

POSITION PAPER OF TEKOM EUROPE ON THE EC GUIDE TO APPLICATION OF THE MACHINERY REGULATION (EU) 2023/1230

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Contribution to the work of European Commission's Expert Group on Machinery (E03676) in charge of preparing the EC Guide to application of the Machinery Regulation (EU) 2023/1230

The European Association for Technical Communication – tekom Europe wants to contribute to the preparation of the EC Guide to application of the Machinery Regulation (EU) 2023/1230 (hereinafter referred to as "EC Guide"). We advocate for instructions for use that provide information tailored to the needs of target audiences, so that machinery and related products are used safely, securely, efficiently, and in a sustainable way.

We want to propose some clarifications to the EC Guide to make the interpretation of provisions in Machinery Regulation 2023/1230 more unambiguous and therefore easier to apply for machinery manufacturers, their suppliers, and other parties involved in the application of the Machinery Regulation.

We propose

- for the definition of instructions for use: explanations regarding the importance of the risk assessment, supporting standards as technical guidance, the relation between instructions for use and safety information
- to reference EN IEC IEEE 82079-1:2020 "Preparation of information for use (instructions for use) of products - Part 1: Principles and general requirements" for technical guidance as in previous editions of the EC Guide
- for Article 10 (7) regarding instructions in digital formats provided on a website: clarification that the information on how to access the instructions and how to navigate is part of the instructions and information accompanying the machinery or related products
- for Article 10 (7): more detailed guidance and criteria to elaborate essential safety information to be provided in paper format, in a gradual approach depending on the risk
- for Article 10 (7): to recommend the Identification Link (IL) according to EN IEC 61406-1:2022 for the unambiguous identification of digital information

With around 9,500 members, tekom Europe represents the creators of information products which are necessary for the safe, efficient, effective, and sustainable use of products¹. Technical communicators are in charge of preparation of instructions for use, technical files, and technical documentation and are one of the most concerned parties in the application of Machinery Regulation 2023/1230.

For more detailed argumentation, see the full text below.

Introduction

Machinery Regulation (EU) 2023/1230 sets provisions for instructions for use (the term “instructions for use” also comprises assembly, installation, and connection instructions) and technical documentation in various articles and three annexes:

- Article 3 Definitions
- Article 10 Obligations of manufacturers of machinery and related products
- Article 11 Obligations of manufacturers of partly completed machinery
- Article 13 Obligations of importers of machinery and related products
- Article 14 Obligations of importers of partly completed machinery
- Article 15 Obligations of distributors of machinery and related products
- Article 16 Obligations of distributors of partly completed machinery
- ANNEX III ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY OR RELATED PRODUCTS
- ANNEX IV TECHNICAL DOCUMENTATION
- ANNEX XI ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY

Article 10 “Obligations of manufacturers of machinery and related products” is the backbone of obligations dealing with instructions for use and obligations dealing with partly completed machinery, and those dealing with obligations of the importer or distributor are based on these. Consequently, the focus of the following comments is based on Article 10, and we recommend adapting the text for the other articles accordingly.

However, Article 3 needs to be addressed with its definition of instructions for use.

Article 3 Definitions

(17) ‘instructions for use’ means the information, provided by the manufacturer when the machinery or related product is placed on the market or put into service, to inform the user of the machinery or related product, of the intended and proper use of that machinery or related product, as well as information on any precautions to be taken when using or installing the machinery or related product, including information on the safety aspects, and on how to keep that machinery or related product safe, and to ensure that it remains fit for purpose during its entire lifetime;

tekom Europe wants to highlight that the definition of instructions for use includes the following aspects and should therefore be integrated in the EC Guide:

- **Entire lifetime as extended consideration:** The definition of instructions for use extends the scope of consideration to the entire lifetime of the machinery and related product. Thus, it also requires information for safe use, for example, in relation to repair, refurbishment, upgrades, and recycling as far as applicable.

