

# Exemplary regulatory overview & recommendations

## Recommended wording for a relevant provision in a future Omnibus-Regulation

Based on the existing phrasing in the respective product-related harmonisation legislation, the following wording can be used across all legal acts instead of the current wording (see *exemplary overview below*) to enable digital provision of information for use.

Manufacturers\* shall ensure that the *scope/product group* is accompanied by the instructions and safety information or, alternatively, manufacturers\* shall provide the internet address or machine-readable code where the instructions and safety information can be accessed.

Digital instructions and safety information shall be made accessible online for the expected lifetime of *scope/product group* and in any event for at least 10 years after the placing on the market.

*\*Similar edits shall also be made for other economic operators.*

### Recommendation for a respective adjustment of Blue Guide 2022 chapter 3.1, point 4, footnote 114:

*As a general rule, when placing a product on the market the manufacturer must take all measures necessary to ensure that the manufacturing process assures compliance of the products (109) and in particular: [...]*

*4. accompany the product with instructions and safety information (110) (111) as required by the applicable Union harmonisation legislation (112), in a language easily understood by consumers and other end-users, as determined by the Member State concerned (113). Unless otherwise specified in specific legislation, instructions and safety information need to be provided (114), whether the product is intended for consumers or other end-users. [...]*

**Footnote 114:** ~~Unless otherwise specified in specific legislation, whilst the safety information needs to be provided on paper, it~~ *It* is not required that ~~all the set of~~ instructions ~~and safety information is are 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 ~~and safety information~~ 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~~ *expressly desire* it ~~at the moment of purchase~~. 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.

Legal act	Listed manufacturer information	Other essential documents and information to be supplied	Current wording
Low Voltage Directive (LVD) 2014/35/EU	Instructions and safety information (Article 6 Para. 7)	<p>Name and postal address of the manufacturer and, if imported into the EU, also of the importer</p> <p>To be indicated on the product or, in special cases, on the packaging or in the accompanying documents (Article 6 para. 6)</p>	Manufacturers shall ensure that the electrical equipment 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. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.
Electromagnetic Compatibility Directive (EMC) 2014/30/EU	Instructions and the information referred to in Article 18 (Article 7 Para. 7)	The name and postal address of the manufacturer and, in the case of imports into the EU, also of the importer must be indicated on the product or, in special cases, on the packaging or in the accompanying documents (Article 7 para. 6).	Manufacturers shall ensure that the apparatus is accompanied by instructions and the information referred to in Article 18 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 and intelligible.
Radio Equipment Directive (RED) 2014/53/EU	Instructions and safety information (Article 10 Para. 8)	<p>Name and postal address of the manufacturer and, for imports into the EU, also of the importer must be indicated on the product or, in special cases, on the packaging or in the accompanying documents (Article 10 para. 7)</p> <p>EU Declaration of Conformity or "simplified EU Declaration of Conformity" (Article 10 para. 9)</p>	Manufacturers shall ensure that the radio equipment 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. Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

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<p>Machinery Directive (MD) 2006/42/EC - valid until 19 January 2027</p>	<p>"[...] necessary information, such as instructions [...]" (Article 5 para. 1 lit. c in conjunction with Annex I No. 1.7.4.)</p> <p>Partly completed machinery: Assembly instructions in the official language accepted by the machinery manufacturer of the final machinery (customer) (Article 13 Para. 1 lit. b) in conjunction with Annex VI)</p> <p>Maintenance instructions Community language "which the specialised personnel understand" (Annex I No. 1.7.4.)</p>	<p>EU Declaration of Conformity (Article 5 (1) (e))</p> <p>Incomplete machines: EU Declaration of Incorporation (Article 13 Para. 1 Lit. c) in conjunction with Annex II Part 1 Section B)</p> <p>Name and address of the manufacturer and, if applicable, of the authorised representative (Annex I No. 1.7.3.)</p>	<p>Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:</p> <p>[...]</p> <p>(b) ensure that the technical file referred to in Annex VII, part A, is available;</p> <p>c) provide, in particular, the necessary information, such as instructions;</p> <p>[...]</p> <p>(e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery; [...].</p> <p><b>New regulation from 26 April 2024</b> (version 2.3 of the Guide to application of the Machinery Directive)</p> <p><b>§ 255 The form of the instructions</b></p> <p>In 2023 no less than 93% of EU households had internet access (source: Eurostat). Under these circumstances, and in light of the new Machinery Regulation's provisions on the format of the instructions, one can consider that respecting those provisions, including the obligation to provide the essential safety information in paper format in the case of non-professional use, also ensures compliance with the corresponding provisions of the Machinery Directive.</p> <p><b><u>Instructions for use when they are provided in digital format</u></b></p> <p>When the instructions for use are provided in digital format, the provisions of Article 10(7) of the new Machinery Regulation can ensure compliance.</p>

