Directive 98/37/EC Machinery Working Group Doc.WG-2009.46

The following text is a draft of the section of the Guide to application of Directive 2006/42/EC with comments on Annex I – section 1.7.

The Editorial Group has examined the draft up to section 1.7.4.1.

Readers should bear in mind that the text is still a draft and will be further amended and completed in light of comments. It should not therefore be presented or quoted as representing the position of the Commission.

Member States and other stakeholders are invited to make comments on this draft, at the latest, by the end of October 2009. Comments should be addressed to:

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1.7 INFORMATION

§244 Information for users

Since the safe use of machinery depends on a combination of design and construction measures taken by the manufacturer and protective measures taken by the user, providing the necessary information and instructions to users is an essential and integral part of the design of the machinery.

Information, warnings and instructions about residual risks concern the third step of the three-step method set out in section 1.1.2 on the principles of safety integration. The fact that this third step is the last in the order of priority implies that warnings and instructions must not be a substitute for inherently safe design measures and integrated protective measures when these are possible, taking into account the state of the art - see §174, comments on section 1.1.2 (b).

The requirements set out in sections 1.7.1 to 1.7.4 apply to machinery in the broad sense, that is to say to any of the products listed in Article 1 (1) (a) to (f) - see §33, comments on Article 2. For application of these requirements to partly completed machinery - see comments on Annex II 1 B.

1.7.1 Information and warnings on the machinery

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.

§245 Information and warnings on the machinery

The requirements set out section 1.7.1 concern the form of information and warnings that are part of the machinery. The first sentence of section 1.7.1 advises manufacturers to use readily understood symbols or pictograms for this purpose. Well designed symbols or pictograms can be understood intuitively and avoid the need for the translation of written or verbal information.

The second sentence of section 1.7.1 applies when information is provided in the form of written words or text on the machinery, on a monitor screen or in the form of oral text provided, for example, by means of voice synthesiser. In such cases the information and warnings must be provided in the official language or languages of the Member States in which the machinery is placed on the market and/or put into service.

The user of machinery may also request the manufacturer to provide the information and warnings on the machinery or on monitor screens accompanied by versions in any other language or languages of the Community that are understood by the operators. This may be for various reasons, for example:

- the persons who are to use the machinery do not understand the official language of the Member State concerned;
- the machinery is to be used in a workplace that has a single working language other than the official language(s) of the Member State concerned;
- the machinery is to be used in one Member State and maintained by technicians from a different Member State;
- remote diagnostics are to be carried out in a Member State different from the Member State where the machinery is to be used.

Providing information or warnings on the machinery in Community languages other than the official language or languages in which the machinery is placed on the market and/or put into service is a matter to be settled by contract between the manufacturer and the user when the machinery is ordered.

§246 The official languages of the EU

There are 23 official Community languages, used in the following Member States:

Austria German Latvia Latvian Lithuania Luxembourg Belgium Dutch, French and German Lithuanian Bulgaria Bulgarian French and German English and Greek Cyprus Malta: English and Maltese Czech Republic - Czech The Netherlands - Dutch Denmark Danish Poland Polish Estonia Portugal Estonian Portuguese Finland Finnish and Swedish Romania Romanian France French Slovakia Slovak Slovenia Germany German Slovenian Greek Greece Spain Spanish Sweden Hungarian Hungary Swedish Ireland English and Irish United Kingdom – English Italy Italian

Certain of the Member States with two or more official languages (Belgium, Finland) accept the use of one language only in areas where only that language is spoken. Manufacturers are advised to check this with the national authorities concerned. Other Member States with two official languages (Cyprus, Malta and Ireland) accept the sole use of English.

In the other countries where the Machinery Directive applies in virtue of the EEA, the MRA between Switzerland and the EU-Turkey Customs Union, the national provisions implementing the Machinery Directive require the use of the official language(s) of the country concerned:

Iceland – Icelandic Switzerland – French, German and Italian

Liechtenstein – German Turkey – Turkish

Norway – Norwegian

1.7.1.1 Information and information devices

The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.

§247 Information and information devices

The requirement set out in section 1.7.1.1 applies to all information on the machinery which is needed to help operators to control its operation. In particular, it applies to the indicators and displays provided with control devices – see §194, comments on section 1.2.2. Such information is subject to the requirements set out in section 1.7.1.

Specifications for the design of information, information devices, indicators and displays are given in standards of the EN 894 series¹ and in standards of the EN 61310 series.²

1.7.1.2 Warning devices

Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.

The requirements of the specific Community Directives concerning colours and safety signals must be complied with.

§248 Warning devices

Section 1.7.1.2 deals with risks for persons due to faults in machinery or parts of machinery that are designed to operate without the permanent supervision of operators. The warning devices must be such as to inform the operators or other exposed persons of dangerous faults in order to enable the necessary action to

¹ EN 894-1:1997+A1: 2008 – Safety of machinery – Ergonomic requirements for the design of displays and control actuators – Part 1: General principles for human interactions with displays and control actuators:

EN 894-2:1997 + A1:2008 - Safety of machinery – Ergonomics requirements for the design of displays and control actuators – Part 2: Displays.