- **Safety information as subset of instructions for use:** The definition of instructions for use covers safety information that is essential for putting the machinery or related product into service and for using it in a safe way as addressed in §10 (7). This safety information is a subset of the instructions for use.
- **Instructions for use based on risk assessment:** Instructions for use related to safety of the machinery or related product shall be based on the risk assessment.
- **Standards are useful technical guidance for instructions for use:** General guidance on the drafting of instructions for use is given in standards EN ISO 12100¹ and EN ISO 20607². Although it is not a harmonized standard under the Machinery Regulation, the guidance given in standard EN IEC/IEEE 82079-1³ on preparing information for use including principles, information management process, content, structure, format, and media of information for use is also useful for instructions for use of machinery or related products. It supports, for example, the implementation of the uncertain legal term “clear, understandable and legible” as required by the MR.

Article 10 Obligations of manufacturers of machinery or related products

7. Manufacturers shall ensure that the machinery or related products are accompanied by the instructions for use and the information set out in Annex III.
The instructions may be provided in a digital format. Such instructions and information shall clearly describe the product model to which they correspond.

tekom Europe wants to highlight in the EC Guide that:

- **Information set out in Annex III covers more than safety-related details.** It refers to general principles of essential health and safety requirements and includes for example instructions for use, markings, and safety-related information such as warnings.
- **Regarding digital formats:** The decision on formats for instructions for use shall be based on the risk assessment to ensure that the required information, whether digital or not, is accessible for the user or other target audiences.
If instructions in digital formats are provided on a website, the information, including navigation and how to access the instructions, is part of the information accompanying the machinery or related products. This information shall therefore be subject to the risk assessment and conformity assessment to ensure it is “clear, understandable and legible” as required.

¹ EN ISO 12100 Safety of machinery - General principles for design - Risk assessment and risk reduction

² EN ISO 20607 Safety of machinery - Instruction handbook - General drafting principles

³ EN IEC/IEEE 82079-1 Preparation of information for use (instructions for use) of products - Part 1: Principles and general requirements

- **For the identification of instructions in a digital format, the Identification Link is useful.** For an unambiguous identification of digital instructions, a direct link is provided by the unique Identification Link (IL) according to EN IEC 61406-1:2022.⁴

When the instructions for use are provided in digital format, the manufacturer shall:

- a) mark on the machinery or related product, or, where that is not possible, on its packaging or in an accompanying document, how to access the digital instructions;
- b) present them in a format that makes it possible for the user to print and download the instructions for use and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machinery or related product; this requirement also applies where the instructions for use are embedded in the software of the machinery or related product;
- c) make them accessible online during the expected lifetime of the machinery or related product and for at least 10 years after the placing on the market of the machinery or related product.

However, at the request of the user at the time of the purchase, the manufacturer shall provide the instructions for use in paper format free of charge within one month.

tekom Europe wants to highlight in the EC Guide that:

- **Indent (a) deals with the way in which digital instructions can be accessed.** Therefore, this information, whether it is a website with or without navigation, must also be “clear, understandable and legible” and subject to the risk assessment and conformity assessment.
- **Indent (b) refers to downloadable and printable digital instructions,** which means, for example, PDF, PNG, SVG, or HTML. In addition, video and audio can also be helpful in enhancing safety; however, formats such as MP4 or AVI do not meet the legal requirements for printability.
- **The request for instructions for use in paper format is not only for users.** From the perspective of the manufacturer, it appears to be the most logical interpretation that the legal person who purchases in his/her own name shall have the right to request delivery of the instructions for use in paper format.
- **One-month period** to provide the instructions for use upon request starts with the availability of the instructions for use upon delivery of the machinery. This is important to mention. In industrial machinery projects in particular, the instructions may not be available until months or even years after the purchase agreement has been signed, because the design and construction process starts after the purchase.

