COMMUNITY LEGISLATION ON MACHINERY

Comments on Directives 98/37/EC

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Paragraph

1.

INTRODUCTION

In 1993, the Commission published the first version of this document entitled "Community Legislation on Machinery - Comments on Directives 89/392/EC and 91/368/EEC[1]". This is an updated version, providing further relevant advice on the machinery Directive, taking into consideration the practical issues which have been raised during its period of implementation.

This document combines the text and the associated comments which are now relevant, from the main Directive and its three amendments.
Since the revision of this text, the Directive has been codified and has become "Directive 98/37/EEC[2] of the European Parliament and the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery". This Directive does not modify any of the text which it replaces. Article 14 of this new Directive states that references to the repealed Directives shall be construed as references to this Directive and read accordingly without modification.

The comments in the document are made by officials, notably Mr Van Gheluwe, an engineer by training, who has taken part in all the work (preparatory work, discussions at the Council, work in committees and sessions of the European Parliament and at the Economic and Social Committee). The comments are intended to answer the kind of questions which are likely to be asked by users of the Directive, such as manufacturers, their representatives and machinery users.

The draft document was submitted to various relevant parties, including the Member State experts from the Committee created by the Directive. Their comments were included, as far as possible, in the final text.

It is important to note that this document only aims at facilitating the interpretation of the Directive and that only the text of the Directive itself is legally binding. The document has no legal status, but should be regarded as a reference to help all relevant parties apply the law in a uniform manner.

In addition to this guide on the application of the machinery Directive, the Commission has published a document, in English only, summarising the main facts relevant to the application of the Directive; it is entitled "Machinery: Useful facts in relation to the Directive 98/37/EC" (available from the Commission Services, fax: 32 2 296 62 73) and which contains the following information:

- questions and answers approved by the Working Group set up by the Directive,
- the list of bodies notified under the Directive,
- the list of harmonised standards published in the Official Journal of the European Communities and other standards and draft standards connected with the Directive,
- "recommendations for use" sheets approved by the coordination of the notified bodies and ratified by the Working Group set up by the Directive.
- useful addresses.

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1 Directive 89/392/CEE of 14 June 1989 (OJ No L 183, 29.06.89, p. 9) as last amended by Directives 91/368/EEC (OJ No L 198, 22.07.91, p. 16); 93/44/CEE (OJ No L 175, 19.07.93, p. 12) and 93/68/EEC (OJ No L 220, 31.08.93, p. 1).

2 Directive 98/37/CE of 22 June 1998 (OJ No L 207, 23.07.98, p. 1).

RECITALS

2.

The recitals[3] have no independent legal value and do not need to appear in the national legislation transposing the Directive. However, in case of litigation, the courts can take them into consideration to ascertain the Council's intention when drafting certain Articles.

You are therefore advised to read the recitals and to bear them in mind when reading the corpus of the Directive; this will remove certain apparent ambiguities and clarify the meaning of certain words which the Directive uses in a restrictive or unusual sense.

No particular importance should be attached to the order in which they appear, which is the same as in the Directive and does not imply any hierarchy.

3.

Recital No 1

Whereas Member States are responsible for ensuring the health and safety on their territory of their people and, where appropriate, of domestic animals and goods and, in particular, of workers notably in relation to the risks arising out of the use of machinery;

4.

The safeguarding of human safety is an obligation and a fundamental prerogative of the Member States. This is confirmed by Article 36 of the Treaty[4] which authorizes derogations to the principle of freedom of movement laid down in Article 30. Article 36 of the Treaty establishing the European Community provides that prohibitions or restrictions on imports, exports or goods in transit are acceptable if justified on grounds of public order such as the protection of health and life of humans. Such prohibitions or restrictions may not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

The Directive no longer allows Member States to invoke Article 36 for the hazards covered by the Directive. It lays down "essential safety requirements" which may justify restrictions on trade if not complied with. Thus the Treaty applies fully to machinery. Member States may not invoke Article 36 to prohibit machinery in the fields covered by the Directive; they may only invoke the fact that a specific requirement is not fully complied with. Member States may obviously ask the Commission to propose an amendment to the Directive in areas they would like to see improved. Meanwhile, they have no legal right to prevent free movement of machinery complying with the Directive.

5.

Recital No 2

Whereas, in the Member States, the legislative systems regarding accident prevention are very different; whereas the relevant compulsory provisions, frequently supplemented by de facto mandatory technical specifications and/or

[3] The recitals are numbered for ease of reading.

[4] Treaty establishing the European Economic Community of 25 March 1957 as amended by the Single European Act of 17 and 18 February 1986 (OJ No L 169, 29.06.1987), the Treaty on European Union of 7 February 1992 (OJ No C 191, 29.07.1992) and the Accession Treaty of Austria, Finland and Sweden signed in Corfu on 24 June 1994 (OJ No C 241, 29.08.1994, p. 9), as amended by the Council Decision of 1 January 1995.

voluntary standards, do not necessarily lead to different levels of health and safety, but nevertheless, owing to their disparities, constitute barriers to trade within the Community; whereas, furthermore, conformity certification and national certification systems for machinery differ considerably;

6.

This recital notes that safety levels in the Member States may be similar but that the means used to attain them are very different. Harmonization of the means will remove barriers to trade caused by safety regulations and so facilitate the free movement of machinery.

7.

Recital No 3

Whereas the maintenance or improvement of the level of safety attained by the Member States constitutes one of the essential aims of this Directive and of the principle of safety as defined by the essential requirements;

8.

See paragraph 10 below.

9.

Recital No 4

Whereas existing national health and safety provisions providing protection against the risks caused by machinery must be approximated to ensure free movement of machinery without lowering existing justified levels of protection in the Member States; whereas the provisions of this Directive concerning the design and construction of machinery, essential for a safer working environment shall be accompanied by specific provisions concerning the prevention of certain risks to which workers can be exposed at work, as well as by provisions based on the organization of safety of workers in the working environment;

10.

These two recitals emphasize that the level of safety already attained in a given Member State must not be lowered. Thus the Directive will both harmonize safety measures and bring about an overall improvement.

These recitals remove in advance all claim to legitimacy of any national technical barrier linked to one of the essential requirements of the Directive maintained after its entry into force. Member States must take over the Directive's essential requirements without removing or adding anything.

This principle is justified by the objective of a high level of safety laid down in Article 100a(3) of the Treaty.

Finally, the end of recital No 4 announces that these machinery design measures are to be supplemented by Directives on the use of machinery to ensure the safety of workers. The most

important of these is Directive 89/655/EEC, as amended[5] concerning use of work equipment by workers. It is important not to confuse the rules for the use of work equipment covered by social legislation (Article 118a of the Treaty). The rules for the use of work equipment, contrary to the machinery design rules, are minimum requirements that Member States are free to make more stringent. However They must not raise barriers to the free movement of machinery complying with the machinery Directive.

11.

Recital No 5

Whereas the machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy;

12.

This recital recognizes the economic importance of the machinery sector; too radical disruptions could have adverse socio-economic effects. The European Commission has published an important communication on the major economic role of the machinery manufacturing industry in the European economy.

13.

Recital No 6

Whereas paragraphs 65 and 68 of the White Paper on the completion of the internal market, approved by the European Council in June 1985, provide for a new approach to legislative harmonization;

14.

The machinery Directive is in line with the objective of the completion of the internal market begun in 1985. The "new approach" is to adopt Directives which lay down binding essential health and safety requirements and make reference to the optional application of harmonized standards as the means of complying with them. This contrasts with the "old approach" where Directives laid down detailed essential technical requirements applicable to products.

15.

Recital No 7

Whereas the social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installations and maintenance;

16.

This recital emphasizes the importance of inherently safe machinery design. Machinery whose safety is ensured by means of "add-ons" or by "patching up" an old design does not comply with the requirements of the Directive. The requirement for inherently safe product design distinguishes the regulations on "new" machinery from those on machinery "in service" and which has been reconditioned (Directive 89/655/EEC, as amended) for which "add-on" safety solutions are perfectly acceptable.

17.

[5] Directive 89/655/EEC of 30 November 1989 (OJ No L, 30.12.1989, p. 13). That Directive was amended by Directive 95/63/EC (OJ No L 335, 30.12.1995, p. 28).

Recital No 8

Whereas the field of application of this Directive must be based on a general definition of the term "machinery" so as to allow the technical development of products; whereas the development of "complex installations" and the risks they involve are of an equivalent nature and their express inclusion in the Directive is therefore justified;

18.

The concept of "machinery" referred to in the Directive is a generic one covering a wide variety of equipment whose main hazards are mechanical. The limits of its scope are discussed in the comments on Article 1.

19.

Recital No 9

Whereas specific Directives containing design and construction provisions for certain categories of machinery are now envisaged; whereas the very broad scope of this Directive must be limited in relation to these Directives and also existing Directives where they contain design and construction provisions;

20.

This recital points out the need to draft particular Directives to deal with specific machinery. The machinery Directive has so far been amended to incorporate hazards of mobile equipment (mainly concerning public works equipment), hazards associated with lifting goods and persons. Lifts[6] and cableway installations designed to carry passengers (cable cars and similar), are regulated by specific Directives.

21.

Recital No 10

Whereas it is also necessary to deal with safety components which are placed on the market separately and the safety function of which is declared by the manufacturer or his authorized representative established in the Community;

22.

Safety components had to be incorporated into the machinery Directive owing to the importance of the work of making machinery in service compliant, imposed by the "social" Directive 89/655/EEC, as amended. It is important for firms wishing to modify old equipment to be able to find reliable safety components on the market. In some Member States, certain safety components were covered by specific regulations. The Directive now ensures free movement of such components.

23.

Recital No 11

Whereas Community law, in its present form, provides - by way of derogation from

6 Directive 95/16/EC of 29 June 1995 (OJ No L 213, 7.9.1995, p. 1).

one of the fundamental rules of the Community, namely the free movement of goods - that obstacles to movement within the Community resulting from disparities in national legislation relating to the marketing of products must be accepted in so far as the provisions concerned can be recognized as being necessary to satisfy imperative requirements; whereas, therefore, the harmonization of laws in this case must be limited only to those requirements necessary to satisfy the imperative and essential health and safety requirements relating to machinery; whereas these requirements must replace the relevant national provisions because they are essential;

24.

This recital illustrates the principle of subsidiarity. The machinery Directive is limited to what is strictly necessary to ensure free movement and the high level of safety provided for by the Treaty. The Directive's essential administrative and technical requirements have been conceived to be proportional and sufficient to achieve the desired effect. The machinery Directive does not therefore restrict Member States' right to regulate machinery in areas other than those dealt with therein. In those other areas, the rules of the Treaty obviously remain in force.

25.

Recital No 12

Whereas the essential health and safety requirements must be observed in order to ensure that machinery is safe; whereas these requirements must be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements;

26.

This recital introduces the second preliminary observation in Annex I. The technical measures imposed by the Directive must be proportionate to the risk, the cost of the machinery and its real conditions of use. Although it may be possible to imagine very sophisticated devices which eliminate every risk, this is required only if it does not make the machinery "uneconomic", i.e. does not entail excessive purchase price or operating costs. The safety devices must also be realistic from the point of view of the use of the machinery by the operator. The Directive obviously does not impose the fitting of devices which make the equipment almost impossible or difficult to use. It is also important to take account of the relevant rules of good engineering practice when designing machinery.

Where the interpretation of this is disputed and all means of arbitration have been exhausted, it is for the Courts to determine the economically realistic threshold in each case.

27.

Recital No 13

Whereas the putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself as intended by the manufacturer; whereas this does not preclude the laying-down of conditions of use external to the machinery, provided that it is not thereby modified in a way not specified in this Directive;

28.

The manufacturer's obligations to design and manufacture inherently safe machinery are limited to intended and foreseeable uses, and do not extend to unorthodox uses. However, the Member States are at liberty to lay down conditions of use of machinery provided these do not entail modifications to the machinery itself; for example, they may lay down an age limit or qualifications for the operator, etc.

29.

Recital No 14

Whereas, for trade fairs, exhibitions, etc., it must be possible to exhibit machinery which does not conform to this Directive; whereas, however, interested parties should be properly informed that the machinery does not conform and cannot be purchased in that condition;

30.

This recital simply introduces Article 2(3). This derogation is necessary because new models of equipment are often exhibited without guards for demonstration purposes. Furthermore, some machinery shown at exhibitions can be intended for export outside the European Economic Area (EEA) where the machinery Directive does not apply.

31.

Recital No 15

Whereas, therefore, this Directive defines only the essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery; whereas, in order to help manufacturers to prove conformity to these essential requirements and in order to allow inspection for conformity to the essential requirements, it is desirable to have standards harmonized at European level for the prevention of risks arising out of the design and construction of machinery; whereas these standards harmonized at European level are drawn up by private-law bodies and must retain their non-binding status; whereas for this purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are the bodies recognized as competent to adopt harmonized standards in accordance with the general guidelines for cooperation between the Commission and these two bodies signed on 13 November 1984; whereas, within the meaning of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by either or both of these bodies, on the basis of a remit from the Commission in accordance with the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (4), as last amended by Directive 88/182/EEC (5), and on the basis of general guidelines referred to above;

32.

This very important recital defines a "harmonized" standard as being both:

- a European standard or a harmonization document, and

- drawn up on the basis of a remit from the Commission of the European Communities.

For harmonized standards to have presumption of conformity, references to them must be published in the Official Journal of the European Communities (see Article 5(1)) and they must be listed in accordance with Article 12 of the Directive.

Directive 83/189/EEC,[7] as amended, laying down a procedure for the provision of information in the field of technical standards and regulations, is the legal framework for European standardization.

33.

Recital No 16

Whereas the legislative framework needs to be improved in order to ensure an effective and appropriate contribution by employers and employees to the standardization process; whereas such improvement should be completed at the latest by the time this Directive is implemented;

34.

This recital, added at the request of the European Parliament, has no direct bearing on the content of the Directive; however, it led the Commission to take certain initiatives to facilitate trade union access to the standardization process.

35.

Recital No 17

Whereas, as is currently the practice in Member States, manufacturers should retain the responsibility for certifying the conformity of their machinery to the relevant essential requirements; whereas conformity to harmonized standards creates a presumption of conformity to the relevant essential requirements; whereas it is left to the sole discretion of the manufacturer, where he feels the need, to have his products examined and certified by a third party;

36.

The basic principle is that the manufacturer makes a declaration of conformity of his machinery without the intervention of a third party. Third-party certification is the exception. This option is justified since thousands of types of machinery are created every year. The general trend of the engineering industry is towards specialization and hence towards the production of machinery in short runs. Manufacturers are increasingly adapting their equipment to their customers' specific needs. This trend makes systematic third-party certification of machinery both technically and economically impossible.

37.

Recital No 18

Whereas, for certain types of machinery having a higher risk factor, a stricter

[7] Directive 83/189/EEC of 28 March 1983 (OJ No L 109, 25.4.1983, p. 8); amended by Directives 88/182/EEC (OJ No L 81, 26.3.1988, p. 75) and 94/10/EC (OJ No L 100, 19.4.1994, p. 30).

certification procedure is desirable; whereas the EC type-examination procedure adopted may result in an EC declaration being given by the manufacturer without any stricter requirement such as a guarantee of quality, EC verification or EC supervision;

38.

Recitals 17 and 18 justify the certification procedures laid down by the Directive, i.e. a declaration of conformity by the manufacturer, in most cases without the intervention of any third party but, in the case of certain machinery, exhaustively listed in Annex IV, an EC type-examination by a third party is needed.

39.

Recital No 19

Whereas it is essential that, before issuing an EC declaration of conformity, the manufacturer or his authorized representative established in the Community should provide a technical construction file; whereas it is not, however, essential that all documentation be permanently available in a material manner but it must be made available on demand; whereas it need not include detailed plans of the sub-assemblies used in manufacturing the machines, unless knowledge of these is indispensable in order to ascertain conformity with essential safety requirements;

40.

In return for the freedom to declare conformity himself, the manufacturer is obliged to compile a technical construction file. The file contains the manufacturer's risk analysis and information on the design process he has followed. The contents of this file are explained in the comments on Article 8 and Annex V.

41.

Recital No 20

Whereas it is necessary not only to ensure the free movement and putting into service of machinery bearing CE marking and having an EC conformity certificate but also to ensure free movement of machinery not bearing CE marking where it is to be incorporated into other machinery or assembled with other machinery to form a complex installation;

42.

This recital does not require any further comments.

43.

Recital No 21

Whereas the Member States' responsibility for safety, health and the other aspects covered by the essential requirements on their territory must be recognized in a safeguard clause providing for adequate Community protection procedures;

44.

The safeguarding of human safety is a matter of public policy, and hence a national prerogative, which does not limit the Directive; quite the contrary. States retain full discretion to restrict the placing on the market and use of any machinery that proves hazardous. They may also contest the content of European standards which they do not think offer an adequate response to the essential safety requirements laid down in the Directive. These prohibition or contestation procedures are the subject of Community consultation in the context of the "safeguard" procedures.

45.

Recital No 22

Whereas the addressees of any decision taken under this Directive must be informed of the reasons for such a decision and the legal remedies open to them;

46.

This recital prevents Member States arbitrarily prohibiting machinery. They must give reasons for this type of decision and inform the parties concerned of the legal remedies open to them.

47.

Recital No 23

Whereas the measures aimed at the gradual establishment of the internal market must be adopted by 31 December 1992; whereas the internal market consists of an area without internal frontiers within which the free movement of goods, persons, services and capital is guaranteed,

48.

The machinery Directive is in line with the objectives for the completion of the internal market provided for by the Treaty: the second part of this recital is taken almost word-for-word from Article 7a of the Treaty. The area without internal frontiers referred to in this recital now corresponds to the 15 Member States of the European Union (Belgium, Denmark, Germany, Greece, Spain, France, Ireland, Italy, Luxembourg, Austria, the Netherlands, Portugal, Finland, Sweden and the United Kingdom) plus the signatories to the agreement on the European Economic Area[8] (i.e. Liechtenstein, Iceland and Norway). The term "European Economic Area" (EEA) refers to all the territories of the above-mentioned 18 countries.

The following clarifications concerning the territories in which the machinery Directive applies may be helpful.

- The machinery Directive applies to any initial placing on the market in the EEA of machinery or a safety component, with or without charge, with a view to its distribution and/or use in the territory of the EEA.

- It does not apply to imports into the EEA market intended for re-export. These operations are carried out under specific Community customs arrangements.

[8] Decision 94/1/EC of the Council and the Commission of 13 December 1993 (OJ No L 001, 03/01/94, p. 1). Switzerland took part in the negotiation of the EEA agreement but did not ratify it.

- It does not apply to the export of machinery or safety components to a country outside the EEA.

49.

Recital No 24

Whereas it is necessary to provide for transitional arrangements enabling Member States to authorize the placing on the market and putting into service of machinery manufactured in accordance with the national rules in force on 31 December 1992;

50.

It was unrealistic to expect that on the night of 31 December to 1 January, on the stroke of midnight, the old national regulations would be replaced by the measures transposing the Directive into national law and that by some miracle all machinery in stock with distributors would be marked at dawn on 1 January 1993.

This recital introduces Article 13, which provides for a gentle transition staggered over 1993 and 1994 so that:

- old stock could be sold;
- the notified bodies would have time to prepare for their certification tasks;
- manufacturers would have time to gradually adapt their products to the essential requirements of the Directive.

51.

It should nevertheless be pointed out that since 1 January 1993 European Union businesses may provide workers only with equipment complying with the technical annex to Directive 89/655/EEC, as amended, where no Community Directive applies to the stage of placing the product on the market.

52.

CHAPTER I
SCOPE, PLACING ON THE MARKET AND FREEDOM OF MOVEMENT

Article 1(1)

1. This Directive applies to machinery and lays down the essential health and safety requirements therefor, as defined in Annex I.

It shall also apply to safety components placed on the market separately.

53.

Article 1 defines the scope of the Directive. Paragraph 1 states that the Directive lays down essential health and safety requirements.

Directive 89/392/EEC as amended applies to two families of products: machinery and similar equipment, and safety components.

The Directive lays down essential requirements for human health and safety mostly concerning operators and persons near to machinery. The essential safety requirements do not directly concern environmental protection or the technological performance of machinery. Some of them can obviously help to ensure these. By way of an example, intrinsic reduction of machinery noise for the operator helps to reduce environmental noise. It is nevertheless possible that the essential safety requirements are difficult to reconcile with other requirements; the collection of gases from machinery and their discharge outside can be an environmental hazard; compliance with safety clearances can give rise to food hygiene problems. Standardization will endeavour to reconcile these various safety requirements. In the technical fields not covered by a European Directive, the Member States remain free to adopt regulations that are in line with the Treaty (Articles 30 and 36).

54.

Directive 89/655/EEC, as amended, obliges businesses in the EEA to bring all their machinery into line with a number of minimum essential safety requirements.

Machinery users, who are not necessarily experts in the field, will have to acquire safety components on the market. It is important that the safety components they are offered fulfil their functions with a high degree of reliability. Safety components sold separately are therefore included in the scope of the Directive: in this case their manufacturers must take certain responsibilities and comply with the provisions of the Directive.[9]

55.

Conversely, when a manufacturer incorporates a safety component into machinery, he takes responsibility for his choice of component. Where necessary, he has drawn up a specification which the component supplier must follow. The manufacturer

[9] See the comment on Article 1(2) below for an explanation relating to safety components.

incorporating the component must assume responsibility for his choice of components and ensure that the finished product complies with the Directive.

56.

Article 1(2)

2. For the purposes of this Directive, "machinery" means an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material.

The term "machinery" also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.

"Machinery" also means interchangeable equipment modifying the function of a machine, which is placed on the market for the purpose of being assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool.

For the purposes of this Directive, "safety component" means a component, provided that it is not interchangeable equipment, which the manufacturer or his authorized representative established in the Community places on the market to fulfil a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons.

57.

Paragraph 2 first defines what the Directive means by machinery. The guiding principle is that machinery is fundamentally "mechanical".

The definition is "universal" in style. The following points should nevertheless be highlighted:

58.

- **an assembly of parts**: this logically excludes basic components. However, as we will see in the last subparagraph, certain basic components such as items of lifting gear (hooks, rings, rings with stud connections) are covered (although not actually safety components or machines, these products are implicitly covered by the Directive). This confirms that other components are excluded. We will also see that some parts forming sub-assemblies or "quasi machinery" are also excluded.[10]

59.

- **the parts must be linked**. This does not exclude machinery which is sold dismantled for ease of transport or in kit form, as the manufacturer is obliged to design his machinery in accordance with the Directive. In these special cases the manufacturer gives the necessary assembly instructions to the customer. CE marking obviously relates only to the actual design of the product and the assembly instructions. Assembly is the user's responsibility. The manufacturer is not responsible for any failure to follow

[10] See the comment for Article 4.

the assembly instructions he has provided. Confirmation of this can be found in essential requirements 1.1.2(a), 1.5.4, 1.7.4(a) and 3.6.3(b) of Annex I.

60.

- **one of the parts must move**. This movement must result from external energy (electricity, battery, fuel, etc.) or stored energy (spring, weight). Thus, by way of exception from this rule, the machinery Directive also covers certain lifting equipment moved directly by manual effort. Other machinery moved by manual effort directly is excluded. Static assemblies (shelving, scaffolding, pallets, hand tools, hand-pushed trolleys, etc.) are therefore excluded.

61.

- **for a specific application**. This implies that machinery which is unfinished, to the extent that it cannot function, is not covered by the Directive. This is confirmed by Article 4(2). The list of applications given here is not exhaustive: the phrase “in particular” means that these are merely examples. However, the concept of “application” implies that machinery is marketed for actual use by an operator. Machinery intended to be scrapped or reconditioned clearly does not have to comply with the machinery Directive 89/392/EEC, as amended. Please refer to the legal arrangements for reconditioned and second-hand machinery at the end of this paper.

62.

Interpretation of the scope of the machinery Directive must not be taken to absurd lengths. The important thing is to understand the benefits sought through it. The Directive’s sole aim is to facilitate the movement of products and improve the safety of hazardous ones. Indeed, the scope of the “new approach” Directives must be understood by combining the very general definition usually given in Article 1 and the hazards referred to. Legally, machinery falling within the definition of Article 1 is covered by the Directive even if such machinery presents none of the hazards referred to in Annex I. “None of the hazards referred to” means before any measure taken at the design stage: it is clear that machinery that presents no risk because it is totally enclosed in a housing is covered by the Directive because hazards do exist if the housing is removed. On the other hand, the question may be raised as to the use of the Directive when applied to a mechanical watch: a watch is “an assembly of linked parts or components, at least one of which moves ... for a specific application” (showing the time). Thus, even without the case, the mechanism presents none of the hazards referred to in Annex I.

63.

Risk is a secondary criterion which enables the scope to be adjusted to avoid improper application of the machinery Directive. Products which do not fall within the definition of “machinery” or safety components cannot be covered by the Directive even if they present some of the hazards referred to in Annex I. These products are governed by other Directives or national law.

64.

It is not always easy to apply the definition of “machinery” in practice.

An internal combustion engine, for example, supplied to be built into a machine, is not “machinery” within the meaning of the Directive since it has no definite application before it is built in. An outboard motor, with its propeller, sold direct to the user, on the other hand, has a definite function of propelling a vessel, without modification or other operation by a specialist. Outboard motors are covered by the Directive whereas in-board motors for propelling boats are not! “Machinery with heat engines for use in underground working” referred to in Annex IV of the Directive is the only exception to

this rule. These motors have been included in the Directive pending the Directive on equipment intended for use in an explosive atmosphere.

65.

The issue is even more ambiguous with products such as motorized valves since it is the intended end use of the product which determines whether or not it is covered by the Directive. This use is sometimes laid down by the manufacturer of the motorised valve where it is a separate whole machine.

66.

In most cases the manufacturer of the motorised valve does not stipulate a particular use, and thus the following rule can apply:
If a motorised valve, such as a lock gate valve sold as such, is installed in isolation, it is covered by the Directive because it has a definite application as supplied. It is the principal part of the lock gate and guarantees correct operating.
If a motorised valve intended to be incorporated in a machine or an assembly is sold to a manufacturer of machinery or more complex assemblies where "CE" marking is required under the "machinery" Directive, it should not be regarded as machinery within the meaning of the Directive but rather an ordinary component. Where necessary it will be accompanied by a manufacturer's declaration as referred to in Annex II.B.

67.

The second subparagraph of paragraph 2 specifies that:

the term "machinery" also covers an assembly of machines or complex installation. A "complex installation" means an assembly of machinery, appliances and mechanisms which, in order to contribute to the same result, generally the same production, are arranged and installed so as to be interdependent in operation. Complex installations form a coherent whole. This provision of the Directive is aimed in particular at robot and automated workshops. Production lines and special machinery made up of several machines are complex installations. This definition is important because it is meaningless to consider the conformity of parts or components, or machinery components (appliances, mechanisms and subassemblies) with the provisions of the Directive considered as a whole. Safety must be designed into a whole system. The drafters kept this concept constantly in mind, and the consequences can be seen in Articles 4(2) and 8(6). We will analyse the latter in more detail below. Large installations such as metal foundries and paper machines are also covered.

68.

The definition of machine assemblies should be applied with common sense and understanding, however. There is no point, for example, in extending it to complete industrial plants such as power stations or oil refineries.

