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The European Machinery Regulation with new requirements for digital instructions for use

With the publication of the Machinery Regulation 2023/1230 in the Official Journal of the European Union on June 29, 2023, the cat is finally out of the bag: From 2027 onward, instructions for use may also be published in digital form within a defined framework. The continuous lobbying of tekomp and industry representatives was successful.¹



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From directive to regulation

The Machinery Regulation will replace the Machinery Directive published in 2006 (Directive 2006/42/EC). The Machinery Directive is based on the principles of the “New Approach” of 1985, which means that the law establishes binding basic requirements for products, and standards specify technical details that are necessary to fulfill the requirements. European directives must be implemented nationally, which leads to divergences in the member states across the EU.

The EU Commission justifies the proposal for a revision of the Machinery

Directive with the following objectives, among others:³

- “Reduce paper-based requirements for documentation”
- “Reduce possible divergences in interpretation derived from transposition”
- “Ensure coherence with other NLF legislation”

The directive therefore became the Machinery Regulation with the option of providing instructions for use in digital form. The EU’s New Legislative Framework (NLF) has been modernizing and supplementing the “New Approach” since 2008 and provides the regulatory framework for European product regulation. It states the following about instructions for use and other information:⁴

Quote: “Article 1 General principles

3. Economic operators shall be responsible for ensuring that all infor-

mation they provide with regard to their products is accurate, complete and in compliance with Community rules applicable.

Article R2 Obligations of manufacturers

7. Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.”

Advantages of digital formats for instructions for use and technical documentation

The effects of greater digitization of instructions for use and technical documentation were outlined in connection with the revision of the Machinery Directive⁵. With regard to financial savings through digital formats, it is assumed that printing costs currently account for 1-4% of companies’ turnover per year. Based on the turnover of EUR 663 billion in the machinery sector in 2017, this would mean annual costs of EUR 6.63 billion to EUR 26.5 billion.

Digital instructions are also preferred by users: according to surveys on preferences for the format, 62.7% of respondents want manuals only in digital form. This means that EUR 4 billion to EUR 16.6 billion

¹ Position paper of the DKE AK 113.0.4 on providing instructions in digital form 2020-04-08 <https://www.technical-communication.org/technical-communication/position-paper-instructions-in-digital-form>

² 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, services <https://www.technical-communication.org/technical-communication/defining-technical-communication>

³ SWD(2021) 83 final COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on machinery products

⁴ DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products

⁵ SWD(2021) 82 final COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the Proposal for a Regulation of the European Parliament and of the Council on machinery products

could be saved annually – based on 82,239 companies, this would lead to EUR 48,000 to EUR 201,000 per company. On the other hand, there are costs for digital instructions for use due to the purchase, installation and maintenance of servers and printing costs for digital instructions for use. If, after purchasing the machinery, the user decides to use the paper version of the instructions for use in one language, the printing costs per manual are assumed to be EUR 0.40.

However, there is no systematic comparison and consideration of the advantages and disadvantages of digital formats and paper formats in terms of user-friendliness – how quickly can I find the relevant information and how specifically has it been created for a target audience in each case – and accessibility – information for use must be accessible to the target audience during the expected lifetime of the machinery (e.g. technically available and legible). The blanket statement that digital formats are “more sustainable” certainly falls short. Digital formats also consume resources and have an “ecological rucksack”, or environmental impact.

Digital formats of information for use are already commonplace in many industries. Above all, the software industry has been working mainly with digitally provided information for use for years. A tekomp survey⁶ conducted back in 2015 revealed that 75% of all software companies surveyed had a print share of less than 25%, measured against the total volume of documentation. In contrast, 50% of the industrial companies surveyed had a print share of 75% or more. The Machinery Regulation will certainly increase the proportion of digital formats for instructions for use.

The Machinery Regulation 2023/1230

With the Machinery Regulation, instructions for use, assembly instructions and technical documentation can also be made available in digital formats from 2027 onward. tekomp has produced a whitepaper⁷ that examines the Machinery Regulation with regard to innovations for instructions for use and technical documentation. The following explanations are selective excerpts from this whitepaper on Articles 3 and 10 of the Machinery Regulation – the whitepaper is more comprehensive.

