission to adopt, where appropriate, implementing acts to ensure the uniform application of this Regulation in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

Those implementing acts will be adopted in accordance with the provisions on implementing acts laid down in 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 the Member States of the Commission's exercise of implementing powers.

3.7. Delegated acts

The proposal empowers the Commission to adopt delegated acts in order to modify the category of a specific risk to take into account the progress of technical knowledge or new scientific evidence.

3.8. Final provisions

The proposed Regulation will become applicable two years after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements.

However, the designation of notified bodies pursuant to the new requirements and process needs to start shortly after the entry into force of this Regulation. This will ensure that by the date of application of the proposed Regulation, sufficient notified bodies will have been designated in accordance with the new rules so as to avoid problems with production continuity and market supply.

Transitional provisions are foreseen for products manufactured and the certificates issued by notified bodies under Directive 89/686/EEC so as to allow stocks to be absorbed and ensure a smooth transition to the new requirements.

Directive 89/686/EEC will be repealed and replaced by the proposed Regulation.

3.10. Union competence, legal basis, subsidiarity principle and legal form

Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union.

Subsidiarity principle

The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 89/686/EEC, namely, the economic operators' obligations, the traceability provisions, the provisions on the assessment and notification of conformity assessment bodies.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the EU, which undermines the objectives of Directive 89/686/EEC. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

The new or modified obligations do not impose unnecessary burdens and costs on industry - especially on small and medium sized enterprises - or administrations. Where modifications have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

Legislative technique used

The proposal takes the form of a Regulation.

The proposed change from a Directive to a Regulation takes into account the Commission's general objective to simplify the regulatory environment and the need to ensure a uniform implementation throughout the Union of the proposed legislation.

The use of a Regulation does not conflict with the subsidiarity principle. This legislation is based on Article 114 TFEU with the objective of ensuring the proper functioning of the internal market for personal protective equipment. To achieve this objective, the PPE Directive 89/686/EEC is a total harmonisation directive. Member States are not allowed to impose more stringent or additional requirements in their national legislation for the placing on the market of PPE. In particular, the mandatory essential health and safety requirements for products and the conformity assessment procedures to be followed by manufacturers must be identical in all of the Member States. Given this level of harmonisation, which is necessary to avoid obstacles to the free movement of PPE, Member States have almost no flexibility in transposing the Directive into their national law and its content is in many cases reproduced word for word in the national transposition legislation.

The same applies to the new provisions that will be integrated into the text following the alignment to the NLF Decision No 768/2008/EC. These provisions lay down requirements, obligations and procedures for the manufacturers, importers and distributors of PPE and for the notified bodies that carry out the conformity assessment procedures. All of these provisions are clear and sufficiently precise to be applied directly by the actors concerned.

The obligations set by the legislation for the Member States, such as the obligation to assess, appoint and notify the conformity assessment bodies are, in any case, not transposed as such into national law but implemented by the Member States by means of the necessary

regulatory and administrative arrangements. This will not change when the obligations concerned are set out in a Regulation.

The change from a Directive to a Regulation will not lead to any change in the regulatory approach. The characteristics of the New Approach will be fully preserved, in particular the flexibility given to manufacturers in the choice of the means employed to comply with the essential requirements (harmonised standards or other technical specifications) and in the choice of the procedure used to demonstrate compliance from among the available conformity assessment procedures. The existing mechanisms supporting the implementation of the legislation (standardisation process, working groups, market surveillance, administrative cooperation (AdCo), and the development of guidance documents…) will not be affected by the nature of the legal instrument and will continue to operate in the same manner under the Regulation as they currently do under the Directive.

Finally, the use of Regulations in the area of internal market legislation, in accordance also with the preference expressed by stakeholders, avoids the risk of 'gold plating'. It also allows manufacturers to work directly with the Regulation text instead of needing to identify and examine 28 transposition laws.

On this basis, it is considered that the choice of a Regulation is the most appropriate solution for all involved parties as it will allow a more rapid and coherent application of the proposed legislation and will establish a clearer regulatory environment for economic operators.

4. BUDGETARY IMPLICATION

This proposal does not have any implication for the EU budget.

5. OPTIONAL ELEMENTS

Repeal of existing legislation

The adoption of the proposal will lead to repeal of Directive 89/686/EEC.

European Economic Area

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

2014/0108 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on personal protective equipment

(Text with EEA relevance)

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,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Council Directive 89/686/EEC[13] 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 on a new approach to technical harmonisation and standards[14]. Thus, it sets only the essential safety requirements applying to PPE, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council[15]. Conformity with the harmonised standards so set, the reference number of which is published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 89/686/EEC. Experience has shown that those basic principles have worked well in this sector and should be maintained and even further promoted.