The question of applying the "machinery" Directive to a complex industrial installation only arises when the new installation is first put into service. Subsequently, the installation is always the responsibility of the manager, who may modify it for operating reasons, and national transposition of Directive 89/655/EEC is sufficient to cover the main safety requirements applicable. The "machinery" Directive does not therefore add anything useful concerning the safety of industrial units and common sense would suggest that it should not apply to complete installations. On the other hand, it will often be possible to identify homogeneous functional units that can be described as machinery as defined in Article 1 of the Directive.

69.

The concept of machinery extends to "interchangeable equipment" modifying the basic function of a machine. This was added to take account of hazards due to equipment retrofitted to mobile or lifting equipment. This often consists of a basic machine (e.g. a tractor) to which a wide variety of equipment can be attached to transform it into a ploughing, harvesting, excavating, lifting or loading/unloading machine, etc. Such equipment is often purchased long after the basic machine and from a different supplier. In order to avoid divergent design principles and safety standards of machinery and interchangeable equipment, the latter are subject to the machinery Directive. The coverage of both by the same legal instrument should help users to make the connection in safety. In this spirit, interchangeable equipment need not itself comply with all the criteria of the definition of machinery in Article 1 of the Directive. The decisive criterion which makes it subject to the Directive is that it is intended for use with machinery covered by the Directive or with a tractor, where such combined use alters the basic function of the equipment. All such interchangeable equipment must therefore be certified and marked with the "CE" logo in accordance with the machinery Directive.[11]

70.

The concept of interchangeable equipment[12] must not be taken literally from a purely technical point of view. It is a legal concept specific to the machinery Directive. Under no circumstances does it cover the many machinery spare parts. These spare parts are technically interchangeable but do not alter the machinery's basic function and do not therefore constitute "interchangeable equipment" in the legal sense.

71.

Safety components. This term arises in the second Directive amending the machinery Directive (91/368/EEC).

The following safety components are subject to EC type examination (Annex IV):

- electro-sensitive devices to detect persons (non-material barriers, sensor mats, electromagnetic detectors, etc.);
- logic units which ensure the safety functions of bi-manual controls;
- automatic movable screens (power-operated guards) to protect metalworking presses, injection or compression plastics- or rubber-moulding machines with manual loading or unloading.;
- roll-over protective structures (ROPS);
- falling-object protective structures (FOPS).

72.

Safety components covered by a manufacturer's conformity declaration without a type examination by a notified body are not specifically listed. The question arises as to what type of components should be regarded as "safety components". "Safety component" within the meaning of the machinery Directive is a very precise legal concept which should not be applied indiscriminately to any component.

Any component of machinery, whatever it is, must be safe and reliable owing to the general safety obligation which applies to any supplier and the obligation to observe good engineering practice. The requirements for component reliability and safety do not

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11 See additional comments on point 3.6.3 of Annex I.

12 The minutes of the Council meeting on "Internal market" of 20 June 1991 state that the Council and the Commission declare that a tool means a terminal part of a machine, in direct contact with the part or material to be worked, such as drill or concrete-breaker bits, grinding wheels or saw blades.

qualify all components as “safety components” within the special meaning of the machinery Directive.

73. Reading Article 1(2) allows one to get a better grasp of the “safety component” concept. The list of safety components subject to type examination also helps to clarify its meaning.

A “safety component” is a component. A subassembly of machinery within the meaning of Article 4(2) cannot therefore be classed as a safety component. Still less can a safety component be a complete machine or interchangeable equipment within the meaning of Article 1(2).

74. A safety component does not make a direct or main contribution to machinery’s “defined use”. The safety function is the specific characteristic of a safety component. This safety function is secondary to the machinery’s main function.

The absence, failure or faulty operation of the component can endanger the health or safety of the persons exposed to the machinery. A component whose failure has no adverse influence on safety is not a “safety component”.

75. The safety component concept is objective and unquestionable for a number of components, and in this case the manufacturer has no choice in the matter. For other components, the question is more delicate because their legal status will depend on the function that the manufacturer intends to give them. In this case, he will choose whether to declare them as “safety components”. Thus a limit switch can be used for the normal operation of the equipment. It is not a safety component. The same limit switch with a safety function only could be described as a “safety component”. There are no great difficulties in making the distinction.

For example, speed reducers or ball bearings are clearly not safety components, wherever they are fitted to a machine, because when they are sold separately the manufacturer or distributor does not attribute any safety function to them in the technical documentation, as he does for a two-hand control or a non-return valve for a hydraulic circuit.

76. After consulting the experts of the Member States, the Commission excluded components having a functional role from the scope of safety components. The main purpose of “functional components”, as perceived by manufacturers and users, is not safety-related. This obviously does not mean that these components may be unsafe or unreliable, only that they are not covered by the machinery Directive. Their failure may cause a hazard. It is for the component manufacturer to reduce the hazard through good product design practice and by applying any applicable regulations.

77. It is for the machinery manufacturer who acquires components for incorporating into machinery to avoid the failure of the component affecting the whole machine. The machinery manufacturer can choose from several “strategies”. For example, he can choose a highly reliable safety component for a particular safety function. He can also use two slightly less reliable components from different sources; the second component acting as a backup for the first if it fails.

78.

The experts of the Member States are of the opinion that only components providing a direct safety function should be regarded as safety components within the meaning of the Directive. A direct safety function is one where a malfunction would increase the risk of injury or health risks.

79.

The examples below illustrate the definition of a “safety component”.

The following are safety components:

. emergency stopping devices;

. non-return valves designed as safety devices for equipment’s hydraulic systems;

. safety belts and restraining devices in the event of overturning;

. control or monitoring modules of safety-related parts of control systems, such as the position detectors in a locking mechanism;

products preventing undesired operation of machinery;

. products preventing repetition of a machine cycle;

. temperature-control products or systems to keep machinery within safe operating limits;

. smoke or dust extraction systems for machinery;

. guards and their locking mechanisms;

. noise reduction enclosures;

. anti-derailment mechanisms for suspended lifting machinery;

. load control devices for lifting equipment;

. hold-to-run controls (requirement 5.5 of Annex I).

80.

Secondary emergency safety systems are full safety systems with the status of safety components. A limit switch placed after the normal stop of the machinery to avoid hazards related with the malfunctioning of this stop is a “safety component”.

It is customary practice in industry to regard certain components which have a safety function inseparable from another function as safety components.

This is the case, for example, of a synchronous bimanual control for metalworking presses, or manual control used in a degraded mode of the machine in the absence of a protection system (teaching or maintenance of a robot). In these examples the safety function is so critical for the safety of the operator that these components are regarded by manufacturers and users alike as “safety components”.

81.

It is not easy to give a more precise definition of the "safety component" concept. The Commission was unwilling to regulate many families of components. Only components entirely or mainly performing safety functions should be covered by this definition. Conversely, components whose main function is not safety are not "safety components" even if the functions they do perform are in some way connected with the safety of the equipment. Thus hoisting cables are never safety components as the machine cannot function at all without a cable. The main function of the cable is lifting and not the safety of lifting. The breakage of the cable can obviously be dangerous but this is not sufficient reason to classify it as a "safety component" .

82.

If a manufacturer classifies a product as a "safety component" he must comply with the essential safety requirements of Annex I. It is true that these requirements were written for machinery rather than for safety components. Note, however, the principle set out in the first opening remark of Annex I. The essential requirements apply only when the corresponding hazard exists. A manufacturer of safety components will select the relevant technical requirements for his product in the Annex to the Directive. He must follow the same certification procedures for safety components as for machinery, with the exception of "CE" marking.

83.

The Annex to the Directive includes several points applicable to safety components. For example, under requirement 1.3.2 machinery parts must withstand the operating stresses foreseen by the manufacturer. Requirement 1.4. lays down the regulations applicable to guards and protection devices. The machinery Directive could have laid down a general obligation on the safety and performance of safety components. In practice, the manufacturers of certain safety components already use testing methods for assessing their reliability. Standardization will have a crucial role to play in defining these methods.

84.

Regarding "administrative" obligations, safety component manufacturers must assemble a technical construction file and provide an instruction manual and a conformity declaration. The contents of construction files and instruction manuals must reflect the real situation of safety components. Account must be taken of the fact that the parts of the Directive on files and components were written before safety components were covered. It would be absurd to require a manufacturer of a non-material barrier or non-return valve to state the noise level of his safety component.

85.

Where a safety component is supplied directly to a user as an original spare part by the original machinery manufacturer, the question arises as to whether or not it needs to undergo the procedures of the Directive, in particular the type examination procedure for components of Annex IV. The supply of an original spare part could in fact be considered to be a continuation of the initial sales contract.

86.

Article 1(3)

3. The following are excluded from the scope of this Directive:

- ***machinery whose only power source is directly applied manual effort, unless it is a machine used for lifting or lowering loads,***
- ***machinery for medical use used in direct contact with patients,***
- ***special equipment for use in fairgrounds and/or amusement parks,***
- ***steam boilers, tanks and pressure vessels,***
- ***machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity,***
- ***radioactive sources forming part of a machine,***
- ***firearms,***
- ***storage tanks and pipelines for petrol, diesel fuel, inflammable liquids and dangerous substances.***
- ***means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or on road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, on public road or rail networks or on water. Vehicles used in the mineral extraction industry shall not be excluded,***
- ***seagoing vessels and mobile offshore units together with equipment on board such vessels or units,***
- ***cableways, including funicular railways, for the public or private transportation of persons,***
- ***agricultural and forestry tractors, as defined in Article 1(1) of Council Directive 74/150/EEC of 4 March 1974 on the approximation of the laws of the Member States relating to the type-approval of wheeled agricultural or forestry tractors, as last amended by Directive 88/297/EEC,***
- ***machines specially designed and constructed for military or police purposes.***
- ***lifts which permanently serve specific levels of buildings and constructions, having a car moving between guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal and designed for the transport of:***
  - ***persons,***
  - ***persons and goods,***
  - ***goods alone if the car is accessible, that is to say, a person may enter it without difficulty, and fitted with controls situated inside the car or within reach of a person inside,***
  - ***means of transport of persons using rack and pinion rail mounted vehicles,***
  - ***mine winding gear,***
  - ***theatre elevators,***
  - ***construction site hoists.***

87. Article 1(3) contains an exhaustive list of exclusions.

Some of the exclusions listed warrant further clarification:

(a) the exclusion of machinery whose only power source is directly applied manual effort. The drafters of the Directive sought to exclude hand tools such as pliers, pincers, scissors, shears, hand drills, hand-operated guillotines, hand-operated bending machines, etc. which cease to act as soon as the manual effort is no

longer applied, even if this effort is geared down by mechanical means (gears, lever arms, etc.).

Hand-pushed mobile machines, hand carts, trolleys and barrows are also excluded.

88.

Conversely, machinery which is powered by manual effort stored in springs, hydraulic or pneumatic accumulators, etc., the dangerous action of which can be produced or can continue after the manual effort has ceased, is covered by the Directive.

89.

Lifting equipment, even if powered by directly applied human effort, such as jacks, hoists and hand winches, is covered by the Directive because it presents particular hazards, even if it lifts to a low height only.

90.

(b) radioactive sources forming part of a machine. This exclusion applies only to the source itself, i.e. the "capsule" containing the radioactive product.

Machinery using a radioactive source for a specific application is covered by the Directive (see essential requirement 1.5.10 on the prevention of radiation hazards). Machinery using a radioactive source but powered by directly applied human effort is excluded from the scope of the Directive, however (e.g. certain industrial X-ray machines).

91.

(c) Simple pressure vessels are covered by Directive 87/404/EEC,[13] as amended. Simple pressure vessels placed on the market for incorporation into machinery must comply with Directive 87/404/EEC. Simple pressure vessels designed by machinery manufacturers for their machines must also comply.

92.

Directive 97/23/EC excludes pressure equipment up to category I within the meaning of that Directive and which would be included in the Directives on machinery, lifts, low voltage, medical devices, gas appliances, or equipment intended for use in potentially explosive atmospheres, this last Directive generally being known as "ATEX".

Pressure equipment, whether covered by Directive 87/404/EEC (simple pressure vessels), Directive 97/23/EC of 27 May 1997 covering other pressure equipment (regardless of category) or excluded (like pipes and tubes), is not covered by the machinery Directive if it is placed on the market independently. However, the machine in which pressure equipment is incorporated (such as an oleopneumatic accumulator or a pressure line) is indeed covered by the essential requirements of the machinery Directive where the risk of breakage in service or risks due to

[13] Directive 87/404/EEC of 25 June 1987 (OJ No L220, 8.8.1987, p. 48); amended by Directives 90/488/EEC (OJ No L270, 2.10.1990, p. 25) and 93/68/EEC (OJ No L220, 31.8.1993, p. 1).

energy sources other than electrical are concerned, notwithstanding the application of such Directives to the pressure equipment itself.

93.

(d) means of transport. This exclusion applies only to vehicle intended solely for transport and not vehicles with other functions covered by the machinery Directive (lorry-mounted crane, train-mounted crane, dumper lorry, etc.) or vehicles fitted with other equipment (auxiliary cranes, tail lifts, compaction mechanisms, concrete carboys, etc.). Risks linked to the transport function are not covered by the machinery Directive under Article 1(4) since they are already covered by specific Community Directives concerning lighting, visibility of roadways, maximum permitted axle loads, braking, etc. In contrast, other hazards induced by additional equipment come under the machinery Directive and have to be seen in terms of the equipment as a whole (e.g. stability of the equipment when unloading a skip or during lifting operations, visibility of the working area from the control position of compaction, mixing equipment, etc.).

94.

The exclusion of means of transport has given rise to many questions. For example, what about motor-racing vehicles (cars, motor bikes, etc.)? These are excluded, as the exclusion refers to means of transport for transporting passengers on road networks, without specifying whether the latter are public or private. A racing circuit, even if it is off the public highway, can be regarded as a road network for the duration of the race. Conversely, vehicles designed solely for use on sites not open to public traffic such as a factory compound, airport, golf course, etc., are generally not subject to the highway code and are covered by this Directive in respect of the hazards they present. Nevertheless, it would be going too far to say that an ordinary private vehicle which does not leave business premises should be regarded as machinery for the purposes of the Directive. Even if it is not registered or inspected by the competent administrative authorities, a private vehicle is assumed to comply with the applicable technical design rules.

95.

(e) Seagoing vessels and mobile offshore units together with equipment on board them are excluded since they are covered by the IMO Conventions. However, fixed offshore platforms and their equipment are covered by the Directive, as are vessels which are not considered to be seagoing, i.e. those of less than 500 tonnes, those not designed to put out to sea and those intended for inland navigation on rivers, canals, lakes, etc. The boat as a means of transport, including its propulsion system, is not covered by the Directive, but the machinery used on board (cranes, capstan, etc.) is.

96.

(f) "Lifts which permanently serve ..." are excluded. They are covered by the "lifts" Directive 95/16/EC,[14] but lifting platforms moving vertically or obliquely intended for the transport of handicapped persons are covered by the Directive, as are similar devices fitted on staircases.

97.

[14] Directive 95/16/EC of 29 June 1995 (OJ No L 213, 7.9.95, p.1).

(g) Theatre elevators are defined in a statement recorded in the Council minutes[15] as "devices for the lifting of persons which are installed permanently or temporarily in theatres and which enable persons, be they actors or stagehands, to move from the stage to places adjacent to the stage (basement, flies, wings, orchestra pit, scenery) and vice versa". One can hardly imagine a singer appearing on stage surrounded by barriers!

98.

(h) "Machines specially designed and constructed for military or police purposes" means machinery designed exclusively for such purposes. However, all "ordinary" machinery which can be used by military or police forces but is not designed specially for their use is covered by this Directive. We would point out here that Article 223 of the Treaty stipulates that any Member State may take such measures as it considers necessary for the protection of the essential interests of its security which are connected with the production of or trade in arms, munitions and war material. Note that fire services are not regarded as a public order agency, and that even machinery purpose-built for fire service use is therefore covered by the machinery Directive.

99.

Article 1(4)

4. Where, for machinery or safety components, the risks referred to in this Directive are wholly or partly covered by specific Community Directives, this Directive shall not apply, or shall cease to apply, in the case of such machinery or safety components and of such risks on the implementation of these specific Directives.

100.

There are "horizontal" Directives covering mainly electromagnetic phenomena,[16] the "ATEX" Directive,[17] and the Directive on the sound power level of concrete-breakers and drills.[18] This Directive therefore quite naturally ceases to apply in the case of the hazard covered by a more specific Directive.

It is possible for the specific Directive to lay down a more stringent certification procedure, for example EC type-examination or EC product verification. In this case, such examinations or verifications must be limited to the hazard covered by the specific Directive and must not concern the other hazards referred to in Annex I to this Directive. As stated in the comments on Article 1(3), the scope of a Directive is limited to the hazards covered. Moreover, a body notified under a Directive cannot take action under another Directive for which it is not notified. But in the case of the machinery Directive, a body can be notified only for machinery listed in Annex IV, and the list is very short. A body notified for the machinery Directive will obviously not examine the specific hazards (explosion, electromagnetism, noise, pressure) that a

15 Minutes of the Council meeting on internal market of 20 June 1991.

16 Directive 89/336/EEC of 3 May 1989 (OJ No L139, 23.5.1989, p. 19), as amended by Directives 91/263/EEC (OJ No l128, 23.5.1991, p. 1), 92/31/EEC (OJ No l126, 22.5.1992, p. 11) and 93/68/EEC (OJ No L220, 31.8.1993, p. 1).

17 Directive No 94/9/EC of 23 March 1994 (OJ No L 100, 19/4/1994, p. 1).

18 Directive 84/537/EEC of 17 September 1984 (OJ No L 300, 19/11/1994, p.13), as amended by Directive 85/409/EEC (OJ No L 233, 30/8/1985, p. 20). There are many Directives on noise.

body notified under these specific Directives would do. There is obviously nothing to stop a body notified under several Directives from issuing several certificates in a single operation.

As "new approach" Directives enter into force, practical difficulties of applying the essential requirements of the Directives will probably appear. Here too, common sense and moderation are needed to interpret them. It is better to be guided by a concrete and realistic risk analysis than a legalistic and abstract analysis of the text of the various Directives. The legislator did not intend to cumulate the technical and administrative requirements of the Directives.

101.

The product-liability Directive[19] is sometimes referred to when studying machinery safety issues. It is important to understand the relationship between this Directive, the machinery Directive and the other "new approach" Directives.

102.

The "new approach" Directives harmonize national technical legislation concerning human safety and fair trading. They are technical regulations for preventing risks or more exceptionally fraud, e.g. Directive 90/384/EEC, as amended,[20] on non-automatic weighing instruments. They lay down binding rules that manufacturers must comply with before placing their products on the market.

This is not the aim of the product-liability Directive. It partially unifies the procedures for compensating bodily injury caused by unsafe products. It therefore aims to harmonize only a limited aspect of the civil liability systems applicable in the Member States. It gives precise definitions of the concept of "producer" or the person placing a product on the market. It therefore provides very precise definitions for the application of the "new approach" Directives. Under no circumstances does it determine the content of the technical specifications that producers must observe before placing their product on the market. For a victim of a defective product it merely simplifies the procedures of providing proof by exempting him from proving the manufacturer's liability.

The very existence of the Directive simply encourages manufacturers and their insurers to pay more attention to product safety. The Directive contains no precise guidelines as to how products should be modified or what information purchasers should be given. It all depends on the nature of the product, how real the danger is, and which regulations apply.

103.

Several European Directives harmonize the laws concerning the award of public supply or works contracts.[21] Technical harmonization has been extended to the water, energy, transport and telecommunications sectors.[22] These Directives stipulate that the awarding bodies lay down the technical specifications of the general or contractual documents for public contracts in relation to national standards transposing European standards. The awarding bodies may derogate from this rule under certain conditions.

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19 Directive 85/374/EEC of 25 July 1985 (OJ No L 210, 7.08.1985, p. 29).

20 Directive 90/384/EEC of 20 June 1990 (OJ No L 189, 20/7/1990, p. 1); amended by Directive 93/68/EEC (OJ No L 220, 31/8/1993, p. 1).

21 Directive 93/36/EEC of 14 June 1993 on public supply contracts (OJ No L 199, 09.08.1993, p. 1).
Directive 93/37/EEC of 14 June 1993 on public works contracts (OJ No L 199, 09.08.1993, p. 54).

22 Directive 93/38/EEC of 14 June 1993 (OJ No L 199, 9.08.1993, Article 18, p. 84).

Reference to European standards is made "without prejudice to compulsory technical rules in so far as these are compatible with Community law".[23]

The machinery Directive is therefore compulsory for machinery and safety components supplied under public contracts.

104.

Neither the machinery Directive nor the "public contracts" Directives make the standards mandatory. The "public contracts" Directives require public procurement agencies to refer to the standards in the specifications. Private purchasers are free to do so or not. There are some exceptions to the obligation to refer to the standards in public invitations to tender, however. For instance, the legal obligation to refer to the standards applies solely to the awarding entity. The manufacturer's obligation to comply with European standards is of a strictly contractual nature. If the contract makes no provision for it, the manufacturer is not bound to comply with European standards in public supply contracts. Therefore, the public contracts Directives do not undermine the general economy of the machinery Directive.

105.

Article 1(5)

5. Where, for machinery, the risks are mainly of electrical origin, such machinery shall be covered exclusively by Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits.

106.

Certain types of electrical equipment, also regarded as machinery, are completely excluded from the scope of the machinery Directive, in line with Article 1(3).

To determine whether exclusion from the scope of the machinery Directive under Article 1(5) applies to a given product which can be regarded as a machine under Directive 89/392/EEC and as electrical equipment under Directive 73/23/EEC, the manufacturer must analyse the hazards presented by that product.

The principles that can be used to evaluate risks are set out in European Standard EN 292 - Parts 1 and 2 (machine safety, basic concepts, general design principles) and in EN 1050 (machine safety, risk assessment principles).

Where the manufacturer's assessment shows that hazards are linked primarily to an electrical failure, the equipment is deemed to be exclusively in compliance with the low voltage Directive in which all aspects of safety, including machine safety, are taken into account.

A series of standards on electrotechnical products already exists, and these may make it easier to decide on whether or not Article 1(5) applies.

[23] Article 13 of Directive 90/531/EEC of 17 September 1990 (OJ No L 297, 29.10.1990, p. 1).

With the exception of machines cited in Article 1 (5), all electric machines activated at between 50 and 1000 volts in alternating current and between 75 and 1500 volts in direct current fall within the scope of both the "machinery" Directive and the "low voltage" Directive, the latter applying additionally for electrical hazards.

107. The following points apply to electrically-operated machinery within the voltage limits laid down by the "low voltage" Directive.

(a) The requirements of the "low voltage" Directive concerning electrical hazards must be met, and compliance with the corresponding harmonised standards which have been published under the "low voltage" Directive assumes compliance with these fundamental requirements.

(b) For all such machinery, including machinery falling within the scope of Annex IV to the machinery Directive, the conformity assessment procedures specified in Article 8 of the machinery Directive are applicable to all hazards. Where electric equipment is put in circulation separately to be incorporated into a machine in accordance with the machinery Directive, assessment of conformity, on the basis of the machinery Directive, may be limited to aspects linked to assembly and assessment of the overall safety of the machine.

108.

Article 2(1)

1. Member States shall take all appropriate measures to ensure that machinery or safety components covered by this Directive may be placed on the market and put into service only if they do not endanger the health or safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for their intended purpose.

109. Article 2(1) draws attention to one of the fundamental duties of the Member States and to their obligation to apply the Directive properly and monitor its application not only because it is a Community Directive but also because they have an inherent duty to do so.[24]

Article 2 obliges Member States to take "all appropriate measures" with regard to dangerous machinery, irrespective of whether or not it complies with the Directive. Machinery complying with the letter of the Directive may be prohibited if it proves dangerous, regardless of whether the hazard concerned is dealt with by the Directive. Where it concerns an essential safety requirement, the prohibition of dangerous machinery must follow the procedure concerning safeguard clauses laid down in Article 7. Within the limits of Articles 30 and 36 of the Treaty, Member States are entitled to prohibit machinery for other reasons (fair trading, environmental protection).

110.

[24] See the first recital and the accompanying comment.

It is important to stress that the marketing of a series of machines may be prohibited only if the hazard is inherent in the design. This presupposes that equipment has proved dangerous in a configuration that is installed, maintained and used as intended by the manufacturer. One cannot therefore prohibit a series of machines if the hazard originates in the user's behaviour (use of the machine for purposes other than those intended, for example).

Article 2 makes no distinction as to origin and the Directive applies to all machinery, whether or not manufactured in the European Economic Area (EEA), for own use or for sale. The machinery must however be intended for use in the EEA, as confirmed in the comments on Article 4.

This paragraph introduces the concepts of "placing on the market" and "putting into service".

111.

As we have already said, placing on the market should be interpreted as the act of first making machinery manufactured in the European Economic Area or imported from a third country available, for sale or otherwise, with a view to its distribution and/or use within the territory of the EEA. Placing on the market for the first time thus means all operations permitting the transfer of machine ownership or the right to use it from the manufacturer (or his authorised representative) to the first end user.

If the machinery is manufactured in the EEA, the act of first making it available implies that the Directive applies only to new products. In contrast to machinery imported from a country outside the EEA, however, the act of first making it available concerns all products, whether new or used. A note at the end of this booklet summarizes the rules governing the free movement of used and hired machinery.

112.

Machinery can be placed on the market either by the manufacturer or by his authorized representative established in the EEA. Article 8(6) provides for a further possibility which will be discussed in the analysis of that Article.

Placing on the market refers to each individual machine which physically exists and has been completed, irrespective of the time and place of manufacture.

Where machinery is offered for sale in a catalogue, placing on the market occurs when it is first effectively made available. However, machinery offered for sale must comply with the Directive if it is intended for use on the territory of the EEA.

113.

The concept of placing on the market must be clearly distinguished from sale. Placing on the market relates to the physical availability of the product regardless of the legal aspects of the act of transfer (loan, gift, sale, hire). Theft is obviously excluded from the concept of "placing on the market". The moment of the transfer of ownership is of little importance (when the contract is signed or when payment is complete).

In certain countries the law governing sales deems that the transfer of ownership takes place when the parties reach an agreement (in France, for example). The conformity of the machinery sold will be assessed not when ownership is transferred but when it is actually made available to the customer. In practice the conformity of the machinery with the regulations is assessed upon provisional or final acceptance of the product.

In other countries or in certain contracts the final transfer of ownership is subject to full payment for the machinery by the user. The conformity of the machinery will be assessed when the machine is first made available and will obviously not wait until ownership is transferred.

114.

The question arises as to whether the Directive applies to machinery placed on the market after the date of entry into force of the Directive but designed on the basis of earlier specifications and contracts. The answer is yes. The transitional periods are specifically intended to give firms the time to allow for the Directive in their contracts before it becomes fully applicable. The machinery Directive is a “public policy” Directive which takes precedence over current contracts in so far as it concerns a higher interest: the protection of persons. It is quite clear that the immediate application of the machinery Directive in current contracts has to be done with understanding. The application of a Directive to current contracts is a derogation to ordinary contract law. The contract establishes the “law of the parties”. There must be a reason of public policy to alter the contents of a contract. This is the exclusive privilege of laws of public policy. Technical standards, even if they are harmonized, have no such privilege under any circumstances. It is abusive

115.

That being so, machinery designed before the Directive can very well be in conformity with it, especially if it complied with national regulations very close to the Directive. Marketing the machinery with CE marking will raise no difficulties other than those related to the marketing procedures.

