PPE Directive 89/686/EEC update

Changes to the PPE Directive

The history and future of PPE Certification

A whitepaper

bsi.

...making excellence a habit.™

The **PPE Directive** at a glance

The Personal Protective Equipment (PPE) Directive 89/686/EEC is a fundamental piece of European legislation relating to occupational safety throughout Europe. It can be described as covering any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards, and it is mandatory if a PPE product falls within the scope of the directive. However, there are some exemptions such as PPE used by the military and for law enforcement.

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

The history of **PPE standards** in Europe

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 **PPE Regulation** 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.

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 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 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** ?

The draft version of the Regulation has already been approved by the European Commission and Parliament. The next phase involves the European Council to reach an agreement on the text by the end of summer 2015. There are a number of changes that are being proposed taking place including:

- Moving hearing protection from Category 2 to Category 3 PPE
- Changing life jackets from Category 2 to Category 3 PPE
- Issuing a Declaration of Conformity with each PPE or at least a link to where it can be obtained
- Possibly covering domestic PPE (for example oven gloves)
- Bringing the Regulation in line with similar European requirements such as the Medical Devices Directive by suggesting a five-year certificate validity

Once the current Directive is re-issued as a Regulation in 2018, the scope is likely to be changed significantly. The current proposed wording for this is described in the proposed scope below.

The **proposed scope** of the Regulation

It is currently proposed that the following products fall under the scope of the Regulation. This is important as it will help you to understand whether your products are covered by the Regulation.

1 This Regulation shall apply to personal protective equipment (PPE)

2 This Regulation shall not apply to PPE that is:-

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 and intended for private use to protect against atmospheric conditions that are not of an extreme nature;

d for exclusive 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 Regulation 22 of the United Nations Economic Commission for Europe (UNECE) on uniform provisions concerning the approval of protective helmets and of their visors for drivers and passengers of motor cycles and mopeds.

Where to from here?

All manufacturers of PPE need to be aware that any existing certifications they currently hold will expire when the Regulation comes into force at the end of 2018. So it is therefore important to keep up to date with the coming changes and prepare for the impact on business. This would also apply to new manufacturing and distributor companies.

At this stage you need to consider the following:-

Because new EC Type Examination certificates will have to reference the specifics, 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 such as life jackets or hearing protection etc. onto the market, be aware of what the change in classification will mean.
- If you are a distributer, be aware that there are parts of the directive that will have direct implications to you. As more information becomes available we will produce updates on this.

Obligations for **all** manufacturers

The PPE Regulations are 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. 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 that distributors or anyone 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

Category 1 – Simple PPE

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

a superficial mechanical injury;

b contact with water or cleaning materials of weak action;

c contact with hot surfaces not exceeding 50°C;

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

e atmospheric conditions that are not of an extreme nature.

Category 2 – Intermediate PPE

PPE in this category protects users against risks other than those listed in categories I and III, as well as made-to-measure PPE (excluding PPE that falls under category I. The following products are included as examples:

- Safety spectacles and goggles
- Industrial helmets and bump caps
- Bicycle helmets

Category 3 – Complex PPE

PPE falling under this category is designed to protect against mortal danger or dangers that may seriously and irreversibly harm health; the immediate effects of which the designer assumes that the end user cannot identify in sufficient time.' Risks include:

a inhalation of harmful substances;

b aggressive chemicals;

c ionising radiation;

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

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

f falling from a height;

g electric shock and live working;

h drowning;

i cuts by hand-held chain-saws;

j high-pressure cutting;

k bullet wounds or knife stabs;