² EN 61310-1:2008 - Safety of machinery — Indication, marking and actuation — Part 1: Requirements for visual, acoustic and tactile signals (IEC 61310-1:2007);

EN 61310-2:2008 - Safety of machinery - Indication, marking and actuation - Part 2: Requirements for marking (IEC 61310-2:2007).

protect persons at risk to be taken. Where appropriate, the warning devices can be fitted to the machinery itself or be activated at a distance.

Standard EN 61310-1 gives specifications for visual and acoustic signals.

The last paragraph of section 1.7.1.2 refers to Directive 92/58/EEC³ which lays down the minimum requirements for signs at the workplace to be used by employers. The national regulations implementing that Directive do not therefore apply directly to manufacturers. However, section 1.7.1.2 requires machinery manufacturers to comply with the technical requirements of that Directive in the interest of uniformity of safety signs in the workplace.

1.7.2 Warning of residual risks

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.

§249 Warning of residual risks

The requirement set out in section 1.7.2 refers to residual risks, that is to say, risks that cannot be eliminated or sufficiently reduced by inherently safe design measures and that cannot be completely prevented by integrated protective measures — see §174, comments on section 1.1.2 (b). Warnings about residual risks on the machinery are complementary to the information about the residual risks to be given in the manufacturer's instructions — see comments on section 1.7.4.2 (I). Warnings on the machinery are useful where operators or other exposed persons need to be informed of particular precautions to be taken with respect to residual risks during the use of the machinery such as, for example, the presence of hot surfaces or lasers. They can also be useful to recall the need to use PPE.

The warnings marked on the machinery shall comply with the requirements set out in section 1.7.1. The warnings provided by means of warning devices shall comply with the requirements set out in section 1.7.1.2.

Directive 92/58/EEC and standard EN 61310-1 include guidance that is relevant for the design of such warnings.

1.7.3 Marking of machinery

All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

- the business name and full address of the manufacturer and, where applicable, his authorised representative,
- designation of the machinery,

³ Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) - see Annex VI – minimum requirements for illuminated signs, and Annex VII – minimum requirements for acoustic signs.

- the CE Marking (see Annex III),
- designation of series or type,
- serial number, if any,
- the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

§250 Marking of machinery

The first paragraph of section 1.7.3 deals with particulars that must be marked on all machinery, in addition to other information or warnings to users about residual risks. Apart from the CE marking and the ATEX marking, section 1.7.3 does not impose any particular form for the marking on the machinery, providing it is visible, legible and indelible. The marking must therefore be affixed in a place on the machine that is visible from the outside and not hidden behind or beneath parts of the machinery. Taking account of the size of the machinery, the characters used must be large enough to be read easily. The marking technique used must ensure that the marking will not be effaced during the lifetime of the machinery, taking account of the foreseeable conditions of use. If the marking is displayed on a plate, it should be permanently fixed to the machinery, preferably by welding, riveting or bonding.

In the case of products which are too small to bear a legible marking of the particulars required by section 1.7.3, the marking can be displayed on a durable label attached to the product.

The language requirements set out in section 1.7.1 do not apply to the particulars referred to the in first paragraph of section 1.7.3. However, these particulars should be written in one of the official Community languages.

The following comments refer to the six indents of the first paragraph of section 1.7.3:

 the business name and full address of the manufacturer and, where applicable, his authorised representative

The purpose of the requirement set out in the first indent of section 1.7.3 is to enable the user or the market surveillance authorities to contact the manufacturer in case of a problem - see §79 to §81, comments on Article 2 (i). The same information must be given in the EC Declaration of Conformity – see comments on Annex II.1 A.

The term 'business name' refers to the name under which the company concerned is registered.

The term 'full address' means the postal address that enables a letter to reach the manufacturer. The name of the country or town is not sufficient. There is no obligation to mark the manufacturer's e-mail address or Website, although these can usefully be added.

The business name and full address of the authorised representative of the manufacturer established in the Community must also be marked on the machinery in

cases where the manufacturer has mandated such an authorised representative – see §84 and §85, comments on Article 2 (j).

designation of the machinery

The term 'designation of the machinery' refers to the usual name of the category of machinery to which the specific model of machinery belongs. (The term has a similar meaning to the terms 'generic denomination and function' used in Annex II with respect to the EC Declaration of conformity). Wherever possible, the term used to designate the category of machinery concerned in harmonised standards should be used. The same information must be given in the EC Declaration of conformity – see comments on Annex II.1 A.

If it is not practicable to include in the marking an explicit designation of the machinery, for example, in the case of very small machinery, the designation can be provided in the form of a code, providing that this code is explained and the explicit designation is given in the instructions supplied with the machinery – see comments on section 1.7.4.2 (b) and in the EC Declaration of conformity of the machinery – see comments on Annex II.1 A.