116.

An analysis of the concept of placing on the market makes it possible to resolve several practical cases. When a manufacturer builds or installs machinery, it will be regarded as “placed on the market” only at the end of the manufacturer’s certification procedure. When the manufacturer affixes CE marking and issues the conformity certificate, then the machinery can undergo conformity assessment. In the case of machinery referred to in Annex IV, the notified body will issue the type examination certificate when the machinery has been finished and tested.

Until the formalities of affixing CE marking and handing over the conformity certificate are complete, machinery is not regarded as placed on the market. The manufacturer may operate it and carry out adjustments before it is fully compliant. He must obviously take the necessary precautions to protect the staff responsible for the tests. Since the machinery is still under construction, conformity to the Directive may not be required.

117.

Putting into service refers to the first time machinery is used on EEA territory by the end user. The concept of “putting into service” was incorporated into the Directive to avoid national barriers to trade arising from regulations governing intermediate technical operations between placing on the market and actual use. Member States may not adopt safety regulations restricting the putting into service of machinery by laying down obligations regarding acceptance or preliminary testing, for example, or even prohibiting sales.

118.

The Council[25] has defined **putting into service** as "the operations required to ensure that the machinery can subsequently work and be used safely". This is therefore a technical operation carried out at the customer's premises, such as assembly or installation. The guide on the application of the new-approach Directives states that putting into service refers to the first use on EEA territory. The guide also states that products which are ready for use as soon as they are placed on the market without assembly or installation and whose safety cannot be affected by distribution conditions (transport, storage, etc.), are considered to be put into service when they are placed on the market, in so far as the moment they are first used cannot be determined.

119.

This suggests that if there are no such assembly or installation operations or if they are not customized (normally the case of a sale to a private consumer), the machinery Directive is taken to apply solely from the date the machinery is first placed on the market. Although it is not directly connected with freedom of movement, the concept of putting into service was introduced because certain machinery cannot be finished, made safe, and therefore certified, until it is installed on site.

120.

Article 2(2)

2. This Directive shall not affect Member States' entitlement to lay down, in due observance of the Treaty, such requirements as they may deem necessary to ensure that persons and in particular workers are protected when using the machinery or safety components in question, provided that this does not mean that the machinery or safety components are modified in a way not specified in the Directive.

121.

Paragraph 2 indicates that Member States retain the right to lay down rules on the use of machinery, provided such rules do not require the machinery to be modified. These rules may concern obligations such as the wearing of protective equipment, working no more than a certain time on a type of machine, a minimum age requirement, periodical medical check-ups, or the need for training. During discussions within the Council, it was agreed that modifications could be required if the machinery was not used for its intended purpose.

Community rules on the use of machinery are based on Article 118a of the Treaty, which states that only minimum requirements may be laid down. Each Member State can therefore supplement Directives 89/391/EEC[26] and 89/655/EEC, as amended, with requirements reflecting its own philosophy and tradition in the field.

122.

Article 2(3)

25 Minutes of the Council meeting on internal market of 14 June 1989.

26 Directive 89/391/EEC of 12 June 1989 (OJ No L 183, 29.6.1989, p. 1).

3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of machinery or safety components which do not conform to the provisions of this Directive, provided that a visible sign clearly indicates that such machinery or safety components do not conform and that they are not for sale until they have been brought into conformity by the manufacturer or his authorized representative established in the Community. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

123.

Paragraph 3 authorizes the showing of machinery which does not comply with the Directive at fairs, exhibitions and demonstrations.

The drafters hereby recognize that, in certain cases, visitors may need to see what a tool does and how it does it. This may, for example, require the removal of protective devices. For demonstrations of machinery which does not comply with the Directive there are risks; the operators must therefore be particularly competent and sufficient additional safety measures must be taken.

Paragraph 3 also authorizes the showing of machinery intended for markets outside the European Economic Area (EEA). Such machinery, even completed, need not bear CE marking or comply with the Directive's essential requirements. All these derogations are allowed on condition that a sign clearly indicates that such machinery cannot be placed on the market or used within the EEA as exhibited.

124.

Article 3

Machinery and safety components covered by this Directive shall satisfy the essential health and safety requirements set out in Annex I.

125.

This Article sets out the manufacturer's technical obligations under the machinery Directive: the machinery he designs and manufactures must meet the essential requirements laid down in Annex I. This does not preclude other obligations arising out of the contract (performance) or other regulations, regarding environmental protection, for example.

The part of the machinery Directive which dates back to 1989 was drafted mainly in view of the mechanical hazards of machine tools and similar. The amendments to the Directive extended the scope to include the hazards of mobile machinery, goods lifts and passenger lifts and to take account of public works vehicles and lifts. The final version of the Directive is drafted in terms of hazards, however, rather than families of machinery. The manufacturer must analyse his product in terms of all the essential requirements of the Directive. It is important to remember, however, that the drafters were thinking of particular families of products when drafting the essential safety requirements. They did not intend to go to absurd lengths by imposing requirements such as the static and dynamic test for lifting equipment on a tool holder in a machining shop.

126.

The designer must examine **all** the essential requirements, whichever section of the Annex they appear in, and assess whether or not the corresponding hazard exists. If it

does, he must indicate the measures taken to overcome it in the file referred to in Article 8 and Annexes V or VI.

127.

Article 4(1)

1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of machinery and safety components which comply with this Directive.

128.

Article 4(1) institutes the free movement of machinery. Obviously, it is only on grounds linked to the Directive that Member States are barred from prohibiting machinery which complies with it. Not all hazards are covered by the Directive, in particular environmental problems. Thus noise pollution in residential areas may be dealt with differently: one Member State may prohibit the use of certain machinery between 10 p.m. and 7 a.m., while another may prohibit the use of machinery which emits noise above certain levels.

The Directive permits both types of measure, both of which apply to the use of machinery. However, where the hazard is linked to one of the essential requirements covered, however cursorily, by the Directive, the Member States may not take steps that restrict the free movement of machinery unless they are covered by the Directive's safeguard clause.

129.

Article 4(2) - first subparagraph

2. Member States shall not prohibit, restrict or impede the placing on the market of machinery where the manufacturer or his authorized representative established in the Community declares in accordance with Annex II.B that it is intended to be incorporated into machinery or assembled with other machinery to constitute machinery covered by this Directive except where it can function independently.

130.

This is probably one of the most innovative and least well understood paragraphs in the Directive.

Article 1 of the machinery Directive defines its scope.

In defining a precise scope the aim is to delimit the products which will have to fulfil the technical and administrative obligations imposed by the Directive, namely compliance with the procedures for placing on the market and the technical annex to the Directive.

131.

The general principle underlying the whole Directive is that machinery safety has to be conceived as a whole by the party who takes overall responsibility for the design. It is the designer's job to pass on the essential safety requirements, which seem relevant to him, to his component suppliers.

This approach is based on two principles:

1. There is no technical sense in checking the conformity of an individual component with the whole technical annex to the Directive.[27]

2. A legal requirement on the various manufacturers, each supplying part of the components at different stages, to comply with the Directive would be totally ineffective. The obligations would be completely watered down. All those involved would be subject to the whole Directive. In the end it would be impossible to know who should do what since everyone would be responsible for everything. By defining a clear and incontestable level of responsibility, namely project supervisor for the machinery as a whole, the Directive requires "safety engineering" to be organized. This objective is very important and should never be forgotten when interpreting the legal position of subassemblies.

What are the provisions of the machinery Directive regarding components and subassemblies?

132.

Components and subassemblies, with the exception of safety components, certain lifting accessories and interchangeable equipment, are not covered by the Directive. They are therefore not classed as machinery within the meaning of Article 1 of the Directive. Article 3, which establishes the principle that Annex I must be complied with, and Article 4(3) which lays down mandatory procedures for placing products on the market, are therefore not applicable to them.

Article 4(2) is therefore an independent provision unconnected with the provisions regarding machinery. It is aimed neither at manufacturers nor at products. It requires Member States to allow free movement for certain subassemblies.

This obligation of freedom of movement is an adjustment of the general legal rule of free movement of goods set out in Article 30 of the Treaty. The physical similarity of certain subassemblies to complete machines ready for use made it necessary to clarify matters by introducing a special model declaration.

133.

What type of product does the "incorporation" declaration of Annex II.B apply to?

Only mechanized subassemblies are covered by Article 4(2)

Article 4(2) covers machinery intended to be incorporated into other machinery. These subassemblies satisfy the main technical criteria that allow them to be classed as "machinery".

[27] We will tackle the very specific case of safety components later.

These subassemblies are made up of parts or units connected together, at least one of which moves. They may, if appropriate, be fitted with actuators, control or power circuits. Subassemblies often have no independent controls.

Mechanized subassemblies clearly do not meet all the criteria of machinery within the meaning of Article 1, since they cannot perform a specific application, alone and independently of the remainder of the installation.

One could class the subassemblies referred to in Article 4(2) as "quasi-machinery". They are governed by the machinery Directive only from the point of view of freedom of movement. The declaration of incorporation is the only formality envisaged.

Basic components which cannot be treated as "quasi-machinery" do not require the declaration of incorporation provided for in Article 4(2). A ball bearing, fastener, fuse, cutter, brake, metal plate or grille are not complex enough to be classed as mechanized subassemblies falling within Article 4(2).

These basic products are completely outside the scope of the machinery Directive and are governed by ordinary law.[28]

The concept of subassembly covers parts of machinery, such as electric motors or heat engines, which have no "specific application" on their own, have a specific application but cannot function alone (no controls, for example), or if the application has no *raison d'être* of its own (turning a motor shaft is not a useful application); it also covers almost finished machinery intended for a complex assembly, as attested by the manufacturer in a certificate.

134.

Only subassemblies which cannot function independently may circulate under the arrangements set out in Annex II.B

The point of this restriction is clear. Machinery which is intended for use in an automated production line but can also be isolated from the line under the control of an operator, must have the safety equipment necessary for his protection.

135.

Obligations applicable to subassemblies under Article 4(2)

Do manufacturers of subassemblies circulating with an Annex II.B declaration have technical or administrative obligations with respect to safety?

An important point of law has to be clarified here. The machinery Directive and national technical regulations transposing it are now fairly well known by safety specialists: manufacturers, users, technical inspectors, administrations, etc.

These specialists are not usually lawyers. They naturally tend to assume that the machinery Directive is the only legal act requiring a manufacturer of mechanical products to ensure they are safe. Outside the scope of the machinery Directive the manufacturer would be free to do as he wishes. This is obviously an illusion. If a product is exempt from the technical and administrative essential requirements of the machinery

[28] Article 30 of the Treaty or other technical Directives.

Directive that does not mean it is not subject to anything. Let us examine the particular case of subassemblies circulating with an Annex II.B declaration.

136.

What legal rules are applicable to subassemblies?

Observance of the applicable regulations

The machinery Directive does not cover components. Other European Directives or certain national laws can cover them for certain aspects (electrical hazards, electromagnetic compatibility). Subassemblies must obviously comply with the regulatory texts applicable to them.

137.

Good engineering practice

A subassembly must always be in conformity with "good engineering practice". The concept of "good engineering practice" or the "state of the art" is a legal "standard" commonly used in most Member States of the EEA. The machinery Directive could have provided that subassemblies circulating with an Annex II.B should be in line with good engineering practice. In the same spirit, Article 2 of the low-voltage Directive (73/23/EEC) states that the Member States must take all appropriate measures to ensure that electrical equipment may be placed on the market only if it has been constructed in accordance with good engineering practice. The Directive on general product safety (92/59/EEC)[29] states that the conformity of a product to the manufacturer's general safety obligation shall be assessed having regard to the state of the art and technology (Article 4). In the same spirit, the product-liability Directive states that the safety of a product is what a person is entitled to expect, taking all circumstances into account. "Good engineering practice" means all appropriate technical practice that one is entitled to expect from a professional. This practice is accessible to the professionals concerned. It takes the form of the implementation of a raft of technologies corresponding to the state of the art at the time of manufacture. Good engineering practice covers several technologies which are technically and economically proportional to the desired objective. It offers the customer a good level of quality and safety. Good engineering practice corresponds only to techniques which exist and have been validated by experience. They therefore differ from the "state of science" and "experimental" techniques. Good engineering practice is not necessarily written down. It can be observed on a case-by-case basis by experts appointed by the courts. Good engineering practice is also determined by consulting national or European trade organizations, engineering societies and technical treatises.

138.

Terms of the contract

Subassemblies have to satisfy the technical requirements specified in the contract by the customer. Within this legal framework, the contract may require the subassembly manufacturer to comply with certain technical standards. Ordinary contract law, private international contract law and the legal obligations applying in most Member States impose a dual general obligation on the manufacturer of safety and information. The safety obligation will automatically lead to good engineering practice. Observance of good practice will mean that certain essential requirements of the machinery Directive are also observed.

[29] Directive 92/59/EEC of 29 June 1992 (OJ No L228, 11.8.1992, p. 24).

139.

Why did the Directive not make subassemblies directly subject to Annex I of the Directive?

We have already seen that it would be meaningless to apply the whole of Annex I to a subassembly. If the Directive had simply required subassemblies to comply with "relevant technical provisions" of that Annex, would that not solve the problem?

Certainly not. The issues are what essential requirements are relevant when applied to a component and who will have to supervise compliance?

It is obviously possible to quickly identify certain fundamental essential requirements in Annex I to the Directive which will always be relevant to any subassembly. One can confidently state that all the components used in a machine must be able to withstand the stresses to which they are subject when used as foreseen by the manufacturer (essential requirement 1.3.2). One can also state unequivocally that the materials used in the design of a subassembly have to be appropriate to the characteristics of the working environment envisaged by the manufacturer, notably as regards phenomena such as fatigue, ageing, corrosion and abrasion. This is all a matter of common sense and good engineering practice. These essential requirements apply equally to suppliers of bolts, ball bearings and gears and to the designer of a whole machine.

140.

Let us continue our reading of the same essential requirement 1.3.2. "Where a risk of rupture or disintegration remains despite the measures taken the moving parts must be mounted and positioned in such a way that in case of rupture their fragments will be contained". Is it up to the supplier of a grindstone to provide a guard or is that the job of the integrator? Should a conveyor supplier ensure safety around his system or is it up to the assembler who is to incorporate it? While certain essential requirements clearly can apply "naturally" to subassemblies, for most, it is impossible to know who should do what unless precise rules are laid down in the contract.

141.

The automatic application of the machinery Directive to subassemblies would leave joint contractors in total uncertainty as to their respective legal obligations. The application of the Directive to subassemblies could even have encouraged certain assemblers to provide no technical specifications and to design complex assemblies without any thought of safety. In the event of subsequent problems they could indeed have sued the subassembly suppliers on the grounds that they were automatically responsible for compliance with the essential requirements of the Directive.

142.

What contractual precautions should be taken when acquiring a subassembly? How should safety information be obtained from subassembly suppliers?

Suppliers should spontaneously provide the information the assembler needs.
It is important to note that suppliers of all products have a general obligation to provide information. This applies equally to finished machinery, subassemblies and ordinary components. This general obligation to provide information arises from ordinary contract law. It is recognized by the United Nations Convention on contracts for the international sale of goods of 11 April 1980 (Vienna Convention). Arbitration decisions of the

international Chamber of Commerce have several times sanctioned the obligation to provide information or advice.

143. The subassembly supplier will discharge this obligation by providing his customer with the information necessary to use and assemble his product, the safety precautions, etc. For certain products this information will take the form of an instruction manual or technical file. The instruction manual or technical documents provided may coincide completely or partly with the instruction manual and technical file of the machinery Directive. This type of information can be provided spontaneously by the supplier of subassemblies under his general obligation to provide information. The subassembly supplier will himself assess the nature, amount and form of the information to be notified to his customer. Information will vary according to the complexity of the products supplied and the competence of the purchaser.

Note, however, that the general principles of the *lex mercatoria* require a certain amount of care on the part of the professional purchaser. The professional purchaser has a duty to inform himself about the product sold to him. The professional purchaser cannot legitimately claim ignorance if he remained completely passive in the negotiations. *Caveat emptor*. The seller's obligation to provide information is therefore not unlimited. Machinery purchasers are therefore advised to express their "curiosity" by explicitly asking their suppliers to provide information connected with the safety of the product.

144. **The assembler explicitly requests the information he needs in the specifications.**
The assembler will have to publish an instruction manual and so will need to collect specific information. He will also have to make a risk analysis which will appear in his construction file. The assembler will therefore ask his supplier to provide him with the relevant technical information to enable him to write the whole manual and incorporate the share of risk inherent in the component into his risk analysis for the complete assembly. In order to write the maintenance instructions, it is important for the **assembler** to have access to the information concerning the risks of the subassembly.

145. **The assembler buys a complete technical dossier from the subassembly supplier**
It is probably excessive and unnecessary to ask suppliers to systematically provide a technical manufacturing file and a full instruction manual. The general technical dossier and the final instruction manual should not simply be a compilation of the documents received from the subassembly suppliers. The assembler cannot escape thinking about overall conformity by restricting himself to collecting documents from his suppliers.

Even so, the assembler is strongly advised to require his suppliers under contract to provide the information he needs to assess the risks, meet the essential health and safety requirements and establish his technical file. The supplier must provide this information only if the contract explicitly requires it. It must therefore be negotiated and taken into consideration in the price. An assembler cannot invoke the machinery Directive to oblige a subassembly supplier to provide a technical file free of charge. Neither may he invoke the machinery Directive to breach intellectual property rules protecting the plans, drawings or patented systems described in the supplier's information.

The provision of a complete file has a significant effect on the level of responsibility of the assembler. Surely, an assembler who requires full details of a subassembly himself

becomes “informed”? If he has the manufacturer’s own information, could the purchaser claim to be ignorant of any safety defect or oversight?

146.

The assembler ensures that a file is available

Rather than requiring the supply of a full technical file, the assembler can simply make sure that he has the minimum information on the precautions to be taken to incorporate the product and the main hazards it can present.

In addition to this information, the assembler can include a clause stipulating that the subassembly supplier must provide all or part of a technical file within a reasonable time in the event of reasoned request by the authorities.

Failure to do so will mean the possibility of criminal or administrative fines for the assembler rather than the supplier.

147.

Role of the Annex II.B declaration

The assembler requires an “Annex II.B declaration”

The assembler asks for an “Annex II.B declaration”. Clearly, he will not require a statement of conformity of the subassembly to the machinery Directive on the model of Annex II.A. The subassembly supplier can obviously voluntarily declare which essential requirements of the Directive he took into account. Subassemblies circulating with an “Annex II.B declaration” cannot bear CE marking under the machinery Directive. They can however bear CE marking for other reasons, e.g. under the electromagnetic compatibility Directive (89/336/EEC, as amended).

148.

Abuses of the Annex II.B declaration

The use of the Annex II.B declaration must not give rise to abuses of the law, by which we mean the excessive use of a legal prerogative. This is when someone holding a right departs from the “rules” governing the lawful use of that right. The Annex II.B declaration must not be used to circumvent the machinery Directive. Machinery which is ready for use but which has its guards removed and which is to be put into operation as it is cannot be treated as a subassembly under Annex II.B. A manufacturer of woodworking machinery may not offer for sale a saw which is ready for use but has no guards, on the grounds that it is a subassembly that the user will add to later. The seller cannot artificially transfer his legal obligations to the customer. A mechanism provided for by the Directive may not be used artificially to evade its application.

149.

Can certain subassemblies bear CE marking under the machinery Directive?

It is acceptable for certain incomplete machinery to circulate with CE marking under the machinery Directive provided that the missing part serves only to connect up to the customer’s site.

As an example, overhead travelling cranes cannot function without their track. The manufacturers of overhead travelling cranes comply with the machinery Directive in full. In theory, however, they cannot affix CE marking to their product because the machinery consists of an “overhead travelling crane and track” assembly. The latter is often the

customer's sole responsibility. It is acceptable, however, for an overhead travelling crane manufacturer to affix CE marking to the product he supplies and specify in his manual, or even in his declaration, that the marking does not apply to the track. The manufacturer has made the effort to design an inherently safe product and to comply with almost all of the Directive. It would not be right to deny him CE marking.

The overhead travelling crane manufacturer describes the technical features of the track in his manual and clearly specifies the limits of his CE marking.

The Directive requires manufacturers who supply complete machines but without the accessories for connecting to the customer's site or energy supplies (piping, electrical switches, guides, rails or pneumatic systems) to affix CE marking to their equipment. Such is the case of tower cranes or pumps, for example.

150.

Replacement of machinery which is a component of a complex assembly

In the event of replacement by other machinery of machinery which is a component of a complex assembly originally complying with the Directive, the user must ensure, pursuant to Directive 89/655/EEC, as amended, that the modified assembly is no less safe than the original. Maintaining the conformity level presupposes a good knowledge of the characteristics of the complex assembly. If the user is treated as the manufacturer, he has the technical file for the complex assembly and should therefore have that information. In any event, whether they themselves are the assembler or not, it is important that operators of new complex assemblies think, when drafting their specifications for suppliers, of how the assembly is to develop and the safety problems that a modification could pose. It is therefore advisable to ask subassembly suppliers to notify relevant information to that end.

151.

This obviously does not mean forcing the user to repeat the procedures for placing on the market, as these procedures apply only when the product is first placed on the market; the equipment in question is in operation and has therefore passed that stage. The user does not have to amend a technical dossier that he generally does not have. No new conformity declaration is required. The external participants (the maintenance or repair firm, or even the original manufacturer) are not required to comply with the Directive because they are not placing machinery on the market. The user should ensure that his contract states that he wishes modifications to be done in the conformity with the original regulations.

152.

Article 4(2), second subparagraph

"Interchangeable equipment", within the meaning of the third subparagraph of Article 1(2), shall be regarded as machinery and accordingly must in all cases bear CE marking and be accompanied by the EC declaration of conformity referred to in Annex II(A).

153.

This subparagraph states that interchangeable equipment, as defined in Article 1, is not regarded as "quasi-machinery" circulating with an Annex II.B declaration.[30]

[30] See section 69 for a definition of interchangeable equipment.

154.

The concepts of "manufacturer" and "authorized representative"

We should explain here what the Directive means by "manufacturer" and "authorized representative".

Several manufacturers of components or even of major machinery parts (subcontracting of subassemblies) may be involved, but for the Directive there is only one "**manufacturer**", i.e. the person who takes responsibility for the design and manufacture of the machinery and puts his name on it.

155.

A distributor selling machinery under his brand name is the "apparent manufacturer" of the equipment. Appearance alone is sufficient for legal purposes with respect to third parties and in particular private consumers. Customers cannot know the exact legal situation of the seller in relation to the machinery if the latter bears a distributor's brand name. The seller must accept all the obligations of a manufacturer (assembly of the technical file, declaration, marking, compliance with essential requirements, etc.).

156.

The machinery Directive obviously does not require the manufacturer to be established in the EEA. There is nothing to stop a manufacturer from a non-EEA country from carrying out the formalities for placing machinery on the market directly.

It is the "**manufacturer"** who is responsible for the conformity certification procedures (EC declaration of conformity in his name, drawing up the file, affixing CE marking, etc.).

157.

Similarly, anyone converting new machinery and/or changing its intended use before it is put into service must be regarded as the real manufacturer.

158.

The **authorized representative** is the person expressly appointed by the manufacturer to act on his behalf within the EEA, by meeting certain obligations laid down by the Directive, and nothing else. A manufacturer in a country outside the EEA is not obliged to have an authorized representative in the EEA. However, if the manufacturer appoints an "authorized representative" to fulfil a number of formalities on his behalf, he must be resident in the EEA. In general these are administrative obligations. Thus an authorized representative cannot modify machinery at his own initiative in order to bring it into line with the Directive: apart from the requirement concerning instruction manuals, the authorized representative is not mentioned in Annex I.

159.

It is important here to distinguish clearly the concept of "authorized representative" from the "person responsible for placing on the market". A manufacturer's agent is legally bound to the latter. A person placing machinery on the market may have no mandate from the manufacturer. Professional machinery importers, retailers, or even end-users importing directly, are responsible for placing on the market but are not necessarily "authorized representatives" of the manufacturer.

160.

Council Decision 93/465/EEC concerning the conformity assessment procedures in the technical harmonization Directives[31] states that the manufacturer's technical construction file must be kept in the EEA. Different provisions are laid down in Annex V to this Directive and they prevail: the technical file must be made available in response to a substantiated request by a Member State; however, the technical file may remain on the premises of the manufacturer, whether or not he is established in the EEA. This point will be examined more closely in the comments on Annex V.

The authorized representative established in the EEA may or may not be in possession of the technical file. However, a person who places machinery or a safety component on the market but who is neither the manufacturer nor his authorized representative established in the EEA but who avails himself of the facilities of Article 8(6) must have the file at his disposal. If it is not actually at his disposal he must make every effort to ensure that he can obtain it from the supplier of the imported machinery within a reasonable time. The importer is recommended to obtain formal assurances in writing from the manufacturer that the file will be made available in response to a substantiated request.

161.

Article 4(3)

Member States may not prohibit, restrict or impede the placing on the market of safety components as defined in Article 1(2) where they are accompanied by an EC declaration of conformity by the manufacturer or his authorized representative established in the Community as referred to in Annex II, point C.

162.

This paragraph concerns the particular form of the EC declaration of conformity for safety components, but otherwise adds nothing new.

163.

Article 5(1)

1. Member States shall regard the following as conforming to all the provisions of this Directive, including the procedures for checking the conformity provided for in Chapter II:

- machinery bearing CE marking and accompanied by the EC declaration of conformity referred to in Annex II.A.;

- safety components accompanied by the EC declaration of conformity referred to in Annex II.C.

In the absence of harmonized standards, Member States shall take any steps they deem necessary to bring to the attention of the parties concerned the existing national technical standards and specifications which are regarded as important or relevant to the proper implementation of the essential safety and health requirements in Annex I.

164.

[31] Council Decision 93/465/EEC of 22 July 1993 (OJ No L 220, 20.8.1993, p. 23).

This Article concerns the use of standards and the way in which they help the manufacturer, or his authorized representative established in the EEA, to demonstrate conformity with the Directive.

The Directive implicitly differentiates between several types of standard:

Types of standards

- **Harmonized standards**: as we saw in the recitals, these are European standards or harmonization documents drawn up by the European standards bodies.[32] Harmonized standards are drafted by these bodies on the basis of a general specification agreed between these organizations and the European Commission. Harmonized standards are drafted on the basis of a mandate setting out the purpose of the standard. The Member States are consulted for their opinion on the mandate via a committee set up by Directive 83/189/EEC, as amended (known as the "83/189 committee"). The European standards bodies present the harmonized standard to the Commission which publishes the references in the Official Journal. The harmonized standard is taken over unchanged in the Member States' national collections.

- **Harmonization documents:** (HDs for short): CEN and CENELEC draft harmonization documents if transposition into identical national standards is unnecessary or not feasible. This happens when there are certain national divergences. In practice CEN has not been drafting harmonization documents for several years. CENELEC has published many, and tends to transform them into European standards when they come up for revision.

- **European standards**: these are standards established by the European standards bodies to meet industrial or commercial requirements but with no particular link with a "new approach" Directive or legal constraint. Any national standard dealing with the same subject must be withdrawn and replaced by the transcription of the European standard. European standards, whether or not harmonized, are available only through the Member States' national collections. They are characterized by the letters "EN" in the name of the standard.

- **National standards**: these can be of strictly national origin, European origin (see the previous categories) or international origin. Some European standards also take over the contents of international standards.

