PPE manufacturer's instructions and information : Good practice guidance (digital and printed form)

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Preliminary notes

This good practice guide has been prepared by the secretariat and members of the European Safety Federation. Other stakeholders, such as concerned authorities, notified bodies and other trade organisations have been consulted, e.g. during a workshop organised on 19/02/2024.

The authors have prepared the document to the best of their knowledge and in good faith. The authors and/or their organisation or company cannot be held responsible if other interpretations than those reflected in the document are applied.
This document is under no circumstances legally binding.

While the term used in the legislation is “manufacturer’s instructions and information”, in practice this is often referred to as “user instructions (UI)” or “instructions for the user (IFU)”. In this document we use the term as used in the legislation (e.g. in the PPE Regulation).

Introduction

The purpose of this good practice guide is to **provide a common understanding** for manufacturers and all stakeholders, related to the manufacturer’s instructions and information **when provided in digital format**.

The PPE Regulation (EU) 2016/425[1] defines the requirements that must be met by the economic operators. Specifically, the obligations on the instructions and information, are included in article 8.7 (manufacturer), 10.4 (importer) and 11.2 (distributor). Requirements concerning the content are mainly included in Annex II point 1.4, completed with further requirements for specific cases throughout Annex II. The manufacturer has the sole and ultimate responsibility for the conformity of his PPE (including instructions and information), within the limits described further in this document (e.g. 1.1). **The Regulation does not specify that the manufacturer’s instructions and information need to be printed**.

Further information on the above mentioned parts of the Regulation is available in the relevant paragraphs of the PPE Regulation Guidelines (currently 3rd edition – October 2023)[2].

In paragraph 11.6. of the **PPE Regulation Guidelines there is no longer a mentioning of paper or printed format for the instructions** and information, as was the case in previous editions. Reference is made to section 3.1 of the **Blue Guide**[3] which in footnote 114 mentions the **possibility to provide the information on “electronic or other data storage format or even a website”**. However, the Blue Guide refers to **“safety information”** as included in a number of specific product legislative acts. For safety information the obligation to provide this **in printed format** is mentioned. It has to be remarked that the notion ‘safety information’ is not included in the PPE Regulation.

Concerning the manufacturer’s instructions and information, the PPE Regulation does not make the distinction between PPE destined for professional or private (consumer) use, nor

[1] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425
[2] PPE Regulation Guidelines - Guide to application of Regulation EU 2016/425 on personal protective equipment 3rd edition - https://ec.europa.eu/docsroom/documents/56514
[3] The ‘Blue Guide’ on the implementation of EU product rules (edition June 2022) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

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between the 3 risk categories for PPE. Therefore, this good practice guidance does not make these distinctions either. However, it has to be remarked that for professional use, the obligations as set out in Directive 89/656/EEC[4] concerning the use of PPE, remain applicable.

It has to be mentioned that manufacturers need to adopt the principles and legal acts related to the twin transition, meaning both “the European Green Deal” and “A Europe fit for the digital age”.

1. Requirements for manufacturer’s instructions and information for PPE

This section is applicable to **both digital and printed format**.

1.1. General

This section is not intended to be exhaustive, as both the PPE Regulation and the PPE guidelines already provide requirements and guidance. A number of key points are highlighted here to clarify the importance, whatever the format is.

There is **no difference in requirements** related to the content **between digital or printed** manufacturer’s instructions and information. If the instructions and information exist in both formats, both shall have the same information as required by the PPE Regulation and approved by the Notified Body.

The requirements for the marking of the PPE remains unchanged. These shall not be replaced by e-labelling. The marking needs to be explained in the manufacturer’s instructions and information, as per the requirement of annex II 1.4. (g) of the PPE Regulation.

The manufacturer’ instructions and information (in one language acceptable for type examination purposes) shall be approved by the Notified Body responsible for the EU Type Examination (module B – not applicable for category I PPE). Any change to the content of the instructions and information shall be approved by the same Notified Body.

For clarity, the use of pictograms, symbols and graphics, should be considered as much as possible.