Article 3 Definitions related to technical communication

Article 3 Definitions contains explanations on “(17) ‘instructions for use’”, “(18) ‘manufacturer’”, “(34) ‘lifetime’” and “(36) ‘professional user’”, whereas the Machinery Directive 2006 only contains definitions for “manufacturer”. The other definitions have been newly included in the Machinery Regulation.

The instructions for use are not regarded as a document, but as the sum of all the information to be provided by the manufacturer. It is noteworthy that the information to be provided on the fitness for purpose of the machinery or the related product relates to the entire lifetime. It is therefore conceivable that the instructions for use must not only contain instructions for “standard” maintenance, but also information for repairs. This extension of the manufacturer’s responsibility is probably due to the “European Green Deal” as a political guideline of the EU Commission and the idea of sustainability.

There is a definition for “professional users”, but not for “non-professional users”.

A look at Article 1 “Subject matter” of the Machinery Regulation can help

to narrow down the term “non-professional user”: This states that it involves “a high level of protection of the health and safety of persons, in particular consumers and professional users”. This indicates that non-professional users are primarily consumers. Manufacturers face the challenge of assessing whether the machines are used by professional or non-professional users – different requirements apply to both user groups with regard to the digital instructions for use. If the “reasonably foreseeable conditions” cover both user groups, the “Guide to the application of the Machinery Regulation” to be drawn up by the European Commission should clarify the extent to which use by non-professional users has an impact on the instructions for use. tekomp suggests „the understanding that a minority of non-professional users should not be sufficient to classify the machinery as intended for ‘non-professional users’.”

The definition of “professional user” means that the user may not be sufficiently skilled, or almost unskilled. However, Annex III, 1.7.4.2 sets out requirements for taking into account the skills of “professional users”, and the regulations on health and safety at work based on Article 153 of the Treaty on the Functioning of the European Union take “professional users” into account. However, this construct does not exist for “non-professional users”. Thus, if the machinery is intended for non-professional operators when drafting the instructions for use, the wording and layout “shall take into account the level of general education and acumen that can reasonably be expected from such operators” in accordance with Annex III, section 1.7.4.1 b).

The tekomp whitepaper therefore states: “If use by non-professional users is unwanted, it must be precluded by suitable measures, such as distribution instructions and paths as well as a clear statement to this effect in the instructions.”

⁶ <https://www.tekom.de/technische-kommunikation-das-fach/wichtige-normen-der-technischen-kommunikation/standard-titel>

⁷ Heuer-James, J.-U., Schmeling, R. (2023) tekomp Whitepaper 2/2023, New Machinery Regulation (EU) 2023/1230 Instructions for Use and Technical Documentation

The term “manufacturer” under the Machinery Regulation also includes manufacturers who produce machinery and related products for their own use.

Article 10 Obligations of manufacturers of machinery and related products

Article 10 sets out in detail the obligations of manufacturers, including those relating to instructions for use – paragraph 7 is particularly noteworthy here. The wording is similar to that in other regulations and directives under the NLF. With the Machinery Regulation, the requirements have been moved from a rather “secret and hidden place” in Annex I, Chapter 1.7.4 of the Machinery Directive to a more prominent place in the main body of the Machinery Regulation. The new position emphasizes the importance of the instructions for use. Any non-compliance with these obligations is considered a formal non-conformity, which allows the market surveillance authorities to take appropriate measures to remedy this formal non-conformity in accordance with Article 46.

Quote, Machinery Regulation 2023/1230

“Article 10 Obligations of manufacturers of machinery and 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.

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.

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.

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.”

The wording “Manufacturers shall ensure that the machinery or related products are accompanied by the instructions for use and the information...” is also found in other directives and regulations under the NLF. For years, it was not clear whether “accompanied by” meant that the instructions had to be provided in paper format. Market surveillance authorities have required the paper format if the applicable EU regulation or directive requires the product

to be “accompanied by” instructions. With the Machinery Regulation, it could now be argued that the “new” understanding of “accompanied” – which now also means instructions for use in digital form – can be generalized and applied to other directives and regulations under the NLF that do not explicitly allow digital formats. This applies, for example, to equipment covered by the Low Voltage Directive, pressure equipment and radio equipment.

