LEGAL INFORMATIVE NEWSLETTER

No. 4 September 2016

We are pleased to provide you with the new issue of our legal information newsletter.

Topical legal questions are discussed and those related to issues that you might encounter.

We hope that you will find it of interest. We would welcome any comment you might have.

THE PERSONAL PROTECTIVE EQUIPMENT - P.P.E. REGULATORY FRAMEWORK AND THE NEW P.P.E. REGULATION (E.U.) 2016/425

INTRODUCTION - Personal protective equipment (PPE) are products that the user can wear or hold, in order to be protected against hazards either at home, at work or whilst engaging in leisure activities. Statistics on fatal and major work accidents underline the importance of protection and prevention, for which personal protective equipment plays an important role.

The European Union has issued a number of Directives to improve health and safety at work and to ensure high quality PPE.

LEGISLATIVE FRAMEWORK - The PPE Directive 89/686/EEC covers the manufacture and marketing of personal protective equipment. It defines legal obligations to ensure that PPE on the European market provides the highest level of protection against hazards. The CE marking affixed to PPE provides evidence of this protection.

As this is a 'New Approach' Directive, manufacturers or their authorised representative in the EU can comply with the technical requirements directly or with European Harmonised Standards. The latter provides a presumption of conformity to the essential health and safety requirements. The PPE guidelines aim to facilitate a common interpretation and application of the PPE Directive. It should be noted however that only the national transposition of the Directive is legally binding.

THE NEW REGULATION (EU) 2016/425 - As of 21 April 2018, Directive 89/686/EEC will be repealed by the new Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

The new PPE Regulation is aligned to the New Legislative Framework policy. In addition it slightly modifies the scope and the risk categorisation of products. It also clarifies the documentary obligations of economic operators.

This Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) which is to be made available on the market, in order to ensure protection of the health and safety of users and establish rules on the free movement of PPE in the Union.

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SCOPE – The Regulation applies to PPEs, unless they are:

(a) specifically designed for use by the armed forces or in the maintenance of law and order;

(b) designed to be used for self-defence, with the exception of PPE intended for sporting activities;

(c) designed for private use to protect against atmospheric conditions that are not of an extreme nature, damp and water during dishwashing;

(d) for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;

(e) for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds.

MARKET AVAILABILITY - PPE shall only be made available on the market if, where properly maintained and used for its intended purpose, it complies with this Regulation and does not endanger the health or safety of persons, domestic animals or property.

Essential health and safety requirements

PPE shall meet the essential health and safety requirements set out in Annex II of the Regulation, which apply to it.

MANUFACTURERS OBLIGATIONS – When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements.

Manufacturers shall draw up the technical documentation referred to in Annex III of the Regulation ('technical documentation') and carry out the applicable conformity assessment procedure or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity and affix the CE marking.

Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market.

Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, 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.

Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.

Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE. The address shall indicate a single point at which

the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of the Regulation Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

The manufacturer shall either provide the EU declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of the Regulation Annex II at the internet address at which the EU declaration of conformity can be accessed.

Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

AUTHORISED REPRESENTATIVES – A manufacturer may, by a written mandate, appoint an authorised representative.

The obligation to draw up the technical documentation shall not form part of the authorised representative's mandate.

An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for 10 years after the PPE has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

IMPORTERS – Importers shall place only compliant PPE on the market. Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in the Regulation has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in the Regulation.

Where an importer considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not place it on the market until it has been brought into conformity. Furthermore,

where the PPE presents a risk, 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 or, where that is not possible, on its packaging or in a document accompanying the PPE. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

Importers shall ensure that the PPE is accompanied by the instructions and information set out in the Regulation Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

DISTRIBUTORS - When making PPE available on the market, distributors shall act with due care in relation to the requirements of the Regulation.

Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required documents and by the instructions and information set out in the Regulation and that the manufacturer and the importer have complied with the requirements there in set out.

Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Distributors shall ensure that, while PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

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 make sure that the corrective measures necessary to bring it into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where the PPE presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have made available on the market.

CONFORMITY OF THE PPE - PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in the Regulation Annex II covered by those standards or parts thereof.

DECLARATION OF CONFORMITY – The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in the Regulation Annex II has been demonstrated.

The EU declaration of conformity shall have the model structure set out in the Regulation Annex IX, shall contain the elements specified in the relevant modules set out in Annexes IV, VI, VII and VIII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is placed or made available on the market.

By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the PPE with the requirements laid down in this Regulation.

THE CE MARKING – The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE.

The CE marking shall be affixed before the PPE is placed on the market.

For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure set out in Annex VII or VIII.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.

CONFORMITY ASSESSMENT - The PPE shall be classified according to the risk categories set out in the Regulation, Annex I.

The conformity assessment procedures to be followed for each of the risk categories set out in Annex I are as follows:

(a) Category I: internal production control (module A) set out in Annex IV;

(b) Category II: EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C) set out in Annex VI;

(c) Category III: EU type-examination (module B) set out in Annex V, and either of the following:

(i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII;

(ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

By way of derogation, for PPE produced as a single unit to fit an individual user and classified according to Category III, the procedure referred to in point (b) may be followed.

Procedure at national level for dealing with PPE presenting a risk

Where the market surveillance authorities of one Member State have sufficient reason to believe that PPE covered by the Regulation presents a risk to the health or safety of persons, they shall carry out an evaluation in relation to the PPE concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation the market surveillance authorities find that the PPE does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the PPE into compliance with those requirements, to withdraw the PPE from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

The economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE concerned that it has made available on the market throughout the Union.

Where the relevant economic operator does not take prompt adequate corrective action, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the PPE being made available on their national market, to withdraw the PPE from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

The information shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, the origin of the PPE, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the PPE to meet requirements relating to the health or safety of persons; or

(b) shortcomings in the harmonised standards conferring a presumption of conformity.