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The new PPE Regulation 2016

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WIRTEX

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Old wine in new barrels?

The real changes in the new PPE Regulation

With the transition from the European Economic Union (EEC) to the European Union (EU) in the 1980s the market entry rules for products in Europe were standardised. The primary aim of the EEC was to ensure free traffic of goods within Europe. Starting with the Maastricht treaties, guidelines were issued for many products as part of the "new concept" so that the same rules for placing products on the market applied in every country of the European Union. In addition to standardisation of product requirements for the European market, the minimum requirements for occupational health & safety were established.

In 1989 the two directives applicable to personal protective equipment (PPE) - 89/686/EEC (PPE Manufacturers Directive) and 89/656/EEC (PPE User Directive) - were drawn up. In 1996 the legislative in Germany transposed these two directives into national law. The Manufacturers Directive became the 8th ProdSV (Ordinance on the Product Safety Act) and the User Directive was transposed by the Occupational Health and Safety Act, the PPE User Ordinance and the Workplace Ordinance.

In 2008, Decision No 768/2008/EC created the "New Legal Framework" for placing certain products on the market. This "New Legal Framework" categorised and standardised the procedures to assess conformity for all sorts of product groups. Furthermore, many terms, such as placing on the market, making available on the market, manufacturer, importer, distributor, etc. were defined.

The new PPE Regulation (EU) 2016/425 adapted the older Directive 89/686/EEC to this "New Legal Framework".

The new PPE Regulation at a glance

Recitals		
Chapter I	Art. 1-7	General provisions
Chapter II	Art. 8-13	Obligations of economic operators
Chapter III	Art. 14-17	Conformity of the PPE
Chapter IV	Art. 18-19	Conformity assessment
Chapter V	Art. 20-36	Notification of conformity assessment bodies
Chapter VI	Art. 37-41	Union market surveillance and control of PPE entering the Union market and Union safeguard procedure
Chapter VII	Art. 42-44	Delegated and implementing acts
Chapter VIII	Art. 45-48	Transitional and final provisions
Annex I		Risk categories of PPE
Annex II		Essential health and safety requirements
Annex III		Technical documentation for PPE
Annex IV to VIII		Module A, B, C, C2 and D
Annex IX		Declaration of conformity
Annex X		Correlation table

1. PPE Directive becomes PPE Regulation

Initially the transition from the PPE directive to the PPE regulation resulted in a very legal formal amendment. While the European directive established a legal framework, which had to be transposed into national law by the individual Member States, the PPE regulation has ensured full harmonisation. According to Art. 288 of the Treaty on the Functioning of the European Union (TFEU), the regulation has direct application in every Member State and hence is immediately binding and applicable. There is, therefore, no scope left for Member States during transposition. The Member States are merely responsible for this and are also required to regulate national market surveillance and sanctions following non-compliance with the PPE regulation.

2. Scope of application of the PPE regulation is expanded

The PPE regulation regulates its exact field of application, as does the directive. There is a basic definition whereby equipment is to be classified as personal protective equipment in the sense of the ordinance. However, certain types of PPE are excluded from the scope of application defined in the basic definition.

According to Art. 3 (1) personal protective equipment means in particular equipment designed and manufactured to be worn or used by a person for protection against one or more risks to that person's health or safety. From this definition, it can be inferred that the manufacturer is largely able to determine the use and intended purpose of the equipment and hence the applicability or non-applicability of the PPE regulation.

Some products, even if they are personal protective equipment, are excluded from the scope of application of the regulation. The regulation has adopted the list of exceptions from the PPE directive, but with one exception:

In the PPE Directive, PPE for private use against heat is excluded from the scope of application; however, this is not the case in Art. 2 (2) c. The argumentum a contrario means that PPE for private use against heat now comes under the scope of application of the PPE regulation. In practice this means, for example, that oven gloves now must comply with the requirements of the PPE regulation.

PPE intended for private use as protection against the weather is still excluded from the scope of application. However, this exception is now limited to protection against weather conditions that are not extreme. Hence outdoor wear would only come under the scope of the PPE regulation if it is intended to protect against extreme cold.

