ejendals
PROTECTING HANDS AND FEET

New EU regulation 2016/425

BACKGROUND

The EU directive 89/686/EEC has been in use for over 20 years (first applied 30 June 1995). It was one of the first 'New Approach' Directives which means that businesses can make use of harmonized standards as they benefit from a 'presumption of conformity' with the requirements set out in the relevant European legislation. The Directive defines 'essential requirements' which PPE must satisfy at the time of manufacture and before it is placed on the market.

The aim of the Directive is to ensure the free movement of PPE between the member states. The Directive specifies details of both Essential Health and Safety Requirements (EHSRs) for PPE and the conformity assessment procedures. PPE protecting against more serious risks require a third part intervention of a so-called 'Notified Body'. Notified Bodies are institutes appointed by the member states that perform EC type examination, approval and monitoring of quality assurance systems.

European Commission

WHY THE CHANGE?

The Directive was found successful but improvements were needed due to new technology and new materials in the market. The goal is to better protect the health and safety of the PPE user and to ensure fair competition between companies. The new regulation (EU) 2016/425 was published in the Official Journal of the European Union on 31 March 2016. It came in force on 21 April 2016 and will be applicable from 21 April 2018.

The change means a re-implementation of the directive as a regulation. A directive contains certain results that each member state must achieve and for this they need to transpose the directive into their national laws. A regulation on the other hand is a legal act that becomes immediately enforceable as law in all member states simultaneously without the need for national implementation.

HOW EJENDALS ARE DEALING WITH THE NEW PPE REGULATION (EU) 2016/425

At Ejendals we embrace the implementation of the new regulation and take the opportunity to improve our products even further. When recertifying a product, the product needs to comply with the latest version of a standard. None of the standard related to shoes have recently been updated, meaning all Jalas® shoes comply with the latest version of the applicable standards.

Two glove standards have recently been updated, EN388 (mechanical risks) and EN374 (chemical and microorganism risks)

Therefore, all Ejendals gloves that are certified against EN388 and EN374 are being re-tested to comply with the latest versions.

This may lead to differences in performance levels and markings, due to the differences in test methods.

Ejendals are preparing for the recertification, and from 21 April 2018 the new EU type examination certificates[1] can be issued.

After 21 April 2019, all gloves that are placed on the market must comply with the new regulation. 'Placed on market' is defined as when an individual product is made available on the European Union market for the first time. Therefore, the only economic operators that can 'place products on the market' are manufacturers or importers. 'Making available on the market' is defined as when an individual product is supplied on the EU market for distribution or consumption or use. Distributors can make products available on the market with no end date.

Between 21 April 2018 – 21 April 2019 there is a transition period. This means that a mixture of products with old and new markings can leave the warehouse depending on stock levels.

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[1] EC type Examination – Directive 89/686/EEC

EU Type Examination – Regulation 2016/425

There have been misunderstandings concerning what the date '21 April 2023' refers to. The EU Commission has therefore published a document to clarify; Regulation (EU) 2016/425 on personal protective equipment - Guidance document on the implementation of Article 47 on transitional provisions.

In this document, the EU Commission states that PPE may be placed on the market after the full applicability of the Regulation (21 April 2019) based on an EC type-examination certificate in accordance with the PPE Directive, until 21 April 2023. However, this is not applicable when the design/manufacture of the PPE has changed, or a European standard has been updated, so-called 'change in the state of the art'. This means that manufacturers can base the Declaration of conformity on existing EC type certificates until 2023 if the PPE have not changed since the latest certification and are tested for the latest version of applicable European standards. 21 April 2023 only refers to the validity of the EC Type Examination. Products that are already in the supply chain, hence have already been lawfully placed on the market, before 21 April 2019 can be sold/ distributed forever.

MAIN CHANGES IN THE NEW REGULATION ARE:

- The scope has been enlarged, for example concerning private use against heat (oven gloves)
- Clothing intended for private use with reflective or fluorescent elements is not covered by this Regulation.
- Product categories I, II and III are defined
- No product examples, categories are defined by risk alone
- Some products will change categories, e.g. chain saw gloves move from cat. II to cat. III
- Distance selling (online) is subject to this Regulation
- 5-year validity period for EU type examination certificates
- Declaration of Conformity in all required languages, with the PPE or weblink.

To comply with the new regulation some obligations for manufacturers have been extended to include importers and distributors.

All (manufacturers, distributors, importers, authorized representatives), involved in the supply and distribution chain, should take appropriate actions to ensure the PPE is in conformity with the Regulation.