With the short sentence “The instructions may be provided in a digital format”, manufacturers are now permitted to use digital formats for instructions for use. However, the wording “digital format” leaves room for interpretation, as it is not defined. It is therefore at the discretion of the economic operators whether the “provision in digital format” takes place through

- Downloading from the internet
- Mass storage device delivered with the product
- Mass storage integrated into the product together with all means needed to display the instructions alongside the product
- Reading device delivered with the product, e.g., a tablet

Also, the type of digital format (HTML, PDF, etc.) to be used has not been defined. However, it must require a clear, understandable, and legible presentation.

Another requirement is that the digital format must allow creating a printed version of the instructions for use.

Quote, Machinery Regulation 2023/1230

“7. ...

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

...

(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”.

The printable instructions for use are the baseline, while non-printable digital formats (such as videos) can enhance and supplement the printable instructions for use.

The requirement “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” appears anachronistic. Here, tekoma Europe “would have preferred it to be up to manufacturers to decide based on their risk assessments whether printed instructions for use are needed on request, e.g., to ensure safety or usability. Instructions for use are a safety-related part of the machinery like any other physical safety-related part. Manufacturers are responsible for deciding on safety-related parts they use in their design. There is no reason why instructions for use should be dealt with in a different way.”

Safety information in paper format

Quote, Machinery Regulation 2023/1230 Article 10

“7. 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.”

For machinery and related products intended for or used by non-professional users, there is a requirement to provide safety information

in paper format. The law leaves a certain amount of room for interpretation here, as the phrase “safety information that... is essential” is not defined. tekoma Europe favors the interpretation that the provision of printed essential safety information or printed instructions for use with reduced content focuses on safe putting into service and use, while other information on maintenance, repair, disposal, etc. could still be provided in digital formats.

The bicycle industry on safety information in paper format and digital instructions for use

Electric bicycles fall within the scope of the Machinery Regulation.

details are to be regarded as “essential safety information” and would have to be provided by the bicycle manufacturer in paper format. To this end, ZIV is liaising with representatives of manufacturers, testing institutes, market surveillance, and tekoma Germany and has drawn up the following proposal presented in Figure 2.

This essential safety information in paper format is part of the instructions for use and must be viewed in conjunction with the other information products of the digital instructions for use.

As soon as this proposal has been consolidated, it will be incorporated into the standardization process and included in the revision of the



Figure 1: Electric bicycle Photo: Gabriela Fleischer/Wotan Chabod

“ZIV – German Bicycle Industry” (ZIV) is planning ahead as to how to implement the requirements for safety information essential for the safe putting into service and use of electric bicycles. In the preliminary work, it is being discussed which

harmonized DIN EN 15194 “Cycles – Electrically power assisted cycles – EPAC Bicycles” so that all interested parties can reach a consensus on essential safety information. As soon as the harmonized standard is published in the Official Journal of

Safety information

This information sheet contains **safety information** that is essential for **putting** the electric bicycle **into service** and **using** it in a safe way.

The safety information is part of the instructions for use. The digital part of the instructions for use can be accessed *[here...]*. / The digital part of the instructions for use can be downloaded *[here...]*.

If required, the printed instructions for use can be ordered *[here...]*.



Warning: Reading the safety information does not release you from the obligation to read and observe the other information in the instructions for use!

Failure to observe the instructions for use can lead to dangerous riding situations, falls, accidents and damage to property.

Putting into service

- Familiarize yourself initially with the driving and braking behavior as well as the level of motor assistance and the start-up assistance (if available), especially with different loads, wet conditions, and loose surfaces.
- Failure to comply with the intended use can result in the failure of components and materials with the risk of accident and injury:
 - Observe the restrictions of the specified classification for bicycle usage/intended area of use/vehicle category.
 - Do not exceed the permissible total weight/total mass/system weight (electric bicycle + rider + payload + trailer if applicable).
 - Observe the manufacturer's specifications for transporting people and loads.
 - Manipulation of the drive system, in particular tampering, is not permitted.
- Observe the manufacturer's specifications for attaching add-on parts (bags, lock, child seat, carrier systems, etc.) and for the use of a trailer.