165.

Although they are not mandatory, each type of standard has a role to play.

The role of harmonized standards is explained in the comments on Article 5(2).

European standards cover various traditional areas of standardization: characteristics not covered by a "new approach" Directive (environmental impact, etc.), dimensional interchangeability, functional interchangeability (performance), design methods, test methods, etc.

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[32] European standards bodies:
European Committee for Standardization (CEN)
European Committee for Electrotechnical Standardization (CENELEC)
European Telecommunications Standards Institute (ETSI)

In many cases they make fair trading possible, and this is why the "public contracts" Directives require awarding authorities to refer to them in their invitations to tender, with limited exceptions. They can also serve as the basis for quality marks. They exist in areas covered by national or European regulations or unregulated areas. It is important to know them to design a good product.

166.

Voluntary nature of standards

The general principle clearly stated in Community law and in particular by the Resolution of 7 May 1985[33] and the "new-approach" Directives is that technical standards are always applied voluntarily. Failure to comply with them is never in itself a fault, because any fault implies a prior obligation. Compliance with harmonized standards implies "presumption of conformity" to the regulations. Since compliance with the standard is voluntary, it is a "praiseworthy" act on the part of the manufacturer. The inspection authorities take account of it in their policy of monitoring the market. Even so, non-compliance with a standard never necessarily means that the product does not conform to regulations. The manufacturer remains free not to follow the standard. It is important to stress that the standard is not infallible. Standards are drafted with all the limitations of any documents which are subject to long negotiations and compromises.

167.

Cases where the standard is mandatory

Standards are mandatory in only three cases:

- The standard is imposed by regulation. With a few exceptions, this is not the case of the "new approach" Directives. Within this framework, the provisions of the standard become full regulatory provisions.

- The standard is incorporated into a private or public contract. Compliance with the standard then becomes a contractual obligation which, like any undertaking of that nature, is freely negotiable.

- The standard codifies "good engineering practice". Contrary to popular opinion this happens very rarely. It is not the standard which is mandatory, but rather the rules of good practice. A standard cannot claim always to reflect good engineering practice. It must really be an incontestable expression of actual professional practice widespread in the trade concerned.

168.

Standards are drafted for new machinery only

Whether or not they are harmonized, standards are drafted for the design of new products. A standard can apply only to a product designed after the standard is adopted.

Harmonized standards drafted under Article 100a are intended for the design of new machinery and not for bringing into line machinery in use in industry as provided for by Directive 89/655/EEC, as amended. The Commission has not asked the European

33 Council Resolution of 7 May 1985 (OJ No C 136, 4.6.1985, p. 1).

Committee for Standardization to deal with this aspect of machinery safety. In any case, machinery users were not involved in the drafting of the standards from the point of view of bringing their existing machinery into conformity.

169.

Important or useful documents

Lastly, in the absence of harmonized standards, European standards, European harmonization documents, national standards or specifications (such as the UVV requirements of the *Berufsgenossenschaften*, the technical parts of national regulations, etc.) can be used. National technical specifications are recognized as important and useful documents but do not imply presumption of conformity to the Directive since this applies to harmonized standards only. They are withdrawn as soon as a harmonized standard is published in the technical field they cover.

For a designer, a harmonized standard or European standard should offer a convenient means of complying with a "new approach" Directive. Even if he has other ways in which he can comply with the Directive, the standard offers the advantage of establishing a certain safety level: if he does not follow the standard, he nevertheless has an idea of the target safety level. In the absence of harmonized or European standards, he must look for this target elsewhere. This is where national standards or national technical specifications come in useful, especially those that Member States have identified as being of particular interest.

170.

How can all the parties concerned be made aware of the references of national documents and specifications that Member States consider useful for the application of the machinery Directive? The Directive does not lay down any obligation, so the Member States have complete liberty to decide for themselves. However, this information must be "brought to the attention of the parties concerned" and cannot, therefore, be reserved for specific correspondents.

171.

Two countries have so far notified the Commission of the references of national documents useful for the application of the machinery Directive.

Germany published a list of national technical documents in an official bulletin of the Ministry of Labour (Bundesarbeitblatt, March 1993).

France refers to a booklet of the national research and safety institute (I.N.R.S) on inherently safe machinery design.

Some worry that a Member State, having notified a list of national standards to the Commission, could refuse machinery because it does not comply with one of these standards. Remember that to refuse machinery bearing CE marking it must be proved that **at least one essential requirement** is not satisfied. Failure to comply with a standard, especially a national one, is not in itself sufficient to justify a prohibition measure.

172.

Article 5(2)

2. Where a national standard transposing a harmonized standard, the reference for

which has been published in the Official Journal of the European Communities, covers one or more of the essential safety requirements, machinery or safety components constructed in accordance with this standard shall be presumed to comply with the relevant essential requirements.

Member States shall publish the references of national standards transposing harmonized standards.

173.

This Article introduces the principle of presumption of conformity that follows from compliance with harmonized standards.

Publication of the references of standards and presumption of conformity

The European standard is available only through the national collections of the Member States. As soon as the European standard is available in the collection of an EEA Member State, it acquires legal force.

Presumption of conformity arises subject to two legal notification measures: the publication of the references of the standard in the OJEC and references of the corresponding national standards in the national official journals. The latter formality is important because, in most States, the publication of the references of the national standard is an important condition for changes in the internal legal order. Transposition alone is not sufficient. It should not be forgotten that the presumption of conformity deriving from harmonized standards can concern areas not covered by Community law, such as criminal law. The national public authorities must therefore take specific action in order for presumption of conformity to arise.

174.

The Member State is required to publish the references of the harmonized European standards whose references are listed in the OJ. If it fails to do so, it must state imperative reasons involving public order[34] and initiate a procedure against the standard under the safeguard clause. A Member State which refuses to publish a harmonized European standard, without justification in the form of a safeguard clause against the standard, causes real damage to manufacturers wishing to avail themselves of the standard. Such an attitude is still less justifiable in that public procurement agencies coming under the authority of the same Member State will have to refer to that standard pursuant to the "public contracts" Directives. The Court of Justice of the European Communities may be called upon to decide whether a manufacturer may invoke the direct effect of the Directive against a Member State acting in that way.

175.

Presumption of conformity and inspection of machinery

Harmonized standards enable inspection bodies to grant to compliant machinery presumption of conformity to the relevant essential requirements of the Directive. Clearly this does not mean that machinery not complying with the standards is assumed not to comply with the Directive. Like all standards, they are not mandatory and manufacturers will always be able to satisfy the essential requirements in other ways. In any case, as we saw earlier, the manufacturer must follow the technical safety regulations

[34] The Treaty of Rome, Article 36.

dictated by good engineering practice in his profession or arising out of ordinary contract law.

176. For certain products the machinery Directive states that safety coefficients should be laid down by standardization. The Directive merely lays down a general coefficient which can be adapted by standards according to the product concerned. It was impossible in the Directive to envisage all possible cases. In practice, manufacturers will observe the coefficients laid down by the standards unless they set out reasons in the technical dossier for using another value that ensures an equivalent level of safety, for example by taking additional measures.

177. Where a manufacturer chooses to follow one or more harmonized standards in order to satisfy the essential health and safety requirements which they cover, he has acted with due care. He is not bound to follow the standards. If a Member State contests a technical solution arising from a harmonized standard, it must apply the safeguard clause (Article 7) in respect of the harmonized standard and not the machinery that complies with it. Applying the solutions laid down in the harmonized standards does not fully protect the manufacturer from the possibility of the safeguard clause being applied, but it does provide a "high level of safety".

Note that since the standards are not mandatory, they cannot make testing or examinations by a third party mandatory.

178. ***How, in the context of the machinery Directive, can presumption of conformity be linked to certain harmonized standards?***

For the purposes of its contract with the Commission, CEN has defined three types of harmonized standard, A, B and C. This terminology is specific to the standards drafted under the machinery Directive. Classes A, B and C do not have the same meaning under other Directives, such as "construction products" (89/106/EEC as amended).[35]

- **A standards** deal with basic concepts concerning all machinery; standard EN 292 is an example of this category;

- **B1 standards** deal with safety aspects concerning a range of machinery such as safety distances, calculation methods for lifting equipment, etc.; examples of these are EN 294 on safety distances and EN 563 on temperatures of touchable surfaces;

- **B2 standards** deal with components or devices, such as safety devices, which are used on a wide variety of machinery; EN 281, on the design of pedals, is an example;

- **C standards** are "vertical" standards covering a single type of machinery.

179. ***"A" and "B" standards***

[35] Directive 89/106/EEC of 21 December 1989 (OJ No L 40, 11.2.1989, p. 12; Directive 93/68/EEC of 22 July 1993 (OJ No L 220, 31.8.1993, p. 1).

Some have said that since standards of type A or B do not deal directly with an essential requirement they cannot be regarded as harmonized standards. Type A standards concern basic concepts or design principles. Type B standards deal with an aspect of safety or with a type of safety device affecting the safety of a wide range of machinery. It is therefore difficult to make an overall assessment on a machine solely from conformity with an A or B standard. How can they give rise to presumption of conformity?

Quite apart from the reasons already given in the comments of Article 5, these standards are essential to give consistency to the preliminary observations and requirement 1.1.2 of this Annex. They are therefore harmonized and their references are published in the Official Journal. They thus provide presumption of conformity for the sole objective that they serve.

180.

Although it is easy to understand the concept of compliance with a C standard, and how such compliance can confer presumption of conformity with the essential requirements covered by the standard, some people wonder how presumption of conformity can be obtained through compliance with certain B standards and would prefer to have only C standards published in the Official Journal of the European Communities. If we take the example of the B1 standard, EN 1088, defining various types of locking device - with one detector, two detectors, two detectors and error checking, etc. - we can understand this doubt. However, if we apply this B1 standard in conjunction with another B1 standard, EN 1050, on risk assessment, we can say that the **simultaneous** application of both standards can confer presumption of conformity to essential requirements 1.3.7 and 1.3.8. It is important to make quite clear that the presumption of conformity deriving from a harmonized standard covers only the technical points handled in the standard and nothing else. Presumption of conformity of a standard on locking mechanisms allows one to assume that locking devices are compliant but not that the machinery is compliant with all the other points of Annex I. The Commission considers B1 and B2 standards to be the most useful for the purposes of the Directive, mainly because there will never be as many C standards as types of machinery, and is keen for them to remain harmonized standards. It is nevertheless true that certain A, B1 and B2 standards are drafted by industrial risk prevention staff or specialists who are sometimes far removed from the reality of industry. Whatever the category of the standard, the standardizer has the fundamental moral obligation to know and understand the current state of the art in the trade which will have to apply the standard.

It should also be stressed that this distinction between A, B1, B2 and C standards is specific to the CEN and is not found in any Community legislative text. One cannot therefore base an interpretation of the Directive on this distinction.

181.

There is an important difference between Article 5(1) and Article 5(2). The former states that machinery bearing CE marking is to be **regarded** as conforming to the Directive, whereas the latter states that machinery conforming to harmonized standards is to be **presumed** to comply with the essential requirements covered by those standards. The use of two different terms is important. Machinery complying with the Directive but not with standards enjoys freedom of movement. The inspection authorities place greater confidence in machinery complying with the standards.

182.

Presumption of conformity deriving from the standards and legal presumption

A legal clarification is needed. For criminal law specialists, there is a general "presumption" of conformity of products which is quite simply the application of the principle of the general presumption of a citizen's innocence. This legal presumption of conformity under ordinary law applies to all machinery bearing CE marking and accompanied by a declaration of conformity. The expression used in Article 5 of the Directive "Member States shall regard the following as conforming ..." is simply a reminder that presumption of conformity exists under ordinary law. It is for the party contesting the conformity of machinery (inspection bodies or users) to provide evidence that machinery does not comply. This legal rule applies even if machinery does not comply with harmonized standards.

183.

From a legal point of view, the "presumption of conformity" deriving from the European standards is actually an "enhanced presumption of conformity". **Under no circumstances does a machinery manufacturer who does not comply with harmonized standards have to provide legal "proof" of conformity.**

"Enhanced presumption of conformity" deriving from European standards does not reverse the burden of legal proof for products not complying with standards.

For convenience, we can say that a manufacturer who does not comply with a standard will have to "prove" the conformity of his product. This way of presenting the operation of the Directive does not have to be taken literally. The "proof" referred to here is obviously not "proof" in the legal or judicial sense. We use the word "proof" simply to mean that the manufacturer will have to describe in more detail the safety solutions he has implemented; that he would not have had to do so had he complied with a harmonized standard: nothing more! This is how the resolution of 7 May 1985 should be understood when it states that the producer has the option not to manufacture in accordance with the standards, but in that case the burden of proof of the conformity of his products with the requirements of the Directive rests with him (Annex II).

Indeed, the resolution explicitly states:

"the determination of a limitative list of means of attestation only concerns the system of presumption of conformity but cannot have the effect of restricting the possibility for a member of the trade to prove, by any means he sees fit within the framework of a dispute or court proceedings, the conformity of the product with points II and III" (Annex II point VIII).

184.

"Administrative presumption of conformity" and "administrative proof" which designate the conformity declaration procedures provided for by the "new approach" should therefore be clearly distinguished from "presumption of conformity" and legal or judicial "proof".

The "new approach" was never intended to modify civil or criminal law or the system of law enforcement in the Member States.

In practice it is more difficult for an authority to contest the compliance of machinery conforming to standards than machinery that does not. Legally, presumption of conformity deriving from compliance with standards is guaranteed only by the use of a national standard reproducing the whole content of a harmonized standard.

185.

Non-transposition of a harmonized standard

If a national standardization body has not included the text of a European standard in its collection, the use of the original harmonized standard or a transposition in another Member State ensures the same presumption of conformity. This is not the same situation as described above where the Member State refuses to publish the references of the standard harmonized in its Official Journal. Note, however, that the standard must be reproduced in the national standards collection of at least one EEA Member State.

186.

"Ageing" of a standard

Presumption of conformity granted to machinery complying with harmonized European standards can prove delicate if a standard becomes obsolete. If a manufacturer is clearly aware of this obsolescence, we can only encourage him to depart from the standard and be guided by the state of the art and good engineering practice in his industry. In most States good practice has greater legal authenticity than standards. Indeed, in the event of accident, its good faith will be better demonstrated by following the state of the art and good engineering practice ensuring a higher level of safety than by following a clearly obsolete standard. The Directive refers to both concepts.[36]

187.

Article 5(3)

3. Member States shall ensure that appropriate measures are taken to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonized standards.

188.

Article 5(3) calls on the Member States to ensure that all the social partners are associated with the standardization process. The main purpose is to ensure that workers' representatives are not forgotten, as they are generally left out. The term "social partners" also covers employers. Contrary to popular opinion, industry is far from being present in all technical standardization committees. The absence of manufacturers in technical committees dealing with general technical subjects may lead, in the long term, to the contents of standards gradually deviating from good engineering practice. We should never lose sight of the fact that standards drafted under the machinery Directive are designed to be applied by manufacturers to ensure the safety of machinery operators. They are not designed to collect the scientific discussions of specialists in one or other discipline (acoustics, radiation). Standards must retain a truly operational function.

189.

Article 6(1)

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5(2) do not entirely satisfy the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the

[36] Preliminary remark No 2 of Annex I to the Directive, with regard to the state of the art.

Committee set up under Directive 83/189/EEC, giving the reasons therefor. The Committee shall deliver an opinion without delay.

Upon receipt of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the published information referred to in Article 5(2).

190.

Article 6 introduces the two committees which are to deal with difficulties relating to the application of the Directive. Paragraph 1 refers to the Standing Committee set up under Council Directive 83/189/EEC, as amended. This Committee is entitled to give standardization remits to the European standardization bodies. It accordingly has the right to inform them that the remit has not been satisfactorily fulfilled where it considers that a standard does not satisfy the essential requirements.[37]

191.

Article 6(2)

2. A standing committee shall be set up, consisting of representatives appointed by the Member States and chaired by a representative of the Commission.

The standing committee shall draw up its own rules of procedure.

Any matter relating to the implementation and practical application of this Directive may be brought before the standing committee, in accordance with the following procedure:

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

192.

Paragraph 2 sets up an advisory committee to advise the Commission on any difficulties with an essential requirement which may become apparent in practice. Although the Commission is not bound by the Committee's opinion, it must take "the utmost account" of it.

193.

The European Commission, Member States, manufacturers and their industry can and must interpret the Directive to take account of specific situations. Such interpretations must obviously be made in good faith and in line with the intention of the legislator. The legislator's principal intention was to introduce common-sense and realistic

[37] See also Article 7.

legislation which helps to ensure free movement of products and improve safety. Extreme interpretations of the Directive which lead to absurd situations must be ruled out from the start. The Directive should not be read too strictly otherwise manufacturers will be penalized and barriers to trade will reappear. The spirit of the Directive must take precedence over the letter. It should not be interpreted in a lax way, however, but with moderation. Provided these interpretation guidelines are followed, there is nothing to stop the parties concerned from producing realistic interpretations of the scope, procedures and essential technical requirements of the text. These interpretations are obviously subject to the sovereign interpretation of the national jurisdictions and, if necessary, of the Court of Justice of the European Communities in Luxembourg. The Commission, with the assistance of the Committee set up by the Directive, can help establish a common and uniform reading of the obligations of the Directive and thereby avoid or at least minimize the difficulties which might arise between Member States, notified bodies, manufacturers, users, etc.

194.

Article 7(1)

1. Where a Member State ascertains that
- machinery bearing CE marking,
or
- safety components accompanied by the EC declaration of conformity, used in accordance with their intended purpose, are liable to endanger the safety of persons, and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such machinery or safety components from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof.

The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-conformity is due to:
(a) failure to satisfy the essential requirements referred to in Article 3;
(b) incorrect application of the standards referred to in Article 5(2);
(c) shortcomings in the standards referred to in Article 5(2) themselves.

195.

Only a Member State may initiate an administrative procedure prohibiting marketing against a manufacturer. This is the safeguard clause; it enables Member States to adopt measures, where warranted, restricting placing on the market as a derogation from the obligation to allow free movement provided for in Article 4(1). That Article allows Member States to question the manufacturer's claims and to contest the veracity of the declaration of conformity accompanying machinery bearing CE marking and used in accordance with the purpose intended by its manufacturer.

This removes from the scope of Article 7 any machinery not bearing CE marking or not used in accordance with its intended purpose. In these two cases the Member State does not need to explain the grounds on which such action is based as clearly as it is required to do when invoking Article 7.

It is important to note that the safeguard clause in Article 7(1) concerns only machinery which may endanger persons' safety.

Simple formal non-compliance with regulations, such as the infringement of an administrative procedure, does not come under the safeguard clause. Member States are free to sanction formal non-compliance with the Directive. Article 7(3) concerns the problems of non-compliance regardless of the danger of machinery. A Member State may obviously invoke the safeguard clause of Article 7(1) in respect of dangerous machinery and take appropriate measures against the manufacturer as referred to in Article 7(3).

196.

Paragraph 1 restricts any arbitrary action by a Member State restricting the marketing of machinery it considers dangerous. The Member State must inform the European Commission of the measure and state the grounds for its decision. The adoption of a restrictive measure against machinery therefore implies that the Member State has sufficient technical evidence to prove that the equipment in question is dangerous. It is not sufficient simply to refer to one of the three possibilities given in points (a), (b) and (c), but the grounds given must be classified in one of these three categories so that the Commission can examine the case and the manufacturer can defend his rights where appropriate.

The grounds referred to in point (a) require no further clarification, but what is meant by the grounds referred to under (b) and (c)?

197.

Incorrect application of the standards (point (b)) only concerns cases where the manufacturer undertakes to comply with standards, i.e. where the manufacturer wishes to avoid an EC type-examination of machinery listed in Annex IV or where the technical file for other machinery merely declares, in respect of a given essential requirement, that the machinery conforms to a harmonized standard without giving further details. Since the application of standards is optional, point (b) does not apply in any other case.

If (c) applies, the safety problem is assumed to come from the harmonized standard itself.

There are several possibilities:

- The standard may have proposed a technical solution which proves dangerous in practice.
- The standard may have proposed a safety solution which proves inadequate in practice.
- The standard may have dealt correctly with a hazard but not solved other related technical problems. Certain safety solutions can create more problems than they solve. One example is reconciling the need for cleaning in food hygiene and prohibiting access to moving parts.
- The standard may explicitly infringe an essential safety requirement of the Directive. It would then be hard to understand how the European standardization bodies could submit such a standard to the Commission, but the case could arise.
- The standard may be obsolete in relation to good engineering practice. This often happens. The periodic revision of standards by the European standardization bodies is generally enough to bring standards into line with the state of the art. The safeguard clause should therefore be used only where obsolescence poses real problems.

198.

The safeguard clause must not be misused, however. It should not be used to artificially call into question a consensus reached on a vote by the European standardization bodies. It must be used only if there is a real technical problem and not as a device to reopen a debate which has been closed.

In practical terms, as soon as the hazard to the health and/or safety of persons has been recognized, the Member State takes appropriate measures. These measures must be proportionate to the danger, i.e. not necessarily an immediate comprehensive ban, and the grounds must be stated. The measures taken cannot be permanent: they are precautionary measures intended to protect users, without prejudice to the responsibilities or errors of the manufacturer. They can be lifted at any time. Such measures do not require prior authorization from the Commission, but it must be informed immediately.

199.

Recourse to the safeguard clauses for standards or machinery now operates within the framework of the European Economic Area. A safeguard clause invoked against a standard or machinery circulating in the European Union is processed by the Commission. A safeguard clause directed against machinery placed on the market in a Member State of the EEA but not of the European Union is processed by the EEA surveillance committee. Where a safeguard clause affects both the EU and the EEA, the Commission and the EEA surveillance committee coordinate their action.

200.

Article 7(2)

2. The Commission shall enter into consultation with the parties concerned without delay. Where the Commission considers, after this consultation, that the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States. Where the Commission considers, after this consultation, that the action is unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community. Where the decision referred to in paragraph 1 is based on a shortcoming in the standards, and where the Member State at the origin of the decision maintains its position, the Commission shall immediately inform the Committee in order to initiate the procedures referred to in Article 6(1).

201.

Article 7(2) indicates what happens next. It is now time for the manufacturer to organize their defence to avoid the measure being confirmed and, consequently, extended to the whole of the EEA. Member States are obliged to prohibit the placing on the market of machinery which has been recognized as dangerous and/or non-compliant with the Directive. The manufacturer should take appropriate legal advice, collect as much documentation on the machinery in dispute as possible and inform the Commission of any difficulties he encounters.

The Commission enters into consultations with the parties concerned. The number of parties depends on the seriousness of the problem: the national authorities invoking the safeguard clause, the Member State of the manufacturer if they are established in the EEA, the manufacturer or his authorized representative, the manufacturers' trade organizations, users, trade unions, inspection bodies, etc. It is in the interest of the

manufacturer or his authorized representative to follow the Commission's work step by step and, if necessary, to organize his own consultations and put forward proposals.

Once the Commission has decided that the measure is justified, it is rather late for the manufacturer to defend himself. He may still appeal to the courts, but court proceedings tend to be very slow to produce practical results and the measures taken are not generally suspended pending the outcome.

If the manufacturer considers he has suffered a loss during such procedures and wishes to claim damages, he must do so under the jurisdiction of the State which initiated the safeguard clause and in accordance with the laws of that State.

202.

Article 7(3)

3. Where
- machinery which does not comply bears CE marking,
- a safety component which does not comply is accompanied by an EC declaration of conformity,
the competent Member State shall take appropriate action against whomsoever has affixed the marking or drawn up the declaration and shall so inform the Commission and the other Member States.

203.

Article 7(3) refers to the Member States' obligation to take appropriate action in respect of machinery not complying with the Directive. Article 7(3) should not be confused with the "safeguard clause" in paragraph 1. This relates only to machinery bearing CE marking and which is dangerous. Paragraph 3 concerns all machinery bearing CE marking which is not compliant, whether for administrative reasons (no conformity declaration, for example) or technical reasons. It is hardly relevant whether or not the machinery is dangerous.

The aim of paragraph 3 is twofold.

1. It requires Member States to act against their own nationals in the event of non-conformity. The nature of the measures to be taken is not specified. It could therefore consist of a warning to the manufacturer, an obligation to have machinery checked or even prohibition or legal proceedings. The Court of Justice of the European Communities checks the effectiveness of the measures taken. In particular it assesses whether the sanctions taken against the national are sufficient to be effective.

2. The Member State must inform the Commission and the other Member States of any measures it takes against non-compliant machinery. Information is all that is required. There is no provision here for consultation as envisaged for the safeguard clause in Article 7(2). Such notification is therefore aimed solely at non-compliant machinery bearing CE marking. Member States are not obliged to inform the Commission and their counterparts when they restrict the placing on the market of non-compliant machinery not bearing CE marking.

One assumes that the information transmitted by the Member State will be taken into account by the other Member States who will then decide to adopt similar measures.

204.

Article 7(4)

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

205.

Article 7(4) calls on the Commission to "ensure" that the Member States are kept informed.

206.

CHAPTER II - CERTIFICATION PROCEDURE

Article 8(1)

1. The manufacturer or his authorized representative established in the Community must, in order to certify that machinery and safety components are in conformity with this Directive, draw up for all machinery or safety components manufactured an EC declaration of conformity based on the model given in Annex II, A or C as appropriate.

In addition, for machinery alone, the manufacturer or his authorized representative established in the Community must affix to the machine the CE marking referred to in Article 10.

207.

Article 8 is one of the most important Articles in the Directive from the manufacturer's point of view; it lays down the procedure he must follow to certify that his machinery conforms to the Directive. The various paragraphs of this Article refer repeatedly to the Annexes. Annex II.A is the general declaration of conformity for machinery, Annex II.B is the declaration of incorporation of a subassembly into machinery, while Annex II.C is the declaration of conformity for safety components.

208.

Paragraph 1 lays down the "external" signs of the procedure, i.e. each machine must bear CE marking and be accompanied by an EC declaration of conformity. Safety components are not marked but do have an EC declaration of conformity. The content of this declaration is specified in detail in Annexes II.A and II.C. Whatever procedure is to be followed (we will see in paragraph 2 that there are several procedures, depending on the type of machinery or safety component), paragraph 1 stipulates that it is always the manufacturer who must follow the procedure. Whether or not he is established in the EEA, he can delegate his administrative obligations to an authorized representative, the only requirement being that the representative must be established in the EEA.

209.

Safety components may not bear CE marking under the machinery Directive but may under other Directives.[38] It is only by reading the instruction manual and the EC declaration of conformity, if any, that one can find out exactly which Directives the component manufacturer has applied.

210.

Article 8(2)

2. Before placing on the market, the manufacturer, or his authorized representative established in the Community, shall:

[38] For example the low-voltage Directive (73/23/EEC, as amended) or the electromagnetic compatibility Directive (89/336/EEC, as amended).

(a) if the machinery is not referred to in Annex IV, draw up the file provided for in Annex V;

(b) if the machinery is referred to in Annex IV and its manufacturer does not comply, or only partly complies, with the standards referred to in Article 5(2) or if there are no such standards, submit an example of the machinery for the EC type-examination referred to in Annex VI;

(c) if the machinery is referred to in Annex IV and is manufactured in accordance with the standards referred to in Article 5(2):

- ***either draw up the file referred to in Annex VI and forward it to a notified body, which will acknowledge receipt of the file as soon as possible and keep it,***
- ***submit the file referred to in Annex VI to the notified body, which will simply verify that the standards referred to in Article 5(2) have been correctly applied and will draw up a certificate of adequacy for the file,***
- ***or submit the example of the machinery for the EC type-examination referred to in Annex VI.***

211.