Regarding the scope of application, the recitals (10) clarify that clothing intended for private use with fashionable or decorative fluorescent or reflective elements does not come under the scope of the PPE regulation. Therefore, insofar as clothing has fluorescent and/or reflective elements but is not described as providing any protective function, the scope of application of the PPE regulation does not apply and in this respect the requirements contained in Annex II 2.13 need not be complied with.

3. Obligations of economic operators

The PPE Directive 89/686/EEC, also known as the "PPE Manufacturers Directive", was so called because it primarily described the obligations of the manufacturer. Already, under the PPE Directive, court judgments extended responsibility to beyond the manufacturer (e.g. importers). The new PPE regulation still assigns the main responsibility to the manufacturer, but also introduces additional persons bearing responsibility and reduces the obligations of lower-tier economic operators. Art. 3 contain an exact description of the responsible economic operators. Arts. 8-12 of the PPE regulation contain a very detailed and differentiated list of the individual obligations of the economic operators involved; these are described in more detail in the following clauses 3.1 to 3.4. There is one obligation that applies to all economic operators equally: In accordance with

Art. 13 all economic operators must provide the market authorities with information on from whom they have procured PPE and/or to whom they have delivered PPE. All documents that can contain information on procurement and delivery of PPE must be retained by the economic operators for 10 years.

3.1 Obligations of manufacturers

The obligations of the manufacturer only to place PPE on the market if the essential health and safety requirements set out in Annex II are complied with have naturally been retained with the PPE regulation (Art. 8 (1)). Art. 8 stipulates new obligations that hitherto did not exist so explicitly:

Now the manufacturer must identify his products with his contact address, whereby the postal address is meant; a web address or an email address is not sufficient. In fact, the legislator recommends including a web address in addition (Recital 13). Products must also be marked with an identification mark so that, should product defects occur, the relevant products can be taken more rapidly off the market without any margin for error. Identification marks can be type, batch, serial or item numbers. Whereas the manufacturer previously only had to fill out a declaration of conformity and retain it in the event of an inspection by the market authority, the PPE regulation now stipulates that the manufacturer must now supply a declaration of conformity with all PPE, i.e. in addition to the manufacturer's instructions and information that still has to be provided. The addition of the declaration of conformity can be replaced by an Internet link in the manufacturer's instructions and information, as long as they contain certain information [Annex II 1.4 i)-l)].

The obligations of the manufacturer do not end with placing legally compliant PPE on the market. In fact, the obligation to monitor products has been added, which can involve sample testing depending on the risk related to the PPE provided. The manufacturer must investigate every complaint about his products and document them (register of complaints, Art. 8 (4)). The manufacturer must inform his customers (distributors) of all these subsequent acts of monitoring. The new regulation stipulates specifically that the manufacturer must keep technical documentation and the EU declaration of conformity for ten years after the PPE has been placed on the market (Art. 8 (3)). A manufacturer who believes that his product poses a risk must inform the market authorities (obligation to notify the authorities, Art. 8 (9), also known as a "self-incrimination obligation").

3.2 Obligations of importers

The obligations of the importer apply when the actual manufacturer is located outside the EU. Since such manufacturers are not readily accessible to the market authorities, the PPE regulation moves responsibility to the importer located in the EU. However, the term importer is only used if the product itself can be assigned to a manufacturer (trade mark of the manufacturer is visible). Therefore, the importer does not bear the full weight of manufacturers' obligations but he does bear more responsibility than a mere reseller (distributor). In accordance with Art. 10 (1) the importer has the obligation to place only compliant PPE on the market. Although the importer is considered to play a very important role in placing PPE on the market, his obligations are more of a supervisory nature. For example, in accordance with Art. 10 (2) the importer must check whether the (foreign) manufacturer has carried out the conformity assessment procedure referred to in Art. 19 and whether he has compiled the technical documentation and whether the PPE bears the CE marking and is accompanied by the required documents (manufacturer's instructions and information, declaration of conformity).

The special function of the importer is emphasised by the fact that he must also identify the PPE products with his name. At the same time, he must check whether the product is also identified with the name of the manufacturer. Therefore, if an importer places PPE on the market, the PPE must be doubly identified. The importer does not have to carry out the conformity assessment procedure himself but must check whether

it has been carried out (in this aspect he does not bear the full responsibility of a manufacturer). However, exactly like the EU manufacturer, the importer must implement product monitoring and where necessary random checks of the PPE placed on the market. Regarding this lower tier responsibility after placing products on the market, the responsibility of the importer does not differ from that of the manufacturer (see 3.1). If a company located in the EU imports PPE from third countries and then sells it as its own product with its own trade name, then the company is not an importer but is a (quasi) manufacturer (see 3.4).

