Next year, a new European regulation will come into force which we would like to explain briefly from the perspective of the PPE user. The current PPE Directive 89/686/EC governs the sale and distribution of personal protective equipment (PPE). As of 21 April 2018, this will be superseded by Regulation (EU) 2016/425.

PPE is defined as equipment which is 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, e.g. helmets, respirators or fall protection, but not gas detectors.

Let’s get the most important part out of the way first: this new Regulation governs the obligations of manufacturers, authorised representatives, distributors and importers, as well as test facilities and certification bodies. **They are the first to be affected by these changes. For PPE users, the new Regulation brings more safety and transparency.**

Here is a summary of the main changes:

1) New responsibility for distributors and importers

While the current Directive governs the obligations of manufacturers or their authorised representatives, in the new Regulation, importers and distributors will also be affected. All economic players will bear responsibility for ensuring that only PPE that meets the requirements of the new Regulations will be placed on the market.

2) New PPE categorisation

The current Directive places PPE into one of three categories. This in turn stipulates the kind of conformity assessment procedure that applies. The new Regulation stipulates the categories according to the level of risk from which the PPE should protect the user. The three categories are:

- **Category I** includes small risks, e.g. superficial injuries (PPE: gardening gloves) or harm to the eyes from the sun’s rays (PPE: sunglasses). For these types of PPE, an internal production check by the manufacturer is sufficient.

- **Category III** includes risks that can have very serious consequences, such as death, or irreversible damage to health, e.g. hazardous substances and mixtures (PPE: respiratory devices, chemical protection suits) or falls (PPE: fall prevention equipment). Harmful noise is recognised in the new Regulation as an irreversible health hazard. **Hearing protection, life jackets and PPE to protect against chainsaw injuries have been placed in category III for the FIRST time.**

  For PPE in category III, an EC type examination is required, ie testing and certification by a notified body. A notified body must also carry out recurring product tests at irregular intervals, or monitor (audit) the quality assurance system. Furthermore, internal production control by the manufacturer is a requirement to ensure that any manufactured PPE corresponds to that tested at the Notified Body s.

- **Category II** includes risks that are **not** included in category I or III. For corresponding PPE, an EC type examination and an internal manufacturer product control are required.

3) Extended CE marking

PPE that has passed the conformity assessment procedure (and only such items may be put in circulation) is given, as is already the case, the CE marking. For PPE in category III, the reference number of the monitoring body is also added to the CE marking.

4) Declaration of Conformity

The EU declaration of conformity*) is the manufacturer's written confirmation that an item of PPE meets all the requirements of the PPE Directive, or from April 2018, the PPE Regulation. In future, the declaration of conformity must be provided with all deliveries of PPE. Alternatively, the user instructions can give a website link from which the declaration of conformity can be downloaded.

5) Transitional provisions

The new Regulation is valid from 21 April 2018, and on the same date the old Directive will be repealed. PPE that met the requirements of the old Directive before this date may continue to be sold if its EC type examination certificates are valid. Until 21 April 2019, even PPE that complies with the old Directive may still be placed on the market. At the latest by 21 April 2023, however, all EC type examination certificates issued in accordance with the old Directive will cease to be valid. From this date, all PPE sold must comply with the new Regulation. New EC type examination certificates will be issued with maximum validity of 5 years – this is already the case with certificates from some Notified Bodies.

It should be highlighted that for you, as a PPE user, only the "New PPE categorisation" and "Practical instruction" apply; all other changes concern businesses, such as manufacturers. For PPE in category III, the obligation of the employer to provide practical instruction continues to be valid. Please note that e.g. hearing protection is now placed in this category.

As a responsible manufacturer, MSA naturally only supplies products which comply with all legal requirements. With MSA, you can rest assured that all our products comply with European legislation. We hope that the above information will be helpful to you in your task of selecting PPE.

The complete PPE Regulation (EU) 2016/425, published in April 2016, is available in all European languages: http://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32016R0425

*) The EU declaration of conformity is the manufacturer's written confirmation that an item of PPE meets all the requirements of the PPE Directive, or subsequently, the PPE Regulation. It shall contain the name and address of the manufacturer, the description of the PPE, information on standards or technical specifications, and details of the conformity assessment procedure used, e.g. the number of the EC type-examination certificate and which quality assurance procedure has been applied.

MSA declarations of conformity are available today via our distribution partners. Once the Regulation (EU) 2016/425 comes into force, the declarations of conformity shall be made even easier to access.