⁴ EN IEC 61406-1 Identification Link - Part 1: General requirements

In the case of machinery or a related product intended for non-professional users or that can, under reasonably foreseeable conditions, be used by non-professional users, even if not intended for them, the manufacturer shall provide, in paper format, the safety information that is essential for putting the machinery or related product into service and for using it in a safe way.

tekom Europe wants to emphasize in the EC Guide that

- **The share of non-professional users should be above 10% to be relevant.** If the manufacturer intends to sell the machinery to non-professional users, the instructions for use cannot be provided as they would be to professional users. The decision on whether the restrictions set forth in Article 10 (7) 4th paragraph do apply does not only depend on the intentions of the manufacturer. As is common in product safety law, the intentions may be overruled by the facts in the sense that the reality of machinery use in the market regarding the user target audience may differ from the manufacturer's intention. This may give reasons to state that the machinery is in fact machinery for non-professional users, although the manufacturer designed it for professional users. This may be due to some sort of migration of the machinery from a professional market to the consumer market and non-professional users. If, for example, the machinery is marketed via online platforms, which are freely accessible to non-professional users, that manufacturer must acknowledge that its machinery is aimed at non-professional users. However, facts indicating distribution to non-professional users will have to be of some significance; an individual, single instance in which machinery is sold to a non-professional user will most likely not be deemed relevant. In similar cases, market surveillance authorities consider a product to be a "consumer product" when sales to consumers exceed 10% of the total quantity.
- **More guidance is needed for safety information in paper format for non-professional users with a gradual approach depending on the risk.** Manufacturers and others need some guidance to separate essential safety information from other content of the instructions for use of machinery or related products used by non-professional users. Essential safety information is required in paper format; other content in, or parts of, the instructions for use can be provided in any format that ensures accessibility. For preparing essential safety information, the life phases "putting into service" and "use" shall be considered. However, other content in the instructions for use may be not relevant for the essential safety information as, for example, the explanation of functionalities, possibilities to expand the machinery or related product by additional accessories not provided with the machinery. The elaboration of essential safety information shall be based on the risk assessment. With the non-professional user in focus, the level of essential safety

information to be provided in paper format varies according to the type of machinery or related product and its intended use. A gradual approach is recommended addressing the corresponding risk. At the lowest level of risk, the essential safety information is the safety-related reference to consider the instructions regarding safety information for putting the machinery into service and using it. At the next levels of risk, essential safety information comprises selected content of the instructions for use of Annex III 1.7.4.2. At the highest level of risk, the essential safety information may comprise all safety-related information of the instructions for use and should therefore be provided in paper format. Information in instructions that relates to non-safety-related activities and functions usually does not need to be printed.

The instructions for use, the safety information and the information set out in Annex III shall be in a language which can be easily understood by users, as determined by the Member State concerned, and shall be clear, understandable and legible.

tekom Europe emphasizes that the implementation of uncertain legal terms needs guidance in the EC Guide to best support manufacturers of machinery or related products.

- EN IEC IEEE 82079-1:2020 provides technical guidance on how to implement uncertain legal terms (as clear, understandable and legible) in a practical manner in instructions for use. This standard, though not harmonized under the Machinery Regulation, should be included in the EC Guide as technical guidance.

The European Association for Technical Communication - tekom Europe e.V. is the largest professional and technical association for technical communication worldwide. It was founded in 2013 and represents around 9,500 members in 11 country organizations and three corporate members. It aims to promote the professional interests of all persons involved in technical communication. Technical communication is the process of defining, creating, and delivering information products of information for use – for the safe, efficient, effective, and sustainable use of products (goods, technical systems, software, and services).

European Association for Technical Communication – tekom Europe e.V.

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Heilbronner Strasse 86

70191 Stuttgart

GERMANY

President: Dr. Tiziana Sicilia

Executive Director: Dr. Michael Fritz

Contact: Dr. Gabriela Fleischer g.fleischer@tekom.org