The manufacture's designation of the machinery should not be construed as a basis for determining whether or not certain EHSRs or conformity assessment procedures are applicable, which must be determined independently.

the CE Marking (see Annex III)

The requirements for the CE marking are set out in Article 16 and Annex III. According to Annex III, the CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique - see §141, comments on Article 16 and comments on Annex III.

designation of series or type

The designation of the series or type is the name, code or number given by the manufacturer to the model of machinery concerned that has been subject to the relevant conformity assessment procedure. The designation of the series or type names often includes a trademark.

serial number, if any

A serial number is a means of identifying an individual item of machinery belonging to a series or type. The Machinery Directive does not require machinery to bear a serial number, but where a serial number has been attributed by the manufacturer, it must be indicated after the designation of the series or type.

 the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

The year of construction is defined as the year in which the manufacturing process is completed. For machinery that is assembled in the manufacturer's premises, the

manufacturing process can be considered to be completed, at the latest, when the machinery leaves the manufacturer's premises to be transferred to an importer, a distributor or to the user. For machinery that is only finally assembled at the user's premises, the manufacturing process can be considered to be completed when the assembly of the machinery on site has been completed and is ready to be put into service. For machinery manufactured by the user for his own use, the manufacturing process can be considered to be completed when the machinery is ready to be put into service – see §80, comments on Article 2 (i).

In addition to the general requirements on marking set out in section 1.7.3, additional requirements on marking for mobile machinery are set out in section 3.6.2; additional requirements on marking for chains, ropes and webbing, lifting accessories and lifting machinery are set out in section 4.3; additional requirements on marking for machinery for lifting persons are set out in section 6.5.

It should be noted that, on machinery subject to the Outdoor Equipment Directive 2000/14/EC, the CE marking is accompanied by the marking of the guaranteed sound power level – see §92, comments on Article 3, and §271, comments on section 1.7.4.2 (u).

1.7.3 Marking of machinery (continued)

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Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

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§251 Conformity marking for ATEX Machinery

The third paragraph of section 1.7.3 applies to machinery that is subject to the ATEX Directive 94/9/EC⁴ in addition to the Machinery Directive - see §91, comments on Article 3 and §228, comments on section 1.5.7. The CE marking signifies the conformity of the machinery with the applicable Community Directives that provide for its affixing – see §141, comments on Article 16. In addition to the CE marking, the ATEX Directive provides for a specific marking for explosion protection:



The ATEX marking is followed by the symbol of the equipment group and category.

⁴ Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres – OJ L 100, 19.04.1994, p. 1.

1.7.3 Marking of machinery (continued)

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Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.

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§252 Information essential for safe use

The fourth paragraph of section 1.7.3 requires the machinery to bear the necessary information essential for its safe use. This information is subject to the requirements relating to pictograms and language set out in section 1.7.1. The requirement relating to information and information devices set out in 1.7.1.1 should also be taken into consideration.

The manufacturer is not expected to mark on the machinery all the information for safe use provided in the instructions. However information concerning essential aspects of safe use must be marked on the machinery, such as, for example, the maximum dimensions of workpieces, the maximum dimensions of the tools to be used, the maximum slope on which the machinery is stable, the maximum wind speed and so on. The information to be marked on the machinery is usually specified in the relevant harmonised standards.

1.7.3 Marking of machinery (continued)

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Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.

§253 Marking parts of the machinery to be handled with lifting equipment

The requirement set out in the last paragraph of section 1.7.3 is complementary to the requirements relating to the design of machinery to facilitate its handling – $\sec \S 180$, comments on section 1.1.5. It applies to parts of machinery that have to be handled during use, the weight, size or shape of which prevent them from being moved by hand. The requirement is to be applied in the light of an analysis of the different phases of the lifetime of the machinery concerned – $\sec \S 173$, comments on section 1.1.2 (a).

The mass must be marked on such parts in order to enable the user to employ lifting machinery with a sufficient lifting capacity. In order to avoid ambiguity, the mass should be marked in kilograms in a visible place on the part concerned, preferably in the immediate vicinity of the attachments for the lifting machinery.

1.7.4 Instructions

All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.

The instructions accompanying the machinery must be either 'Original instructions' or

a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand.

The instructions must be drafted in accordance with the principles set out below.

§254 Instructions

Section 1.7.4 deals with one of the obligations to be fulfilled by the manufacturer before machinery is placed on the market and/or put into service – see §103, comments on Article 5 (1).

The first paragraph of section 1.7.4 states that the manufacturer's instructions must accompany the machinery. This entails that the instructions must be drawn up before the machinery is placed on the market and/or put into service and must accompany the machinery until it reaches the user. Importers or distributors of machinery must therefore ensure that the instructions are passed on to the user – $see \S 83$, comments on Article 2 (i).

In addition to the general requirements for instructions set out in sections 1.7.4, supplementary requirements for instructions are set out in the following sections:

- sections 2.1.2, 2.2.1.1 and 2.2.2.2 foodstuffs machinery and machinery for cosmetics or pharmaceutical products, portable hand-held and hand-guided machinery and portable fixing and other impact machinery;
- sections 3.6.3.1 and 3.6.3.2 mobile machinery and machinery with multiple uses;
- sections 4.4.1 and 4.4.2- lifting accessories and lifting machinery.