Paragraph 2 makes a distinction between the families of machinery or safety components listed in Annex IV and those which are not.

The list in Annex IV is exhaustive. A Member State may not add other machinery or safety components to this list. If the need arises, the list can be amended only by an equivalent legislative act, i.e. a European Parliament and Council Directive.

The manufacturer or his authorized representative established in the EEA is completely free to choose the means he uses to demonstrate that his equipment conforms to the Directive. However, he must comply with certain rules, which vary depending on whether or not the machinery or safety component is listed in Annex IV:

212.

(a) Machinery not covered by Annex IV

This procedure is known in the industry as the "self-certification procedure". It is the common law procedure applicable to machinery. If a machine or safety component is not listed in Annex IV, the manufacturer must, before completing the administrative formalities laid down in paragraph 1, ensure that the means which he has used to conform to the essential requirements are recorded in a technical file, that the file is available or can be made available promptly and can be presented in response to any reasoned request by a Member State.

The content of the file is specified in Annex V and in the corresponding comments.

The file need be presented only in response to an express substantiated request from a national authority. The manufacturer is not required to present the whole file but only that part which relates to the reason stated by the authority;

213.

(b) Machinery covered by Annex IV

Article 8(2) allows for Two possibilities:

• EC type-examination

If the machinery or safety component is listed in Annex IV, the manufacturer or his authorized representative established in the EEA must submit an example of the machinery for EC type-examination by a notified body. The notified body examines the machinery on the basis of an expert's statement. The notified body does not subject the issue of the EC type-examination certificate to compliance with standards since the machinery is subject to an EC-type examination precisely because it does not comply with harmonized standards.

EC type-examination is described in detail in Annex VI.

214.

- Conformity to harmonized standards

Where the machinery complies completely with the harmonized standards covering all the relevant essential safety requirements, the manufacturer may himself declare that his machinery conforms to the Directive. In this case, the manufacturer must send a notified body a copy of the technical file provided for in Annex VI, indicating the option chosen.

Option one: the notified body acknowledges receipt of the technical file for machinery in Annex IV that conforms to the harmonized standards and does not examine it.

Option two: the notified body draws up a certificate of adequacy for machinery listed in Annex IV that conforms to harmonized standards

In this case the notified body verifies the technical file for the machinery and certifies, after examining the file, that the harmonized standards have been complied with.

Option three: the notified body carries out an EC type-examination for machinery listed in Annex IV that conforms to harmonized standards
The procedure followed is then that of a normal EC type-examination, including the procedures for modifications to the model, refusals of certificates and the language of the file (see Article 8(3) below).

For a reminder of what is meant by a harmonized European standard, see the comments on the recitals and Article 5.

215.

What is a notified body?

A notified body is a third party which is **competent** to carry out conformity assessment tasks in the context of a prior inspection procedure for a product and which has been **designated** by a Member State from among the bodies under its jurisdiction which meet the criteria of competence and which has been **notified** to the Commission.

Member States may only notify bodies for the machinery and safety components listed in Annex IV. There can be no notified body for other machinery or safety components.

216.

A body may be notified for only part of Annex IV, for example only for presses for cold working of metals, woodworking machinery or lifting devices. However, for these families of machinery, the body is responsible for examining their conformity to the whole of the Directive. Bodies notified under the machinery Directive obviously may not take account of the specific hazards handled by other Directives, however (simple pressure vessels, electromagnetic compatibility, noise limits), unless of course they have also been notified for those purposes. This rule applies even for hazards mentioned in Annex I to the Directive (see Article 1(4)).

217.

Annex II to the machinery Directive defines the contents of the EC declaration of conformity circulating with machinery and safety components. For machinery covered by Annex IV, it stipulates that the declaration must bear the name and the address of the notified body involved. Contrary to what we said in the first version of this guide, the manufacturer need not name the notified bodies involved under other Directives (e.g. those involved under the explosive atmospheres Directive). Some, such as the low-voltage or electromagnetic-compatibility Directives, provide for specific conformity declarations which do not necessarily circulate with the product. If the manufacturer wishes, he can obviously merge all the declarations into a single document. In this way, machinery could circulate with a declaration of conformity based on Annex II.A mentioning any body involved under the electromagnetic compatibility Directive. For the rest of the EC declaration of conformity, please refer to the comment on Annex II.

218.

Annex VII of the Directive lists the minimum criteria to be met by a notified body. The EN 45000 series standards explain these criteria in greater detail. However, a body which satisfies all the criteria has no automatic right to be notified. The Member State has complete discretion in this matter. If the Commission has doubts regarding the competence of a notified body, it may ask the Member State concerned to justify its choice.

The Commission and all the Member States must be kept constantly informed of the list of notified bodies and of any notifications which are withdrawn.

Member States are not obliged to notify one or more competent bodies.

Manufacturers can choose to deal with any notified body and notified bodies can offer their services outside the territory of the Member State which notified them. Manufacturers must deal with a single notified body for each particular application for a type-examination, however. They may not “try their luck” elsewhere if their application for examination is refused. While manufacturers may not have the same file examined several times, there is nothing to stop them from comparing the prices and quality of the services of the bodies before submitting their application.

A manufacturer obviously need not submit all his applications to the same body. He is free to change.

219.

The notified bodies have established European coordination with a view to unifying methods for issuing type-examinations.

220.

A body outside the EEA cannot be notified until this is provided for by mutual recognition agreements. Similarly a Member State may not notify a body outside its jurisdiction. The guide to the "new approach"[39] published by the Commission describes the operation of notified bodies.

221.

Article 8(3)

3. Where the first indent of paragraph 2(c) applies, the provisions of the first sentence of paragraph 5 and paragraph 7 of Annex VI shall also apply.

Where the second indent of 2(c) applies, the provisions of paragraphs 5, 6 and 7 of Annex VI shall also apply.

222.

What cases are covered by Article 8(3)?

Article 8(3) gives some practical information for machinery listed in Annex IV which is manufactured in accordance with the harmonized standards. In Article 8(2) we saw that this machinery could be exempted from type-examination subject to certain formalities.

Article 8(3) specifies some details for the following two cases:

- the manufacturer sends the construction file to the notified body (first indent of Article 8(2)(c)). The notified body issues a simple acknowledgement of receipt.

- the manufacturer asks the notified body to check conformity to the harmonized standards. The latter issues a certificate of adequacy in relation to the standards. (second indent of Article 8(2)(c)).

223.

What obligations apply to the procedures for issuing acknowledgements of receipt and certificates of adequacy to the standards?

. Obligation to inform the notified body of changes made to the machinery
The manufacturer, or his authorized representative established in the Community, must inform the notified body of any modifications, even of a minor nature, which he has made or plans to make to the machinery to which the example relates (first sentence of Annex VI point 5).

This obligation is binding on the manufacturer when he asks for a simple acknowledgement of receipt or a certificate of adequacy to the standards.

. Obligation for the notified body to inform its Member State if it refuses to issue a certificate.
A body refusing to issue an EC type certificate must inform the other notified bodies. A body withdrawing an EC type certificate must inform the notifying Member State. It must inform the other Member States and the Commission, stating the grounds for its

[39] Guide on the application of the Community technical harmonization Directives based on the new approach and the global approach (Office for Official Publications of the European Communities, 1994).

decision (Annex VI point 6). This obligation also applies to bodies refusing to issue a certificate of adequacy to the standards.

224.

. Language of files and correspondence

Files and the correspondence referring to CE type-examination procedures are written in an official language of the Member State in which the notified body is established, or in a language accepted by it (Annex VI point 7).

Files communicated by manufacturers must comply with these language rules. In the case of the issue of a simple acknowledgement of receipt, the notified body must nevertheless be able to read the file. This is especially true when the body has to study the file to assess adequacy to the harmonized standards.

225.

Article 8(4)

4. Where paragraph 2(a) and the first and second indents of paragraph 2(c) apply, the EC declaration of conformity shall solely state conformity with the essential requirements of the Directive.

Where paragraph 2(b) and the third indent of paragraph 2(c) apply, the EC declaration of conformity shall state conformity with the example that underwent EC type-examination.

226.

Paragraph 4 makes an interesting distinction regarding the content of the EC declaration of conformity.

- In the case of machinery subject to a manufacturer's EC declaration of conformity, without intervention of a third body (machinery not listed in Annex IV), the manufacturer directly declares that each machine conforms to the essential requirements of the Directive.

- For machinery in Annex IV which is issued an EC type declaration by a notified body, each example marketed must be declared to **conform to the certified model**.

  The manufacturer must state in the technical file how he guarantees continuity of conformity over time (last indent of Annex VI point 2). The concept of "model" can be interpreted in terms of "families" of the manufacturer's machinery. The type-examination procedure aims to take account of the "range effects" limiting the economic impact of the procedure on short runs of equipment.

227.

Article 8(4)(a)

4a. Safety components shall be subject to the certification procedures applicable to machinery pursuant to paragraphs 2, 3 and 4. Furthermore, during EC type-examination,

the notified body shall verify the suitability of the safety component for fulfilling the safety functions declared by the manufacturer.

228. The machinery Directive is not concerned with the performance of machinery. Safety components are a special case because the safety function depends on the performance of the product. It is mainly for this reason that safety components are regulated here. Moreover, they obviously must not give rise to a potential hazard mentioned in Annex I to the Directive. The notified body must make sure of this. Harmonized standards for safety components must also take account of both aspects: performance and safety.

229.

Article 8(5)

5.(a) Where the machinery is subject to other Directives concerning other aspects and which also provide for the affixing of CE marking, the latter shall indicate that the machinery is also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the Directives and accompanying such machinery

230. This paragraphs refers to machinery also covered by other Directives requiring the affixing of CE marking, i.e. "new approach" Directives.

Thus, CE marking affixed to construction plant subject to Directives limiting noise does not imply that it complies with them. Indeed, conformity to those Directives requires the sound power level of the machinery to be clearly marked on it, using a system other than CE marking.

The EC declaration of conformity must list the Directives **requiring such marking** to which the machinery conforms. This is all the more important as during the transitional period, "CE" may mean that the machinery conforms to machinery Directive only.

The Directives used must be indicated by means of the references to them as published in the Official Journal of the European Communities (OJ), rather than the references of the national regulations transposing those Directives.

231. The Directives so far adopted **requiring CE marking** are as follows:

- 73/23/EEC "low voltage"[40]
- 87/404/EEC "simple pressure vessels"[41]

[40] Directive 73/23/EEC of 19 February 1973 (OJ No L77, 26 March 1973, p. 29), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

- 88/378/EEC "safety of toys"[42]
- 89/106/EEC "construction products"[43]
- 89/336/EEC "electromagnetic compatibility" (EMC)[44]
- 89/686/EEC "personal protection equipment" (PPE)[45]
- 90/384/EEC "non-automatic weighing instruments"[46]
- 90/385/EEC "active implantable medical devices"[47]
- 90/396/EEC "appliances burning gaseous fuels"[48]
- 91/263/EEC "telecommunications terminal equipment"[49]
- 92/42/EEC "efficiency of boilers"[50]
- 93/15/EEC "explosives for civil uses"[51]
- 93/42/EEC "medical devices"[52]
- 93/97/EEC "satellite earth station equipment"[53]
- 94/9/EEC "equipment and protective systems intended for use in potentially explosive atmospheres"[54]
- 94/25/EC "recreational craft"[55]
- 94/62/EC "packaging and packaging waste"[56]
- 95/16/EC "lifts"[57]
- 97/23/EC "pressure equipment"[58]

The following are being drafted or considered for adoption:

- In vitro diagnostic medical devices (proposal)[59]
- Cableway installations designed to carry passengers (proposal)[60]

232.

Article 8(6)

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41 Directive 87/404/EEC of 25 June 1987 (OJ No L220, 8.8.1987, p. 48), as amended by Directives 90/488/EEC (OJ No L270, 2.10.1990, p. 25) and 93/68/EEC (OJ No L220, 31.8.1993, p. 1).

42 Directive No 88/378/EEC of 3 May 1988 (OJ No L187, 16.7.1988, p. 1), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

43 Directive No 89/106/EEC of 21 December 1989 (OJ No L40, 11.2.1989, p. 12), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

44 Directive No 89/336/EEC of 3 May 1989 (OJ No L139, 23.5.1989 p. 19), as amended by Directives 92/31/EEC (OJ No L126, 22.5.1992, p. 11), 92/31/EEC (OJ No L 126, 22/5/1992, p. 11), 93/68/EEC (OJ No L220, 31.08.1993, p. 1) and derogated by Directive 93/97/EC (OJ No L 290, 24/11/1993, p. 1).

45 Directive No 89/686/EEC of 21.12.1989 (OJ No L399, 30.12.1989, p. 18), as amended by Directives 93/68/EEC (OJ No L220, 31.08.1993, p. 1) and 93/95 (OJ No L276, 9.11.1993, p. 11).

46 Directive No 90/384 of 20 June 1990 (OJ No L189, 20.7.1990, p. 1), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

47 Directive No 90/385 of 20 June 1990 (OJ No L189, 20.7.1990, p. 17), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

48 Directive No 90/396/EEC of 29 June 1990 (OJ No L196, 26.7.1990, p. 15), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

49 Directive No 91/263/EEC of 29 April 1991 (OJ No L128, 23.5.1991, p. 1), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

50 Directive No 92/42/EEC of 21 May 1992 (OJ No 167, 22.6.1992, p. 17), as amended by Directive 93/68/EEC (OJ No L220, 31.08.1993, p. 1).

51 Directive No 93/15/EEC of 5 April 1993 (OJ No L121, 15.5.1993, p. 20).

52 Directive No 93/42/EEC of 14 June 1993 (OJ No L169, 12.7.1993, p. 1).

53 Directive No 93/97/EEC of 29.10.1993 (OJ No L290, 24 January 1993, p. 1).

54 Directive No 94/9/CE of 23 March 1994 (OJ No L100, 19.4.1994, p. 1).

55 Directive No 94/25/CE, 16 June 1994 (OJ No L169, 30.6.1994, p. 15).

56 Directive No 94/62/CE of 20 December 1994 (OJ No L365, 31.12.1994, p. 10).

57 Directive No 95/16/CE of 29 June 1995 (OJ No L213, 7.9.1995, p. 1).

58 Directive No 97/23/CE of 27 May 1997 (OJ No L181, 9.7.1997, p. 1).

59 Proposal for a Directive (OJ No C172, 7.7.1995, p. 21).

60 Proposal for a Directive (OJ No C70, 8.3.1994, p. 8), as amended (OJ No C22, 26.1.1996, p. 12).

Where neither the manufacturer nor his authorized representative established in the Community fulfils the obligations of the preceding paragraphs, these obligations shall fall to any person placing the machinery or safety component on the market in the Community. The same obligations shall apply to any person assembling machinery or parts thereof or safety components of various origins or constructing machinery or safety components for his own use.

233.

Article 8(6) lays down the procedures for the application of the machinery Directive in various situations.

<u>Case 1</u>: direct importation of machinery from a non-EEA country

Where machinery is imported direct from a non-EEA country for use on the territory of the EEA it must be in conformity when placed on the market and put into service.

234.

A non-EEA manufacturer wishes to market machinery in the EEA

When a manufacturer of a non-EEA country sells machinery for use on the territory of the European Union, he must comply in full with the technical and administrative requirements of the Directive.

235.

A non-EEA manufacturer does not wish to market machinery in the EEA

A company located in the EEA may nevertheless buy new machinery directly from a non-EEA country without the non-EEA manufacturer even knowing where it is going.

Article 8(6) stipulates that in this case, the importer-user who places the product on the market is regarded as a manufacturer. He will be responsible for modifying the machinery if it does not comply with the technical requirements. Such modifications will probably be difficult and will be able to cover only minor points because the principle of inherently safe design must be observed. The importer-user will have to ensure that he can obtain a technical construction file or, failing that, constitute this file himself. He must draw up and sign the conformity declaration. He will also affix CE marking.

Article 8(6) allows companies acquiring machinery directly in a non-EEA country, with a view to placing it on the market or putting it into service in the EEA, to be made responsible for its conformity to the Directive. This is in line with the legal logic of the product liability Directive (85/374/EEC) which attributes a manufacturer's responsibilities to any person placing a product on the market. If the manufacturer is not established in the EEA, it is the "person" placing the product on the market, namely the end-user, who is liable in the event of prosecution. Article 8(6) does not aim to encourage users to take the manufacturer's place, quite the contrary. It draws their attention to the need to demand products that conform or be prepared to assume the responsibilities of a manufacturer.

236.

Abusive interpretation of Article 8(6)

No manufacturer, whether domiciled in the EEA or not, can invoke this paragraph to artificially discharge himself from his responsibilities to a third party (retailer, wholesaler, user, etc.). This would be a clear misuse of the law intended to circumvent the application of the Directive. Only the person who places the machinery on the market can avail himself of it at his own risk. He then decides to assume the full responsibility of a manufacturer even though he is not one. In any event, whether he wishes it or not, the person placing the machinery on the EEA market may be held jointly responsibility with the manufacturer in a non-EEA country or any representative he may have. Since the possibilities for initiating legal proceedings against a manufacturer established outside the EEA are relatively limited, it is likely that the direct importer will have to face the consequences alone of non-conformity or an accident.

237.

Case 2: building a new machine from subassemblies

The second sentence of paragraph 6 treats anyone assembling machinery or machinery parts from various origins, or a user building a new machine for his own use, as a manufacturer. Whether or not the subassemblies come from a supplier established in the EEA is immaterial here.

The rule which treats an "assembler" of subassemblies or machinery as a manufacturer should be read in the light of the definition of the concept of machinery and in particular an "assembly of machines" described in the second subparagraph of Article 1(2). It is only when the complete assembly can be described as "machinery" within the meaning of the Directive that Article 8(6) applies. If the complete assembly is not "machinery" (for example if it is a lift excluded from the Directive), it will not apply.

This rule which treats an "assembler" as a manufacturer is consistent with the legal arrangements for subassemblies circulating with the declaration of incorporation provided for in Article 4(2). Subassembly suppliers use the declaration of incorporation of Annex II.B to formally notify the "assembler" that he will be responsible for the conformity of the complete assembly.

Several cases can arise:

238.

a) Design of a new assembly from subassemblies

The assembler, who may be a manufacturer, assembler, engineering company or the end-user himself, designs a new assembly from several machines. If the assembler controls the whole project, he is regarded as responsible for supervising safety. He may buy or import subassemblies which may or may not be compliant and bear CE marking. According to the case, they will be accompanied by the certificates referred to in Annex II.A or II.B. The project supervisor is responsible for the procedures relating to the assembly: drawing up the overall technical file, compliance of the technical annex, providing an overall instruction manual, affixing of CE marking to a place representing the assembly (e.g. main control console) and drawing up an EC declaration of conformity clearly identifying the assembly concerned.

239.

It is very important that the project supervisor takes care of safety from the moment the orders are placed and specifications drawn up for the components. All too often these documents are compiled solely from the point of view of performance. It is unrealistic to assume that an assembly of machines that comply individually with the Directive will form an assembly that also conforms. Safety is not cumulative. The project supervisor must make the effort to think of overall safety and specify the part he wishes each of his suppliers to play. They cannot guess this. The project supervisor must anticipate putting together an overall technical file. This overall technical file is not the sum of the documents provided by the various suppliers. It is both more and less than that. More, in that it has to describe the overall risk analysis which by definition is beyond each subassembly supplier. Less, in that a large part of the suppliers' technical documentation is irrelevant to the objectives of the technical file set out by the Directive.

In practice, the project supervisor's orders need not systematically require a technical dossier based on the model of the Directive. On the other hand he should clearly define the nature of the safety information that he needs from suppliers to carry out his overall risk analysis. There are probably many operating parameters or technical features of the subassemblies which can influence the final result. This information must be available or at least kept at his disposal. The same applies to instruction manuals. A manual for a complex assembly is both more than a compilation of the subassembly manuals and much less. A compilation of instruction manuals and any safety indications can be completely useless to the end-user and bury him under an unusable stack of paper. The assembler should pick out what is relevant to the customer. He should supplement the suppliers' information with specific details for the operation of the assembly.

240.

b) Problems associated with the development of complex assemblies

The project supervisor may also come onto the scene several years after the machinery has been put into service if, for example, he is modernizing a production line by installing a common control system for several machines.

The problem lies with the use of machinery covered by Directive 89/655/EEC, as amended. It stipulates that "the employer shall take the measures necessary to ensure that, throughout its working life, work equipment is kept, by means of adequate maintenance, at a level such that it complies with" the European Directive applicable to it when it was first put into service or, failing this, with the technical annex to Directive 89/655/EEC, as amended. This does not mean that users may not modify their machinery, but rather that machines must maintain their original level of safety. Directive 89/655/EEC, as amended, obviously does not force users to reorganize the administrative procedures when modifying equipment in service (technical file, declaration, marking).

The responsibility for maintaining the level of safety provided for by Directive 89/655/EEC, as amended, is a "social" obligation of the employer aimed at ensuring the safety of his staff. This obligation does not apply to service providers who work on the basis of orders and specifications determined by the user. The user is therefore advised to stipulate in the contract that the level of

safety must remain equivalent to that of the original regulations, and if appropriate with the technical annex to Directive 89/655/EEC, as amended, or with Annex I to the machinery Directive, as amended, if the modified equipment was put into service after 1 January 1995.

241. This rule obviously applies provided that it does not give rise to abuses of the law aiming at artificially circumventing the application of the machinery Directive. Clearly, if the "complex" installation in service is nothing more than a set of gears or an engine dating back to the beginning of the century and the "subassemblies" to be incorporated into it consist of a new production line 100 metres long, the machinery Directive will apply rather than Directive 89/655/EEC, as amended.

Conversely, an abuse of the law on the part of inspection bodies could involve requiring an installation to comply with the machinery Directive as soon as the user wishes to upgrade it. Such a requirement, besides there being no legal basis for it, would dissuade companies from improving the safety of equipment in service.

The basic rule remains that extending or modernizing machinery or adding elements at an existing site is not the same as placing new machinery on the market, even if the original site conforms to the machinery Directive. The level of safety of the Directive must be maintained.

242. It is only if the user (project supervisor) assembles several new components to put a new complex assembly into service that he is considered to be placing new machinery on the market.

A manufacturer or user replacing a new component in new machinery which has not yet been put into service should update the technical construction file. The user (project supervisor) is treated as a manufacturer pursuant to Article 8(6). The last sentence of paragraph 6 must be applied with discretion. Indeed, in the case of test benches or platforms it can prove inapplicable. Moreover, in this case there is no problem involving freedom of movement related to Article 100a.

243.

(c) Case 3: users building machinery for their own use

Article 8(6) of the machinery Directive requires users building machinery for their own use to comply with the Directive. This does not concern modification of machinery in service but rather design of entirely new equipment. Although there is no problem of freedom of movement since the machinery is not being placed on the market, the machinery Directive is applicable to ensure that this type of new machinery is as safe as that available on the market. Article 2 of the Directive requires Member States to monitor the safety of machinery when it is placed on the market and also when put into service. Machinery built by a user for his own use is not placed on the market but is put into service on EEA territory, and is therefore covered by the Directive.

244.

Article 8(7)

7. The obligations laid down in paragraph 6 shall not apply to persons who assemble with a machine or tractor interchangeable equipment as provided for in Article 1, provided that the parts are compatible and each of the constituent parts of the assembled machine bears CE marking and is accompanied by the EC declaration of conformity.

245.

Paragraph 7 states that paragraph 6 does not apply to interchangeable equipment which, although modifying the function of a machine, is designed to be fitted and removed by the user. The user cannot be expected to have the skills that are required of the project supervisor referred to in the preceding paragraph.

However, the user is obliged to ensure, before assembling such equipment, that the equipment is compatible with the base machine; details of compatibility must be given in the instruction manual accompanying the interchangeable equipment. Similar information must be given in the instruction manual of the base machine.

246.

Article 9

1. Member States shall notify the Commission and the other Member States of the approved bodies which they have appointed to carry out the procedures referred to in Article 8 (1) and (2) together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the Official Journal of the European Communities a list of the notified bodies with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

2. Member States shall apply the criteria laid down in Annex VII in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relevant harmonized standards shall be presumed to fulfil those criteria.

3. A Member State which has approved a body must withdraw its notification if it finds that the body no longer meets the criteria referred to in Annex VII. It shall immediately inform the Commission and the other Member States accordingly.

247.

Each of these three paragraphs starts with a reference to the Member States. This makes it quite clear that they are solely responsible for designating the notified bodies. They are also solely responsible for choosing the designation criteria.[61]

The Commission's only obligation is to publish the information received from the Member States.

[61] See the comments on Article 8(2).

Since conformity to the Directive is indivisible, a body is notified for the whole procedure connected with the Directive. It can be notified for only some machinery listed in Annex IV; it may subcontract certain tests, etc., but remains responsible for the whole procedure. Bodies may be notified under the machinery Directive only for machinery in Annex IV.

There are competent bodies which offer their services to manufacturers of machinery not covered by Annex IV to help them design their products. These bodies are not notified and may not claim to be when giving advice, even if they are nevertheless notified for machinery in Annex IV.[62]

248.

Paragraph 2 refers to Annex VII, which lists the minimum criteria for the evaluation of bodies, then refers to the relevant harmonized standards (the EN 45000 series).

Paragraph 3 obliges Member States to withdraw their notification of any body which no longer meets the criteria listed in Annex VII. Although this is not stated, notification may also be withdrawn on other grounds, such as repeated poor examinations, price agreements, etc. Only the Member State on whose territory the body is established can take measures for or against it. Other Member States can only invoke the safeguard clause (Article 7) in respect of machinery examined by the body in question which they consider to be dangerous.

A Member State may notify bodies only if they are under its jurisdiction to preserve its "powers" over them. Bodies may not therefore be notified outside the EEA unless mutual recognition agreements concerning the machinery Directive are concluded with non-EEA countries.

62 See the comments on Article 8(2).

249.

CHAPTER III - CE MARKING

Article 10(1)

1. The CE conformity marking shall consist of the initials "CE". The form of the marking to be used is shown in Annex III.

250.

Article 10 gives practical details of CE marking.

CE marking has only one meaning: conformity to European "new approach" Directives! It cannot be used for commercial purposes since all products concerned must bear this marking and other products may not bear it. CE marking is not a mark of origin. CE marking does not mean "manufactured in the EEC".

The model set out in Annex III must not be distorted in any way (e.g. use of italic characters, dynamic or other visual impression).

N.B. CE marking must not be affixed to safety components under the machinery Directive.

251.

Article 10(2)

2. CE marking shall be affixed to machinery distinctly and visibly in accordance with point 1.7.3 of Annex I.

252.

Paragraph 2 states that marking must be distinct from the other inscriptions on the machinery and large enough to be clearly visible (the actual size will depend on the size of the machinery).

253.

Article 10(3)

3. The affixing of markings on the machinery which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility and legibility of the CE marking is not thereby reduced.

254.

Paragraph 3 does not prohibit the affixing of other marks, such as the manufacturer's logo, an optional quality mark, etc., but it does prohibit marks whose shape or meaning could be confused with CE marking. This voluntary marking may not refer to aspects covered by the Directive.

There are also obligatory marks in European legislation which will continue alongside CE marking, such as those for explosive atmospheres, noise of construction equipment, etc.

