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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Industrial Transformation and Advanced Value Chains  
**Advanced Engineering and Manufacturing Systems**

# **Guide to application of the Machinery Directive 2006/42/EC**

**Edition ~~2.2~~ 3 – October 2019** **April 2024**  
**(Update of 2<sup>nd</sup> Edition)**

## Introduction to the update of the 2<sup>nd</sup> Edition

**Directive 2006/42/EC** is a revised version of the **Machinery Directive**, the first version of which was adopted in 1989. The new Machinery Directive has been applicable since **29<sup>th</sup> December 2009**. The Directive has the dual aim of harmonising the health and safety requirements applicable to machinery on the basis of a high level of protection of health and safety, while ensuring the free circulation of machinery on the EU market. The revised Machinery Directive does not introduce radical changes compared with the previous versions. It clarifies and consolidates the provisions of the Directive with the aim of improving its practical application.

While, at the time, ~~the revised~~ Machinery Directive 2006/42/EC was being discussed by the Council and the European Parliament, the Commission agreed to prepare a ~~new~~ Guide to its application. The purpose of the Guide is-being to provide explanations of the concepts and requirements of Directive 2006/42/EC in order to ensure uniform interpretation and application throughout the EU. The Guide also provides information about other related EU legislation. It is addressed to all of the parties involved in applying the Machinery Directive, including machinery manufacturers, importers and distributors, Notified Bodies, standardisers, occupational health and safety and consumer protection agencies and officials of the relevant national administrations and market surveillance authorities. It may also be of interest to lawyers and to students of EU law in the fields of the internal market, occupational health and safety and consumer protection.

It should be stressed that only the Machinery Directive and the texts implementing its provisions into national law are legally binding.

The 2<sup>nd</sup> Edition of the Guide was endorsed by the Machinery Committee on 2 June 2010. In comparison with the 1<sup>st</sup> Edition, it was completed with comments on Annexes III to XI of the Machinery Directive. Some errors noticed by readers have been corrected. Legal references and terms have been updated in line with the Lisbon Treaty -- in particular, where the Directive refers to *"the Community"*, the Guide now refers to *"the EU"*.

Following discussion with the industry, the comments relating to chains, ropes and webbing for lifting purposes in §44, §330, § 340, §341, and §357 have been revised in order to clarify the practical application of the requirements relating to these products.

The 2<sup>nd</sup> Edition also includes a thematic index to facilitate consultation of the Guide. The numbering of the sections of the Guide is unchanged.

The Guide takes account of the amendment to Directive 2006/42/EC introduced by Regulation (EC) No 569/2009 relating to the regulatory procedure with scrutiny for the Machinery Committee. It also takes account of the provisions of Regulation (EC) No 765/2008 relating to market surveillance, which apply in a complementary way.

The 1<sup>st</sup> ~~Update~~ to the 2<sup>nd</sup> Edition of the Guide (~~–further named~~ Edition 2.1), has been completed to include the amendments made to the Machinery Directive by the Directive 2009/127/EC on Pesticide Equipment and the Regulation (EU) No 167/2013 on the approval and market surveillance of agricultural and forestry vehicles (Tractors). In addition, guidance on “partly completed machinery” and “assemblies” has been added, as well as inserting clarifications and corrections to the concepts of “safety components”, “new and used machinery”, “marking of machinery”. A number of key guidance decisions of the Machinery Working Group have been incorporated into this text.

~~This The 2<sup>nd</sup> Update to the 2<sup>nd</sup> Edition of the Guide (Edition 2.2), further named Edition 2.2, contains contained~~ a number of clarifications and corrections to the concepts of “safety components” and “partly completed machinery”, and some edits to ensure coherence with the LVD Guide. There are two newly added paragraphs about the machinery control units (§417) and safety components which are considered to be logic units (§418).

~~This 3<sup>rd</sup> update (Edition 2.3) contains clarifications on instructions for use and EC Declaration of Conformity, as well as the assembly instructions for partly completed machinery and Declaration of Incorporation when provided in digital format.~~

The Guide is published on the Commission’s Website EUROPA<sup>1</sup> in English. This updated Edition 2.~~2~~3 is intended to be a living document, edited and updated with new guidance once approved by the Machinery Working Group. It might be made available in other EU languages, but only the English version will be checked by the Commission. Therefore, in case of doubt, the English version should be taken as the reference.

The Guide can be downloaded and is presented in a printable format. The text of the Directive is presented in boxed red italic type - the comments follow in black type.

