NEW EU REGULATION 2016/425
Changes at a glance

Every single day, three DuPont brands - Tyvek®, Tychem® and ProShield® provide reliable protection for workers across the globe. In 2018, we've harmonised our product identification system and unified the packaging to enable easier identification of our products as well as facilitate garment selection. By this improvement we are not only making it easier to select the right garment for any application but also ensure compliance of our products with the latest EU regulation on Personal Protective Equipment. This white paper explains the DuPont response to the new Regulation (EU) 2016/425.

TIMELINE

The current PPE directive 89/686/EEC will be repealed on the 21st of April 2018 by the new PPE Regulation (EU) 2016/425. The below timeline shows the key milestones related to the new regulation as well as the implementation plan from DuPont.

EU REGULATION 2016/425: WHAT ARE THE MAIN CHANGES?

In this section, we highlight some of the key changes that will take place moving from the PPE directive to Regulation (EU) 2016/425. The new PPE regulation document can be downloaded in different language versions at:
http://eur-lex.europa.eu/legal-content/uk/ALL/?uri=CELEX%3A32016R0425

DIRECTIVE BECOMES REGULATION

While the directive was an established legal framework for national law set up by the individual member states, the regulation has immediate application and binding character in all member states.

SCOPE OF APPLICATION AND PRODUCT CATEGORIZATION

The new regulation has adopted the scope of the old directive with a few exceptions.

The category definition remains unchanged, however the categorization of products is slightly modified. Category III has been extended by some specific protection needs such bullet wounds of knife stabs, high pressure jets but also broadened in scope as for example by "substances & mixtures which are hazardous to health". Moving from Cat. II to III are: life jackets and hearing protection. The following table provides an overview by PPE Category.

PPE Category	PPE Directive 89/686/EEC	PPE Regulation (EU) 2016/425
Cat. I Includes exclusively minimal risks	Self-declaration by manufacturers	Self-declaration by manufacturers (Module A)
Cat. II Includes risks other than those listed in cat. I & II	EU type examination (Article 10)	EU type examination (Module B)
Cat. III Includes exclusively risks that may cause very serious consequences such as death or irreversible damage to health	EU type examination (Article 10) Article 11A (Quality control delegation to notified body) Article 11B (Manufacturer run quality control system, audited by notified body)	EU type examination (Module B) Module C2 (Quality control delegation to notified body) Module D (Manufacturer run quality control system, audited by notified body)

DECLARATION OF CONFORMITY

With the PPE regulation it becomes a requirement to supply the Declaration of Conformity with product or alternatively to provide a web address in the instructions for use where the document can be downloaded. It shall be translated into the language required by the member state in which PPE is placed on the market or made available.

Declarations of conformity have the same validity as EU Type-examination certificates (5 years) and must be retained by manufacturer for 10 years after product introduction on the market.

FIVE YEAR CERTIFICATE VALIDITY

EU Type-examination certificates validity will be limited to 5 years. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions, together with the technical documentation at the disposal of national authorities, for 10 years after the PPE has been placed on the market. It is the manufacturer's responsibility for their PPE products to be certified to the latest version of the applicable harmonised standards.

OBLIGATIONS OF ECONOMIC OPERATORS THROUGHOUT THE SUPPLY/DISTRIBUTION CHAIN

With the introduction of the PPE Regulation the compliance responsibility will be extended to all economic operators in the value chain. The PPE regulation defines "Economic operator" as anyone involved in the supply and distribution of PPE products. It includes manufacturers, authorised representatives, importers and distributors (including online vendors). The regulation requires all economic operators to take full compliance responsibility that products are in conformity with harmonised standards claimed in the certification.

	PPE Directive 89/686/EEC	PPE Regulation (EU) 2016/425
Manufacturers	✓	✓
Authorised Representatives	✓	✓
Importers / Distributors	✗	✓

Distributors and importers placing PPE products on the market under their own name and/or brand have to meet manufacturer obligations as outlined in the PPE regulation.

MANUFACTURERS OBLIGATIONS (Extract PPE Regulation (EU) 2016/425)

Manufacturer holds full responsibility that PPE products placed on market have been designed and manufactured in accordance with the essential health and safety requirements laid out in the PPE Regulation.
A technical documentation is mandatory that specifies the means used by the manufacturer to ensure the conformity of the PPE with the essential health and safety requirements.
Archiving responsibility: Technical documentation, EU type examination certificate and EU declaration of conformity have to be retained for 10 years after the PPE product has been placed on the market.
Need to ensure that procedures are in place for series production to remain in conformity with the PPE Regulation.
Declaration of conformity is to be provided with PPE product or alternatively an internet address where the document can be downloaded in user instructions.
Product labelling: Mark the product with type, batch or serial number or other element allowing its identification, plus postal address. Packaging can be considered as alternative, when size or nature of product does not allow it.
Instructions for use are to be supplied with the smallest individual sales unit in a language which can be easily understood by the member state where product is placed on market.
Products at risk: Manufacturers who consider or have reason to believe that PPE they placed on market is not in conformity with the regulation, shall take immediate corrective actions necessary to bring product into conformity to withdraw or to recall it.