CE marking must be affixed to the machinery itself. The Directive provides for an exception for lifting accessories including components such as cables and ropes. Such products cannot be marked. The manufacturer may put the information on a plate or any other means firmly fixed to the accessory.[63]

255.

Article 10(4)

4. Without prejudice to Article 7:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;

(b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.

256.

CE marking is reserved for products covered by a Directive requiring it. Marking of products not covered by a "new approach" Directive, such as on components or subassemblies referred to in Article 4(2), may be regarded as improper and abusive marking, and hence a more serious infringement.

[63] See requirement 4.3.2. of Annex I.

257.

CHAPTER IV - FINAL PROVISIONS

Article 11

Any decision taken pursuant to this Directive which restricts the placing on the market and putting into service of machinery or a safety component shall state the exact grounds on which it is based. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.

258.

This Article supplements or restates in broader terms the guarantee to manufacturers against arbitrary decisions by Member States, particularly as regards Article 7.

259.

Article 12

The Commission will take the necessary steps to have information on all the relevant decisions relating to the management of this Directive made available.

260.

The relevant decisions taken by the Commission, where appropriate after consulting the Committee set up by Article 6(2), must be made available. A means of making them available has yet to be established.

"Relevant decisions" means inter alia:

- The notification of bodies for EC type examination. These are published for information only. The list need not be published in the OJ for the notification to be valid.
- The references of harmonized standards. The publication of the harmonized European standard is an essential condition for creating presumption of conformity deriving from compliance with harmonized European standards. The Member State is obliged to publish the references of a harmonized standard in its national official journal from the date of publication of that harmonized standard.
- The interpretation of an essential requirement in a specific case, after consulting the committee set up by Article 6(2).
- Information on the scope of the Directive where there is an overlap with other Directives.
- Types or models of machinery prohibited following the invoking of a safeguard clause and termination of the ensuing procedure.

261.

Article 13

1. Before 1 January 1992 Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

The Member States shall apply the measures in question with effect from 1 January 1993, except as regards the equipment referred to in Directives 86/295/EEC, 86/296/EEC and 86/663/EEC, for which these measures shall apply from 1 July 1995.

2. Furthermore, Member States shall allow, for the period until 31 December 1994, except as regards the equipment referred to in Directives 86/295/EEC, 86/296/EEC and 86/663/EEC, for which this period shall end on 31 December 1995, the placing on the market and putting into service of machinery in conformity with the national regulations in force in their territory on 31 December 1992.

Directives 86/295/EEC, 86/296/EEC and 86/663/EEC shall not impede implementation of paragraph 1 as from 1 July 1995.

3. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

4. The Commission shall, before 1 January 1994, examine the progress made in the standardization work relating to this Directive and propose any appropriate measures.

262.

A Directive is always addressed to the Member States which are instructed to transpose it into their national law. Member States have a certain latitude regarding the legal form and the means of transposition into their national law. The important thing is that the desired useful effect of the Directive is achieved. The Commission checks that these transpositions are faithful to the spirit of the Directive but it could overlook certain things, resulting in inconsistencies between certain transpositions. Parties discovering such inconsistencies must notify the Commission.

This Article gives the dates on which Directive 89/392/EEC and its first amendment are to take effect.[64] There are several dates, as it would be inconceivable to change from one set of rules to another without a transitional period.

A general 2-year transitional period has been established in order to:

- enable notified bodies to carry out the EC type-examinations of the machinery listed in Annex IV;
- allow stocks to be cleared; and
- allow standardization to proceed. Paragraph 4 provides for a review of progress made one year before the Directive takes full effect.

The Directive did not take full effect until 1 January 1995. From that date, however, pursuant to Directive 89/655/EEC, as amended, employers may no longer put non-

64 Directive 89/392/EEC of 3 May 1989 (OJ No L183, 29.6.1989, p. 9); Directive 91/368/EEC of 20 June 1991 (OJ No L198, 22.7.1991, p. 16).

compliant machinery into service for the first time, even if it has already been placed on the market.

The transitional period has been put back and reduced for equipment already covered by an "old approach" Community Directive which is applied in full. Such equipment already enjoys freedom of movement, and since the Directives in question are of recent date, the legislator considered it unreasonable to require manufacturers to amend their design too often and accordingly allowed them a longer period to adjust.

With regard to lifting equipment and safety components, now covered following the amendment in Directive 93/44/EEC,[65] the above dates are generally postponed by two years.

263.

Directive 93/44/EEC
Article 2(1)

1. Before 1 July 1994 Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Member States shall apply these provisions with effect from 1 January 1995.

264.

Directive 93/44/EEC
Article 2(2)

2. By way of derogation from the third subparagraph of paragraph 1, Member States shall apply the laws, regulations and administrative provisions necessary to comply with the provisions listed below as from 1 July 1994:
- ***Article 1(10) excluding (a), (b) and (q)***
- ***Article 1(11)(a) and (b)***
- ***Article 1(12)(c), (d), (e) and (f).***

265.

These exceptions are no longer relevant and so do not require any particular explanation.

266.

Directive 93/44/EEC
Article 2(3)

[65] Directive 93/44/EEC of 14 June 1993 (OJ No L 175, 19.7.1993, p. 12).

3. However, until 31 December 1996 Member States may allow the placing on the market and putting into service of safety components and of machinery for the lifting or moving of persons which conform with the national provisions in force in their territories as at the date of adoption of this Directive.

267.

The transition period for machinery for the lifting or moving of persons and for safety components ends on 31 December 1996.

268.

Directive 93/44/EEC
Article 2(4)

Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

269.

The first amending Directive (91/368/EEC) repealed several "old approach" Directives. Article 14 of that Directive provides as follows.

270.

Directive 91/368/EEC
Article 2

The following are hereby repealed as from 31 December 1994:

- ***Articles 2 and 3 of Council Directive 73/361/EEC of 19 November 1973 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire ropes, chains and hooks, as last amended by Directive 76/434/EEC,***

- ***Commission Directive 76/434/EEC of 13 April 1976 adapting to technical progress the Council Directive of 19 November 1973 on the approximation of the laws of the Member States relating to the certification and marking of wire ropes, chains and hooks.***

The following are hereby repealed as from 31 December 1995:

- ***Council Directive 86/295/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to roll-over protective structures (ROPS) for certain construction plant,***

- ***Council Directive 86/296/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to falling-object protective structures (FOPS) for certain construction plant,***

- ***Council Directive 86/663/EEC of 22 December 1986 on the approximation of the laws of the Member States relating to self-propelled industrial trucks, as last amended by Directive 89/240/EEC.***

271.

The European Commission indicated the dates of application of the Directive to ROPS and FOPS in communication 94/C published in OJ No C 253 of 10 September 1994, page 3.

272.

Article 14

This Directive is addressed to the Member States

273.

The Treaty of Rome states that Directives are addressed to the Member States (under the ECSC Treaty, Directives are addressed to the Member States or companies). Directives require Member States to deliver results but leave them a certain latitude as to the form of national transposition. The Court of Justice of the European Communities had the opportunity of pointing out the obligation "to choose the most appropriate forms and methods to ensure the effectiveness of the Directives" (CJEC, judgement in case 48/75, Royer, ECR 497). Member States have to arrive at the expected results namely, for the machinery Directive, freedom of movement and human safety. The chosen method of transposition must make it possible to attain those objectives. Under the machinery Directive the transposition measures must be binding. A simple recommendation or administrative circular is not sufficient.[66] Those persons required to satisfy the obligations provided for by the Directive i.e., for the machinery Directive, manufacturers and others treated as manufacturers, must be able to find out what their rights and obligations are. In certain cases, where the provisions of a Directive are unconditional, the Court recognizes the right of private individuals to avail themselves of the provisions of a Directive which has not yet been transposed.

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66 CJEC, judgment in case 96/81, Commission v Netherlands, ECR 1791.

ANNEX I
ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY AND SAFETY COMPONENTS

274.

Certain requirements (definitions in section 1.1.1 of Annex I and requirements which are already sufficiently clear) are reproduced without further comment. Standardization work is sometimes referred to without the number of the standard in question being indicated. This is because the standard has not yet reached the public enquiry stage and the number is not yet known.

Use of the appropriate word at the right time and in the right place is one of the bases of safety, particularly in the drafting of standards and the instructions for machinery.

Standard EN 292 is recommended reading: in addition to basic safety concepts, it gives a precise definition of many concepts and words.

Where the comments on certain requirements are long they have been divided into different sections, each one preceded by an extract of the requirement in question. This extract is in a box without background.

275.

For the purposes of this Annex, "machinery" means either "machinery" or "safety component" as defined in Article 1(2).

276.

PRELIMINARY OBSERVATIONS
First preliminary observation

1. The obligations laid down by the essential health and safety requirements apply only where the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer. Whatever the case, requirements 1.1.2, 1.7.3 and 1.7.4 apply to all machinery covered by this Directive.

277.

The essential requirements are applied as a function of the hazards.

The preliminary observations lay down principles which may appear to be self-evident, but are none the less important. The requirements apply only where the hazard exists.

The manufacturer must therefore identify the hazards associated with his machinery and the corresponding requirements; he alone is in a position to do so. The technical file referred to in Article 8 and Annex VI must include a list of the requirements and the means used to meet them. In the extreme case, a machine whose operation never required human intervention and which could operate only in a locked room would not need to meet most of the essential requirements. The technical annex needs to be read with discernment, the Council and the Commission never meaning to impose technical requirements which proved absurd for any given product.

278.

Second preliminary observation

2. The essential health and safety requirements laid down in this Directive are mandatory. However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In this case, the machinery must as far as possible be designed and constructed with the purpose of approaching those objectives.

279.

Adoption of solutions proportionate to the hazard

Attempting to meet the requirements may lead to overcomplicated or excessively expensive solutions; they may even be impossible to meet. For example, how can you design a hand-operated wood-saw so that the blade can cut the wood but not the operator's hand! The Directive does not allow such requirements to be ignored, but recognizes the importance of the state of the art (and let us not forget that one of the recitals refers to economic requirements). The Directive imposes only such preventive measures as are proportionate to the hazard, the cost and the technical level of the product.

The Directive imposes more an obligation to use available means than an obligation to achieve results. It is possible that, given the current state of the art, not all of the Directive's objectives can at present be attained, but that this will become possible some years from now. In practice, the manufacturer must construct machinery which meets the need of the customer and try to reconcile this with safety. This is one of the definitions of quality which the Commission has decided to promote in the European Union.

280.

State of the art

Definitions

There are several references to "state of the art". This is an important concept for the implementation of the "new approach" and requires certain explanations.

The concept takes account of all the material circumstances affecting a product, whether technical, economic, social or environmental. CEN provides a definition of state of the art which is worth repeating:
«developed state of technical possibilities, at a given time, relating to products, processes and services, as based on scientific knowledge, technology and experience». Good engineering practice comprises suitable technical behaviour, available to the respective professional body and corresponding to the state of the art at that particular time. Good engineering practice is generally the expression of a technical custom. It is therefore attached to this source of the law. Only proven uses form part of good engineering practice. This assumes «long-standing, constant, well-known and general use». The technical uses which form part of good engineering practice include all the theoretical and practical knowledge which is currently applied in industrial companies. The majority of these uses are passed on to junior engineers and technicians by the technical establishments and during their apprenticeships in the company. These uses include, for example, the methods of graphic representation of machine parts, knowledge of design solutions (enclosing of parts, assembly techniques, choices of materials, definition of the product, etc.).

281.

Long-standing, constant, well-known and general use

Long-standing technical use is no longer an absolute criterion as such. With the rapid technological advancement of our times, a technology can reach the level of "good engineering practice" without waiting several years. We are witnessing the emergence of rapidly formed “customs”. Certain uses may be recent and firmly “*anchored”* in the technical practices of the profession.

Use forms part of good engineering practice when it is “well-known”. “Well-known” use is use which is known to the profession and can be shown to exist with certainty. This use is constant. It has a certain stability over time. It is not transitory, even if it can age and gradually disappear. Use is general. It is not limited to a single person.

Other criteria better illustrate the nature of “code of practice” which adopts only current “techniques". This involves the techniques which exist in industrial practice as opposed to potential or experimental techniques. Current techniques also supplant techniques of the past. Techniques suitable for forming part of good engineering practice have to be “necessary”, “appropriate” and “useful”. The measures taken by the expert have to be “traditional” and “suitable”. The need for a special technique depends on the case in point. The technique used has to be “proportionate” to the objective to be achieved. Good engineering practice provides a range of techniques selected from all techniques offering a good quality level. This range allows a certain latitude in the choice of means used by the expert according to the circumstances. The expert is not automatically required to choose the best or the most expensive technique. That said, a desire for economy, even when requested by the customer, can under no circumstances justify failure to abide by good engineering practice.

282.

Differences between standards and good engineering practice

Good engineering practice is a separate entity from and operates outside standardization. Good engineering practice is not written. Standards may codify good engineering practice at any given time, but this is soon out of date. At best an attempt can be made to take account of it at any given time. Standards, on the other hand, are written and therefore unbending documents (between each revision) drawn up by formal and official procedures. Good engineering practice has a customary value and is essential. It thus has more legal bearing than standards. The professional must always give priority to good engineering practice over the optional standard where the latter seems to be contradictory.

283.

Certain standards may codify good engineering practice. Coincidence between good engineering practice and standard is above all a question of fact. For some standards, like the graphical symbols used on equipment (e.g. ISO standard 7000), it is not possible to generalize this coincidence. In the field of machinery harmonized standards cannot claim to systematically “codify” the state of art because they include many other factors such as the requirements of the Directive, the wishes of the “safety experts”, and the ideas of research workers and specialists. Good engineering practice to be taken into consideration is the code of the professionals who apply it. Nonetheless, if a standard is to remain true to its vocation it must always keep a certain link with good engineering practice of the professionals who use

it. The concept of standard by the ISO and Directive 83/189/EEC, as amended,[67] provides for inclusion in the standard of professionals' experience. Several European Directives, such as the "low-voltage" Directive[68] and the "general product safety" Directive,[69] officially recognize the major role played by good engineering practice in fulfilling safety obligations. The "machinery" Directive does not mention this concept explicitly, but it is implicit throughout Annex I

284.

Need to take account of all constraints

Good engineering practice takes account of all constraints, including economic constraints, encountered in the manufacture and use of a machine. The means used to meet the objective of safety which are acceptable according to good engineering practice at a given time are no longer acceptable if developments make a new generation of machines safer or allow the design of a different and safer machine for the same purpose.

285.

Thus, while standards must take account of the state of the art they do not themselves define the state of the art. Standards can also take account of other factors, such as the expectations of insurance brokers, research institutes, universities, etc.

The means described in a harmonized standard intended to apply the Directive must always be achievable, unlike the objectives of the essential requirements which are not always achievable.

286.

Third preliminary observation

3 The essential health and safety requirements have been grouped according to the hazards which they cover.

Machinery presents a series of hazards which may be indicated under more than one heading in this Annex.

The manufacturer is under an obligation to assess the hazards in order to identify all those which apply to his machine; he must then design and construct it taking account of his assessment.

287.

Risk analysis throughout Annex I

Some people ask whether such-and-such a machine must meet the requirements of Chapter 1, 2, 3 or 4 of Annex I. A machine must in principle meet all applicable requirements, whatever Chapter they appear in, as was said in the first preliminary observation. It is however true that the "machinery" Directive was first drawn up on the basis of the traditional risks of machine tools and the like (original version of 14 June 1989, Chapters 1 and 2 of Annex I). It was only

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67 Directive 83/189/EEC of 28 March 1989 (OJ No L 109, 26.04.83, p. 8), as amended by Directives 88/182/EEC (OJ No L 81, 26.03.88, p.75) and 94/10/EC (OJ No L 100, 19.04.94, p.30) and Council Decision of 1 January 1995 (OJ No L 1, 01.01.95).

68 Directive 73/23/EEC of 19 February 1973 (OJ No L 77, 26.03.73, p. 29), as amended by Directive 93/68/EEC (OJ No L 220, 31.08.93, p.1).

69 Directive 92/59/EEC of 29.06.92 (OJ No L 128, 11.08.92, p.24).

at a later date that risks connected with lifting and mobility were incorporated, mainly from experience gained in the sector of lifting and civil engineering equipment. This manner of drawing up the Directive can be seen in the drafting of certain requirements which aimed at specific equipment. This should be remembered when interpreting the text.

288.

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS
1.1. General remarks
1.1.1. Definitions
For the purpose of this Directive
1. 'danger zone' means any zone within and/or around machinery in which an exposed person is subject to a risk to his health or safety;
2. 'exposed person' means any person wholly or partially in a danger zone;
3. 'operator' means the person or persons given the task of installing, operating, adjusting, maintaining, cleaning, repairing or transporting machinery.

A number of key concepts essential to the understanding of the Directive are defined in the header to the essential safety requirements.

289.

Danger zone

The concept of danger zone makes it possible to locate the places where there is exposure to a hazard. Appraisal of any danger in an area is made without taking account of the protective systems since the aim is to determine the need to equip machinery with them. In certain special cases, the manufacturer will protect a danger zone inside an area which is already protected. A compressor is normally enclosed. It presents no risk connected with revolving elements. If the operator needs to open this casing to make an adjustment it may be necessary enclose an internal part which is near the adjustment mechanism.

290.

Exposed person

The concept of exposed person is very general, referring mainly to persons who are likely to be in the immediate vicinity of the machine and who are not operators or specialized maintenance personnel. Exposed persons can therefore be other company staff or visitors. The "machinery" Directive does not deal with the problems of the environmental outside the company. People living close to the company are not therefore "exposed persons" within the meaning of the "machinery" Directive.
This concept also refers to private individuals using machinery for their own purposes and to their surroundings.

291.

Operator

The concept of operator is defined very broadly. It includes both the person responsible for operating the machine during production and the person undertaking maintenance or handling operations. It must be stressed here that the Directive imposes an obligation on the

manufacturer only in the various types of use, adjustment, assembly, etc., set out in the instructions.

292.

1.1.2. Principles of safety integration

(a) Machinery must be so constructed that it is fitted for its function, and can be adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen by the manufacturer.

The aim of measures taken must be to eliminate any risk of accident throughout the foreseeable lifetime of the machinery, including the phases of assembly and dismantling, even where risks of accident arise from foreseeable abnormal situations.

(b) In selecting the most appropriate methods, the manufacturer must apply the following principles, in the order given:

- ***eliminate or reduce risks as far as possible (inherently safe machinery design and construction),***
- ***take the necessary protection measures in relation to risks that cannot be eliminated,***
- ***inform users of the residual risks due to any shortcomings of the protection measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.***

(c) When designing and constructing machinery, and when drafting the instructions, the manufacturer must envisage not only the normal use of the machinery but also uses which could reasonably be expected.

The machinery must be designed to prevent abnormal use if such use would engender a risk. In other cases the instructions must draw the user's attention to ways - which experience has shown might occur - in which the machinery should not be used.

(d) Under the intended conditions of use, the discomfort, fatigue and psychological stress faced by the operator must be reduced to the minimum possible taking ergonomic principles into account.

(e) When designing and constructing machinery, the manufacturer must take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment (such as footwear, gloves, etc.).

(f) Machinery must be supplied with all the essential special equipment and accessories to enable it to be adjusted, maintained and used without risk.

293.

(Extract)
[1.1.2. Principles of safety integration

(a) Machinery must be so constructed that it is fitted for its function, and can be adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen by the manufacturer.

The aim of measures taken must be to eliminate any risk of accident throughout the foreseeable lifetime of the machinery, including the phases of assembly and dismantling, even where risks of accident arise from foreseeable abnormal situations.

(...)]

294.

Principle of integrating safety from the design stage

This is probably the most important section of Annex I and must be borne in mind at all times by the manufacturer.

Safety integration is the fundamental approach of the Directive.

Safety must be integrated at the design stage, i.e. as early as possible. Safety must be integrated into the machine not only as used for production purposes, but also during adjustment, maintenance, assembly and dismantling (see section 1.7.4 (a)). This is made clear both in the first paragraph of section 1.1.2 and in the definition of the operator in section 1.1.1.

295.

Concept of foreseeable lifetime

The foreseeable lifetime of the machinery is an important concept (N.B. the first preliminary observation emphasizes that requirement 1.1.2 applies to all machinery).

The “machinery” Directive requires the foreseeable lifetime of machinery to be taken into account only when it has a direct effect on the safety of the equipment.

The durability of machinery, i.e. the potential duration of operability for the functions for which it was designed under given conditions of use and maintenance, does not fall within the scope of the Directive where it does not concern safety. The problems of operational availability, industrial performance and contractual warranty period are governed by ordinary contract law.

The foreseeable lifetime of a machine can have an impact on safety for certain equipment. As an example, some overhead travelling cranes are designed exclusively for the lifting of only one load at a regular interval. The weight of the load to be lifted is therefore known very exactly, as is the number of operations that the overhead travelling crane will complete during its foreseeable lifetime. If this is 10 000 lifting operations the manufacturer will not have to calculate his overhead travelling crane on the basis of a million operations.

It is the manufacturer who determines the foreseeable lifetime of the machinery for it to be safely operated. This may be just the time or the maximum number of operations. He will use this as a basis for his calculations of stress resistance and fatigue, his choice of components and the drafting of the maintenance instructions, etc. The manufacturer must specify the foreseeable lifetime in the technical file if it has a bearing on the integration of safety into the design and to justify certain choices, but he is not obliged to inform the customer thereof, unless it forms part of the contractual conditions.

296.

Conditions foreseen by the manufacturer : consideration of fundamental anthropometric factors

The "conditions foreseen by the manufacturer" and "foreseeable abnormal situations" are other important concepts. The manufacturer must, of course, be acting in good faith when he specifies the conditions of use of the machinery. To prevent manufacturers from protecting themselves by specifying artificially strict conditions, the Directive requires them to consider foreseeable abnormal situations. For example, basing the ergonomic design of machinery on male anthropometric data and stating in the instructions that the machinery is to be used by men only, without any scope for adjustment, when it is obvious that both men and women are employed to do the job in question, does not take account of a foreseeable situation. Such machinery meets neither this requirement nor that laid down in paragraph (d). In certain cases, ergonomic design will mean finding the best possible compromise between work constraints and anthropometric data.
It will not always be possible to fit very small mobile machinery for working in confined spaces (mini-diggers), for example, with big, wide cabs; but other measures can be taken to adapt the driving position to operators and to reduce postural strain .

297.

Foreseeable abnormal situations are sometimes more difficult to identify, e.g. the instinctive movements or reflexes of the operator. Again, if the safety devices installed are such as to hinder the operator or reduce his productivity substantially, it is foreseeable that the user will be tempted to disable them. The designer must take account of this potential hindrance in his risk analysis.

298.

(Extract)
[1.1.2. Principles of safety integration
(...)
(b) In selecting the most appropriate methods, the manufacturer must apply the following principles, in the order given:
- eliminate or reduce risks as far as possible (inherently safe machinery design and construction),
- take the necessary protection measures in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.

(...)]

299.

This paragraph requires the manufacturer to specify the uses of the machinery clearly in the instructions. Requirement 1.1.2(a) refers to assembly and dismantling, and the drafter of the instructions must pay particular attention to these points, as the abnormal movements which give rise to accidents often occur during these stages. The manufacturer lays down which of the assembly and dismantling operations are usually for the customer to perform. The manufacturer can reserve the right to attend to part or all of the assembly. This restriction may be justified by the technical nature of the operation, the high precision required or safety considerations. If the manufacturer feels that some of the assembly operations are beyond the technical capacity of the customer he must warn the latter that such operations can only be performed by a specialist. The manufacturer is not obliged to furnish the technical information relating to operations which are not for the customer.

If a machine can be used in several configurations, requiring specific protection devices, the instructions must provide all the information needed for the machine to be used with the said devices in each configuration.

The same attention must be paid to identifying the ways in which the machinery should not be used. A manufacturer who sells a commercial mixing machine to a restaurant need not design it to be flame-proof, but the same machine sold for use in explosive atmospheres in the chemical industry would have to be flame-proof.

Finally, a simple warning in the instructions cannot be considered satisfactory if devices exist which could be reasonably integrated into the machine and would automatically limit or eliminate the risks in question.

300.

(Extract)
[1.1.2. Principles of safety integration

(...)

(c) When designing and constructing machinery, and when drafting the instructions, the manufacturer must envisage not only the normal use of the machinery but also uses which could reasonably be expected.

The machinery must be designed to prevent abnormal use if such use would engender a risk. In other cases the instructions must draw the user's attention to ways - which experience has shown might occur - in which the machinery should not be used.

(...)]

301.

What can be "reasonably" foreseen?

-The lessons of experience

Requirement 1.1.2(a) obliges the manufacturer to take account of foreseeable "abnormal situations". Point (c) reemphasizes this need by establishing a link with the

drafting of the instructions. Lawyers use the term “legal standard” for this type of vague and flexible concept. A “reasonable” person in legal terms is a person “with sound judgement and normal (average) comprehension capacity”. He is neither a genius nor an idiot! The supposed capacities of the operator are seen in theoretical and abstract terms. This requires a real effort on the part of the manufacturers. The design offices of manufacturers are very familiar with the design of the product, which sometimes makes it difficult for them to understand users' reactions. The feedback from the after-sales service can be invaluable for determining the average ”profile” of the target clientele. The manufacturer is required to foresee only “reasonable” situations, i.e. based on logic, rational usage and common sense. The manufacturer's assessment has to be pitched within this “average”. In practice the manufacturer can use statistical methods of risk evaluation, as proposed by certain standards. This is more a quality judgement than a “mathematical” one.

For example, if the position of the guard is such that it could be used as a footboard (guard for a low hopper on a concrete mixer, or guards on certain agricultural machinery) such guards have to be made strong enough to support the weight of a worker plus any work tools or materials he needs.

302.

In any event the concept of “reasonably foreseeable” precludes the irrational in technical matters and “the cat in the microwave” argument. Fortunately, “reasonably foreseeable” occurrences are less numerous than “possible” occurrences, and “possible” occurrences are less numerous than “imaginary” occurrences.

303.

-Compliance with legislation by the user

. Importance of Directive 89/655/EEC, as amended, and of local regulations

The normal use which can reasonably be expected of a professional machine user is first and foremost compliance with the legislation governing the use of work equipment (Directive 89/655/EEC, as amended[70]). This Directive details the organizational measures that employers in the EEA must take when dealing with machinery. It stresses training and worker information and the provision of instructions on the use of the machinery. The employer must also make an initial check of the machinery where safety depends on the installation before the actual use of the equipment. Machinery subject to deterioration effects which are likely to lead to dangerous situations should be checked periodically.

It is up to users to choose equipment which is suited to their working environments. Directive 89/655/EEC, as amended, provides that when choosing machinery employers must take account of the conditions and specific nature of the work and the risks encountered in the company. This provision concerns primarily the workstations and potential risks resulting from the use of a new machine (Article 3).

Users must also adhere to any other technical regulations to do with the use of machinery. These regulations are often specific to the Member States although some of them have come in for minimum harmonization at European level. These are mainly regulations concerning

[70] Directive 89/655/EEC of 30 November 1989 (OJ No L 393, 30.12.89, p. 13). This Directive was amended by 95/63/EC (OJ No L 335, 30.12.95, p. 28).

legal metrology, the limits on pollutant emissions into the environment and at the workplace, and rules on the design of buildings.[71]

304.

