

Get a Head Start

As European PPE regulations change we are making sure our valued customers stay informed

The European PPE Directive 89/686/EEC has ensured the safety of personal protective equipment (PPE) for over 20 years. In order to keep pace with changes in the design, manufacture and use of PPE in industry, the PPE Directive is soon to be superseded by the new PPE Regulation.

The publication of the PPE Regulation (EU) 2016/425 of the 9th March 2016 has started a two-year transition period to prepare for its introduction into industry on the 21st of April 2018. This paper provides an overview of the changes resulting from the new PPE Regulation, along with information to help you prepare your business and supply chain for the future.



What the new PPE Regulation (EU) 2016/425 will cover



Personal Protective Equipment (PPE) is defined in the new PPE Regulation as:

- (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), and
- (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.

Categorisation in the PPE Regulation (EU) 2016/425

PPE is organised into categories in the new PPE Regulation as follows, with changes from the PPE Directive explained.

Category I – Simple PPE:

PPE designed to protect users against minimal risks.

PPE DIRECTIVE 89/686/EEC	NEW PPE REGULATION (EU) 2016/425
Superficial mechanical action	Superficial mechanical injury
Contact with hot surfaces <50°C	Contact with hot surfaces not exceeding 50°C
Sunlight (sunglasses)	Exposure to sunlight (other than during observation of the sun)
Atmospheric conditions that are not exceptional	Atmospheric conditions that are not of an extreme nature
	Contact with cleaning materials of weak action or prolonged contact with water



Category II – Intermediate PPE:

Includes risks other than those listed in Categories I and III.

The description of this category will not change in the new PPE Regulation.

Examples include:

Safety spectacles and goggles	Industrial helmets and bump caps	Industrial helmets and bump caps	Cut resistant gloves
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Both the hearing protection and life jackets PPE categories are moving from Category II to Category III in the new PPE Regulation.



Category III – Complex PPE: PPE in this category ‘includes exclusively the risks that may cause very serious consequences, such as death or irreversible damage to health.’

Risks and changes include:

PPE DIRECTIVE 89/686/EEC		
<ul style="list-style-type: none"> • Filtering respiratory devices • High-temp environments >100 °C • PPE against electrical risks 	<ul style="list-style-type: none"> • Respiratory protective devices • Low-temp environments <-50 °C • Fall arrest 	<ul style="list-style-type: none"> • PPE for chemical attack e.g. Chemical resistant gloves or for ionizing radiation
NEW PPE REGULATION (EU) 2016/425		
<ul style="list-style-type: none"> • Substances and mixtures which are hazardous to health • Harmful biological agents • Electric shock and live working • High-temp environments >100°C • Low-temp environments <-50°C 	<ul style="list-style-type: none"> • Atmospheres with oxygen deficiency • Ionising radiation • Drowning • Hearing protection • Life jackets 	<ul style="list-style-type: none"> • Bullet wounds or knife stabs • Falling from a height • Harmful noise • Cuts by hand-held chainsaws • High-pressure jets



Major changes in the new PPE Regulation

The main changes in regulation that are currently proposed in the new PPE Regulation are:

- A Declaration of Conformity to be issued with each PPE, or a link to where it can be obtained
- EU Type Examination Certificates will be valid for a maximum of five years
- Bespoke PPE will now be covered in the PPE Regulation, and
- New responsibilities for importers and distributors are required, as described below.

Who will be affected by the new PPE Regulation?

The existing PPE Directive only focuses on PPE manufacturers, whereas the new PPE Regulation will have an impact on the whole supply chain. The specific compliance responsibilities that manufacturers, importers and distributors (economic operators) will need to adhere to are as follows:



MANUFACTURERS OF PPE

PPE manufacturers will need to meet all the necessary requirements of the new PPE Regulation.

In particular this will involve:

- Products currently certified to revised standards will have to be tested to the latest versions in order to meet the reference standards of the new EU Type Examination certificates,
- All existing product ranges must meet the latest product specifications, and
- Certain types of products placed on the market will change category, as discussed on page 2-3.

IMPORTERS OF PPE

The new PPE Regulation will place a number of new responsibilities on all importers, as defined in Article 10:

- 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 jeopardise its conformity.
- Importers shall, for 10 years after the PPE has been 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 can be made available to those authorities, upon request.

DISTRIBUTORS OF PPE

The new PPE Regulation will place new responsibilities on distributors, as defined in Article 11, some of which are:

- When making PPE available on the market, distributors shall 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 jeopardise 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.

Planning for the new PPE Regulation

New EU Type Examination Certificates to the PPE Regulation will be issued from 21st April 2018. Existing certificates linked to the PPE Directive will remain valid until 2023, assuming that no expiry date is listed on the certificate.

Regardless of your place in the supply chain, it is important for all economic operators to keep up to date with the new regulation and category changes. This will prepare economic operators to manage any relevant impact on their businesses and will ensure that they are at the forefront of our changing industry. In order to plan for the changes, it is recommended that economic operators carry out the following:

1. Review your product ranges and identify those that are tested to revised standards. Prepare to test them to the latest specifications.
2. Be aware of existing certifications you hold, and when they will expire, now that the PPE Regulation transition period has begun.
3. Plan how you will meet any changes in classification that affect your products (see page 2-3).
4. Consider developing an on-going surveillance system to maintain continuous product compliance.
5. For importers and distributors, ensure that you manage product documentation effectively and have access to all required material.
This may include:
 - Holding a copy of the Manufacturer's Module B EU Type Examination Certificate,
 - Accessing the Declaration of Conformity for the product you are handling,
 - Ensuring that User Instructions are in the correct language, and
 - Making provision to hold records for at least 10 years.

Timeline

The important dates in the process of introducing the new PPE Regulation are explained below:



We aim to stay at the forefront of this innovation and change in the PPE industry and help our customers maintain compliance to evolving regulations.

Regularly engaging with industry organisations will ensure that Kimberly-Clark Professional* will continue to develop and commercialise PPE solutions with the utmost integrity.

To stay up to date with such changes, or to find out more about what new regulations mean for you, please contact us at kimtech.support@kcc.com.

References

- Kimberly-Clark PROFESSIONAL* internal intelligence
- [BSI New PPE regulation](#)