3.3 Obligations of distributors

Even a reseller in the strict sense of the word, who sells PPE one more time after it has been placed on the market, has obligations according to the new PPE regulation, albeit limited. This is clear from the very first sentence of Art. 11, according to which a distributor must act with due care in relation to the requirements of the PPE regulation. Put simply, this means that he can only be required to do what he is capable of doing within the scope of his business.

Distributors have purely formal inspection obligations, such as checking that there is a CE marking and that the manufacturer's instructions and information are available in the correct language. In contrast to an importer, a distributor does not have to check whether the manufacturer has carried out a conformity assessment procedure correctly. Nor is he subject to the product monitoring obligation that manufacturers and importers have to comply with. Only if the distributor knows with certainty that the PPE he wishes to sell does not comply with the requirements of the PPE Regulation, does he have to take action, namely inform the market authorities and start to take corrective action.

3.4 Obligations of quasi manufacturers

Every company that affixes its name and trade name to the products of another and places them on the European market for the first time is treated as a manufacturer. This quality of quasi

manufacturer can apply both to importers as well as distributors. Whoever acts as though he is placing his own products on the market must accept that he will be treated as a manufacturer and will be subject to all the obligations of a manufacturer (see above 3.1). This legal consequence, which also exists in civil liability (Art. 4 (1) 2 of the Product Liability Act (ProdHaftG)), derives from Art. 12.

4. Validity of the EC-Type Examination Certificate is limited

The conformity assessment procedure for Categories II and III PPE includes type-examination (Art. 19) by an accredited test institute (so-called notified bodies in accordance with Art. 24). These test institutes must check whether the type sample complies with the requirements of the PPE regulation. If the result is positive, the test institute will issue the manufacturer with an EC-Type Examination Certificate. The Type Examination Certificate is, so to speak, the "driving licence" to place Category II and III PPE on the market. Under Directive 89/686/EEC there was no time limit to the validity of this type examination certificate.

The test institutes could limit its validity or issue an open-ended certificate at their own discretion. This led to very unequal validity periods of type examination certificates within the EU. Since 2010 the German certification institutes have undertaken internally to issue examination certificates with a maximum validity of 5 years. This limitation introduced voluntarily by Germany has now become mandatory throughout the EU with the new PPE regulation (Annex V, 6.1). This means that the type examination certificate must be reviewed at the latest six months before it expires, albeit in a simplified review procedure, even if no changes have been made to the approved type or state-of-the-art (Annex V No. 7). The costs for the simplified review procedure must be reasonable.

5. „Technical documentation" now for all PPE categories

Based on the justification "to increase the efficiency of market monitoring it is necessary to extend the obligation to compile complete technical documentation to all PPE" the requirements for "technical documentation" have been significantly extended and stated more precisely. "Technical documentation" must now comply with Annex III, Art. 8 (2). What is new is that the scope now also applies to Category I personal protective equipment, i.e. to all categories of PPE. For the manufacturer this means a considerable amount of extra administrative work for Category I products.

6. Appeal against decision of notified bodies

Art. 33 of the PPE regulation stipulates that the notified bodies must ensure that a transparent and accessible appeal procedure against their decisions is available. However, this "right of appeal" is not an opposition proceeding under public law, which would allow a complaint under administrative law on rejection of the opposition. In fact, Art. 33 can only be understood as an obligation to establish the notified body's own complaints office. Disputes will be dealt with on the basis of an existing test contract exclusively under civil law.

7. Notified bodies are required to cooperate in standardisation and in the coordination group

Previously participation of notified bodies in standards work was voluntary. Participation in horizontal and vertical European coordination groups was previously also simply a criterion for approval as a notified body. The new PPE regulation requires notified bodies to collaborate in these committees. The horizontal and vertical coordination groups are intended to ensure that economic operators are treated equally and that there is a standardised technical application of the conformity assessment procedure (Art. 24 (11)).