. Case of new machinery modified by the user before being put in service

Users have to adapt, if need be, their new equipment to the special conditions of their company. Directive 89/655/EEC, as amended, lays down that the employer should take the measures necessary to ensure that the work equipment made available to workers in the undertaking is suitable for the work to be carried out or properly adapted for that purpose (Article 3). It is possible that some users may not find machinery on the market which fully meets their needs. They have the right to modify the new machines that they acquire before first putting them to use provided they maintain the original safety level and comply with the formal obligations of the "machinery" Directive (new declaration, addition to instructions, etc.). In practice, modifications to a new machine by a user before it is first used release the manufacturer from responsibility for the part modified or for the consequences that the modifications can have on the unchanged part. In some cases manufacturers can warn the user that any modifications to the machinery supplied nullify the original declaration of conformity and even the contractual guarantee. The obligation to put a machine into operation in accordance with the Directive is thus incumbent upon the user. The declaration of conformity delivered by the manufacturer concerns only the machine in its initial state. The user will probably have to draft a new declaration attesting to the conformity of the modified new machine. It is probably going too far to liken a user who modifies a new machine to a user who builds a machine for his own use. This is covered by Article 8(6) of the Directive, which likens anyone constructing machinery for his own use to a manufacturer. In our opinion, anyone who modifies a new machine is similar to a manufacturer only for the part modified. He cannot be expected, for example, to draw up a technical dossier for the parts he did not modify (insofar as the modifications do not affect the safety of those parts).

305.

. Modification of machinery in accordance with the "machinery" Directive after already being put into operation.

The user can still amend after it has first been put into operation, but the "machinery" Directive is then no longer applicable. Directive 89/655/EEC, as amended, takes over. Article 4(2) of that Directive states that "the employer must take the measures necessary to ensure that, throughout its working life, work equipment is kept, by means of adequate maintenance, at a level such that it complies with the provisions of the European Directive at the time of being placed on the market or put in service". The user is thus obliged to maintain the level provided for by the essential safety requirements of the "machinery" Directive. In the event of a modification, the user must ensure that it does not alter this level. He does not, however, have to draw up a new declaration or observe the administrative procedures set out in the "machinery" Directive.

306.

. Compliance with legislation by the user is always presumed

[71] The principal Directives on health and safety at work applicable to undertakings in the EEA are contained in a report in "*Social Europe"* entitled *Health and safety at work in the European Communities* (ISSN 0255-0792) available from the Office for Official Publications of the European Communities (Luxembourg).

For a judge "ignorance of the law is no excuse". This is an irrefutable presumption both for the user and for the manufacturer. On the other hand, there is no presumption of knowledge of optional standards. A car salesman assumes that his customer obeys the Highway Code. The law has never required salesmen to sell vehicles which cannot do more than 90 k.p.h. A salesman of chain-saws assumes that his machines will not be used to kill, this being outlawed in countries signatory to the EEA.

307.

-Compliance with good engineering practice by professionals

The manufacturer can also assume that the use of his machinery in accordance with the “code of practice” of the customer sector is equally foreseeable. A baker uses a kneader according to the traditions of his trade, and a building worker uses a concrete-breaker in accordance with the “good engineering practice” of his trade. In practice, however, it is important for the salesman to know the habits of users. Sometimes the salesman may find it necessary to outlaw certain known bad practices of the customer. The practice of some people in the butcher’s trade of cutting frozen meat with wood saws could, for example, be forbidden by the sellers of such equipment. Contrary to what some people think, the manufacturer is not obliged to design machinery to limit the risks connected with these bad practices. While truck races are sometimes held in the docks of certain ports in Europe the manufacturers of such trucks are not obliged to make them “racing trucks”. While it may be the "practice" in certain building trades to raise persons on fork-lift trucks the manufacturers of fork-lift trucks are not obliged in any way to design them as person-lifting appliances. The fact that people occasionally hang on to the sides of construction site machines does not mean that the manufacturers have to provide footboards.

There is, strictly speaking, no “good engineering practice” for private consumers. The foreseeable behaviour of a consumer is more difficult to determine as it can cover all age ranges, capabilities and experience.

308.

-Compliance with the contract and the instructions

“Reasonably foreseeable” use of a product is also use in accordance with the contractual commitments entered into by the buyer. This point is important in the case of complex machinery needing detailed specifications to be drawn up by the two parties. Complying with the operating procedure has a significant contractual value in that it is implicit, and even explicit, in the contract.

309.

Buyers have the contractual obligation of diligence in using the product. This is a legitimate return for the seller’s safety and information obligations. Knowledge of the method of use and adherence to it by the user has the force of customary usage, especially where the buyer is an experienced professional.

310.

(Extract)
[1.1.2. Principles of safety integration
(...)

(d) Under the intended conditions of use, the discomfort, fatigue and psychological stress faced by the operator must be reduced to the minimum possible taking ergonomic principles into account.

(...)]

311.

Taking account of working conditions in the design of machinery

Ergonomics enables the manufacturer to take account of body sizes in the design of equipment. It looks at operator positions, body movements and physical strength. The development of automatic operations has reduced the physical effort, but it has often increased the effort in terms of attention that the operator has to make to check the machine. It is therefore important that the designer should carefully choose the indicators for the machine. Once again a balance must be achieved. Too much information clouds the clarity of the message. The type, clarity and frequency of display of messages must be reviewed. Special attention must be paid to the design of controls such as handles, switches and panels. The lighting on machinery should also avoid any risks of dazzling or stroboscopic effects.

312.

Role of ergonomics standards

European standards may be of use, in particular EN 614-1, which defines the principles and concepts of ergonomics as applied to work equipment, EN 894, which defines good positioning for controls, EN 979, which defines the main body sizes, and EN 1005, which lays down limits on the effort that can be demanded.

The general ergonomics standards drawn up by the CEN lay down principles which have to be adjusted to each individual machine. Abstract application in advance is not possible. C standards help apply the general principles of ergonomics to the cases in point. Where there are no C standards the manufacturer has to try to apply the general principles as far as possible.

313.

Need for ergonomics in preventive measures

An important point needs to be made on the ergonomics of the safety systems themselves. A safety device which increases the difficulty of the tasks excessively should be discarded. Preventive measures must be “ergonomic”. By way of example, reducing the noise of a machine, in itself a very good thing, but can end up posing genuine problems if the noise is used by the operator as a source of information (on the running of the machine and any incidents). A balance has to be struck. This or that safety device cannot therefore be imposed arbitrarily on a manufacturer regardless of the general context in which the product is used. The “machinery” Directive asks specialists in prevention not to adopt “all in” solutions without taking time out to think about their suitability for the machine and the risk in question.

314.

(Extract)

[1.1.2. Principles of safety integration

(...)

(e) When designing and constructing machinery, the manufacturer must take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment (such as footwear, gloves, etc.).

(...)]

315.

Provision for use of personal protective equipment (PPE)

The manufacturer of machinery must take account of the reasonably foreseeable wearing of personal protective equipment in normal use of the equipment. If need be, the parts of the machinery and particularly the controls should be sized and designed to be actuated by an operator wearing "PPE". For certain machines, wearing PPE is not only foreseeable, it is inevitable. Machinery intended to function under conditions of extreme cold or heat assume that protective clothing is worn. In such cases the controls must be operated with gloves. More generally speaking, control pedals on many industrial machines have to be big enough for use with protective shoes.

Personal protective equipment worn to prevent any other risks inherent in the machinery forms part of important information that the manufacturer has to indicate in the instructions.

316.

Recommended choice of PPE

Insofar as the machine is designed to be used with personal protective equipment (e.g. a grinder with a mask), the manufacturer can recommend the type of PPE explicitly. In any event the manufacturer can ask his customers to use his machinery only with personal protective equipment in accordance with Directive 89/686/EEC,[72] as amended, on the design of PPE duly bearing the "CE" marking.

It is often difficult for the manufacturer to make a precise recommendation in the choice of PPE. The manufacturer does not necessarily know all the contexts in which his machinery or products will be used. The manufacturer can thus ask users (by way of the instructions) to comply with Directive 89/656/EEC[73] which specifies the methods of using PPE by workers. The Commission has published a Communication[74] with a view to guiding users in their choice of PPE. This communication sets out the circumstances and the situations in which the use of such equipment is necessary. It also specifies the factors to be taken into account when choosing equipment. This document can help the manufacturer to formulate his instructions.

317.

(Extract)
[1.1.2. Principles of safety integration

[72] Directive 89/686/EEC of 21 December 1989 (OJ No L 399, 30.12.89, p. 18), as amended by Directives 93/68/EEC (OJ No L 220, 31.08.93, p.1), 93/95/EEC (OJ No L 276, 09.11.93, p. 11) and 96/58/EC of 3 September 1996 (OJ No L 236, p. 44).

[73] Directive 89/655/EEC of 30 November 1989 (OJ No L 393, 30.12.89, p. 13).

[74] Commission Communication No 89/C 328/02 concerning the assessment of the safety aspects of personal protective equipment with a view to the choice and use thereof (OJ No C 328, 30.12.89, p. 2).

(...)

(f) Machinery must be supplied with all the essential special equipment and accessories to enable it to be adjusted, maintained and used without risk.

(...)]

318.

Supply of accessories

Ordinary contract law compels the seller to deliver the product with its accessories and everything needed for its every-day use. The "machinery" Directive applies this general rule, which is accepted in the majority of the countries signatory to the EEA, in particular to the problems of safety. The essential requirement targets mainly technical accessories, for example, special spanners if the operator cannot use ordinary spanners. It might also apply to handles. The question may arise as to whether the manufacturer is obliged to provide the PPE. The answer is negative except where use of the machine requires special PPE not found on the market (e.g. protective goggles against laser radiation whose wavelength is specific to the machine. Employers are obliged to provide PPE under Directive 89/655/EEC, as amended. Insofar as the requisite PPE is difficult to obtain for certain machines intended for use by the general public, it may be worth the manufacturer's supplying the machinery with the PPE. It should be remembered that if it is necessary to wear PPE for the safety of the operator, the manufacturer is obliged to mention this in the instructions.

319.

The Directive targets only safety accessories.

The essential requirement concerns only accessories directly connected with the safety of the machine. This article cannot be invoked to require the supply of other types of accessories. Common law might possibly settle this type of question. The "machinery" Directive does not compel the manufacturer to provide the tools or options for the machinery. After all, a safety device can never be sold as an option. For his part, a buyer cannot require a manufacturer to supply a machine without its safety device. The consent of the buyer to such a practice does not exonerate the manufacturer of his responsibilities vis-à-vis the "machinery" Directive. The responsibility of the buyer is obviously involved.

The "machinery" Directive does not impose the supply of other legal accessories such as, for example, the administrative authorizations not referred to by the "machinery" Directive, the documents of title and the contractual guarantees. The "machinery" Directive does not have the role of regulating all aspects of machinery sales.

320.

1.1.3. Materials and products

The materials used to construct machinery or products used and created during its use must not endanger exposed persons' safety or health.

In particular, where fluids are used, machinery must be designed and constructed for use without risks due to filling, use, recovery or draining.

321.

Prevention of risks connected with materials and products

This requirement refers both to the constraints arising from the material used to construct the machinery and, where appropriate, the hazards arising from the material processed (e.g. sheet metal in the case of shears, the bar on a lathe, etc.) or a chemical auxiliary product (such as cutting oil, hydraulic fluid, etc.).

322.

Materials making up the machinery

The designer can use the design rules and materials specified in the current technical literature or trade rules (FEM rules, ASME code, etc.) and take account of the expected lifetime of the machinery. The concept of mechanical strength is stated more explicitly in requirement 1.3.2. Requirement 1.1.3 focuses on certain problems not very obvious at the time of design of the machinery. By way of example, when a saw blade is placed in a table, using a wooden block will avoid any dangerous contact between metal parts. When some machines are in use materials can give off dangerous or toxic products as they heat up. The use of certain paints or surface coatings can also be the source of hazards. The working conditions of the user sector can also make certain materials unusable (e.g. plastics in foundry).

323.

Materials worked with machinery

The manufacturer designs his machine with a view to working one type of material or another. It is in the interest of the manufacturer to indicate the type of materials envisaged when designing the machine. Warnings or things to avoid can be foreseen for certain materials. Generally speaking, users should be reminded that the working of materials has to be done in accordance with local laws (e.g. the machining of products containing asbestos or the processing of food).

324.

Auxiliary products of machinery

Manufacturers must be aware of the risks connected with the auxiliary products necessary for the operation of machinery. Machinery manufacturers are seldom specialists in chemicals and may find it useful to obtain safety instructions from the suppliers of chemicals or oil to be passed on to the end user.[75] They can also make inquiries within the national institutions responsible for safety on the harmlessness for health and the environment of the auxiliary products that they provide or recommend. As regards chemicals, there are abundant world (transport of dangerous substances) and European regulations (labelling of products, exposure limits). Machinery manufacturers who place a “dangerous” substance on the market with their machinery are obliged to comply with such regulations where the product supplier has not

[75] Directive 91/155/EEC of 5 March 1991 (OJ No L 76, 22.03.91, p. 35), as amended by Directive 93/12/CE (OJ No L 314, 16.12.93, p. 38)

done so.[76] The obligation of labelling dangerous substances is particularly important for operator safety.

325.

Operations relating to fluids

The second paragraph deals with filling or draining machinery of its fluids. This problem may seem anodyne, but it is a sensitive point for the safety of the staff responsible for such operations. Provision must be made, for example, for work on the fluid circuits, with accessible filling and draining points and the possibility of completely emptying the tanks or reservoirs, as well as for the risks specific to certain fluids, such as toxic steam, etc. Standards EN 982 on hydraulic transmission and EN 983 on pneumatic transmission may be useful.

326.

1.1.4. Lighting

The manufacturer must supply integral lighting suitable for the operations concerned where its lack is likely to cause a risk despite ambient lighting of normal intensity.

The manufacturer must ensure that there is no area of shadow likely to cause a nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects due to the lighting provided by the manufacturer.

Internal parts requiring frequent inspection, and adjustment and maintenance areas, must be provided with appropriate lighting.

327.

Where the supply of integral lighting is necessary

The aim of this article is that provision should be made in the design for the work area and maintenance areas to be properly lit if it can be "reasonably" foreseen that ambient lighting will be insufficient. This justifies the need for integral lighting. It is not necessary to provide integral lighting if normal ambient lighting is sufficient for an operation without risk.

The manufacturers of high precision machinery generally provide auxiliary lighting in the work area because they assume that the ambient lighting of the user workshop will be insufficient for safe working conditions.

328.

Characteristics of lighting

The lighting that the manufacturer has to provide is in the work area of the machine and, if necessary, in the internal parts of the machine. Requirement 1.1.4 draws the manufacturer's attention to the need to illuminate these areas where it is foreseeable that the lighting of the

[76] Directive 67/548/EEC of 27 June 1967 (OJ No L 196, 16.08.67, p. 1), as amended by numerous implementing provisions.

workshop will not be sufficient. The manufacturer is obviously not responsible for the problems of lighting specific to the workplaces of his customers.

Some C standards give precise details of the parts of the machine that need to be lit. For example, standard EN 115 on escalators stipulates that illumination measured at ground level has to be at least 15 lux at the entry and at the exit. Standard EN 474-1 on earthmovers states that the cabin has to be equipped with a fixed internal lighting system making it possible to read the instruction manual.

In practice, lighting devices in or on machinery can be fixed appliances or, where appropriate, plugs that can connect to portable light fixtures and lamps. For lighting incorporated in the machines a supply voltage of under 50 V is recommended. Higher voltages can pose problems, especially if the equipment is intended for use in a humid atmosphere.

It is often preferable to give priority to direct current for lighting so as to avoid any dangerous stroboscopic effects on certain machines. Section 4.4.3 of standard EN 614-1 gives general guidelines for the design of lighting for machinery. Section 17.2.1 of standard EN 60204-1 deals with the safety of lighting while standard EN 1837 covers integral lighting in machinery.

329.

Special cases

Construction site equipment for working outdoors (see requirement 3.1.2) need the provision of lighting to see both the ground over which such equipment moves and the information on the instrument panel. Using machinery underground does not necessitate the provision of lighting as galleries are lit up. Lighting the machine might cause an explosion, which is why requirement 5.3 lays down explicitly that the machinery lighting requirement does not apply to machinery intended for underground work.

330.

Concept of normal ambient lighting

Normal ambient lighting is the illumination that can “normally” be expected at the workplace of a user belonging to the professional sector for which the machine is intended. Under no circumstances does the “machinery” Directive oblige the manufacturer to assume responsibility for the ambient lighting of the workplace of his customer. The regulations and standards applicable to the ambient lighting of the workplace do not therefore have to be reflected directly in the design of the product.

Users of machinery in the EEA are obliged to meet the minimum requirement provided for by Directive 89/654/EEC[77] concerning the minimum safety and health requirements for the workplace, and in particular, that concerning lighting:

“Workplaces must as far as possible receive sufficient natural light and be equipped with artificial lighting adequate for the protection of workers' safety and health” (Annex I, point 8.1).

Ambient lighting values can be found in a European standard in preparation (pending its publication national standards such as NF X 35-103 or DIN 5035 can be used).

[77] Directive 89/654/EEC of 30 December 1989 (OJ No L 393, 30.10.89, p. 1)

Average lighting values at the workplace would be:

- machine tools : 300 lux
- woodworking machinery: 500 lux
- micromechanics precision machinery with operator: 1 500 lux.

The obligation to provide a machine fitted with lighting must, however, be seen against the real conditions of use of the equipment and the "code of practice" applicable in the user sector. Blacksmiths, for example, need to work in semi-darkness so as to judge the heat of the forging by its colour. Lighting of the workplace should not therefore be required which would run counter to normal industrial practice.

By the same token, the level of lighting will differ appreciably between a loading platform on a big machine and a workstation for a micromechanics precision machine.

331.

1.1.5. Design of machinery to facilitate its handling

Machinery or each component part thereof must:

- ***be capable of being handled safely,***
- ***be packaged or designed so that it can be stored safely and without damage (e.g. adequate stability, special supports, etc.).***

Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:

- ***either be fitted with attachments for lifting gear, or***
- ***be designed so that it can be fitted with such attachments (e.g. threaded holes), or***
- ***be shaped in such a way that standard lifting gear can easily be attached.***

Where machinery or one of its component parts is to be moved by hand, it must:

- ***either be easily movable, or***
- ***be equipped for picking up (e.g. hand-grips, etc.) and moving in complete safety.***

Special arrangements must be made for the handling of tools and/or machinery parts, even if lightweight, which could be dangerous (shape, material, etc.).

332.

Taking account of handling operations

Requirement 1.1.5 prompts the manufacturer to take account of machine handling conditions at the design stage, especially, although not solely, for portable machines. The manufacturer must look at the risks involved in the movement of big machinery parts. This could be the dividing plate of a milling machine, for example.

Requirement 1.1.5(e) covers both the handling of the various parts of a machine at the time of assembly and dismantling and the handling of the whole machine where this is normally

foreseeable. It also covers the risks involved in the handling of fixtures and interchangeable equipment when using, servicing or adjusting the machine. Standard EN 614-1 gives general guidelines as to the efforts required of operators.

The requirement specifically refers to threaded holes for shoulder screw eye bolts. A sufficient number of such holes must be suitably located as a function of the capacity of the bolts to be used (a European standard is being prepared, pending which other standards, e.g. ISO 3266, can be used). Use of a standard, even a European one, is not compulsory: the designer may use an alternative standard, but he must indicate in the instructions the standard to which the threaded holes relate.

Threaded holes are not the only means of holding lifting attachments. Certain machines have integral equipment for lifting fixtures. Others require special slings, in which case a sling attachment must be permanently fixed to the part in question.

333.

Marking of weight

Requirement 1.1.5 can be related to requirement 1.7.3 on marking. Manufacturers of heavy machinery can be directed towards precise laws for calculating working or permanent loads that can be borne by a structure which might usefully be passed on to machinery suppliers and users.

Weight is not a sufficient criterion to warrant affixing a special mark, and an ergonomics standard, if improperly applied, could lead to the weight of all parts heavier than 25kg (if 25kg is taken as the standard) being marked.

Marking should not be obligatory for parts which need to be dismantled regularly for manufacturing operations (e.g. cutter heads, holding devices, dividing plate, etc.).

334.

1.2. Controls

1.2.1. Safety and reliability of control systems

Control systems must be designed and constructed so that they are safe and reliable, in a way that will prevent a dangerous situation arising. Above all they must be designed and constructed in such a way that:

- ***they can withstand the rigours of normal use and external factors,***
- ***errors in logic do not lead to dangerous situations.***

335.

Concept of control system

A control system can be defined as a set of electrical, electronic, pneumatic, hydraulic and mechanical components which, by function or organization, are designed to order the operations of a machine.

The control system must not be confused with control device, which is the external part of the control system on which the operator works. A control device may come in different shapes and sizes, e.g. handle, push button, lever, etc. The aim of requirement 1.2.1 goes well beyond

the simple ergonomics of the control device and encompasses the reliability and safety of the entire system.

336.

Safety problems connected with control systems

The constraints placed on control systems may come from intensive use, interior and outside temperature, vibration, impact, dust, water, steam, or electromagnetic disturbances.

The problems of logic in control systems may have several sources: design error in the system set-up, cabling defects, etc. The safety of a control system can be illustrated by a construction site machine where certain controls are rendered inoperative if the stabilizers are not extended and locked. However, there are more complex cases where the designer has to draw on experience and common sense.

The control system can be altered by the environment. An electronic chip may be faulty or the energy supply may be damaged. The consequences may be significant: unexpected start-up of the machine, machine running too fast or impossible to stop, neutralization of safety mechanisms.

337.

Preventive measures

Prevention amounts to a thorough analysis of the various starting and stopping possibilities. A definition of precise operating methods for each machine configuration is also fundamental. Using components where the type of failure is always foreseeable is particularly useful. It may be necessary in some cases to duplicate circuits (or parts of circuits) consisting of components which are not intrinsically safe with other circuits not prone to common mode failure (principle of redundancy). These circuits then have to be self-monitoring so that in the event of discordance between them due to failure of a sensitive component the system calls up the right safety measure: stopping the machine, preventing it from restarting, setting off an alarm, etc. (principle of self-monitoring).

In terms of software dedicated to safety functions, preference will always be given to software locked in read-only memory and using the principles of redundancy and self-monitoring. Standards EN 954-1 and 954-2 gives guidelines for control circuit design.

The requirement expressed in the second indent of requirement 1.2.1 has appeared difficult to understand in some quarters: control systems must be designed and constructed in such a way that dangerous situations do not arise due to errors of logic.
This requirement refers to errors of logic which can lead to dangerous situations due to:

- simultaneous activation of two contradictory or independent controls,
- failure to follow the sequential order of controls provided for in the operating procedure,
- selection of the wrong operating mode.

Taking account of this requirement means providing the control system with mechanisms between moving parts, or between certain moving parts and mechanical, electric or pneumatic safety devices or between certain instruments and preactivators.

338.

1.2.2. Control devices

Control devices must be:

- ***clearly visible and identifiable and appropriately marked where necessary,***
- ***positioned for safe operation without hesitation or loss of time, and without ambiguity,***
- ***designed so that the movement of the control is consistent with its effect,***
- ***located outside the danger zones, except for certain controls where necessary, such as emergency stop, console for training of robots,***
- ***positioned so that their operation cannot cause additional risk,***
- ***designed or protected so that the desired effect, where a risk is involved, cannot occur without an intentional operation,***
- ***made so as to withstand foreseeable strain; particular attention must be paid to emergency stop devices liable to be subjected to considerable strain.***

Where a control is designed and constructed to perform several different actions, namely, where there is no one-to-one correspondence (e.g. keyboards, etc.), the action to be performed must be clearly displayed and subject to confirmation where necessary.

Controls must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles. Constraints due to the necessary or foreseeable use of personal protective equipment (such as footwear, gloves, etc.) must be taken into account.

Machinery must be fitted with indicators (dials, signals, etc.) as required for safe operation. The operator must be able to read them from the control position.

From the main control position the operator must be able to ensure that there are no exposed persons in the danger zones.

If this is impossible, the control system must be designed and constructed so that an acoustic and/or visual warning signal is given whenever the machinery is about to start. The exposed person must have the time and the means to take rapid action to prevent the machinery starting up.

339.

There are a wide variety of control devices: rocker switches, push buttons, touch sensitive switches, cursors, turn buttons, levers, handles, wheels, pedals, capstans, detector mats, bars, cables, and many more.

340.

(Extract)
[1.2.2 Control devices

Control devices must be:
- clearly visible and identifiable and appropriately marked where necessary,
(...)]

341.

First indent: identification of control devices

The first indent lays down the principle of good identification of the control devices. The colours and pictograms chosen should, as far as possible, be standard symbols and pictograms. The standard EN 60 204-1 has a chapter on standardized colours. The international standard ISO 7000 describes the graphic symbols that can be used on equipment. Use of these pictograms avoids the need to identify control devices in words in the language of the user. In general, manufacturers use the following colours to identify the principal functions of a machine:

- starting up and powering up: white
- stopping and powering down: black
- emergency stopping: red
- elimination of abnormal conditions: yellow

Users should standardize the colours of the machinery used in one and the same workshop.

To back up the pictograms it is not rare to see the machine consoles include the functions of the control devices in words. These can be adopted by the user as a function of the technical terms specific to his company or region.

Not all control devices need to be clearly identifiable, however. The manufacturer of mobile machinery does not have to identify the steering wheel. Identification and marking are necessary where the function of the device is not obvious.

342.

(Extract)
[1.2.2 Control devices

Control devices must be:
- (...)
- positioned for safe operation without hesitation or loss of time, and without ambiguity,

(...)]

343.

Second indent: ergonomic positioning of control devices

The second indent concerns the positioning of control devices. The general arrangement of the control devices is important for avoiding risks. The relative positioning of the control devices and information mechanisms must ensure that the operator can, without a long learning process, take note of information and take rapid, safe and effective action. Ideally the control devices and control instruments (dials, switches, digital displays) should be positioned in the same place and meet both vision and reach requirements.

Where the indicators are placed and the height of the controls will vary according to whether the operator at his workstation is seated or standing. The size of the characters displayed by the indicators or on the control devices must be adjusted to the distance from which the operator can see them.

Control devices can be placed in several, relevant subassemblies. They can be grouped by type of function (stop, start, etc.) or according to the subassemblies of the machine that they control.

The arrangement of the control devices on the machine must also, as far as is possible, tie in with operator usage. If the machine comprises several workstations the control devices can be logically expected to be located and displayed in the same way at each workstation.

In any event, the objective is to avoid positioning which might prompt any inadvertent, dangerous action. Control devices too close to one another can lead to errors. Control devices not readily accessible or located in an area without direct vision for the operator are also sources of risks.

344.

(Extract)
[1.2.2 Control devices

Control devices must be:
- (...)
-designed so that the movement of the control is consistent with its effect,
(...)]

345.

Third indent: consistency of movement of the control with its effect

The control devices have to show a natural link between the action on the control device and the anticipated effects.

A push-button with an arrow pointing down can hardly be the control for an upward motion. Whatever the country or culture of the operator, up is up and down is down! Moving an element to the left is generally achieved by moving the lever or handle to the left. Increasing the parameters of a machine will usually be done by turning a needle clockwise to the right.

