The PPE Directive and the PPE Regulation

The history and future of PPE Certification

A whitepaper
The current **PPE Directive** at a glance

The PPE Directive was one of the first new approach directives and is now over 20 years old. To reflect current technologies and processes for developing and bringing PPE to the market, it is of being replaced by a new PPE Regulation (EU) 2016/425. This whitepaper is designed to help you understand the changes, the timelines and who will be impacted by the Regulation.

The Regulation was adopted on January 12, 2016 and was published in the Official Journal 20 days later. This starts the two-year transition period for Member States and Notified Bodies to prepare for the introduction of the new Regulation.

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

The history of **PPE standards** in Europe

The European Council first adopted the PPE Directive on December 21, 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 December 10, 1992 and came into effect on January 1, 1993.

Prior to European EN (European Norm) specifications and CE marking, individual states produced standards for PPE. As the need for standardization grew across Europe, EN standards started to be written. These standards are known as Harmonized 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 are 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. 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 was 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 revisions in recent years. The changes also mean that the old Directive will now be re-implemented as a Regulation rather than remain in its current status. This means that the new Regulation will not have to transfer 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 the February 12, 2016, published on March 31, 2016 and was listed in the Official Journal on April 21, 2016. This starts 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 were proposed including:

- Moving hearing protection from Category II to Category III PPE
- 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
- Indicated PPE covered in the Regulation

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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
- **D** PPE use on seagoing vessels or aircraft
- **E** Helmets and their visors for drivers and passengers of motor cycles and mopeds
- **F** Designed to be used for self-defense with the exception of PPE intended for sporting activities
- **G** Designed for private use to protect against:
  - I Atmospheric conditions that are not of an extreme nature
  - II Damp and water during dishwashing
  - III PPE on seagoing vessels or aircraft
  - IV 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 that the Regulation transition period has started. It is 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 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 (life jackets, hearing protection, etc.) onto the market, be aware of what the change in classification will mean and the need to have an on-going surveillance system in place.
- If you are a distributor, be aware that there are parts of the new regulation that have direct implications on you. You now need to ensure the personal protective equipment 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 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 when the Regulation comes into force, 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.
Explaining the different categories of PPE for the PPE Regulation (EU) 2016/425

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**Category I – Simple PPE**

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

- 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:

- Safety glasses and goggles
- Industrial helmets and bump caps
- High 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
- Ionizing radiation
- High-temperature environments whose effects are comparable to those of an air temperature of at least 100 °C
- Low-temperature environments whose effects 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 test them 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 regulations when they come into force.

• **Contacting us to check how you will comply to the new Regulation if you are a manufacturer or distributor of products like dish-washing gloves and oven gloves.**

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**Timelines for the PPE Regulation (EU) 2016/425**

**Key dates**

- PPE Directive 89/686/EEC is repealed with effect from April 21, 2018
- This PPE Regulation (EU) 2016/425 shall apply from April 21, 2018
- Member states will not delay the availability of products covered by the old PPE Directive 89/686/EEC before April 21, 2019
- EC type-examination certificates issued under Directive 89/686/EEC shall remain valid until April 21, 2023 unless they expire before that date

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[Diagram showing timelines for the PPE Regulation (EU) 2016/425]

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**Key dates**

- **Regulation adopted** Feb 12, 2016
- **Regulation listed in OJ**
- **Regulation Applies**
- **Can CE mark to old PPED**
- **Old EC-Type Certificates to PPED invalid**

**Timelines**

- **Two-year Transition**
- **EC-Type Certificate issued to new PPER**
- **EC-Type Certificates to old PPE Directive can still be issued**

**Seven Years:** After 2023, EC-Type Certificates issued to old PPED will be invalid
Validity periods

The PPE Regulation will have a five-year validity period on EU Type Examination Certificates, which is similar to the Medical Devices and Marine Equipment Directives. The renewal has been clarified in the regulation as the manufacturer shall ensure that the PPE continues to fulfill 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 expiration date of the certificate

The manufacturer should submit his or her application, at the earliest 12 months and at the latest six months, prior to the expiration 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 in conformity, he 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 can, for 10 years after the PPE was 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 be made available to those authorities upon request

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 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 which 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 to 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.

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- 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.
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’ll meet all your on-going surveillance requirements under the existing Directive and the new Regulation.

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**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 the European Commission releases more information. This information will be available on our website, and we will send 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.

BSI is a Notified Body - look at our scope of PPE Standards.

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

BSI is a Notified Body for the PPE Directive 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 Innovations and Skills (BIS), to carry out one or more of the conformity assessment procedures to Article 10, 11A or 11B of the PPE Directive. The details of all Notified Bodies and their scope of approval is listed on the Europe website.

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

Call: 1800 862 4977
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or visit: bsigroup.com/ppe-US