Overview of PPE Regulation (EU) 2016/425

From 21st April 2018, PPE Regulation (EU) 2016/425 shall replace Directive 89/686/EEC.

The PPE regulation covers the design, manufacture and marketing of personal protective equipment (PPE). It defines legal obligations to ensure that PPE on the EU internal market provides the highest level of protection against risks. The CE marking affixed to PPE provides evidence of compliance of the product with the applicable EU legislation.

Timescale

1. Products in the supply chain* before 21st April 2019 that comply with the former PPE Directive can continue to be made available after this date.
2. Certificates issued under the former PPE Directive remain valid until 21st April 2023 unless they expire before that date.
3. From 21st April 2019, all newly made products will need to conform to the new PPE Regulation.

How is PPE defined?

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.

What is PPE compliance?

PPE products are classified into one of three categories, depending upon the level of risk associated with their use.

- Category I
- Category II
- Category III

Test Certificates

PPE covered by categories II and III require the product to be certified by a Notified Body (NB).

EU type-examination certificates will be issued for a maximum term of five years, after which the manufacturer must reapply to the Notified Body for renewal.

Additional Manufacturer Obligations

A new section that builds on the former PPE Directive places additional requirements on manufacturers. These relate to:

- Sample testing of PPE.
- PPE Markings.
- Obsolescence.
- EU declaration of conformity.
- Corrective measures for non-conforming PPE.

UNDERSTANDING PPE REGULATION (EU) 2016/425

Background

Directive 89/686/EEC

Until 21st April 2018, PPE within the European Union (EU), was regulated by Directive 89/686/EEC.

- It covered most domestic, leisure and professional safety products.
- All PPE products were required to meet Basic Health and Safety Requirements.
- The PPE Directive was over 20 years old.

Regulation (EU) 2016/425 (The PPE Regulation)

On 21st April 2018, the above Directive was replaced by a new PPE Regulation (EU) 2016/425 in order to reflect current technologies and processes for developing and bringing PPE to the market.

The PPE regulation covers the design, manufacture and marketing of personal protective equipment (PPE). It defines legal obligations to ensure that PPE on the EU internal market provides the highest level of protection against risks. The CE marking affixed to PPE provides evidence of compliance of the product with the applicable EU legislation.

Manufacturers or their authorised representative in the EU must comply with the essential health and safety requirements of the PPE regulation, either directly or by using harmonised European standards.

The change imposed new conditions upon manufacturers and suppliers of PPE in Europe, including the following requirements:

- There are new responsibilities for importers and distributors.
- Products that are bespoke and/or for private use are covered by the Regulation.
- Some products in Category II have been moved to Category III (see compliance below).
- There should be an assessment of the risks against which the PPE is intended to protect.
- Requirements for product marking changed, including manufacturer name, registered trade name or registered trademark, and postal address.
- Instructions for use, labelling and EU Declaration of Conformity must be supplied with PPE and in the language easily understood by consumers and end users.

Key dates in the progression of EU Law relating to PPE:

21st April 2018 PPE Directive 89/686/EEC is repealed.
PPE Regulation (EU) 2016/425 shall apply

1. Products in the supply chain* before 21st April 2019 that comply with the former PPE Directive can continue to be made available after this date.
2. Certificates issued under this directive remain valid until 21st April 2023 unless they expire before that date.
3. From 21st April 2019, all newly made products will need to conform to the new PPE Regulation.

> **** What does "Placed on the market" mean?***
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> *Individual product items of personal protective equipment can be considered as "placed on the market" (i.e., made available for the first time) when they are effectively offered for distribution, consumption or use. The physical handover of these products is not necessary to consider that they have been placed on the market.*
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> *So, products in compliance with the former PPE Directive which are in the warehouse of the manufacturer, can be considered as already placed on the market before 21 April 2019 in the case that these products have been offered for sale in product catalogues, or on websites, or in the manufacturer's own store(s) and/or online store.*

How is PPE defined?

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.

What is PPE compliance?

PPE products are classified into one of three categories, depending upon the level of risk associated with their use.

Category I

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

Examples of Category I PPE include washing-up gloves and sunglasses.

This category of PPE can be 'self-certified' and does not require the services of a Notified Body.

Category II

‘Category II’ PPE claims to provide protection against risks of severe injury.

The following products are included as Category II examples:

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

Manufacturer Responsibilities

Category II product manufacturers shall take all measures necessary to ensure that the manufacturing process and its monitoring conform with the applicable requirements of the PPE Regulation.

The design of the prototype and associated documentation of these items of PPE must be certified by a Notified Body.

The manufacturer will ensure compliance with all relevant European legislation before applying the CE mark and creating the accompanying Declaration of Conformity.

Category III

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

Examples of Category III PPE include

- Footwear offering chainsaw cut
- Chemical, severe thermal and high voltage protection.

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.

Manufacturer Responsibilities

The design of the prototype and associated documentation of such items of PPE must be certified by a Notified Body. In addition, a Notified Body must also be involved with assessment of subsequent production, either by product testing or assessment of the manufacturing quality system.

Category III product manufacturers must also undertake ongoing assessment to check compliance.

Test Certificates

PPE covered by categories II and III require the product to be certified by a Notified Body (NB).

The NB will issue an EU type-examination certificate on successful evaluation of a manufacturer's technical file and independent testing report. EU type-examination certificates will be issued for a maximum term of five years, after which the manufacturer must reapply to the Notified Body for renewal.

Additional Manufacturer Obligations

This is a new section that builds on the former PPE Directive. Additional requirements are shown below:

- Carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls. Keep distributors informed of any such monitoring.
- PPE marking will include type, batch or serial number or other element allowing its identification. Where the size or nature of the PPE does not allow it, the required information is provided on the packaging or in a document accompanying the PPE.
    - PPE bearing identification markings or indicators relating to health and safety, must, if possible, take the form of harmonised pictograms or ideograms.
    - If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
    - Alternatively, instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year.
- The manufacturer shall either provide the EU declaration of conformity accompanying each PPE product or include it in the instructions along with the internet address at which the EU declaration of conformity can be accessed if relevant.

- Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate.
    - Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.