BE PREPARED - The countdown has started...

BSiF
BRITISH SAFETY INDUSTRY FEDERATION

Regulation (EU) 2016/425

On 21st April 2016 the new PPE Regulation entered 'into force'. Having worked to the current PPE Directive since the 1990's, what changes will we experience when it becomes 'applicable' in 2018?

What's new?

Some of the major items that are affected or new are:

- ⇒ **The scope and exclusions are more clearly defined**
- ⇒ **It includes increased obligations on importers and distributors**
- ⇒ **References to Articles 10, 11A and 11B change to Modules B, C2 and D**
- ⇒ **Product Categories (I, II and III) are defined, and some product types will change category**
- ⇒ **An EC Declaration of Conformity (or a web link to it) shall accompany each product**
- ⇒ **New EU Type Examination Certificates will have a maximum validity of 5 years**
- ⇒ **Current EC Type Examination Certificates will need to be renewed by 21st April 2023**
- ⇒ **All products will need to meet the latest versions of the relevant standard**

Obligations and requirements

There are considerably more requirements and obligations written into the new Regulation, but they are not all unfamiliar. Most did not exist when the Directive was written and have come about from later decisions made in Europe, forming a common template known as the New Legislative Framework (NLF).

These decisions have been written into Regulations as they have been created or revised and result in requirements being common across all of them. So in many instances we have already been working to these requirements, but publication of the new Regulation has been the first opportunity to include them in the text.

Timescale

A two year transition period started on 21st April 2016, so the new Regulation is 'in force', but cannot be applied until 21st April 2018, when it becomes 'applicable'.

The current Directive will be repealed on 21st April 2018, but you can continue to place new products which conform to it on the market for a further 12 months. After 21st April 2019 you will only be able to use the Regulation to certify products.

The 5 year validity of certificates also takes effect from 21st April 2018, so current certificates (unless they expire beforehand) will continue to be valid until 21st April 2023, after which a new certificate will be required. The new certificate will have a maximum validity of 5 years.

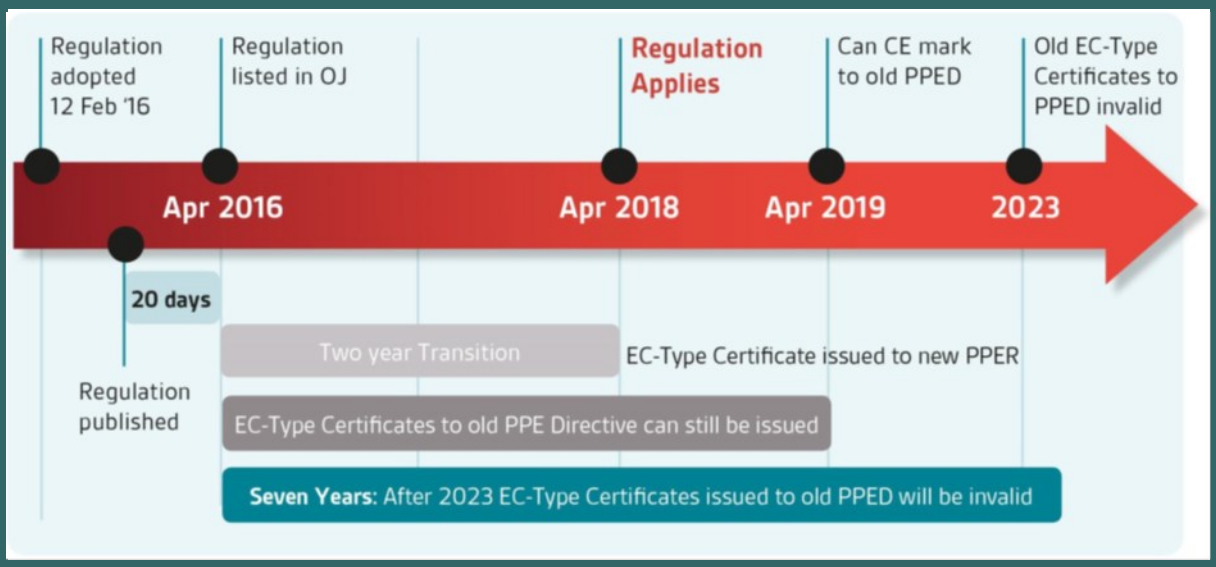
The renewal process is intended to be simple if the product and standard have not changed. Exact details will come from the guidance to be produced to accompany the Regulation. BSIF will help develop the supporting guidance with the EU Commission, and the legal guidance for the UK will be co-authored by BSIF and the Department for Business Innovation and Skills (BIS).

Many products are currently on the market supported by certificates to an earlier version of a standard that has since been revised and has a later date.

Other products are certified to a standard that has been superseded by a new one. Notified Bodies cannot issue new certificates to superseded or earlier versions of standards, so from 21st April 2023 all PPE will have to comply with the latest version of its standard if it is to be certified, or re-certified.

Although Notified Bodies will not be able to issue certificates to the Regulation until 21st April 2018 they can become accredited to make assessments to it from 21st October 2016, and the 2 year transition period is designed to give manufacturers and Notified Bodies time to prepare for the changeover.