The Guide has been prepared with the help of an Editorial Group<sup>2</sup>. The previous ~~Update updates~~ of the 2<sup>nd</sup> Edition ~~has~~ have been carried out by ~~the Commission, assisted by members of the Editorial Group plus~~ an external consultancy<sup>3</sup> ~~and the Commission, assisted by some of the members of the Editorial Group~~. This update has been ~~carried out~~ prepared by the Commission services based on the input from the ~~Commission Expert Group on Machinery~~ Editorial Group. ~~The Commission~~<sup>4</sup> ~~wishes to warmly thank~~

<sup>1</sup> [http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery\\_en](http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en)

<sup>2</sup> The following people have taken part in the work of the Editorial Group: Lennart Ahnström, Emilio Borzelli, Robert Chudzik, Roberto Cianotti, John Colreavy, Mike Dodds, Cosette Dussaugey, Marcel Dutrieux, Pascal Etienne, Ludwig Finkeldei, Gun Fridfelt, Mikael Holst, Tuiro Kerttula, Andreas Kühn, Thomas Kraus, Patrick Kurtz, Kevin Lane, Leila Martin, Wolfgang Lentsch, Göran Lundmark, Thomas Moessner, Anders Mortensen, Phil Papard, Boguslaw Piasecki, Marc Schulze, Katri Tytykoski, Roger Upfold, Wendy Van Aerschot, Gustaaf Vandegaer, Henk van Eeden, Richard Wilson, Jürg Zwicky.

<sup>3</sup> Phil Papard Consulting.

<sup>4</sup> ~~The Commission representatives: Ian Fraser (until 2013), Felicia Stoica, Mario Gabrielli Cossellu, and Mikhail Simonov.~~

~~the members of the Editorial Group both for the huge amount of work they have carried out as well as for the efficient, constructive and cooperative spirit in which the drafts have been prepared. In parallel to the work of the Editorial Group, a Machinery Core Group established by Orgalime, including representatives of the main sectors of machinery manufacturing, has provided invaluable input from the industry. The drafts prepared by the Editorial Group have been submitted to the Member States and stakeholders for comments. The Commission would also like to thank all those who have made comments. We have tried to take them into account as far as possible.~~

~~Of course, t~~The Commission services ~~takes full responsibility~~are responsible for the content of the Guide. Users~~Readers~~ are invited to ~~communicate~~inform the authors about any comments and necessary corrections<sup>5</sup>~~so that they can be taken into account in preparing future updates or a revised 3<sup>rd</sup> Edition.~~

**Brussels, ~~October 2019~~ April 2024**

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<sup>5</sup> Corrections, comments and suggestions for improvement should be addressed to the functional e-mail box: GROW-MACHINERY@ec.europa.eu.

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### **§255 The form of the instructions**

~~Section 1.7.4 does not specify the form of the instructions. 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 access to the means of reading instructions supplied in electronic form or made available on an Internet site. 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.~~

In 2023 no less than 93% of EU households had internet access (source: Eurostat<sup>6</sup>). 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.

#### **Instructions for use when they are provided in digital format**

When the instructions for use are provided in digital format, the provisions of Article 10(7) of the new Machinery Regulation **can ensure compliance**.

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.

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'.

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.

#### **Meaning of 'safety information that is essential' mentioned in the fourth subparagraph of Article 10(7) of the new Machinery Regulation**

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.

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<sup>6</sup> <https://ec.europa.eu/eurostat/databrowser/bookmark/4747b5a6-24ea-4f0b-8b39-de751bc4f2d3>

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.

Based on the risk assessment of the manufacturer, it might be necessary to provide additional information within the safety information that is deemed essential.

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### **§261 Inclusion of the EC Declaration of Conformity in the instructions**

Section 1.7.4.2 (c) concerns the inclusion of the EC Declaration of Conformity in the instructions. Like the instructions, the EC Declaration of Conformity must accompany the machinery – see §103: comments on Article 5 (1). In order to fulfil this obligation, the manufacturer can choose between the two following alternatives:

- the signed EC Declaration of Conformity is included in the instruction handbookinstructions for use. This is appropriate in the case of one-off products or machinery produced in small numbers;
- a documentsection setting out the contents of the EC Declaration of Conformity (not necessarily including the serial number and the signature) is included in the instruction handbookinstructions for use, in which case the completed and signed EC Declaration of Conformity itself must be provided separatelyin addition – see §382: comments on Annex II 1 A.

The instructions for use and EC Declaration of Conformity do not have to have the same format and do not have to form an inseparate physical or digital document. The EC Declaration of Conformity may be provided in paper format even when the instructions for use are provided in digital format (see §255) and vice versa. Such instructions may contain the EC Declaration of Conformity itself, or the internet address or machine readable code, where the EC Declaration of Conformity can be accessed.

When the EC Declaration of Conformity is provided in digital format, the provisions of Article 10(8) of the new Machinery Regulation can ensure compliance.

Compliance with Article 10(8) of that Regulation is appropriate given that the Regulation sets out specific obligations on the manufacturers when they provide EC Declaration of Conformity in digital format.