§255 The language of the instructions

As a general rule, the instructions must be supplied in the official Community language or languages of the Member State in which it is placed on the market and/or put into service – see §246, comments on section 1.7.1.

The second paragraph of section 1.7.4 should be understood in light of section 1.7.4.1. Machinery must be accompanied by original instructions, that is to say, instructions verified by the manufacturer or his authorised representative. If original instructions are not available in the language(s) of the Member State in which the machinery is placed on the market and/or put into service, machinery must be accompanied by a translation of the original instructions together with the original instructions. The purpose of the latter requirement is to enable users to check the original instructions in case of doubt about the accuracy of a translation.

The third paragraph of section 1.7.4 foresees an exception to the general requirement set out in the first paragraph relating to the language of instructions. It applies to maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative. Such specialised personnel may either be staff of the manufacturer or of his authorised representative or of a company that

has a contract or written agreement with the manufacturer or his authorised representative to service the machinery concerned. Instructions that are exclusively intended for such specialised personnel do not necessarily have to be supplied in the language(s) of the country of use but can be supplied in a language understood by the specialised personnel.

This derogation does not apply to instructions for maintenance operations that are to be carried by the user or by maintenance personnel mandated by the user. For the derogation to be applicable, the manufacturer's instructions to the user must therefore specify clearly which maintenance operations are only to be carried out by specialised personnel mandated by the manufacturer or his authorised representative.

§256 The form of the instructions

Section 1.7.4 does not specify the form of the instructions. It is generally agreed that all 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.

All instructions relating to operations to be carried out before the machinery is ready for use, such as instructions for the assembly and installation of the machinery and for the connection of the machinery to supplies of energy and fluids, must be provided in paper form — see §262, comments on section 1.7.4.2 (i). Apart from such assembly, installation and connection instructions, it is acceptable to supply instructions in electronic form only if the machinery itself is fitted with hardware on which the instructions can be read, provided that the relevant software is adequately protected and that paper copies can be printed out if necessary.

1.7.4.1 General principles for the drafting of instructions

- (a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.
- (b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) 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 instructions'.

§257 The drafting and translation of instructions

Paragraphs (a) and (b) of section 1.7.4.1 explain in more detail how the language requirements set out in section 1.7.4 must be fulfilled.

Paragraph (a) of section 1.7.4.1 explains that the original instructions are the language versions of the instructions that have been verified by the manufacturer or his authorised representative. These language versions must bear the words 'Original

instructions' (in the language of each version). Normally, a manufacturer or his authorised representative should prepare and verify original language versions for all of the Member States where he intends to place the machinery on the market and/or put it into service.

Paragraph (b) of section 1.7.4.1 deals with the situation where machinery is placed on the market in a Member State for which the manufacturer or his authorised representative has not prepared original instructions. This may occur, for example, if an importer, a distributor or a user takes the initiative to place the machinery on the market or put it into service in a Member State not initially foreseen by the manufacturer. In such cases, a translation of the instructions into the official Community language(s) of the Member State concerned must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question.

In practical terms, this requirement entails that the person bringing the machinery into the language area in question must either obtain a translation from the manufacturer or his authorised representative or, failing that, translate the instructions himself or have them translated – see §83, comments on Article 2 (i).

The translations must bear the words *'Translation of the original instructions'* (in the language of each version) and must be accompanied by original instructions – <u>see</u> §254, comments on section 1.7.4.

1.7.4.1 General principles for the drafting of instructions (continued)

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(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.

. . .

§258 Preventing foreseeable misuse

Paragraph (c) of section 1.7.4.1 underlines that the instructions are one of the means for preventing the misuse of machinery. This implies that when drafting instructions on each of the aspects listed in section 1.7.4.2, the manufacturer must take account of the errors that operators are liable to make, in the light of experience of past use of similar machinery, accident investigations and knowledge about readily predictable human behaviour— see §172, comments on section 1.1.1 (i), and §175, comments on section 1.1.2 (c).

1.7.4.1 General principles for the drafting of instructions (continued)

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(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.

§259 Instructions for non-professional users

Paragraph (d) of section 1.7.4.1 makes a distinction between machinery intended for non-professional operators and machinery intended for professional use. The wording and layout of the instructions must be adapted to the public to whom they are addressed. Instructions for non-professional users must be written and presented in language that is understandable to laypersons, avoiding specialist technical terminology. This requirement is also relevant for machinery that may be used both by professionals and non-professionals.

Where machinery intended for consumer use is supplied with certain elements dismounted for transport and packaging purposes, particular attention must be given to ensure that the mounting instructions are complete and explicit and include clear, accurate and unambiguous diagrams, drawings or photographs – see comments on section 1.7.4.2 (i).

