



PPE Regulation
(EU) 2016/425

The PPE Directive and the PPE Regulation

The history and future of PPE Certification

A whitepaper

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The current **PPE Directive** at a glance

The Personal Protective Equipment (PPE) Directive was one of the first New Approach Directives and is now over 20 years old. In order to reflect current technologies and processes for developing and bringing PPE to the market, it is in the process of being superseded by a new PPE Regulation (EU) 2016/425. This whitepaper is designed to help you understand the changes, timelines, and who will be impacted by the Regulation.

The Regulation was adopted on the 12 February 2016 and published in the Official Journal 20 days later. This started the two-year transition period for Member States and Notified Bodies to prepare for the introduction of the new Regulation. The Regulation comes fully into force on 21 April 2018 and full effect from 21 April 2019.

The PPE Regulation is mandatory - covering any type of product that falls within its scope. If you are therefore in the PPE industry, it is a legal requirement to comply.

The history of **PPE standards** in Europe

The PPE Directive was first adopted by the European Council on 21 December 1989. It was implemented into UK law as the Personal Protective Equipment (EC Directive) Regulations 1992 (SI 1992/3139) and known as the 'Principal Regulations'. These Regulations were made on 10 December 1992 and came into effect on 01 January 1993.

Prior to European EN (European Norm) specifications and CE marking, individual states produced standards for PPE. As the need for standardisation grew across Europe, EN standards started to be written. These standards are known as Harmonised Standards and are listed in a document

called the Official Journal (OJ) which is available online at: www.eur-lex.europa.eu. If a product meets a standard listed in the OJ, it meets the Essential Health and Safety Requirements of the Directive. Innovative products where no standard exist, and therefore not listed in the OJ, can still be certified to the PPE Directive through the technical specification route.

European standards have a high status globally for being effective in setting performance levels, and are used in many countries without their own product standards.

Why is the **PPE Directive** changing?

The PPE Directive was one of the first New Approach Directives and is now over 20 years old. In order to reflect current technologies and processes for developing and bringing PPE to the market, it needs to be updated.

As well as reflecting new technology, the new Regulation has been shaped to enhance consumer safety and ensure fair competition between companies. It

is also important to bring it in line with other Directives that have undergone a revision in recent years. The changes also mean that the old Directive is being re-implemented as a Regulation rather than remaining in its current status.

This means that the new Regulation will not have to be transposed into each Member State's national law. (A Directive is a legislative act that sets out

an objective that all EU countries must achieve by a given date. However, it is up to the individual countries to decide how this is done. In contrast a Regulation is a binding legislative act, and it must be applied in its entirety across the EU without the need for separate national legislation.)



What are the **main changes** in the new PPE Regulation (EU) 2016/425?

The Regulation text was adopted on 12 February 2016, published on 31 March 2016 and was listed in the Official Journal 21 April 2016. This started the two year transition period for Member States and Notified Bodies to prepare for the introduction of the new Regulation. There are a number of changes that are taking place including:

- Moving hearing protection from Category II to Category III PPE
- The need for a product risk assessment in the technical file
- Moving life jackets from Category II to Category III PPE
- Issuing a Declaration of Conformity with each PPE or at least a link to where it can be obtained
- A compulsory maximum five-year certificate validity
- Responsibilities outlined for importers and distributors
- Bespoke PPE covered in the Regulation
- The inclusion of domestic oven gloves
- The need for manufacturers to place their name and address on the product

The **scope** of the Regulation

When the current Directive is re-issued as a Regulation in 2018, the scope will be: 'This Regulation applies to PPE'. Definitions used within the Regulation are:

'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;
- b** interchangeable components for equipment referred to in point (a) which are essential for its protective function (e.g. filters);

- 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

The PPE Regulation does not apply to, PPE:

- a** specifically designed for use by the armed forces or in the maintenance of law and order;
- b** designed to be used for self-defence, with the exception of PPE intended for sporting activities;

- c** designed for private use to protect against:
 - i** atmospheric conditions that are not of an extreme nature,
 - ii** damp and water during dishwashing;
- d** PPE use on seagoing vessels or aircraft
- e** helmets and their visors for drivers and passengers of motor cycles and mopeds

Where to from here?

All manufacturers of PPE need to be aware of what existing certifications they currently hold and when they will expire now the Regulation transition period has started. So it is therefore important to keep up to date with these changes and prepare for the impact on your business. This would also apply to importers and distributors.

At this stage you need to consider the following:-

- Because new EU Type Examination certificates will have to reference the standards where applicable, all products currently certified to old withdrawn standards will have to be tested to the latest current versions
- Look at existing product ranges and ensure that they are to the latest product specifications
- If you are placing products that will change category such as life jackets or hearing protection onto the market, be aware of what the change in classification will mean and the need to get an on-going surveillance system in place by 21 April 2019 at the latest
- If you are a distributor, be aware that there are parts of the Regulation that will have direct implications on you as you will have to ensure the PPE you sell complies with the new Regulation

Obligations for **all** manufacturers and their supply chains

The PPE Regulation is mandatory - covering any type of product that falls within its scope listed earlier. If you are therefore in the PPE industry, it is a legal requirement to comply. Previously the PPE Directive focused on manufacturers placing products onto the market, but

when the new Regulation becomes effective the whole supply chain will be involved. This means importers, distributors or anyone involved in the supply and distribution chain should take appropriate measures to ensure that PPE meets standard requirements

and that they make available on the market only products which comply with the Regulation, and keep relevant documents for at least 10 years.