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			<p>Compliance with Article 10(7) of that Regulation is appropriate given that the Regulation sets out specific obligations on the manufacturers when they provide the instructions for use in digital format.</p> <p>In addition, in case of machinery for non-professional use made physically available in Member States, it is recommended that the following statement is provided in the essential safety information or on the packaging or on the machinery itself: 'The purchaser has the right to request to obtain, free of charge, the instructions for use in paper format'.</p> <p>This statement should be in a language which can be easily understood by the purchasers in those Member States, as determined by those Member States (see §246). It should be complemented with contact information (postal address and/or telephone) and indicate how those instructions can be requested.</p> <p><b><u>Meaning of 'safety information that is essential' mentioned in the fourth subparagraph of Article 10(7) of the new Machinery Regulation</u></b></p> <p>It is understood that such information should, as a minimum, consist of information relating to assembly, start-up, use, maintenance and transport of the machinery, ensuring that, by following those instructions, the safety or health of the user or a third person is not at risk. This information should be consistent with the instructions for use.</p> <p>Based on the risk assessment of the manufacturer, it might be necessary to provide additional information within the safety information that is deemed essential.</p>

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<p>Machinery Regulation (EU) 2023/1230 – shall apply from 20 January 2027</p>	<p>Instructions for use and information set out in Annex III (Article 10 Para. 7) or, in the case of partly completed machinery, assembly instructions (Article 11 Para. 7 in conjunction with XI) must also be accompanied.</p>	<p>EU Declaration of Conformity (Article 10 para. 8 in conjunction with Annex V, Part A)</p> <p>Partly completed machinery: EU Declaration of Incorporation (Article 11 Para. 8 in conjunction with Annex V, Part B)</p> <p>Name, registered trade name or registered trade mark, postal address, website and e-mail address or other digital contact option of the manufacturer to be indicated to the machinery or the associated product itself or, if this is not possible, on its packaging or in a document accompanying the machinery or the related product (Article 10 Para. 6)</p>	<p>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.</p> <p>When the instructions for use are provided in digital format, the manufacturer shall:</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(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;</li> <li>(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.</li> </ul> <p>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.</p> <p>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</p>

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			<p>information that is essential for putting the machinery or related product into service and for using it in a safe way.</p> <p>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.</p>
ATEX Directive 2014/34/EU	Instructions and safety information (Article 6 Para. 8)	<p>EU Declaration of Conformity (Article 6 para. 2)</p> <p>Name and postal address of the manufacturer and, in the case of imports into the EU, also of the importer</p> <p>To be indicated on the product or, in special cases, on the packaging or in an accompanying document. (Article 6 para. 7)</p>	<p>Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.</p> <p><b>ATEX Guideline Version 5 (April 2024) §74:</b> For the purposes of market surveillance the EU declaration of conformity and, when applicable, the written attestation of conformity must accompany the information given with each single product, or each batch of identical products delivered for the same end user. These documents, as well as the translations according to the language requirements in national legislations transposing the Directive, need to be provided on paper, in a similar way as for safety information that also must accompany the product according to the ATEX Directive. While safety information needs to be provided in paper copy, the other non-safety instructions can be provided on electronic or other data storage format. However, a paper version should always be available upon request and free of charge for the market surveillance authorities and the end-users.</p> <p><b>ATEX Guideline Version 5 (April 2024) § 151:</b> [...] It is generally agreed that all health and safety related instructions must be supplied in paper form, since it cannot be assumed that the user has</p>