The C-type standards for particular categories of machinery specify the content of the instructions but generally do not provide guidance on the drafting and layout. General guidance on the drafting of instructions is given in standard EN ISO 12100-2⁵. Although it is not a harmonised standard under the Machinery Directive, the guidance given in standard EN 62079⁶ on the drafting and layout of instructions may be useful for machinery instructions.

1.7.4.2 Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

- a) the business name and full address of the manufacturer and of his authorised representative;
- b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);

. . .

§259 Contents of the instructions – particulars of the manufacturer and the machinery

Section 1.7.4.2 summarises the main aspects that must be covered in the manufacturer's instructions. The expression 'at least' indicates that the list is not to be taken as exhaustive. Thus, if any information not mentioned in sections 1.7.4.2 (a) to (v) is needed for the safe use of the machinery, it must be included in the instructions. The expression 'where applicable' means that the aspects mentioned in sections 1.7.4.2 (a) to (v) only need to be covered in the instructions if they are relevant for the machinery concerned.

The particulars mentioned in section 1.7.4.2 are the same as the particulars to be marked on the machinery $-\sec \S 250$, comments on 1.7.3. However, in the

⁵ EN ISO 12100-2: 2003 - Safety of machinery - Basic concepts, general principles for design - Part 2: *Technical principles* (ISO 12100-2:2003) - see clause 6.

⁶ EN 62079: 2001 – Preparation of instructions – Structuring, content and presentation.

instructions, the designation of the machinery must be written in full in the language of the instructions. The serial number is not required, since the manufacturer's instructions usually cover a model or type of machinery rather than an individual product.

If the instructions cover more than one model or type, for example, if they cover several models or types of machinery belonging to the same series, it must be made absolutely clear which parts of the instructions apply to each model or type.

1.7.4.2 Contents of the instructions (continued)

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c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;

. . .

§259 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 – $\underline{\text{see } \S 103}$, 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 handbook.
 This is appropriate in the case of one-off products or machinery produced in small numbers;
- a document setting out the contents of the EC Declaration of Conformity (not necessarily including the serial number and the signature) is included in the instruction handbook, in which case the signed EC Declaration of Conformity itself must be provided separately – see comments on Annex II, A.

1.7.4.2 Contents of the instructions (continued)

. . .

- d) a general description of the machinery;
- e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
- f) a description of the workstation(s) likely to be occupied by operators;

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§260 Descriptions drawings, diagrams and explanations

The general description of the machinery mentioned in section 1.7.4.2 (d) aims to enable the user to identify the main parts of the machinery and their functions.

Section 1.7.4.2 (e) deals with the information and explanations necessary for safe use, maintenance and repair of the machinery and for checking its correct functioning. (More detailed requirements on the content of the instructions relating to these aspects are set out in the following sections). Clear and simple drawings, diagrams,

graphs and tables are usually preferable to long written explanations. But the necessary written explanations should be placed adjacent to the illustrations to which they refer.

Section 1.7.4.2 (f) deals with the workstations foreseen for operators. Aspects to be covered include, for example:

- the location of workstations,
- the adjustment of seats, footrests or other parts of the machinery in order to ensure a good posture and reduce vibrations transmitted to the operator – <u>see</u> §183, comments on section 1.1.8;
- the layout and identification of the control devices, the functions they control and their use – see §185, comments on section 1.2.2;
- the different operating or control modes and the protective measures and precautions relating to each mode – <u>see §204</u>, <u>comments on section 1.2.5</u>;
- use of the guards and protective devices fitted to the machinery;
- use of equipment fitted to contain or evacuate hazardous substances or to maintain good working conditions.

1.7.4.2 Contents of the instructions (continued)

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- g) a description of the intended use of the machinery;
- h) warnings concerning ways in which the machinery must not be used that experience has shown might occur

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§261 Intended use and foreseeable misuse

The description of the intended use of the machinery referred to in section 1.7.4.2 (g) must include a precise indication of the purposes for which the machinery is intended. The description of the intended use of the machinery must specify the limits on the conditions of use taken into account in the manufacturer's risk assessment and in the design and construction the machinery $-\sec \S 171$, comments on section 1.1.1 (h).

The description of the intended use of the machinery must cover all the different operating modes and phases of use of the machinery and specify safe values for the parameters on which the safe use of the machinery depends. Such parameters may include, for example:

- the maximum load for lifting machinery;
- the maximum slope on which mobile machinery can be used without loss of stability;
- the maximum wind-speed in which machinery can be safely used outdoors;
- the maximum dimensions of workpieces;
- the type of materials that can be safely processed by the machinery.

1.7.4.2 Contents of the instructions (continued)

. . .

- i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;
- j) instructions relating to installation and assembly for reducing noise or vibration;

§262 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 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).

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 may specify, for example, measures relating to the location of the machinery and its workstations in the workplace, or measures relating to the building to prevent sound reflections from walls and ceilings.

With respect to vibrations, the instructions may include, for example, specifications for foundations with adequate damping characteristics or for the installation of isolators between the machinery and its supports.