Explaining the **different categories** of PPE for the PPE Regulation (EU) 2016/425

PPE Category	Activity	Old PPE Directive 89/686/EEC	New PPE Regulation (EU) 2016/425
Category I Simple PPE	Placing product on to the market	Manufacturers self declaration	Module A (Annex IV) Manufacturers self declaration
Category II Intermediate PPE and Category III Complex PPE	Initial product approval	Article 10 EC Type Examination	Module B (Annex V) EU Type Examination plus Module C (Annex VI)
Category III Complex PPE only	On-going surveillance through testing	Article 11A	Module C2 (Annex VII)
or			
Category III Complex PPE only	On-going surveillance through factory auditing	Article 11B	Module D (Annex VIII)

Category I – Simple PPE

PPE in this category is designed to protect users against minimal risks. These include as examples:

- superficial mechanical injury
- contact with water or cleaning materials of weak action
- contact with hot surfaces not exceeding 50°C
- damage to the eyes due to exposure to sunlight (other than during observation of the sun)
- atmospheric conditions that are not of an extreme nature

Category II – Intermediate PPE

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

The following products are included as examples:

- Safety spectacles and goggles
- Industrial helmets and bump caps
- Hi visibility clothing

Category III – Complex PPE

PPE falling under this category 'includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health'

Risks include:

- substances and mixtures which are hazardous to health
- atmospheres with oxygen deficiency
- harmful biological agents
- ionising radiation
- high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C
- low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less
- falling from a height
- electric shock and live working
- drowning
- cuts by hand-held chainsaws
- high-pressure jets
- bullet wounds or knife stabs
- harmful noise

Early preparation is key

By starting to prepare for these changes now, you will be better equipped to handle the major impact of the new Regulation on the PPE industry.

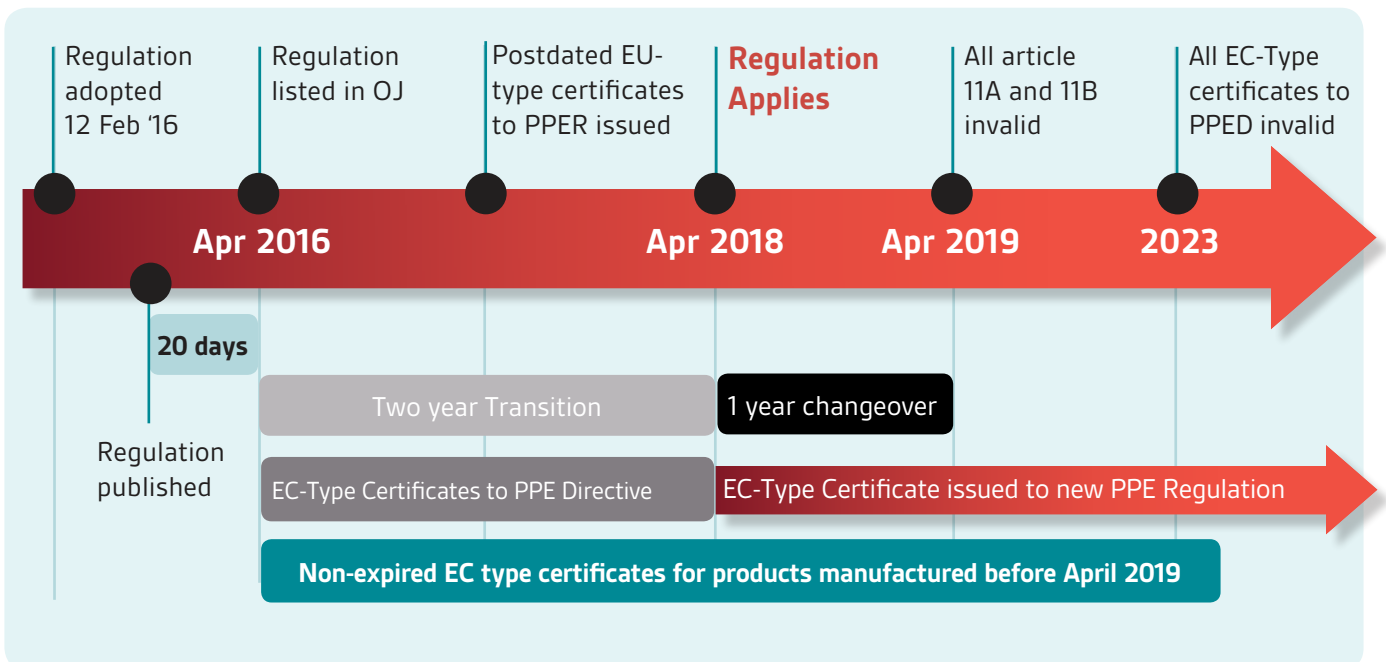
Start your preparation by:

- **Looking at your existing product ranges and identifying those that are tested to withdrawn standards.** Start to prepare to get them tested to the latest specifications
- **Thinking about how you will meet the change in classification if you place hearing protection or life jackets onto the market.** The BSI Kitemark would ensure that you meet all your on-going surveillance requirements, both to the current PPE Directive and the new Regulation
- **Contacting us to check how you will comply to the new Regulation if you are a manufacturer or distributor of products like oven gloves**
- As a Notified Body, we can issue post-dated Module B certificates allowing you to get your documentation in order before 21 April 2018

Timelines for the PPE Regulation (EU) 2016/425

Key dates

- PPE Directive 89/686/EEC is repealed with effect from 21 April 2018
- This PPE Regulation (EU) 2016/425 shall apply from 21 April 2018
- Between April 2018 and April 2019 manufacturers can supply products to both the Directive and Regulation. After April 2019 only products compliant with the Regulation can be placed on the market
- EC type-examination certificates issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date for products in the supply chain



Validity periods

The PPE Regulation will have a five-year validity period on EU Type Examination Certificates which is similar to the Medical Device and Marine Equipment Directives. The renewal has been clarified in the Regulation as; 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.

The manufacturer shall ask the Notified Body to review the EU type-examination certificate either:

- a in the case of a modification to the product or documentation
- b in the case of a change in standards, EHSR's or state-of-the-art
- c at the latest, before the date of expiry of the certificate

The manufacturer shall submit their application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU Type-Examination certificate.

Obligations on **Importers** in the PPE Regulation (EU) 2016/425

The new PPE Regulation places responsibilities on importers some of which are;

- Importers shall place only compliant PPE on the market
- Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedures have been carried out by the manufacturer
- Where an importer considers or has reason to believe that PPE is not compliant, they shall not place it on the market. Furthermore, the importer shall inform the manufacturer and the market surveillance authorities to that effect
- 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
- Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardize its conformity
- 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
- 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.

Obligations on **Distributors** in the PPE Regulation (EU) 2016/425

The new PPE Regulation places responsibilities on distributors some of which are;

- When making PPE available on the market, distributors shall act with due care in relation to the requirements of this Regulation
- Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required instructions in a language which can be understood by end-users in the country where PPE is to be made available
- Distributors shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardize its conformity
- 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 withdraw it or recall it.

Furthermore, where the PPE presents a risk, distributors shall immediately inform the competent national authorities giving details, in particular, of the non-conformity and of any corrective measures taken.

When safety and quality matter most, trust the **BSI Kitemark™**



If you're looking to demonstrate the quality of your PPE and differentiate it with an independent third party certification mark, the BSI Kitemark could be right for you. All models certified with the BSI Kitemark are rigorously tested to the latest standards. Regular batch or product audit testing is undertaken at our laboratories and

regular factory audits are carried out by our assessors to check quality during production. The BSI Kitemark is voluntary, is only available from BSI, and gives end users confidence in the performance and quality of the product. There are a number of BSI Kitemark schemes available for PPE standards such as EN 166 eye protection,

EN 397 industrial safety helmets and EN 149 filtering face masks, plus many more. A product that has earned the BSI Kitemark shows that, especially for Category III PPE, you will be meeting all your on-going surveillance requirements under the existing Directive and the new Regulation.

Support from **BSI**

How BSI can help you through the changes

We will continue to monitor the proposed changes and keep all our clients updated as more information is released from the European Commission. This information will be available on our website and we will be sending out regular updates. Our Certification Managers, Test Engineers, and other colleagues will

be kept up to date on the changes so that we can let you know in advance about the impact that these changes may have.

To find out more about support we have and updates visit: bsigroup.com/PPE-regulation-revision-uk

The role of a **Notified Body** (BSI)

BSI is a Notified Body for the PPE Directive, Regulation and numerous other EU Directives. We have a comprehensive scope, being able to carry out Article 10 (EC Type Examination), Article 11A (on-going surveillance through annual testing) and Article 11B (on-going surveillance through annual factory) for head protection, eye protection, clothing, gloves, respirators, footwear and life jackets as well as many other devices. We can issue EC Type examination

certificates as well as carry out on-going surveillance globally, delivered locally where at all possible.

In the UK a Notified Body is a body which has been appointed by the department for Business, Energy and Industrial

Strategy (BEIS), to carry out one or more of the conformity assessment procedures to Article 10, 11A or 11B of the PPE Directive, or Modules B, C2 and D of the new Regulation. The details of all Notified Bodies and their scope of approval is listed on the NANDO website.

Please contact us,
our team will be happy to help you.

Call: **+44 (0)345 0765 606**

Email: **product.certification@bsigroup.com**

or visit: **bsigroup.com/ppe**