The responsibilities of the manufacturer apply also to a natural or legal person or another economic operator who assembles, packs or labels ready-made PPE and places them on the market under his own trademark.

For traceability reasons, **a version reference or date shall be included** in the instructions and information.

[4] Council Directive of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (89/656/EEC) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01989L0656-20191120&qid=1706267649778

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The PPE Regulation also requires the manufacturer to provide the Declaration of Conformity with the PPE. This can be through different means, in either printed or digital form.

1.2. Language

The manufacturer's instructions and information **shall be available at least in the official language of the Member States** where the product is sold. In Member States with more than one official language, the national legislation on language availability needs to be complied with.

The **manufacturer is responsible** to make the relevant translations and make the languages available. Both importer and distributor have a duty of care to check the availability of the necessary language(s) and have to act when necessary. This means, request the missing language versions from the manufacturer.

1.3. Availability

The manufacturer's instructions and information **shall accompany each single individual PPE, or at least the smallest commercial packaging** (including bulk packaging) of the PPE. This is valid for both digital and printed versions.

Whatever the format, the manufacturer's instructions and information, shall remain available for the foreseeable lifetime of the PPE and for at least 10 years after the placing on the market[5].

The manufacturer's instructions and information should be easily readable, e.g. font size, font type, contrast between background and text, colour of text have an influence on the readability, not only in printed format, but also when consulted on a screen.

1.4. Choice of format

It is the sole **responsibility of the manufacturer to choose the format (printed and/or digital**) for his instructions and information. The choice must be made taking into account the foreseeable use and/or users, as well as the technological evolution.

2. Additional guidance for digital manufacturer's instructions and information

2.1. The link to digital instructions and information and how it relates to the product

When the manufacturer's instructions and information are provided in **digital format**, the manufacturer **shall mark this clearly on the PPE itself or**, where this is not possible in view of the characteristics of the product, **on its smallest commercial packaging**. The operating instructions pictogram (ISO 7000-1641)[6] can be useful to indicate the link to the instructions.

[5] Inspired by the conditions for digital instructions as foreseen in the Machinery Regulation (EU)2023/1230
[6] See https://www.iso.org/obp/ui/#iso:grs:7000:1641

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The mode to access the digital user instruction shall be widely applicable.

Impractical or outdated mediums to store digital instructions and information, such as e.g. Floppy Disks, CD-ROM, are not acceptable forms, as access to the instructions and information needs to be readily available.

A link easily leading to the relevant internet page shall be provided, such that it can be read by the foreseeable users and other relevant parties as defined in the PPE Regulation on their common devices (personal computer, smartphone, tablet).

In 2024, a Data Matrix Code (i.e. a QR Code) can be a tool to lead to the relevant internet page.

The Data **Matrix Codes and/or the link shall be on the product itself, on a label attached to the product or on the smallest packaging**, following the requirements on marking of the PPE Regulation. However, it should be avoided by all stakeholders to put stickers over existing QR codes or links.

Providing both a QR code and a link, means that the manufacturer's instructions and information are accessible by scanning with a smartphone/tablet and by typing the link on a PC.

They also need to be visible and readable for all the foreseeable life time of the products, this means that, for example if a QR Code is on a product or a label, it should be legible at all times, meaning, it also needs to be proven durable as per the care or cleaning procedures prescribed by the manufacturer.

2.2. Access and legibility

Digital manufacturer's instructions and information **need to be easily available** for the end user in the applicable language[7] (e.g. foresee a language choice option).

The manufacturer shall **guarantee access at all times**. This means that the website needs to support high volume visits, in line with the foreseeable demand. In the event of peaks that may occur during an extraordinary event (e.g. health crisis, wildfire, earthquake, …), the manufacturer shall act as soon as possible to support the access for the increased volume.

No barrier (such as compulsory registration) shall be required to access it.

The manufacturer should provide his instructions and information in such a way that they are easily readable on different devices (smartphone, laptop, tablet, etc.). There must be download options to make them easily accessible offline.