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### **§264 Assembly, installation and connection**

Section 1.7.4.2 (i) covers operations to be carried out by or on behalf of the user before the machinery is put into service.

Assembly instructions, which may be provided in digital format (see §255), are necessary for machinery that is not supplied to the user ready to use, for example, where elements of the machinery have been disassembled for transport or packaging purposes. Particular attention must be given to assembly instructions where assembly is



to be carried out by non-professional users – see §258: comments on section 1.7.4.1 (c).

Assembly instructions for interchangeable equipment must specify the type or types of basic machinery with which the equipment can be safely used and include the necessary instructions for the safe assembly of the interchangeable equipment with the basic machinery by the user – see §41: comments on Article 2 (b).

In the case of machinery supplied without a drive system, the instructions must indicate all the necessary specifications for the drive system to be fitted such as the type, power and means of connection, and include precise fitting instructions for the drive system – see §35: comment on the first indent of Article 2 (a).

Installation instructions are necessary for machinery that has to be installed on and/or fixed to particular supports, structures or buildings, on foundations or on the ground, in order to ensure its safe use and stability. The instructions must specify the requisite dimensions and load bearing characteristics of the supports and the means to be used to fix the machinery to its supports. For machinery intended to be installed on means of transport, the instructions must specify the vehicles or trailers on which the machinery can be safely installed, either by reference to their technical characteristics or, where necessary, by reference to specific models of vehicle – see §37: comments on the third indent of Article 2 (a).

Connection instructions must describe the measures to be used to ensure safe connection of the machinery to energy supplies, supplies of fluids and so on. The relevant characteristics of the supplies, such as, for example, voltage, power, pressure or temperature, must be specified. The safe connection of the machinery to the means of evacuating hazardous substances must also be specified, when these means are not an integral part of the machinery.

Paragraph 1.7.4.2 (j) refers to a specific aspect of the installation and assembly instructions relating to the reduction of noise or vibration emissions.

With respect to noise, the instructions must specify, where appropriate, the correct assembly and installation of equipment supplied by the machinery manufacturer to reduce noise emission.

With respect to vibrations, the instructions may include, for example, specifications for foundations with adequate damping characteristics.

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### **§382 The EC Declaration of Conformity of machinery**

Annex II 1 A concerns the EC Declaration of Conformity that must be drawn up by the manufacturer of machinery or his authorised representative in the EU and that must accompany the machinery until it reaches the user – see §103: comments on Article 5 (1), and §109: comments on Article 7 (1). The EC Declaration of Conformity is a legal statement by the manufacturer or his authorised representative attesting that the machinery concerned complies with all of the relevant provisions of the Machinery Directive.

The requirement set out in the first paragraph of Annex II 1 A, that the declaration and translations thereof must be drawn up under the same conditions as the instructions, entails that the EC Declaration of conformity must be drafted in one or more official EU languages. These language versions must bear the words '*Declaration of conformity*' (in the language of each version). The manufacturer may provide "*Declarations of conformity*" in one or more languages. Where no original EC Declaration of conformity exists in the official language(s) of the country where the machinery is to be used, a translation into that or those languages must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words '*Translation of the original Declaration of Conformity*' (in the language of each version) and must be accompanied by original Declaration of Conformity. – see §246: comments on section 1.7.1, §255: comments on section 1.7.4, and §257: comments on sections 1.7.4.1 (a) and (b) of Annex I.

The EC Declaration of Conformity must be typewritten (~~printed~~) or handwritten in capital letters. It must either be included in the instruction manual or provided separately, in which case a document setting out the contents of the EC Declaration of Conformity must be included in the instruction manual – see §261: comments on section 1.7.4.2 (c) of Annex I.

The second paragraph of Annex II 1 A underlines that the EC Declaration of Conformity relates only to the machinery as it has been designed, constructed and placed on the market by the manufacturer. If the manufacturer authorises another economic operator such as an importer or a distributor to modify machinery before it is supplied to the final user, the manufacturer remains legally responsible for the machinery as supplied. However, the manufacturer is not legally responsible for any additions or modifications made to the machinery without his authorisation by other economic operators or by the final user. This must be taken into account when machinery in use is examined by the market surveillance authorities – see §94: comments on Article 4 (1).

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### **§384 The Declaration of Incorporation of partly completed machinery**

Annex II 1 B concerns the Declaration of Incorporation that must be drawn up by the manufacturer of partly completed machinery or his authorised representative in the EU and that must accompany the partly completed machinery until it reaches the manufacturer of the final machinery into which it is to be incorporated - see §104: comments on Article 5 (2), and §131: comments on Article 13. The Declaration of Incorporation shall then form part of the Technical file for the final machinery – see §392: comments on Annex VII A 1 (a).