1.7.4.2 Contents of the instructions (continued)

• • •

k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;

• • •

§263 Putting into service and use

Section 1.7.4.2. (k) refers first to instructions relating to the putting into service of the machinery $-\sec \S 86$, comments on Article 2 (k).

The instructions for putting into service shall indicate all of the necessary adjustments, checks, inspections or functional tests to be carried out after the machinery has been assembled and installed and before it is put into service. Any particular procedures to be followed should be described. The same information shall be provided for putting machinery back into service, for example, following transfer to a new site or after major repairs.

The second aspect of the instructions referred to in section 1.7.4.2 (k) relates to the use of the machinery. The instructions must deal with the different phases of the use of the machinery. The instructions shall cover, as appropriate:

- normal operation, setting and adjustment of the machinery;
- the correct use of control devices, guards and protective devices;
- the use of special tools or equipment provided with the machinery <u>see §117, comments on section 1.1.2 (e);</u>
- the selection and safe use of all operating or control modes <u>see §204,</u> comments on section 1.2.5;
- particular precautions to be taken in specific conditions of use.

§264 Operator training

The third aspect referred to in section 1.7.4.2 (k) is operator training. The machinery manufacturer must indicate whether specific training is needed to use the machinery safely. Normally, this is only appropriate in the case of machinery intended for professional use.

The manufacturer is not expected to provide a full training program or training manual in the instructions. However the instructions should indicate the main aspects to be covered by the operator training in order to help employers to fulfil their obligations to provide appropriate training to operators. In this respect, it should be noted that, for certain categories of machinery, operator training and training programmes may be subject to national regulations implementing Directive 89/655/EEC – see §140, comments on Article 15.

In addition to the basic information on training in the instructions, certain machinery manufacturers also offer operator training services to users, however such services are outside the scope of the Machinery Directive.

1.7.4.2 Contents of the instructions (continued)

. . .

- l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
- m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;

. .

§265 Information about residual risks

Sections 1.7.4.2 (I) and (m) deal with an important aspect of third step of the principles of safety integration – see §174, comments on section 1.2.2 (b). According to section 1.7.4.2 (I), the instructions must include clear statements relating to any risks that have not been sufficiently reduced by inherently safe design measures or by integrated technical protective measures.

The purpose of this information is to enable the user to take the necessary protective measures mentioned in section 1.7.4.2 (m). The measures to be specified in the instructions may include, for example:

- the use of additional screens or guards in the workplace;
- the organisation of safe systems of work;
- the restriction of certain tasks to trained and authorised operators;
- the provision and use of appropriate PPE.

It should be noted that the selection, provision and use of PPE are under the responsibility of employers and are subject to national provisions implementing Directive 89/656/EEC.⁷ However, the machinery manufacturer's instructions may indicate the type of PPE to be used to protect against residual risks arising from the machinery. In particular, if the machinery is fitted with anchorage devices for the attachment of PPE against falls from a height, the compatible PPE must be specified – see §237, comments on section 1.5.15, and comments on section 6.3.2.

1.7.4.2 Contents of the instructions (continued) ... n) the essential characteristics of tools which may be fitted to the machinery; ...

§266 The essential characteristics of tools

Section 1.7.4.2 (n) deals with instructions relating to tools that are not permanently fixed to the machinery and that may be changed by the user. Such tools are not considered as part of the machinery – $\underline{\text{see §41, comments on Article 2 (b)}}$ - however the safe use of the machinery frequently depends on the fitting and use of appropriate

⁷ Council Directive 89/656/EEC 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) - OJ L 393, 30.12.1989, p. 18.

tools. The instructions must therefore specify the characteristics of the tools on which safe use depends. This is particularly important for fast moving or fast rotating tools, in order to avoid risks due to the break-up and ejection of fragments of tools or due to the ejection of the tools themselves – see §207 and §208, comments on sections 1.3.2 and 1.3.3.

The essential characteristics to be specified may include, for example:

- the maximum or minimum dimensions and mass of tools;
- the constituent materials and assemblies of tools:
- the requisite shape or other essential design features of tools;
- the compatibility of the tools with the tool-holders on the machinery.

1.7.4.2 Contents of the instructions (continued)

o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;

. . .

§267 Stability conditions

Section 1.7.4.2 (o) is linked to the requirements set out in sections 1.3.1, 2.2.1, 3.4.1, 3.4.3, 4.1.2.1, 4.2.2, 5.1 and 6.1.2 relating to stability. Where the design and construction of the machinery ensures the stability of the machinery under certain defined conditions, these must be specified in the instructions.

In particular, where stability depends on the observance of certain limits on the conditions of use of the machinery such as, for example, the maximum slope, the maximum wind speed, the maximum reach or the position of certain elements of the machinery, these limits must be specified and the necessary explanations must be given on the use of the corresponding protective and warning devices fitted to the machinery and on how to avoid hazardous situations.

The instructions must also explain how to ensure the stability of the machinery or its parts during other phases of the lifetime of the machinery – see §173, comments on section 1.1.2 (a). Where particular measures are needed to ensure stability during these phases, the measures to be taken and the means to be used must also be specified.

