

PPE REGULATION CHANGES



Background

There are considerably more requirements and obligation written into the New PPE Regulation (EU) 2016/425, but they are not all unfamiliar. Most did not exist when the current PPE Directive 89/686/EEC 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 the British Safety Industry Federation (BSiF) have already been working to these requirements, but publication of the new PPE Regulation (EU) 2016/425 has been the first opportunity to include them in text.



Be Prepared – The Countdown has started

New PPE Regulation (EU) 2016/425

On **21st April 2018**, the current PPE Directive 89/686/EEC will be repealed by the new “PPE Regulation(EU 2016/425)”.

So what changes will we experience as it becomes applicable?

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

- The Scope & Exclusions are more clearly defined.
- It includes significantly increased obligations on Importers & Distributors of PPE & Safety Equipment.
- Surveillance Testing of PPE in production will be enhanced to include auditing of Production Control, Product Verification & Production Quality Assurance where applicable, dependent upon whether PPE Categories I, II or III.
- PPE Product Categories (I, II & III) are defined and some product types will change Category from Cat II to Cat III, for example those protecting against: Biological Risks, Bullet Wounds & Knife Stabs, Cuts by Hand Held Chainsaws, High Pressure Jet Cutting, Risk of Drowning (Life jackets) & Harmful Noise (Hearing Protectors).

- A suppliers 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 are required to be renewed by **21st April 2023**.
- All PPE Products will need to meet the latest versions of their relevant safety standard.

Obligations & Requirements

Obligations on “Economic Operators”

The Regulation (EU) 2016/425 uses a new term “Economic Operators” which it defines as anyone “intervening in the supply & distribution chain of PPE Products” so it includes manufacturers, authorised representatives, importers & distributors (including on-line vendors for the first time) and it requires them to take appropriate actions to ensure their PPE products are fully in conformity with the Standard claimed.

There will be new obligations upon manufacturers, importers & distributors to hold copies of PPE Technical Files, Product Type Examination Certificates and Declarations of Conformity & keep records of these documents for at least 10 years, ensure User Instructions are provided with each product and in the correct language, ensure that transport & storage do not harm the PPE's efficacy or Conformity & to indicate on the PPE their Product Code or I.D. & postal address where they may be contacted.

Note that Distributors & 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 easily be 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.



Obligations & Requirements

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.

Additional obligations on *distributors* are:

- To act with due care.
- To verify that 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.



Product Categorisation

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

For private use, oven gloves are now included, but contrary to proposals dish washing 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'.

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. The table below 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: Article 11A – On-going surveillance through testing or Article 11B – On-going surveillance through factory auditing	Module B – EU Type Examination plus either: Module C2 – Product Verification or Module D – Production Quality Assurance



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.

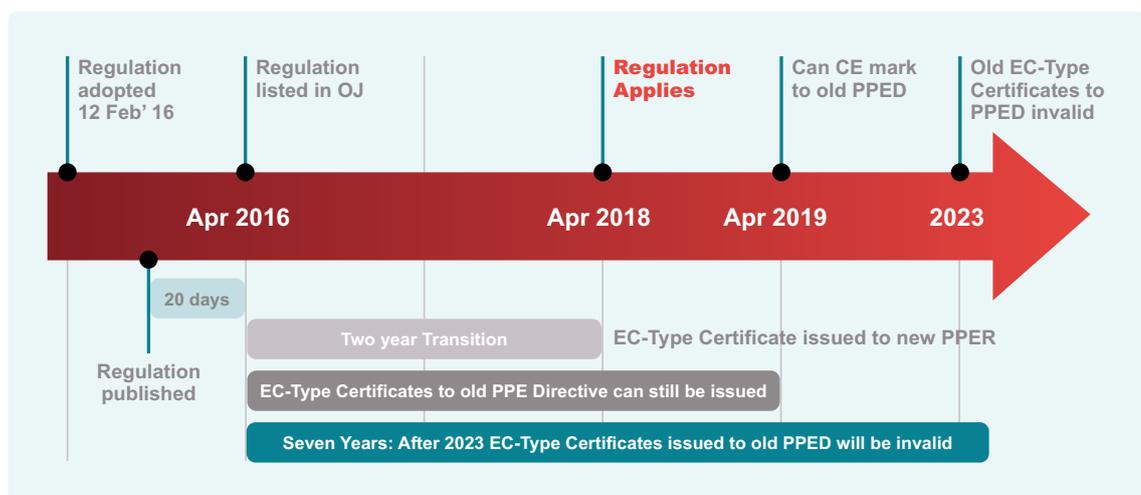
The 5 year validity of certificates also takes effect from **21st April 2018**, so current certificates (unless they expire beforehand) will continue to be valid until **21st April 2023**, after which a new certificate will be required. The new certificate will have a maximum validity of 5 years.

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.





Conclusion

We are fully cognisant of our responsibilities and obligations to you in respect of the New PPE Regulation (EU) 2016/425. Working closely with the BSIF in ensuring that we will be fully compliant at every stage of its implementation on your behalf, we will always be ahead of the game in Protecting People Everyday.

Jon Mellor

Technical Support Manager

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