(3) However, experience with its application has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. In order to take

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13 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).

14 Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (OJ C 136, 4.6.1985, p. 1).

15 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, 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).

account of this experience and to provide clarification in relation to the framework within which products covered by this Regulation may be marketed, certain aspects of Directive 89/686/EEC should be revised and enhanced.

(4) Since the scope, the essential health and safety requirements and conformity assessment procedures are to be identical in all the Member States there is almost no flexibility in transposing Directives based on the New Approach principles into national law. Directive 89/686/EEC should therefore be replaced by a Regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States.

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

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

(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.

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

(9) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. In order to ensure as high level of protection for the user of those products as for the PPE covered by Directive 89/686/EEC, the scope of this Regulation should include PPE for private use against damp, water and heat (e.g. dish-washing gloves, oven gloves), in line with

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

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

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

similar PPE for professional use which is already covered by Directive 89/686/EEC. Artisanal products, such as handmade gloves, for which the manufacturer does not explicitly claim a protective function are not personal protective equipment; they are therefore not concerned by this inclusion. It is also appropriate to clarify the exclusion list set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore are excluded from the PPE Regulation.

(10) In order to facilitate the understanding and uniform application of this Regulation, new definitions for "individually adapted PPE" and "made-to-measure PPE" should be introduced and the conformity assessment procedures for these kinds of PPE should be adapted to the specific conditions of their manufacture.

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

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

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

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

(15) Distributors make PPE available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that their handling of the PPE does not adversely affect the compliance of the PPE.

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

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

(18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be

prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.

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

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

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

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

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

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

(25) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on PPE should be laid down in this Regulation.

(26) It is crucial to make clear to manufacturers and users that by affixing the CE marking to the product, the manufacturer declares that the product is in conformity with this Regulation and takes full responsibility therefor.

(27) The CE marking should be the only marking indicating that PPE is in conformity with Union harmonisation legislation. However, other markings should be allowed as long

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

as they contribute to the improvement of consumer protection and are not covered by Union harmonisation legislation.

(28) In order to ensure compliance with the essential safety requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Directive 89/686/EEC classifies PPE into three categories that are subject to different conformity assessment procedures. In order to ensure a consistently high level of safety for all PPE, the list of products subject to one of the conformity assessment procedures relating to the production phase should be enlarged. The conformity assessment procedures for each category of PPE should be set, as far as possible, on the basis of the conformity assessment modules laid down in Decision No 768/2008/EC.

(29) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of PPE throughout the Union, and all such bodies should perform their functions at the same level and under conditions of fair competition. Therefore obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services under this Regulation.

(30) In order to ensure a consistent level of quality in the performance of conformity assessment of PPE, it is also necessary to set requirements that notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies must fulfil.

(31) In order to take into account the progress of technical knowledge and new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to amend the list of PPE included in each category. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(32) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council[20]. 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.

(33) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(34) In order to allow manufacturers and other economic operators sufficient time to adapt to the requirements of this Regulation, it is necessary to provide for a sufficient transitional period after the entry into force of this Regulation during which PPE which complies with Directive 89/686/EEC may still be placed on the market.

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

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

(36) Directive 89/686/EEC has been amended several times. Since further substantial amendments are to be made and in order to ensure a uniform implementation throughout the Union, Directive 89/686/EEC should be repealed and replaced by a Regulation.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject Matter

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

Article 2

Scope

1. This Regulation shall apply to personal protective equipment (PPE), as defined in Article 3.
2. This Regulation shall not apply to PPE:
   (a) specifically designed for use by the armed forces or for the maintenance of law and order;
   (b) intended to be used for self-defence;
   (c) intended for private use to protect against atmospheric conditions that are not of an extreme nature;
   (d) for use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;
   (e) for head, face or eye protection of users, subject to the relevant Regulation of the United Nations Economic Commission for Europe (UNECE), of two- or three-wheeled motor vehicles.

Article 3

Definitions

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

1. 'Personal protective equipment' (PPE) means:
   (a) equipment intended to be worn or held by a person for protection against one or more risks for his or her health or safety that is placed on the market separately or combined with personal non-protective equipment;
   (b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;
   (c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are intended to connect that equipment to an external

device or structure, that are removable and not intended to be permanently fixed to a structure;

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

3. 'made-to-measure PPE' means PPE produced as a single unit to accommodate the special needs of an individual user according to a basic model, following the instructions of the designer of that basic model and respecting the range of permissible variations;

4. 'making available on the market' means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

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

6. 'manufacturer' means any natural or legal person who designs or manufactures PPE or has it designed or manufactured, and markets it under his name or trademark; for the purposes of the second subparagraph of Article 8(2), the designer of a basic model of made-to-measure PPE shall be considered as a manufacturer;

7. 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

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

9. 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market;

10. 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

11. ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by PPE;

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

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

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

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

16. 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

17. 'recall' means any measure aimed at achieving the return of PPE that has already been made available to the end user;

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

19. 'CE marking' means a marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

20. 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.