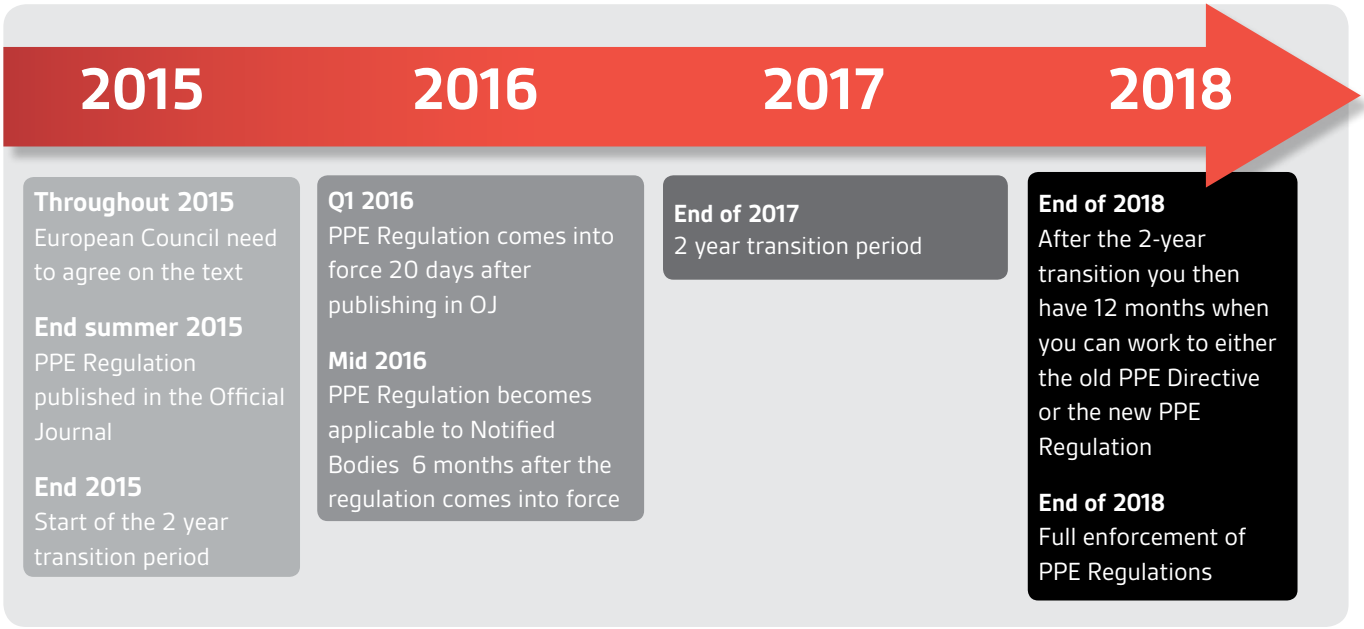
l harmful noise.

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 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.

Timelines



Validity periods

The PPE Directive will most likely have a five-year validity period on EC Type Examination Certificates which is similar to the Medical Devices and Marine Equipment Directives. Interestingly, the council have commented on the fact that the new regulation does not give guidance as to what needs to be done at the end of a five-year certificate validity. They have stated that if nothing is included in the regulation then they may remove the five- year validity requirement altogether. When published, the guidance needs to cover what a manufacturer and Notified Body must do when certificates expire. The principle is to create uniformity across all Notified Bodies. If the validity period is written into the regulation as is expected, then when the regulation comes into force in 2018 certificates will be initially valid for 6 years, after that they will have a 5 year validity.

When safety matters most: the **BSI Kitemark**™ for PPE

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 3 PPE, you will be meeting all your on-going surveillance requirements under the existing Directive and the new Regulations.

bsi.
Personal Protective Equipment
KITEMARK™

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, whitepapers and offering training courses. 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 http://www.ukas.org/CertificationBodies/schedules/PROD/0003Product%20Certification.pdf

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.

Why **BSI?**

Our knowledge, expertise and drive can make a difference to your business:

- We are the pioneers of many of the world's first standards.
- We are renowned for our innovative work in many fields.
- We continue to lead the way with ongoing developments in various industries.
- You can enjoy the benefits of working with BSI teams who have decades of experience helping businesses of all sizes.
- We provide end-to-end support, helping you monitor and maintain your excellence throughout.

Please contact us.

Our team will be happy to help you.
Call: **+44 8450 765606**
Email: **product.certification@bsigroup.com**
or visit: **bsigroup.com**

BSI Group
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes MK5 8PP

T: 0845 0765 606
F: 01908 814920
bsigroup.com