



Manufacturer's instructions : an essential part of the machine

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Standard EN 12100-2

Clause 6 - Information for use :

- *Drafting information for use is an integral part of the design of a machine*

A) The Machinery Directive

The current Directive

- The Machinery Directive 98/37/EC
- is a consolidated version of Directive 89/392/EEC and its successive amendments
- It has been fully applied since 1995

Revision of the Directive

- Commission proposal to Council and Parliament in 2001
- Political agreement in Council in September 2004
- Adoption possible in 2005/2006
- Would be applicable by 2010

Aims of the Machinery Directive

- to ensure free circulation of machinery on the internal market
- to ensure a high level of protection of the health and safety of users and other exposed persons
- to ensure safety by design

The Directive is based on the “New Approach”

- Mandatory essential health and safety requirements (Annex I) define the objectives to be attained
- Voluntary European harmonised standards define technical means of satisfying the objectives

B) Language requirements for machinery

The revised Machinery Directive

- Does not fundamentally modify the current language requirements
- Clarifies these requirements
- Specifies the content of the manufacturer's instructions in greater detail

1) The Technical file

- describes the machinery and shows how the essential requirements have been satisfied
- must be compiled by the manufacturer and produced on request
- *The technical file must be compiled in one or more of the official languages of the Community*

2) The Manufacturer's Instructions

- The instructions must be supplied with the machine
- They are subject to essential health and safety requirements
- They must provide the information necessary for safe use of the machine

Principles of safety integration

1. Eliminate or reduce hazards
2. Integrate measures to protect against hazards that cannot be eliminated or sufficiently reduced
3. Inform users about the residual risks and measures to be taken by the user to ensure safe use

Drafting of the instructions

- *The instructions must be drafted in one or more official Community languages. The words "Original instructions" shall appear on the language version(s) verified by the manufacturer or his authorised representative*

Translation of the instructions

- *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 introducing the machinery into the language area in question. The translations must bear the words "Translation of the original instructions"*

One exception

- *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*

Taking account of the user

- *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*

3) Assembly instructions for partly completed machinery

- These are supplied by the manufacturer of partly completed machinery to the assembler of the final product
- *The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative*

4) 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 the language(s) of the country in which the machinery is to be used and accompanied, on request, by versions in the languages understood by the operators*

5) EC type-examination

- Some categories of machinery are subject to a third-party conformity assessment : EC type-examination
- *Files and correspondence referring to the EC type-examination procedures shall be written in an official language of the Member State where the notified body is established or in a language acceptable to it*

6) The EC declaration of conformity

- The EC Declaration of conformity is established by the manufacturer or his authorised representative
- It must accompany the machine
- *This declaration and translations thereof must be drawn up under the same conditions as the instructions*

C) Information for use and standards

The 3 Types of machinery standards

- A-type standards : design principles for all machinery
- B-type standards : aspects of safety for a wide range of machinery
- C-type standards : safety of one category of machinery

Harmonised European standards

- The harmonised European standards for specific categories of machine (C-type standards) include a clause on the contents of the instructions for use
- The general harmonised standards on machinery safety (A-type standards) provide guidance on content and drafting
- As yet there is no B-type standard on instructions for use for machinery

A-type standards

- EN 292 parts 1 and 2:1991
has been revised and become :
- EN ISO 12100 parts 1 and 2: 2003
*Safety of machinery – Basic concepts,
general principles for design*

Standards EN 12100-1 & 2

- Part 1 : Figures 1 and 2 :

Show instructions for use as the 3rd step in the 3-step method for risk reduction

- Part 2 : Clause 6 :
Information for use:

International standardisation

- ISO/IEC Guide 14:2003
Purchase information on goods and services intended for consumers
- IEC 62079:2001
*Preparation of instructions -
Structuring, content and presentation*
A comprehensive guide for electrical products

Further information

- DG Enterprise and Industry
Machinery Web-site :

[http://europa.eu.int/comm/enterprise/mechan
_equipment/machinery/index.htm](http://europa.eu.int/comm/enterprise/mechan_equipment/machinery/index.htm)

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