1.7.4.2 Contents of the instructions (continued)

• • •

p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;

. . .

§268 Transport, handling and storage

Section 1.7.4.2 (p) is linked to the requirements relating to the handling of the machinery and its parts – see §180, comments on section 1.1.5.

The instructions for safe transport, handling and storage of the machinery and of parts that are to be transported separately shall include, as appropriate:

- instructions for safe manual handling of machinery or parts that are to be moved by hand;
- instructions on the use of attachment points for lifting machinery, the mass of the machinery and of the parts to be transported;
- instructions on the means to be used to ensure stability during transport and storage, including the use of special equipment for that purpose;
- a description of the special arrangements for the handling of hazardous tools or parts.

1.7.4.2 Contents of the instructions (continued)

q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;

• • •

§269 Emergency procedures and methods for unblocking

Section 1.7.4.2 requires the machinery manufacturer to anticipate potential malfunctioning of the machinery and to specify the procedures to be followed to deal with emergencies. The measures to be specified, include, for example, the methods to be used to rescue injured persons, to summon help or to rescue trapped persons – see §236, comments on section 1.5.14.

The instructions must also describe the method to be followed in case of a blockage of moving parts and explain the use of any special protective devices or tools provided for that purpose – see §212, comments on section 1.3.7.

1.7.4.2 Contents of the instructions (continued)

• • •

- r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;
- s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- t) the specifications of the spare parts to be used, when these affect the health and safety of operators;

. . .

§270 Adjustment, maintenance, and spare parts

Section 1.7.4.2 (r) requires the manufacturer to describe the adjustment and maintenance operations to be carried out by the user.

In particular, the instructions must specify the adjustment and maintenance operations that must be carried out and indicate their frequency. The instructions must list the elements or parts of the machinery that must be regularly checked in order to detect excessive wear, the periodicity of these checks (in terms of duration of use or number of cycles), the nature of the necessary inspections or tests and the equipment to be used. Criteria must be given for the repair or replacement of worn parts – $\sec \S 207$, comments on section 1.3.2.

Section 1.7.4.2 (s) is linked to the requirements set out in sections 1.6.1 to 1.6.5 relating to maintenance. The instructions must specify the necessary methods and procedures to be followed in order to ensure that adjustment and maintenance operations can be carried out safely. The appropriate protective measures and precautions to be taken during maintenance operations must be indicated. The instructions shall include, as appropriate:

- information on the isolation of energy sources, the locking of the isolator, the dissipation of residual energies and the verification of the safe state of the machinery – see §241, comments on section 1.6.3;
- measures to ensure safety for maintenance operations that must be carried out while the machinery is operating;
- methods to be used to safely remove or replace components <u>see §239</u>, <u>comments on section 1.6.1</u>;
- precautions to be taken when cleaning internal parts which have contained hazardous substances – see §243, comments on section 1.6.5;
- means of access to be used for exceptional repairs <u>see §240, comments on</u> section 1.6.2.

Section 1.7.4.2 (t) refers to information about spare parts. In general, the supply of spare parts is not covered by the provisions of the Machinery Directive and is thus a matter for contractual agreement between the manufacturer and the user. However, where parts subject to wear and tear need to be replaced in order to protect the health and safety of users, the specifications of the appropriate spare parts must be given in the instructions. Examples of such spare parts include:

- guards for removable mechanical transmission devices <u>see comments on section 3.4.7;</u>
- flexible guards subject to wear and tear see §216, comments on section 2.4.1;
- filters for systems to provide clean air to operating positions see §182, comments on section 1.1.7, and comments on section 3.5.3;
- load bearing components on lifting machinery <u>see comments on sections 4.1.2.4</u> and 4.1.2.5.

1.7.4.2 Contents of the instructions (continued)

. .

- *u)* the following information on airborne noise emissions:
 - the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
 - the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa),
 - the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;

. . .

§271 The noise emission declaration

Section 1.7.4.2 (u) sets out the information on airborne noise emission to be stated in what is currently called the noise emission declaration. This declaration has two main purposes:

to assist users to choose machinery with reduced noise emission;

 to provide information useful for the employer's risk assessment, according to the national provisions implementing Article 6 of Directive 2003/10/EC on the exposure of workers to the risks arising from noise.⁸

In this respect, it should be recalled that the manufacturer's noise emission declaration only provides information about the contribution of the machinery itself to noise in the workplace. The level of exposure of workers cannot be simply deduced from the noise emission declaration since exposure is also influenced by other factors – see §229, comments on section 1.5.8.

The information to be provided in the noise emission declaration includes three different noise emission quantities:

1. The A-weighted emission sound pressure level (LpA) produced by the machinery at its workstation(s). This is the average A-weighted sound pressure level over a specific time representative of a full work cycle of the machinery. Being an emission value, it excludes contributions from the environment of the machinery such as reflections of noise from walls or noise from other sources at the workplace.