The Declaration of Incorporation is a legal statement by the manufacturer of the partly completed machinery or his authorised representative with the following main purposes:

- to inform the manufacturer of the final machinery which of the applicable EHSRs of Annex I to the Machinery have been applied and fulfilled;

- where appropriate, to refer to a declaration of conformity for the partly completed machinery which is also covered by the provisions of other applicable EU legislation;
- to undertake to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery;
- to indicate that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the relevant provisions of the Machinery Directive.

The comments relating to the first paragraph of Annex II 1 A also apply to the first paragraph of Annex II 1 B.

The Declaration of Incorporation and assembly instructions for partly completed machinery do not have to have the same format and do not have to form an inseparable physical or digital document. The Declaration of Incorporation may be provided in paper format even when the assembly instructions are provided in digital format (see §390) and *vice versa*. Such assembly instructions may contain the Declaration of Incorporation itself, or the internet address or machine readable code, where the Declaration of Incorporation can be accessed.

When the Declaration of Incorporation is provided in digital format, the provisions of Article 11(8) of the new Machinery Regulation can ensure compliance.

Compliance with Article 11(8) of that Regulation is appropriate given that the Regulation sets out specific obligations on the manufacturers when they provide Declaration of Incorporation in digital format.

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### **§390 Assembly instructions for partly completed machinery**

The provisions of Annex VI apply to partly completed machinery referred to in Article 1 (g) and defined in Article 2 (g) – see §46: comments on Article 2 (g).

The assembly instructions for partly completed machinery must be drawn up by the manufacturer of the partly completed machinery or his authorised representative and supplied to the manufacturer of the final machinery – see §131: comments on Article 13.

When the assembly instructions are provided in digital format, the provisions of Article 11(7) of the new Machinery Regulation can ensure compliance.

Compliance with Article 11(7) of that Regulation is appropriate given that the Regulation sets out specific obligations on the manufacturers when they provide the assembly instructions for partly completed machinery in digital format.

In addition, in case of partly completed machinery made physically available in Member States, it is recommended that the following statement is provided on the packaging, in an accompanying document or on the partly completed machinery itself: 'The purchaser

has the right to request to obtain, free of charge, the assembly instructions in paper format'.

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.

The assembly instructions shall then form part of the technical file for the final machinery - see §392: comments on Annex VII A 1 (a).

The assembly instructions shall deal with all safety-related aspects of the partly completed machinery and of the interface between the partly completed machinery and the final machinery which have to be considered by the assembler when incorporating the partly completed machinery into the final machinery.

The assembly instructions shall indicate the need to take the necessary measures to deal with the EHSRs applicable to the partly completed machinery that have not been applied and fulfilled or that have only been partly fulfilled by the manufacturer of the partly completed machinery – see §385: comments on Annex II 1 B.

In some cases, the manufacturer of the partly completed machinery may apply and fulfil the EHSRs relating to instructions set out in Annex I ESHR 1.7.4 and state this in his Declaration of Incorporation. For example, the manufacturer of a drive systems with its engine to be incorporated into mobile machinery may provide the manual for the engine. In other cases, the assembly instructions for partly completed machinery shall provide the necessary information relating to the partly completed machinery to enable the manufacturer of the final machinery to draft the parts of the instructions relating to the partly completed machinery. If the manufacturer of the PCM does not declare to have fulfilled ESHR 1.7.4., then only assembly instructions need to be provided. However, the information needed by the manufacturer of the final machine to allow them to compile the user instructions to meet ESHR 1.7.4 must be contained in the assembly instructions.

The assembly instructions are addressed to the manufacturer of the final machinery and must therefore be understandable to him. According to the second paragraph of Annex VI, the assembly instructions must be written in one of the official EU languages acceptable to the manufacturer of the final machinery - see §246: comments on section 1.7.1 of Annex I.

This means that, where the manufacturer of the final machinery is known to the manufacturer of the partly completed machinery, the language of the assembly instructions provided with the partly completed machinery can be agreed between the two parties, for example, in the contract of sale. Where there is no such agreement, the assembly instructions must be provided in the official EU language(s) of the Member State in which manufacturer of the final machinery is established since that manufacturer cannot be presumed to understand another language.

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Work equipment (use of)	<i>Article 15</i>	§140
Working coefficient (definition)	<i>Annex I – Section 4.1.1 (c)</i>	§330
- ropes and chains	<i>Annex I – Section 4.1.2.4</i>	§340
- lifting accessories and components	<i>Annex I – Section 4.1.2.5</i>	§341
- lifting of persons	<i>Annex I – Section 6.1.1</i>	§369

## Y

<i>Year of construction (marking of machinery)</i>	<i>Annex I – Section 1.7.3</i>	<b>§250</b>
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