Use

- Observe the legal regulations applicable in the respective country for use on public roads.
 - Before every journey, check in particular:
 - the correct function of brakes, steering, suspension and lights,
 - the tight fit of handlebars, stem, wheels and pedals and
 - the tire pressure.
- Adjustments and checks must be carried out in accordance with the manufacturer's instructions.
- Check the electric bicycle for possible damage before every ride, in particular to frame, fork, handlebar/stem unit, drive unit and seat post.
- Do not use the electric bicycle if you notice any damage.
- In the event of damage, after a fall or accident, the electric bicycle must be checked by a specialist company before further use.
- Observe the specified torques for the assembly of components.
- Only use batteries and chargers approved by the manufacturer.
- Observe the manufacturer's instructions for charging and using the battery, in particular with regard to ambient temperature and charging location.
- Only use undamaged and unmodified batteries and chargers.
- Be aware of the increased risk of injury due to potentially high temperatures of individual components (e.g. brakes, drive unit, headlight).
- Have the electric bicycle checked regularly by a repair shop in accordance with the manufacturer's specifications and serviced by a specialized company.
- Observe the manufacturer's instructions regarding the transport of the electric bicycle.

Figure 2: ZIV draft content: Essential safety information for electric bicycles in accordance with the Machinery Regulation. Version dated 2024-04-04

the European Union (OJEU), it will provide a presumption of conformity with the Machinery Regulation. It will then be an important aid in deciding what safety information is considered essential, requiring paper format, and what information can be provided in digital format in the instructions for use.

DIN EN IEC/IEEE 82079-1 shows the way

DIN EN IEC/IEEE 82079-1:2021
"Preparation of information for

use (instructions for use) of products – Part 1: Principles and general requirements" is the most important standard for technical communication. It can help with the technical implementation of the Machinery Regulation in many areas. There are the undefined legal terms "clear, understandable and legible", which the Machinery Regulation requires according to Article 10, Paragraph 7 for instructions for use, safety information and information in Annex III "Essential health and safety requirements relating to the design and construction of machinery or related

products". DIN EN IEC/IEEE 82079-1 provides technical implementations for these undefined legal terms in the principles clause, which are also underpinned with further provisions in the clauses Information Management Process, Content, Structure, Media and Presentation of Information for Use and in Professional Competences.

For the "clearly described product model" required in Article 10, Paragraph 7, the standard provides assistance in clause 7.2 „Identifiers“.

The standard provides a pictogram in clause 7.3, Figure 2, for the labeling required by Article 10 on how to access the digital information for use.

The standard is currently being revised internationally, and an important task of the revision is to take even greater account of digital formats for information products for information for use. The aim is to ensure that these can be used in the best possible way to ensure the safe, efficient, effective and sustainable use of products. To this end, the 3rd edition of the standard will address, for example, further provisions on display on screens, structure and navigation in new media and instructional videos.



Figure 3: IEC/IEEE 82079-1 is the most important standard for technical communication
Photo: Gabriela Fleischer

Outlook

Digital formats for information products of information for use are in vogue. They also offer significant advantages for the machinery sector, especially in terms of the user-friendliness of instructions for use, if the information on safe use is prepared in a way that is appropriate for the target audience and good navigation enables quick access.

The decision as to whether paper or digital formats for instructions for use are suitable for the safe use of machinery should also be measured in legislation against how barrier-free access is ensured for all target audiences of the instructions for use and how user-friendly preparation is achieved so that the information is clear, understandable and, where applicable, legible. Only then can the instructions for use fulfill their purpose.

Developments such as the “digital twin” and the “digital product passport” require that information products of information for use are available in digital formats. In the case of the digital twin, this is needed so that the necessary information for use can be called up in the relevant context via links when navigating through the twin. The digital product passport is already in a digital format. IEC PAS 63485:2023 “Intelligent Information Request and Delivery Specification (iIRDS) – A process model for information architecture” opens doors to the digital world for the provision of digital formats of information for use.

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