IMPORTERS OBLIGATIONS (Extract PPE Regulation (EU) 2016/425)

Before placing PPE on the market, importer shall ensure that the appropriate conformity assessment has been carried out by the manufacturer.

Needs to ensure that the manufacturer has drawn up the technical documentation, the PPE bears the CE marking and is accompanied by the required documents.

Product labelling: Shall indicate, on the PPE, their name, registered trade name or trademark and the postal address. Packaging can be considered as alternative, when size or nature of product does not allow it.

Need to ensure that instructions for use are to supplied with the smallest individual sales unit in a language which can be easily understood by the member state where product is placed on market.

Shall ensure that PPE, while under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements.

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, and shall keep distributors informed of any such monitoring.

Archiving responsibility: Technical documentation, EU type examination certificate and EU declaration of conformity have to be retained for 10 years after the PPE product has been placed on the market.

Be prepared to cooperate with national authorities for market surveillance and make available required documentation.

Importers placing PPE products on the market under their own Name and/or Brand have to meet manufacturer obligations as outlined in the PPE regulation.

DISTRIBUTORS OBLIGATIONS (Extract PPE Regulation (EU) 2016/425)

Distributors shall act with due care in relation to the requirement of the PPE Regulation.

Before placing the PPE products on the market, they shall verify that it bears the CE-marking, is accompanied by the required documents, instructions for use in a language that is easily understood in the member state in which the product is placed on the market.

Shall ensure that PPE, while under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements.

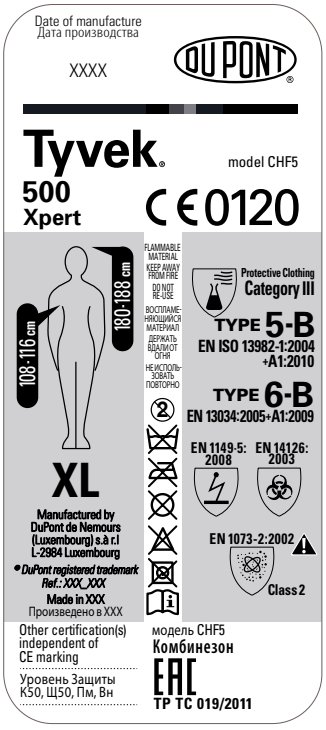
Inform market surveillance authorities, manufacturer or importer if considers or has reason to believe that PPE is not in conformity with the essential health and safety requirements and/or presents a risk.

Be prepared to cooperate with national authorities for market surveillance and make available required documentation.

Distributors placing PPE products on the market under their own Name and/or Brand have to meet manufacturer obligations as outlined in the PPE regulation.

LEGAL PRODUCT DOCUMENTATION: WHAT IS CHANGING?

1. Products shall conform to the latest harmonized standards issued in order to be certified to the new regulation (EU) 2016/425.
2. The name of manufacturer must appear on each garment product label (typically placed on the neck, on the inner side of the garment).
3. Instructions for Use document for each garment should refer to the new Regulation (EU) 2016/425.
4. The Instructions for Use document must clearly explain against which risks the product is designed to protect.
5. The Instructions for Use document should be coupled with the Declaration of Conformity or provide a link to a downloadable document. In the case of DuPont, the Declaration of Conformity document can be downloaded at www.safespec.dupont.co.uk.
6. The CE certificates and Declarations of Conformity documents are valid for 5 years and must be retained for 10 years after the product has been placed on the market.



CO-BRANDED PRODUCTS

COLLABORATION AND QUALITY BENEFITS, DUPONT OFFERS TO DISTRIBUTION PARTNERS

With the significantly increased obligations for distributors placing PPE products on the market under their own Name and/or Brand, **trustful partners offering established and reliable quality systems** are key to remain successful with own PPE range and secure reputation in the marketplace.

✓ Tyvek®: unique fabric technology

DuPont provides you a unique fabric technology, enabling differentiation versus common fabric technologies like microporous film and SMS.

✓ Tyvek®: brand exposure thru cobranded offering

DuPont Tyvek® is a recognised and well established brand for high and reliable quality and protection performance in the marketplace. Our cobranding offer provides distributors full advantage of strong brand image.

✓ Tyvek®: reliable certification and quality assurance process

DuPont offers you a reliable product certification and quality assurance process (Module D) compliant to new PPE regulation.

Tyvek® Classic Xpert (Tyvek® 500 Xpert)	DuPont™ EasySafe (Tyvek® 200 EasySafe)
✓ co-branded	✓ co-branded ✓ private label
Tyvek® Classic Xpert (Tyvek® 500 Xpert) with a large company logo or ID label on the garment centre-back. The label is printed on Tyvek® and up to 4 colours. Ideal for corporate ID or visual differentiation. Printed on a self-adhesive Tyvek® label, the barrier integrity of the suit is retained. Choice of 2 label sizes: 300mm (wide) x 90 mm (high) 150mm (wide) x 45mm (high) *Made to order. Terms and conditions apply.*	Gain brand exposure and market share with a differentiated co-branded type 5/6 coverall from DuPont. DuPont™ EasySafe (Tyvek® 200 EasySafe) garment with your company or branded chest label and packaging. The chest label and packaging is either as an alternative or in addition to the DuPont™ EasySafe brand. *Made to order. Terms and conditions apply.*