Article 4

Making available on the market

Member States shall take all appropriate measures to ensure that PPE is made available on the market only if, where properly maintained and used for its intended purpose, it complies with this Regulation.

Article 5

Essential health and safety requirements

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

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

Article 7

Free movement

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

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

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

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of 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 and carry out the applicable conformity assessment procedure(s) referred to in Article 18 or have them carried out.

   The designer of a basic model of made-to-measure PPE shall draw up the technical documentation referred to in Annex III and carry out the EU type-examination set out in Annex V or have them carried out.

   Manufacturers of made-to-measure PPE shall carry out the conformity assessment procedure set out in Annex VI.

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

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

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.

5. Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification or, where the size

or nature of the PPE does not allow it, that the required information is provided on the packaging or a document accompanying the PPE.

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 set out in point 1.4 of Annex II in a language which can be easily understood by end-users, as determined by the Member State concerned.

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

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

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the PPE, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

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 at least 10 years after the PPE has been placed on the market;

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

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

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(s) referred to in Article 18 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking, is accompanied by the EU declaration of conformity or a simplified EU declaration of conformity, and that it is accompanied by the instructions referred to in Article 8(7) and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

   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 referred to in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

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

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

8. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

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

   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 the requirements of this Regulation shall make sure that the necessary corrective measures are taken to bring it into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, distributors shall immediately inform the market surveillance authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

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.

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 the conformity with the applicable essential health and safety requirements set out in Annex II may be affected.

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 a period of 10 years after they have been supplied with the PPE and for a period of 10 years after they have supplied the PPE.

CHAPTER III

CONFORMITY OF THE PPE

Article 14

Presumption of conformity

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.

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.

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

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

4. Where PPE is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

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

Article 16

CE marking

1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
2. The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the accompanying documents.
3. The CE marking shall be affixed before the PPE is placed on the market. It may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.
4. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure for ensuring conformity to type based on product verification or the procedure for ensuring conformity to type based on quality assurance of the production process.

CHAPTER IV

CONFORMITY ASSESSMENT

Article 17

Risk categories of PPE

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

Article 18

Conformity assessment procedures

The 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 that is 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:

(1) conformity to type based on product verification (module F) set out in Annex VII;

(2) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 19

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.

Article 20

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 25.
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 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 21. In addition that body shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 21

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.

Article 22

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.

Article 23

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 national law 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 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 authorised representative of any of those parties. This does not preclude the use of assessed PPE that are necessary for the operations of the conformity assessment body or the use of such PPE for personal purposes.

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

   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 activities shall have the following:

   (a) sound technical and vocational training covering all the conformity assessment tasks for 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 corresponding harmonised standards and of the relevant provisions of Union harmonisation 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 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 State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the tasks under Annexes V, VII and VIII or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

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

Article 24

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 23 in so far as the applicable harmonised standards cover those requirements.

Article 25

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 23 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 tasks carried out by them under Annexes V, VII and VIII.

Article 26

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 procedure(s) and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body

attesting that the conformity assessment body fulfils the requirements laid down in Article 23.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 23.

Article 27

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 23.

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 procedure(s) 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 26(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 23.

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.

Article 28

Identification numbers and lists of notified bodies

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

   It shall assign a single identification 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.

Article 29

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 23, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

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.

Article 30

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

2. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

3. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.

4. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 38(2).

Article 31

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 applicable essential health and safety requirements set out in Annex II or the corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

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

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

Article 32

Appeal against decisions of notified bodies

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

Article 33

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;

   (b) any circumstances affecting the scope of and 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.

Article 34

Exchange of experience

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

Article 35

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.

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

CHAPTER VI

DELEGATED AND IMPLEMENTING ACTS

Article 36

Delegating power

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

Article 37

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 36 shall be conferred on the Commission for a period of five years from *[the date specified in Article 42(2)]*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period
3. The delegation of powers referred to in Article 36 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect 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 36 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 38

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) 182/2011 shall apply.

CHAPTER VII

FINAL AND TRANSITIONAL PROVISIONS

Article 39

Penalties

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

Article 40

Repeal

Directive 89/686/EEC is repealed.

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 XI.

Article 41

Transitional period

1. Without prejudice to paragraph 2, Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before *[1 year after the date of application]*

2. EC type-examination certificates issued under Directive 89/686/EEC shall remain valid until *[6 years after the date of application]* unless they expire before that date.

Article 42

Entry into force and application

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

It shall apply from [*two years after entry into force*].

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

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*