8. Certain product groups are assigned to category III

Product groups to protect against:

a) substances and compounds injurious to health;
c) harmful biological agents;
i) drowning;
j) lacerations caused by manually operated chain saws;
k) high pressure jets;
l) bullet or stab wounds;

m) harmful noise
have now been added to Category III PPE. This means that some product groups have been re-assigned from Category II to Category III. This re-assignment underlines clearly that chemical protection belongs to Category III (Annex I).

9. Extension and clarification of the requirements for manufacturer's instructions and information

A new requirement is that the manufacturer's instructions and information must be added to the EU declaration of conformity. Alternatively, this can be provided via a URL contained in the manufacturer's instructions and information giving access to the EU declaration of conformity. The requirement that the manufacturer now has to state which risks the PPE is intended to protect against, is also new. With the addition of the words "where necessary" for Accessories [c)], Level of risk [d)], Obsolescence [e)] and Type of packaging suitable for transport [f)] it has been made clear that this information is not mandatory in every case (Annex II, 1.4).

10. Clarification of the requirement of „PPE subject to ageing"

The requirements for "PPE subject to ageing" have not been changed with regard to content but the formulation is more precise and clearer. It is now clear that every item of PPE must be marked indelibly with the date of production and/or date of obsolescence as soon as it becomes known that the performance of new PPE is significantly impaired by ageing. In the event that the manufacturer is not able to given precise details on the service life of the PPE, he must include all useful details in the manufacturer's instructions and information that enable the user to determine the date of obsolescence with due consideration for storage, use, cleaning, servicing and maintenance (Annex II 2.4).

11. Change of the requirements „PPE capable of signalling the user's presence visually" (warning)

Apart from the fact that clothing intended for private use with fashionable or decorative fluorescent or reflective elements does not come under the scope of the new PPE regulation, the limitation of protection through warning contained in the basic requirements was lifted for clothing only. Reflective or fluorescent accessories, such as slap wraps or dangle tags, are now covered by the basic requirements (Annex II 2.13.).

12. Basic requirements for protective clothing with removable protectors

Another change is that Clause 1.3.4 in Annex II has now been included in the basic requirements. Previously only the protectors were evaluated. Now protectors are evaluated together with the relevant clothing. This is intended to ensure that protectors cannot slip in the event of an accident.

13. Conformity assessment modules:

With the transposition of Decision 768/2008/EC into a "New Legal Framework" the conformity assessment modules for product approval have also been categorised and standardised. For Cat. I PPE an "internal production control" in accordance with Module A (Annex IV) must be carried out. Cat. II PPE requires EU type-examination (Module B Annex V) and subsequently confirmation of conformity to type based on "internal production control" (Module C Annex VI). Cat. III PSE requires, in addition to EU type-examination (Module B Annex V), either conformity to type based on "internal production control plus supervised product checks at random intervals" (Module C2 Annex VII) or conformity to type based on quality assurance of the production process (Module D Annex VIII).

14. Transitional provisions

The Regulation (EU) 2016/425 on personal protective equipment and to repeal Directive 89/686/EEC was published in the Official Journal of the European Union on 31 March 2016. Despite Directive 89/686/EEC being repealed with effect from 21 April 2018, Art. 47 allows manufacturers or importers to place PPE products on the market for another year until 21 April 2019, i.e. they can still sell PPE products for the first time to another economic operator. PPE placed on the market until the cut-off date of 21 April 2019 may not be impeded by Member States when it is placed on the market. This means that PPE placed on the market before 21 April 2019 by another economic operator (the distributor, for example, or the textile service company) may be purchased/delivered even if the PPE regulation has become legally valid in the meantime (21 April 2018).

Art. 47 (2) also regulates the validity of the EU type-examination certificates that have been issued on the basis of the Directive or are still issued until 21 April 2018. These are valid until 21 April 2023 maximum if they have been issued for an unlimited period. EU type-examination certificates that have limited validity will become invalid when they reach their expiry date. Art. 47. (2) is intended to relieve the burden on the manufacturer: If he is in possession of a valid type-examination certificate issued on the basis of Directive 89/686/EC on 21 April 2019, he can place the products on the market until 21 April 2023 at the latest, if at the same time he submits a new declaration of conformity and identification of the products in accordance with the PPE regulation.

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