This quantity must be measured for all machinery using an appropriate test code, whether or not the machinery is considered noisy. If the measured value does not exceed 70 dB(A), the instructions must state this. If the measured value exceeds 70 dB(A), the measured value must be stated in the instructions.

2. The peak C-weighted instantaneous sound pressure value (LpC_{peak}). This is the maximum value reached by the sound pressure level over a specific duration representative of a full work cycle of the machine.

This value is relevant for machinery that emits strongly impulsive noise. It only has to be stated in the instructions if the measured value exceeds 63 Pa (130 dB in relation to 20 μ Pa).

3. The A-weighted sound power level (LWA). This quantity represents the airborne sound energy radiated by the machine in space and thus characterises the machine as a noise source. It is the most important noise emission quantity and is independent from the environment in which the machine is placed.

Since the measurement of the LWA may be onerous, this value only has to be measured and stated in the instructions if the LpA at any of the workstations exceeds 80 dB(A).

The second paragraph of section 1.7.4.2 (u) implies that, in the case of series production, testing can be carried out on a representative or samples or samples. In the case of one-off production, the manufacturer must measure the noise emission for each item of machinery supplied.

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⁸ Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) – OJ L 42 of 15.2.2003, p. 38 – see, in particular, Article 6 (f).

According to the third paragraph of section 1.7.4.2 (u), if the measurement of the LWA for the machinery is not significant, for example, because the machinery has several different noise sources resulting in a complex directivity of the sound radiation, the statement of the LWA can be replaced by a statement of the LpA at specified positions around the machinery.

The fourth paragraph of section 1.7.4.2 (u) concerns the methods to be used for measuring noise emission. Operating conditions have a strong influence on noise emission. Measurement of noise emission should therefore be carried out under representative operating conditions. Noise test codes for machinery specify the operating conditions or the range of operating conditions under which the measurements shall be made. Where a test code specified in a harmonised standard is used, a reference to the harmonised standard is sufficient to indicate the operating conditions and measurement methods used. Where other test methods are used, the operating conditions and measurement methods used must be indicated in the noise emission declaration.

The fourth paragraph of section 1.7.4.2 (u) also requires the uncertainties surrounding the values to be specified in the noise emission declaration. Current technical knowledge does not allow the uncertainty associated with the measurement of LpC_{peak} values to be determined. Guidance on determining the uncertainty associated with the measurement of the LpA at workstations and the LWA should be given in the relevant test codes.

The fifth paragraph of section 1.7.4.2 (u) explains how to measure the LpA at workstations for machinery where the operators do not occupy well-defined workstations. If the method set out in this paragraph is used, the noise emission declaration must indicate where the LpA levels have been measured.

The last paragraph of section 1.7.4.2 (u) refers to the Outdoor Equipment Directive $2000/14/EC.^9$ For the machinery in its scope, the Outdoor Equipment Directive applies, in addition to the Machinery Directive, with respect to noise emissions in the environment – see §92, comments on Article 3.

The Outdoor Equipment Directive requires the equipment in its scope to bear a marking, accompanying the CE marking, indicating the guaranteed sound power level (which is the value of the sound power level measured according to the method set out in Annex III of the Directive, plus the value of the uncertainties due to production variation and measurement procedures).

The last paragraph of section 1.7.4.2 (u) means that, for machinery in the scope of the Outdoor Equipment Directive, the third value to be indicated in the noise emission declaration in the instructions is the guaranteed sound power level rather than the measured LWA. However, the requirement to declare the measured values of the LpA and the LpC_{peak} at workstations, according to the first paragraph section 1.7.4.2 (u), remains applicable to such machinery.

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⁹ Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors – OJ L 162, 03/07/2000, p. 1.

1.7.4.2 Contents of the instructions (continued)

. . .

v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.

§272 Implantable medical devices

The requirement set out in section 1.7.4.2 (v) deals with the particular case of residual risk due to non-ionising radiation – $\underline{\text{see } \S232, \text{ comments on section } 1.5.10}$. Information on the nature of such radiation emission must be provided, particularly if it is likely to affect the functioning of implantable medical devices.

1.7.4.3 Sales literature

Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

§273 Sales literature

While the instructions provided with the machinery are primarily intended to ensure safe use of the machinery, sales literature has a principally commercial function. However section 1.7.4.3 requires that the instructions and commercial documents should be consistent. This is particularly important with respect for the intended use of the machinery referred to in section 1.7.4.2 (g), since users are likely choose machinery for their purposes on the basis of sales literature.

The second paragraph of section 1.7.4.3 is intended to help users to choose machinery with reduced levels of emissions of noise, vibrations, harmful radiation or hazardous substances. In particular, the values included in the noise emission declaration required by section 1.7.4.2 (u) and the information on vibrations required by sections 2.2.1.1 and 3.6.3.1 must be included in documents relating to the performance characteristics of the machinery. Many sales brochures or catalogues include a section or table giving the principle performance characteristics of the machinery such as power, speed, capacity, production rate and so on, to enable potential customers to choose machinery appropriate to their needs. This section is the appropriate place to include the required information on emissions.