OBLIGATIONS OF MANUFACTURERS

- Ensure that PPE meets all essential health and safety requirements (Annex II)
- Ensure the technical documentation is available, carry out the conformity assessment, apply the CE mark and draw up the EU declaration of conformity (DoC)
- Keep technical documentation and DoC available for 10 years after PPE is placed on the market
- Ensure that procedures are in place for series production to remain in conformity with the PPE regulation; 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
- Ensure PPE bears a type, batch or serial number
- Indicate on the PPE their name and postal address
- Ensure the PPE is accompanied with the user instruction (UIS)
- Provide the DoC with the PPE or add the internet address to the UIS where the DoC can be accessed
- Take corrective actions in case of incompliance and inform the competent authorities where PPE presents a risk
- Cooperate with authorities in a language which can be easily understood by that authority.

OBLIGATIONS OF DISTRIBUTORS

All economic operators involved in the supply chain now have a much greater role to ensure that PPE is compliant with the regulation.

One important note is that the distributor shall ensure that transport and storage conditions does not jeopardize the PPE's compliance with the health and safety requirements in annex II.

The distributor should:

- Ensure that the CE-mark is applied to the PPE
- Ensure that user instructions are available in the language required
- Ensure that product identification is on the PPE
- Ensure that contact information and postal address is on the PPE
- Distributors who believe that the PPE is not in conformity with the regulation must take all measures to bring it in conformity, whether it's to re-call or withdrawal the PPE
- Distributor must on request from a national authority provide them with all necessary documents to prove conformity
- If the PPE presents a risk, the distributor must inform the proper national authority of its non-conformity.

DOES ANYTHING CHANGE FOR THE USER, EMPLOYER, WEARER?

No, not in particular.

The obligations for employers regarding occupational health and safety and the use of PPE, remains the same as this is not part of this legislation but of directive 89/656 'use of personal protective equipment'. Directive 89/656/EEC lays down the minimum health and safety requirements for use by workers at work. In addition to this, each member state can have additional regulations concerning the employer.

Given that there are no issues with the health and safety requirements in the directive 89/686/EEC and these has not been changed (only minor), PPE certified under the directive 89/686/EEC can still be used without any risks.

CATEGORIES

PPE Category	Action	Old PPE Directive 89/686/EEC	New PPE Regulation (EU) 2016/425
Category I Simple PPE	Placing product on the market	Manufacturer's self declaration	Module A (Annex IV) Manufacturer's self declaration
Category II Intermediate PPE	Initial product approval	Article 10 EC Type Examination	Module B (Annex V)
Category III Complex PPE	Initial product approval	Article 10 EC Type Examination	Module B (Annex V)
Category III Complex PPE	Ongoing surveillance through testing **or** production control	Article 11A **or** Article 11B	Module C2 (Annex VII) **or** Article 11B Module D (Annex VIII)

Category I – Simple PPE

PPE in this category are designed to protect users against minimal risks. These include:

- superficial mechanical injury;
- contact with water or cleaning materials of weak action;
- contact with hot surfaces not exceeding 50°C;
- damage to the eyes due to exposure to sunlight (other than during observation of the sun);
- atmospheric conditions that are not of an extreme nature.

Category II – Intermediate PPE

Category II includes protection agaisnt risks other than those listed in Categories I and III.

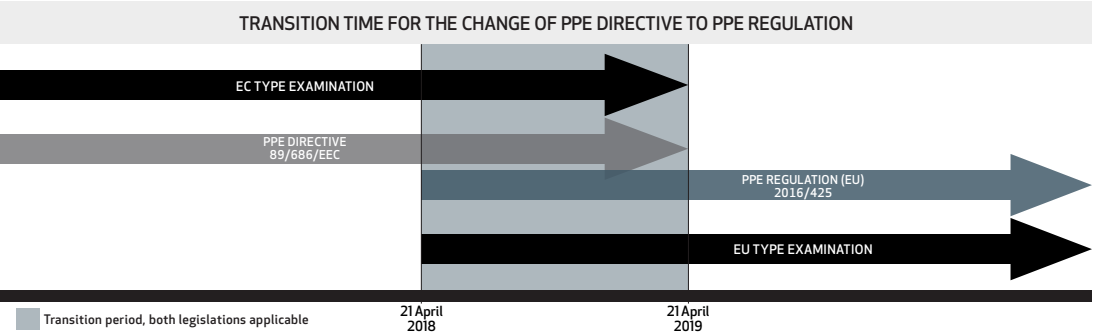
Category III – Complex PPE

PPE falling under this category include exclusively protection agaisnt risks that may cause very serious consequences, such as death or irreversible damage to health.

Risks include:

- substances and mixtures which are hazardous to health
- atmospheres with oxygen deficiency
- harmful biological agents
- ionizing 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

TIMELINE



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