The documents shall also be easily printable (e.g. not locked pdf document) and readable in the printed form.

The delivery formats have to be updated/evaluated to coincide and follow technological developments.

[7] See 1.2. of this good practice document

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It has to comply with any local accessibility or disability equality laws.

2.3. Printed version

At the request of the user at the time of the purchase, **the manufacturer shall provide** his instructions and information in **paper format free of charge** within one month[8]. This can be limited to the language version(s) requested and can be organized at the point of sales or through a simple request to the concerned manufacturer.

2.4. Availability of instructions and information

The manufacturer needs to ensure that the correct and applicable instructions and information are available and downloadable with the product, even if e.g. a website is renewed.

Effective systems and procedures shall be in place to ensure that users can be informed in case of updates or corrective actions with regard to those instructions and information.

The website where the instructions and information are made available must be protected against unauthorized access and tampering of the content.

To ensure that the user can make a reasoned selection of the correct PPE for the intended activity, the digital manufacturer's instructions and information, including the Declaration of Conformity, should be made available preferably prior to the purchase,. This is particularly helpful when the PPE is sold online.

3. Marking

3.1 General requirements

Generally, the **marking information is not impacted by the digital manufacturer's instructions** and information, but rather by the requirements included in the PPE Regulation and in specific standards.

As a general rule, marking is printed on or affixed to the PPE itself. In cases where the size or nature of the PPE does not allow this, exceptions are foreseen for the required marking to be provided on the packaging or in a printed document accompanying the PPE.

The marking or labelling require the following elements:

- CE marking;
- Name, registered trade name or registered trade mark of the manufacturer, including address;
- If applicable, name, registered trade name or registered trade mark of the importer; including address;
- Type, batch or serial number or other element allowing identification of the product;

[8] Inspired by the conditions for digital instructions as foreseen in the Machinery Regulation (EU)2023/1230

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- If applicable, batch, serial number, date of manufacture or date of obsolescence;
- Size designation;
- Identification of the specific applied product standard(s), including pictograms and levels of performance, if so required by the PPE Regulation (and then normally included in concerned product standards).
  e.g. PPE Regulation Annex II
  - 3.5, each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE;
  - 3.8.1, protection class or corresponding operating voltage;
  - 3.10.1, time limit for the storage of new filters
- Care labelling and/or qualification labelling, if required;
- Specific warning statements, such as risk for entanglement or snagging, typically required by the applied product standards (when PPE Regulation Annex II, 2.5 cannot be met).

3.2 Digital manufacturer's instructions and information

The link (whether QR code and/or weblink) **to the digital manufacturer's instructions and information shall be part of the labelling or marking** and should meet the same requirements, including for durability and readability.

4. Safety information

Even while the Blue Guide refers to the need to provide **"safety information"** in printed format, there is no definition nor in the Blue Guide, nor in any EU harmonised legislative act or guidance. In any case, the **PPE Regulation does not refer to safety information** but only to manufacturer's instructions and information. Therefore, this requirement needs to be inferred based on the General Product Safety Regulation (GPSR) (EU) 2023/988[9] and other directives and regulations where the terms have been used[10].

The GPSR requires that, **if the product** by itself under normal/reasonably foreseeable use could **present any new risk for the user**, safety information should be provided in a printed form on the product or in the accompanying documents (see previous paragraph 3).

This means for PPE, that the possible **new risks** related to the use of the PPE should be considered **independently from the protection** it is supposed to provide. Annex II point 1.2. of the PPE Regulation requires innocuousness (absence of risks and inherent nuisance factors, suitable materials, satisfactory surface condition), meaning that in principle, there should not be possible risks that lead to the need to provide safety instructions.

[9] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.135.01.0001.01.ENG&toc=OJ%3AL%3A2023%3A135%3ATOC

[10] See appendix 1 to this good practice guidance

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Not providing appropriate protection in case of incorrect use (including care and maintenance) is not to be considered a risk caused by the PPE as the risk is pre-existing, independent of the use or non-use of the PPE.

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