It may be easier to follow using this diagram:



Source: BSI Group

Product Categorisation

For private use, oven gloves are now included, but contrary to proposals dishwashing gloves are not. Products remain within Categories I, II or III, but the Regulation defines them in terms of risk, e.g. rather than refer to life jackets it identifies 'risk of drowning', and instead of hearing protection it refers to 'harmful noise'.

Products changing category

The definitions of which category PPE falls into are similar to how they are grouped in the current Directive, but some products will move from Cat II to Cat III, including those protecting against:

⇒ Biological risks.
⇒ Bullet wounds and knife stabs.
⇒ Cuts by hand-held chain saws.
⇒ High pressure jet cutting.
⇒ Risk of drowning.
⇒ Harmful noise.

All PPE, including Cat I products, will require a technical file, the contents of which are defined in more detail. CE marking and certification requirements are similar but the references will change. This table shows the new terminology:

PPE Category	Current PPE Directive 89/686/EEC	New PPE Regulation (EU) 2016/425
Category I	Manufacturer's self-declaration	Module A – Internal Production Control
Category II	Article 10 – EC Type Examination	Module B – EU Type Examination *plus* Module C – Internal Production Control
Category III	Article 10 – EC Type Examination *plus either*	Module B – EU Type Examination *plus either*
	Article 11A – On-going surveillance through testing *or*	Module C2 – Product Verification *or*
	Article 11B – On-going surveillance through factory auditing	Module D – Production Quality Assurance

Obligations on 'Economic Operators'

There will be new obligations on importers and distributors to hold copies of product certificates and declarations of conformity, keep records for at least 10 years, ensure user instructions are provided in the correct language, and ensure their transport and storage do not harm the PPE's efficacy.

The Regulation uses a new term 'economic operators' which it defines as everyone 'intervening in the supply and distribution chain', so it includes manufacturers, authorised representatives, importers and distributors (including online vendors for the first time) and it requires them to take appropriate actions to ensure the PPE is in conformity. It defines them individually as:

Manufacturer: who manufactures the PPE, or has it designed and/or manufactured and markets it under his name or trademark.

Authorised representative: established within the EU and holds a written mandate from the manufacturer to act on his behalf in relation to specific tasks.

Importer: established within the EU and places PPE from a third country on the EU market.

Distributor: involved in the supply chain, makes PPE available on the market, and is other than the manufacturer or importer.

Note that distributors and importers who place PPE on the market under their own name or brand take on ALL the obligations of the manufacturer.

All economic operators will have an obligation to:

⇒ take corrective actions in case of non-compliance and inform the competent authorities where PPE presents a risk

⇒ cooperate with authorities and provide all the information necessary to demonstrate compliance in a language which can be easily understood by that authority

Manufacturers and *authorised representatives* shall keep the technical file and the EU Declaration of Conformity available for 10 years after PPE is placed on the market. *Importers* also need to keep the DoC for 10 years, and ensure the technical file can be made available.

Manufacturers shall ensure that procedures are in place for series production to remain in conformity with the PPE Regulation, and *manufacturers* and *importers* shall, if necessary, carry out sample testing of PPE made available in the market, keep a register of complaints and keep distributors informed of such monitoring. How this should be done will also need to be addressed in the accompanying guidance.

Additional obligations on *importers* are:

⇒ To only place compliant PPE on the market.

⇒ To ensure the PPE has the technical documentation available, the conformity assessment has been carried out, the correct markings are available and the PPE is accompanied with the required documents.

⇒ To indicate on the PPE their product ID and postal address where they can be contacted.

⇒ To ensure transport and storage do not jeopardize the PPE's conformity.

Further obligations on *distributors* are:

⇒ To act with due care.

⇒ To verify that the PPE bears the correct markings and is accompanied by the required documents in a language that can be easily understood by the consumers.

⇒ To not make PPE available in the market if the PPE is considered not to meet the essential health & safety requirements.

⇒ To ensure transport and storage do not jeopardize the PPE's conformity.

Regulatory obligations

To formalise more of the New Legislative Framework requirements Member States *shall* establish a Notifying Authority. In the UK this will continue to be the Government Department for Business Innovation and Skills (BIS), who are responsible for the control of Notified Bodies accredited by UKAS.

There are many more obligations now defined for Notified Bodies, with considerable reference to conflicts of interest, impartiality, capabilities, integrity and confidentiality of information, with obligations extended to tasks sub-contracted by them, such as product testing carried out at an external test laboratory.

BSIF is 'ahead of the game'

There is a new obligation for all European Notified Bodies to cooperate and coordinate within a group in Europe. In the UK this has been met for some time by the BSIF Test & Certification Association, through which Notified Bodies regularly meet. The Association has every UK Notified Body scoped for PPE as members.

In addition the EC Commission has considerable powers to address any issues raised over the operation of a Notified Body , including requiring the national Notifying Authority to withdraw accreditation.

Requirements are also defined in detail for national Market Surveillance bodies who police the movement of PPE into and around the EU. The new requirement for an EU Declaration of Conformity to accompany each item of PPE is largely for market surveillance purposes, and in reality as it is required in each language that the user instructions are produced in, in most cases manufacturers will take the option of supplying a web address where the DoC can be viewed in all these languages.

Hopefully this brief summary has given you an indication of the main items that will affect our market. If you have any questions please contact the BSIF.

Watch out for details of our regional seminars in July with BIS, where your views can be heard and addressed.

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