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			<p>access to the means of reading instructions supplied in electronic form or made available on an Internet site. This is particularly relevant for instructions that might need to be read whilst the plant is operational, in the presence of a potentially explosive atmosphere. However, it is often useful for the instructions to be made available in electronic form and on the Internet as well as in paper form, since this enables the user to download the electronic file if he so wishes and to recover the instructions if the paper copy has been lost. This practice also facilitates the updating of the instructions when this is necessary. [...]</p>
<p>General Product Safety Regulation (GPSR) (EU) 2023/988</p>	<p>Clear instructions and safety information.</p> <p>That requirement shall not apply where the product can be used safely and as intended by the manufacturer without such instructions and safety information (Article 9 para. 7)</p> <p>Only relevant for consumer products</p>	<p>Name, registered trade name or registered trade mark, postal address and e-mail address and, if different, the postal address or e-mail address of the manufacturer's central contact point.</p> <p>This information shall be indicated on the product itself or, if this is not possible, on the packaging or in a document accompanying the product.</p>	<p><b>Article 9 para. 7</b> Manufacturers shall ensure that their product is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market. That requirement shall not apply where the product can be used safely and as intended by the manufacturer without such instructions and safety information.</p> <p><b>Article 21: Information in electronic form</b> Without prejudice to Article 9(5), (6) and (7), Article 11(3) and Article 16(3), and the relevant provisions of Union harmonisation legislation, economic operators may additionally make the information referred to in those provisions available in a digital format by means of electronic technical solutions clearly visible on the product or, where that is not possible, on its packaging or in a document accompanying the product. That information shall be in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available</p>

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			on the market, including in accessible formats for persons with disabilities.
Construction Products Regulation (probably valid from December 2025)	Instructions for use and safety information as set out in Annex IV (Article 22, 6)	<p>Name and postal address, telephone, email address and website, if available, of the manufacturer.</p> <p>Unique identification code of the product type, Product description including (a) declared uses; (b) intended users; (c) conditions of uses; (d) estimated average and minimum service life span for declared use (durability); (e) main materials used.</p> <p>Contact details of the product contact point for construction in the Member State in which the product is made available.</p> <p>All these information need to be included in the Digital Product Passport.</p> <p>General information, instructions</p>	<p><b>Article 22 (6)</b> When making a product available on the market, the manufacturer shall ensure that it is accompanied by general information, instructions for use and safety information, as set out in Annex IV in a language to be determined by the Member State concerned or, in absence of such determination, in a language which can be easily understood by users.</p> <p><b>Article 76 Digital Product Passport:</b> (2) A product passport for a product under this Regulation shall: (a) include the following information: (ii) the general information, instructions for use and safety information referred to in Article 22(6);</p>



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		for use and safety information shall also be provided in paper format, free of charge, if requested by the end-user at the time of purchase.	

**Directives and Regulations to be adjusted (not exhaustive):**

- Toy Safety - Directive 2009/48/EU
- Transportable pressure equipment - Directive 2010/35/EU
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Construction products - Regulation (EU) No 305/2011
- Pyrotechnic Articles - Directive 2013/29/EU
- Recreational craft and personal watercraft - Directive 2013/53/EU
- Civil Explosives - Directive 2014/28/EU
- Simple Pressure Vessels - Directive 2014/29/EU
- Electromagnetic Compatibility - Directive 2014/30/EU
- Non-automatic Weighing Instruments - Directive 2014/31/EU
- Measuring Instruments - Directive 2014/32/EU
- ATEX - Directive 2014/34/EU
- Radio equipment - Directive 2014/53/EU
- Low Voltage - Directive 2014/35/EU
- Pressure equipment - Directive 2014/68/EU
- Marine Equipment - Directive 2014/90/EU
- Cableway installations - Regulation (EU) 2016/424
- Personal protective equipment - Regulation (EU) 2016/425
- Gas appliances - Regulation (EU) 2016/426
- Medical devices - Regulation (EU) 2017/745
- In vitro diagnostic medical devices - Regulation (EU) 2017/746
- EU fertilising products – Regulation (EU) 2019/1009

- Lifts - Directive 2014/33/EU
- Batteries - Regulation (EU) 2023/1542
- Drones - Commission Delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems
- Machinery - Regulation (EU) 2023/1230

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