



Personal Protective Equipment
Horizontal Committee of Notified Bodies Coordination Group

To the European Commission,
Manufacturers
& Other Stakeholders

Subject: Information for users

With the publication of the PPE Regulations Guidelines version 3, the guidance relevant to user information was revised to:

“The manufacturer has the obligation to provide his instructions and information to the users with each unit of PPE placed on the market (see also section 3.1. “Article 8 on Obligations of manufacturers” and section § 3.1. “Manufacturers” of “The ‘Blue Guide’ on the implementation of EU product rules”).” – pages 98 & 99 of PPE Regulation (EU) 2016/425 Guidelines 3rd edition.

We understand that the change was to remove ‘paper’ from the PPE Regulation Guidelines as this text already appeared in the Blue Guide, while ‘paper’ specifically does not appear in the PPE Regulation (EU) 2016/425. The ‘Blue Guide’ states the following:

“Unless otherwise specified in specific legislation, whilst the safety information needs to be provided on paper, it is not required that all the set of instructions is also provided on paper but they can also be on electronic or other data storage format or even a website. Where this is the case, the full set of instructions must remain accessible for a reasonable period after the product was placed on the market depending on the intended use of the product. However, a paper version should always be available free of charge for the consumers who request it. The manufacturer must take account of the intended use and end users of the product when deciding the specific format for the instructions and safety information” – Citation 114 of C 247/36

(EU) 2016/425 is safety legislation, and Annex II details the Essential Health and Safety Requirements. Amongst these requirements, item 1.4 addresses the information to be supplied with the PPE which will include safety information. The PPE legislation does not specify an ability to provide safety information on a website.

(EU) 2016/425, Annex II, 1.4 states:

“...instructions that must be supplied with the PPE...”, and also:

“(l) the internet address where the EU declaration of conformity can be accessed.”, and also:

“The information referred to in points [...] (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.”.

As a principle of good law writing, usage of a word shall be under a single definition, and where no definition is provided ‘common usage definition’ should be used. We understand ‘supplied’ to mean physically provided to the user or other economic operator, as where this word is used it is most often in reference to the physical PPE. We understand ‘accompanied’ to mean together with.

The HCNB participants are aware of developments within the European Safety Federation (ESF) to develop guidelines with the hope of adoption at a legislative level for online provision of user information inclusive of safety information. We support their work, and will participate in developing a practical and harmonised approach to notified body conformity assessment of online user information over the coming months to differentiate between safety and other user information.

For the intervening period, in recognition of manufacturer concerns over delays in delivery of new and renewal certification, and the potential for delay a change in process will create - the Notified Bodies shall retain established practice of requiring physical copies of safety information to be supplied with the PPE.

Therefore, the attendees of the 44th meeting of the Horizontal Committee of Notified Bodies request that no manufacturer ceases to provide physical safety information until such a time as a common practice is established to assess online safety information.

Yours respectfully,



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