How the information is presented to the operator must take account of the normal capacities of a human being and the method of operating the machine. There are times and periods for presenting information to make it readily understandable. The operator must not be forced to rely too much on memory. If, however, he has to memorize data this task must be made easier for him by avoiding over-complex formulations. Imprecise but meaningful information is better than perfect but incomprehensible information.

The use of controls should be “intuitive” or at least not contrary to the operator’s “common sense”.

346.

(Extract)
[1.2.2 Control devices

Control devices must be:
- (...)
- located outside the danger zones, except for certain controls where necessary, such as emergency stop, console for training of robots,
(...)]

347.

Fourth indent: location outside danger zones

The control devices must not be located in danger zones. This fundamental rule obviously does not apply to controls where it is impossible to enforce. This is the case with consoles for the training of robots.

In this case additional measure are taken so as to make for training with a push control, slow speed, etc.

348.

(Extract)
[1.2.2 Control devices

Control devices must be:
-(...)
- positioned so that their operation cannot cause additional risk,
(...)]

349.

Fifth indent: safety during control device manoeuvres

Operating the control device must not cause additional risk.

350.

(Extract)
[1.2.2 Control devices

Control devices must be:
-(...)
- designed or protected so that the desired effect, where a risk is involved, cannot occur without an intentional operation,
(...)]

351.

Sixth indent: avoiding inadvertent manoeuvres

The design of control devices must not lend itself to inadvertent actions. They have to be arranged so that they are not triggered inadvertently. It is important to try to pre-empt any wrong movements an operator might make or the risks of a third person passing by the machine becoming caught up in it. Several preventive measures exist, such as flush buttons, covered pedals or indexed levers. Some levers are designed to make any change of position perceptible and necessarily ***intentional*** (such as gear levers on vehicles). Support values on control devices can be one way, among others, of preventing machines from restarting suddenly.

352.

(Extract)
[1.2.2 Control devices

Control devices must be:
-(...)
- made so as to withstand foreseeable strain; particular attention must be paid to emergency stop devices liable to be subjected to considerable strain.

(...)]

353.

Seventh indent: withstanding of foreseeable strain by control devices

The size and nature of the materials used for control devices have to be compatible with the foreseeable use. Devices likely to be struck with force must be impact-resistant.

The ergonomic design of a control device has to take account of the practical methods of using it by the operator. The provisions concerning the strain to be withstood by the control devices depend greatly on the frequency of operations. They will therefore determine the value of the adjusting effort of frequently used push buttons, the length of levers and the diameter of steering wheels. In the case of devices requiring sustained action, such as triggers on portable hand tools, determination of the effort brings into play two conflicting requirements: not setting too high an effort which would tempt operators to lock the trigger in the "on" position (by tying it, for example), and not setting too low a value which might result in the machine starting suddenly.

354.

(Extract)
[1.2.2 Control devices

Control devices must be:
(...)
Where a control is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence (e.g. keyboards, etc.), the action to be performed must be clearly displayed and subject to confirmation where necessary.

(...)]

355.

Second paragraph: control devices with multiple actions

The “machinery” Directive accepts that some control devices may permit different effects. Digital control of machine tools is an excellent example of a control device which can perform a wide variety of actions. The preventive principle is that the action to be performed is clearly displayed and confirmed.

356.

(Extract)
[1.2.2 Control devices

Control devices must be:
(...)

Controls must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles. Constraints due to the necessary or foreseeable use of personal protective equipment (such as footwear, gloves, etc.) must be taken into account.

Machinery must be fitted with indicators (dials, signals, etc.) as required for safe operation. The operator must be able to read them from the control position.
(...)]

357.

Third and fourth paragraphs: general ergonomics of control devices

The third paragraph illustrates once more the principles of ergonomic design of control devices. An overabundance of dials and information can make that information less clear. Generally speaking, the "machinery" Directive is against adopting preventive measures which are not ergonomic. Non-ergonomic preventive measures are often fine for those recommending them, but they are generally less so for those who have to put them into practice.

358.

(Extract)
[1.2.2 Control devices

Control devices must be:
(...)
From the main control position the operator must be able to ensure that there are no exposed persons in the danger zones.

If this is impossible, the control system must be designed and constructed so that an acoustic and/or visual warning signal is given whenever the machinery is about to start. The exposed person must have the time and the means to take rapid action to prevent the machinery starting up.]

359.

Fifth and sixth paragraphs: visibility of danger zones during start-up

The last two paragraphs set forth the principle of the visibility of danger areas during machine start-up. While this principle seems perfectly feasible for small machines it can be a problem for big machines. How can the operator be sure that nobody is inside the machine? Additional means thus have to be provided to ensure visibililty in the danger zone, reducing blind spots as far as possible (exterior mirror, cameras connected to a video screen, etc.).

It is possible to set up access control with locking or interlocking mechanisms. An open guard stops the machine from restarting. Closing that gate does not, however, make the machine start again. Restart is only possible after authorization by a reset device. For certain large machines, such as printing machines or paper mills and textile industry machinery, this type of preventive measure is not possible. An acoustic and/or visual warning must therefore precede start-up.

It is important that the barriers and fencing installed around automated sites are not too big and do not obstruct the view of the work area. Imposing excessively high safety barriers in an automated site can present a real problem for the operator who will no longer be able to see the work area and may be tempted to neutralize the safety measures.

360.

1.2.3. Starting

It must be possible to start machinery only by intentional actuation of a control provided for the purpose.

The same requirement applies:
- ***when restarting the machinery after a stoppage, whatever the cause,***
- ***when effecting a significant change in the operating conditions (e.g. speed, pressure, etc.),***

unless such restarting or change in operating conditions is without risk to exposed persons.

This essential requirement does not apply to the restarting of the machinery or to the change in operating conditions resulting from the normal sequence of an automatic cycle.

Where machinery has several starting controls and the operators can therefore put each other in danger, additional devices (e.g. enabling devices or selectors allowing only one part of the starting mechanism to be actuated at any one time) must be fitted to rule out such risks.

It must be possible for automated plant functioning in automatic mode to be restarted easily after a stoppage once the safety conditions have been fulfilled.

361.

General principle: starting a machine must be the result of intentional action

This general principle is one of the most important for the prevention of accidents caused by machinery. It covers not only “normal” start-up, but also restart after stoppage or a significant change in operating conditions.

Any sudden restart of a machine can take a person working in a danger zone by surprise. An unintentional change can lead to fractures and bursts. Restart or significant changes in operating parameters must therefore be the result of deliberate, intentional action. There must be a specific start control. In principle, any control with a different principal function should not be used to start or restart a machine. Simply closing a housing or a gate should not make the equipment restart. The same goes for uncovering a non-physical barrier or releasing a push-button.

362.

Possibility of restarting by closure of a guard

The last part of the second paragraph adds a slight exception to the rule that machinery must be started or restarted by intentional actuation of a control provided for that purpose.

For some equipment, such as certain small cooking equipment, restart by closure of a guard is acceptable.

Requirement 1.2.3 has to be seen in the light of the principles set out in the preliminary observations, namely, evaluation of risk and proportionality of the measures taken to the risks and the cost of the machinery.

It is for standardization bodies to define concrete cases where restarting a machine by closure of a guard can be done in complete safety.

363.

Case of automated cycles

In such automatic cycles, intentional actuation of a control is not always followed immediately by movement of the dangerous mechanism, as this may be started by a level detector, thermostat, etc. Closure of the power-operated guard can be considered to constitute the first phase of the cycle, so that the rest of the cycle is enabled thereby.

Even if closure of the guard can give rise to a hazard or if there is enough space in the danger zone for a person, closure must be effected by sustained actuation of a control until the guard is fully closed.

364.

1.2.4. Stopping device

Normal stopping

Each machine must be fitted with a control whereby the machine can be brought safely to a complete stop.

Each workstation must be fitted with a control to stop some or all of the moving parts of the machinery, depending on the type of hazard, so that the machinery is rendered safe. The machinery's stop control must have priority over the start controls.

Once the machinery or its dangerous parts have stopped, the energy supply to the actuators concerned must be cut off.

Emergency stop

Each machine must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. The following exceptions apply:

- ***machines in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,***
- ***hand-held portable machines and hand-guided machines.***

This device must:

- ***have clearly identifiable, clearly visible and quickly accessible controls,***
- ***stop the dangerous process as quickly as possible, without creating additional hazards,***

- where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop control has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.

Complex installations

In the case of machinery or parts of machinery designed to work together, the manufacturer must so design and construct the machinery that the stop controls, including the emergency stop, can stop not only the machinery itself but also all equipment upstream and/or downstream if its continued operation can be dangerous.

365.

Requirement 1.2.4 covers two main types of machine stopping: normal stopping and emergency stop.

366.

(Extract)
[1.2.4. Stopping device

Normal stopping

Each machine must be fitted with a control whereby the machine can be brought safely to a complete stop.

Each workstation must be fitted with a control to stop some or all of the moving parts of the machinery, depending on the type of hazard, so that the machinery is rendered safe. The machinery's stop control must have priority over the start controls.

Once the machinery or its dangerous parts have stopped, the energy supply to the actuators concerned must be cut off.

(...)]

367.

Normal stopping of machinery

Normal stopping of machinery can be achieved by the action of a complete stopping device or, if necessary, one or more stopping devices at each workstation.

368.

Complete stopping of machinery

Complete stopping of machinery must be under safe conditions, without, in particular, any risk of restarting. The complete stop control does not have the specific function of preventing a hazard about to happen (except in isolated cases).

A complete stop is generally obtained by a push-button acting on a power switch or a hydraulic or pneumatic valve. Electric switches and pedals are also often used.

369.

Stopping device at each workstation

The obligation to provide for a stopping device at the workstation other than the general stopping device only concerns machines of a certain complexity, generally big machines with several workstations. These might be, for example, automated production, packaging or storage units where operations are connected. The workstation is not only the place where the operator carries out work (loading of the machine, control, etc.), it is also the place where maintenance is normally carried out. The stopping device at the workstation allows an operator working on part of the machine to make a safe stop in order to carry out an operation on the machine. This stoppage from the workstation will often be a partial stoppage of the machine limited to the area of intervention. Stoppage at the workstation makes it possible to avoid complete stoppage of the machine which generally takes some time to start up again. Stoppage at the workstation is not an emergency stop, and the stopping device at the workstation may be a push-button, an ordinary pedal or any other stopping device.

370.

Principle of stop control having priority over start controls

The general stopping of machinery and the specific stops at the workstation must give priority to stop controls over start controls.

371.

Principle of cutting off the energy supply to the actuators

A complete stoppage or stoppage at the workstation means cutting off the machine's energy supply, except, of course, where energy cut-off is a source of risk. Energy may in fact be essential to keep parts in position. This is often the case with automated plant. Where stoppage is effected by mechanical uncoupling of moving components, as in the case of the presses in metal-working, cutting off the energy supply is not necessary for the safety of the components.

372.

(Extract)
[1.2.4. Stopping device
(...)

Emergency stop

Each machine must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. The following exceptions apply:

- machines in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,
- hand-held portable machines and hand-guided machines.

This device must:

- have clearly identifiable, clearly visible and quickly accessible controls,
- stop the dangerous process as quickly as possible, without creating additional hazards,

- where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop control has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.

(...)]

373.

Definition of the function of emergency stop

The "machinery" Directive distinguishes between normal and emergency stops. The choice will depend on a general assessment of the risk. The emergency stop function is designed to prevent risks from dangerous phenomena. These phenomena may appear gradually or suddenly and they may have several origins: human error, problems with the working material. Risks may be simultaneous with the phenomena (e.g. when a machine is racing or gradually overheating). The hazards targeted by the "machinery" Directive are those affecting the safety of people. The "machinery" Directive does not impose emergency stops to lessen the problems related solely to the performance of the machine. Emergency stops are put into effect by human action. The European reference standard is EN 418. Standard EN 60204-1 also makes recommendations for the design of devices.

374.

Concept of emergency stopping device

Emergency stopping device is the actual control actuated by the operator (push-button, pedal). It is also the control system which is the part of the emergency stopping device that gives the order to effect an emergency stop. The idea of emergency stop control thus covers the whole range of parts which contribute to the result: control device, part of control system giving the order to stop, power switching apparatus (contacts, valves, speed variators), mechanical disconnecting system (coupling), brakes.

375.

Whether or not to provide for an emergency stop

The systematic provision of an emergency stop on machinery is often regarded as being a "preventive-type measure". Requiring an emergency stop without analysing the risk is an easy solution. It provides an easy solution but in use it might prove to be a pointless or even dangerous preventive measure. The decision to fit a machine with an emergency stop must be based on a complete analysis of the risk of the machine.

There should be no emergency stop where it generates a risk. Given that applying the brakes to a part revolving at high speed can involve the risk of bursting, there should be no emergency stop.

Similarly, an emergency stop is not needed if the effect that it can produce is the same as that of normal stopping, as required in the previous paragraph. In other words, the emergency stop device is only justified where the time to achieve stopping is shorter than with the general

stopping device. Fitting a braking device, where possible and worthwhile, can reduce that time.

An emergency stop device is justified where the normal stopping of the machine is not sufficient to halt a dangerous phenomenon.

For the majority of machines the purpose of emergency stopping is to obtain optimum deceleration of moving parts.

The purpose of the emergency stopping device is not to replace the guard. This mechanism is an addition to the other protective mechanisms built into the machine.

376.

Technical features of emergency stop devices

Controls actuating an emergency stop are generally red on a yellow background. Emergency stop controls are often push-buttons in the form of a mushroom, cables, bars, handles, pedals without protector hood. Cables are frequently used on long machines such as conveyors.

The emergency stopping device has to be by positive action.

Stopping can be achieved by immediate cut-off of the energy supply to the actuators. It can be achieved, in other cases, by a controlled stop, in which case the actuators remain under power during the stopping process. Once stopping is achieved the energy supply is cut off.

When the emergency stop control has been actuated the emergency stop order must be maintained until the control device is “reactivated”.

377.

(Extract)
[1.2.4. Stopping device
(...)

Complex installations

In the case of machinery or parts of machinery designed to work together, the manufacturer must so design and construct the machinery that the stop controls, including the emergency stop, can stop not only the machinery itself but also all equipment upstream and/or downstream if its continued operation can be dangerous.]

378.

Emergency stop devices must be based on an analysis of the risks and the production requirements of the equipment. They may be all or part of the machine. Where different parts of machinery are fitted with emergency stops it is important to ensure that there can be no possible error in identifying the emergency stop control for that part of the machine. Great care must generally be taken in choosing where to put the emergency stop control. It must always be accessible to the operator and to staff working on the machine.

In complex machinery several mechanisms are interdependent (e.g. spindle movement and feed mechanism on a machine tool). Stopping one mechanism must in turn stop any other mechanisms which, if they continued to operate, could give rise to a dangerous situation (e.g. breakage of a tool).

379.

1.2.5. Mode selection

The control mode selected must override all other control systems with the exception of the emergency stop.

If machinery has been designed and built to allow for its use in several control or operating modes presenting different safety levels (e.g. to allow for adjustment, maintenance, inspection, etc.), it must be fitted with a mode selector which can be locked in each position. Each position of the selector must correspond to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator (e.g. access codes for certain numerically controlled functions, etc.).

If, for certain operations, the machinery must be able to operate with its protection devices neutralized, the mode selector must simultaneously:

- ***disable the automatic control mode,***
- ***permit movements only by controls requiring sustained action,***
- ***permit the operation of dangerous moving parts only in enhanced safety conditions (e.g. reduced speed, reduced power, step-by-step, or other adequate provision) while preventing hazards from linked sequences,***
- ***prevent any movement liable to pose a danger by acting voluntarily or involuntarily on the machine's internal sensors.***

In addition, the operator must be able to control operation of the parts he is working on at the adjustment point.

380.

Principle of priority of the control system selected

The control mode selected has to have priority over the others, with the exception, of course, of the emergency stop device which is a “super-priority” control. Sustained action on a control device having the function of setting the machine in motion should not therefore be able to override the stop controls (see requirement 1.2.4). By way of example, a switch with two stable positions meets this requirement, but this requirement can also be met by monostable switches, pedal or button, provided that the return to the “off” position does not come from the positive mechanical action of a person but from a return spring. There may be a risk of blocking in the “on” position. The cause of blocking may be due to excess friction, seizing, or the loosening of a screw. A “non-repeat” device only allows the machine to restart where the start control has returned to the position in which it does not order starting. In any event, the emergency stop control must remained “locked” in the “off” position and cause the control circuit to be disabled (see comments on requirement 1.2.4)

381.

Principle of locking the mode selector

The principle laid down in requirement 1.2.5 is that the choice by the operator of an operating mode should be reflected by clear, unequivocal action on the control device. The choice of the operator must be reflected by specific positioning and locking of the control device. The

operator should have confidence in the operation that he has just carried out, and the anticipated effect has to occur.

382.

Operation of the machine with more than one mode

Machines often have to function in modes other than the normal production mode. These alternative modes make it possible to carry out adjustment, maintenance and teaching operations. Neutralization of safety devices is made essential by the need to work inside the machine or in the work area. Mode selection must therefore avoid any dangerous operating configurations. The control available to an operator working in these other modes may be a control or a mobile stand with sustained action. Wherever possible, machinery should only be operable on a step-by-step basis, at reduced speed or reduced power with stoppage where action on the operating control is interrupted. Moving parts accessible during any intervention phase must not work automatically and without the control of the operator. Intentional or unintentional action on the machine's internal sensors and automatic cycle information from external parts should not be able to start a movement or a dangerous operation. Selection mode design which takes full account of all operator needs will prevent operators from improvising the "operating mode". The fact of not having a control system adapted to this type of operation might encourage operators to neutralize all the protection systems. Whatever technical measures are adopted in the design of the machinery, individual training of operators working in these other modes is essential.

The person operating the control must have a clear view of the mechanisms he is controlling. When the protection devices are neutralized, two people should not be needed: one to operate the control device and the other to work in the danger zone. On large machinery it is common for the adjuster or maintenance operative to have a portable control unit which he can connect to the control circuit by plugging it into a socket located near the mechanism requiring adjustment. This operation is now often done by remote control. In this case, the designer must provide sufficient space for the adjuster not to have to make any contortions and for him to be sufficiently far away from any dangerous mechanisms.

383.

1.2.6. Failure of the power supply

The interruption, re-establishment after an interruption or fluctuation in whatever manner of the power supply to the machinery must not lead to a dangerous situation.

In particular:

- ***the machinery must not start unexpectedly,***
- ***the machinery must not be prevented from stopping if the command has already been given,***
- ***no moving part of the machinery or piece held by the machinery must fall or be ejected,***
- ***automatic or manual stopping of the moving parts whatever they may be must be unimpeded,***
- ***the protection devices must remain fully effective.***

384.

Risks linked to fluctuating power supply

All types of energy are concerned

Requirement 1.2.6 sets out to prevent dangerous effects caused by failure of the power supply system. Electricity is probably the form of energy most used to operate machinery. Preventing hazards caused by fluctuations is not, however, limited to electricity. All types of energy are concerned, especially hydraulic and pneumatic energy.

The term supply "failure" refers to interruptions as well as fluctuations, one way or the other, in power supply.

385.

Types of failure

Failure, breakdown and deterioration which can create a hazard come in several forms:

- Electricity supply failure due to:

386.

. **defects in the electrical installation at the site of use of the machine.** The manufacturer of the machine obviously does not have responsibility for ensuring compliance with the rules of the art and the local regulations on the electrical installation of the establishment which will house the machine. Insulation failures in the user's electrical installation combined with one or more other defects affecting the control circuit of the machine can cause, in particular, sudden start-up. This risk is avoided by making the machine's control circuit electrically separate from the distribution installation of the place of use by means of, for example, a separate winding transformer.

387.

. **voltage failures** ("dips" or drops in voltage, micro-powercuts, etc.). These can be generated by the general electricity distribution network or by the local network of the user company. The regular operating of protection systems against overcurrents can also be the cause of these energy fluctuations. Short-term power failures and drops in voltage can have inordinate effects on switches and relays and, as a result, the mechanisms may work erratically. Using protection relays at "threshold voltage" or at the electronic equivalent may therefore be necessary.

388.

. **disturbances** ("line" disturbances) such as the "harmonics" of the nominal frequency, "transients" due either to surge capacitor oscillations or to switching or even to disturbances generated by "chopping" supply, etc. An electromagnetic disturbance may be an electromagnetic noise, an unwanted signal or a change in the propagation medium itself. Directive 89/336/EEC,[78] as amended, on electromagnetic compatibility is important for the prevention of disturbances, laying down, as it does, that any electromagnetic disturbances generated should be limited to a level which allows the other appliances to function. This Directive deals with all electromagnetic phenomena likely to cause operating problems in a device, an appliance or a system.

389.

[78] Directive 89/336/EEC of 3 May 1989 (OJ No L 139, 23.05.89, p. 19); as amended by Directives 91/263/EEC (OJ No L 128, 23.05.91, p. 1), 92/31/EEC (OJ No L 126, 22 .05.92, p. 11), 93/68/EEC (OJ No L 220, 31.08.93, p. 1) and 93/97/EEC (OJ No L 290, 24.11.93, p. 1)

. **overvoltages** or voltage “surges” of diverse origin (storms, switching, etc.)

390.

- Failure affecting the pneumatic or hydraulic power supply system

Energy fluctuations may come from overpressure or from pressure surges. Pressure losses may be caused by a break in connection or by internal or external leaks in hydraulic or pneumatic equipment.

391.

Preventive measures against the risk of supply failure

There are several types of preventive measures designed to avoid the consequences of a failure in the power supply system.

- maintenance (locking, clamping) devices which must continue to operate in the event of a power failure, and in general all devices whose permanent operation is required for safety reasons (cooling or heating devices, etc.);
- mechanical retention devices (spindle, wedge, stay, rack) automatically activated are a good way of preventing movement caused by potential energy (gravity, spring, etc.);
- control apparatus (monostable relays, distributors, etc.) to prevent change to a dangerous state when the power fails (e.g. change from slow to fast forward movement, collision of moving parts due to unordered release of the relay).

392.

Risk of unwanted restart

One of the major risks resulting from the interruption in energy supply is the machine restarting when power is restored. In the case of electricity supply, simple solutions exist which are regularly used; in the case of supply by pressurized fluid (hydraulic or pneumatic) solutions exist, but they are seldom used. Special attention must therefore be paid in this case to meeting requirement 1.2.6.

Similarly, to prevent the risk of sudden restart of a machine caused by a failure in the power circuit while a guard is open, provision is often made to supplement the locking device linked to the guard and affecting the control circuit with mechanisms such as:

- locking mechanisms acting directly on the power circuit,
- mechanical retention devices which spring into action when the guard is opened.

393.

Movement has to come from an increase in energy

The following is a more or less general rule for meeting this requirement: controls which start or accelerate movements must involve establishing or increasing an electrical voltage or a fluid pressure (transition to a higher energy state), while the control circuit should transmit commands to stop or slow down by breaking or reducing an electrical voltage or fluid pressure.

394.

1.2.7. Failure of the control circuit

A fault in the control circuit logic, or failure of or damage to the control circuit, must not lead to dangerous situations.

In particular:

- ***the machinery must not start unexpectedly,***
- ***the machinery must not be prevented from stopping if the command has already been given,***
- ***no moving part of the machinery or piece held by the machinery must fall or be ejected,***
- ***automatic or manual stopping of the moving parts whatever they may be must be unimpeded,***
- ***the protection devices must remain fully effective.***

395.

Incorporation of safety in the concept of control logic

Requirement 1.2.7 lays down the principle of the prevention of **dangerous effects caused by a failure in the control circuit .**

As reliable as the component parts of control systems are, and even though these systems can keep any failures down to simple breakdowns (component duplication, self-monitoring), the possibility of one of the dangerous situations referred to in requirement 1.2.7 cannot be ruled out altogether.

The aim of the requirement is to limit this risk with the technologies available.

396.

Control circuit technologies

Several technologies are used in the design of electronic control systems. Any electronic system is an assembly of inter-connected components. The connection between these components is provided by cabling or by printed circuit.

The function performed by the control system can be locked by its cabling (circuit) or depend on software.

397.

“Hardwired logic” circuits

- **Electromechanical ”hardwired logic” circuits** are made up essentially of relays cabled by wire or printed circuit. How they can fail is known and identifiable (coil break, contact welding, etc.). This technology is not particularly prone to common failures, meaning that it is unlikely that two separate components will fail simultaneously. It is possible to obtain control systems with high degree of reliability with this conventional technology.

- **”Hardwired logic” circuits with discreet components** are mainly made up of diodes and transistors with a switching function (1 or 0) which are connected to one another by wires or printed circuits. The ways in which this type of circuit can fail are the same as with electromechanical cabled circuits plus electromagnetic susceptibility and common methods of failure due to fluctuations in supply voltage. Compliance of components with the rules of electromagnetic compatibility is particularly important. Furthermore, the failure of one component can lead to failure in one or more other components.

- **"Hardwired logic" circuits comprising integrated circuits** are made up of several tens of thousands of transistors inside a chip. This high level of integration can make them sensitive to electromagnetic radiation. In addition, a single failure in a chip can cause multiple breakdowns and affect input or output in several parts of one and the same circuit. The manufacturers of machinery provide, where necessary, for general self-checking of the safety system. An analysis can be made directly on diagrams or better still by means of physical simulation of the faults.

398.

"Programmed logic" circuits

- **"Programmed and locked logic" circuits** consist of one or more microprocessors and non-reprogrammable read-only memory (ROM, PROM, EPROM). The risks of failure specific to hardwired logic involving integrated circuits are also encountered here, along with the problems inherent in data processing. Since data processing is above all sequential, any failure can alter the sequence of instructions normally set by the microprocessor. This can result in malfunctioning of the system. Manufacturers use several types of devices to prevent such failures. These, in turn, use self-checking before the installation is set in motion, self-checking during operation, and architectures with general or local redundancy. Manufacturers can also analyse system behaviour in the presence of faults altering the sequence of instructions normally carried out by the microprocessor. Appliances are available for physical simulation.

399.

"Programmable logic" circuits

This type of circuit uses microprocessors and read-only memory, but also random access memory (RAM) or reprogrammable memory (EEPROM), which makes it easy for the user to change the logic of the system by software. To the risks of failure specific to programmed and locked logic circuits must thus be added the risks related to unwanted modification of software. The consequences can be considerable when they concern safety. Thus, automatic controls that can be programmed by the user himself must not be used for safety functions.

400.

Choice of technology and potential risks

The choice of type of control system by the manufacturer will depend on the risk analysis made at the design stage. The reliability of electronic control systems which directly govern safety functions is particularly important. The following functions are generally considered as direct safety functions: emergency stops, guard lockings and interlockings, operating mode switches (where one of the modes involves risks), manual controls of certain movements with "neutralized safety device", and the starting or stopping functions provided by a safety device.

401.

1.2.8. Software

Interactive software between the operator and the command or control system of a machine must be user-friendly.

402.

Concept of user-friendliness

User-friendliness is the capacity to enhance reciprocal exchange. In information technology, user-friendly software is software readily usable by a public not specialized in computing. Machine operators are not usually computer specialists. As far as possible, interactive software between the operator and the control system must meet the aims and tie in with the knowledge of the operator, it must be simple to learn and use, easy to memorize, it must be fast and reliable and it must enable the user to solve any problems.

403.

Principles of ergonomic software

A number of general rules can be given as basic principles:

- compliance with the aims, methods, knowledge and mental capacity of users ;
- reduction to a minimum of repetitive action required of an operator and down time. Where a certain down time is necessary, the user has to be informed;
- provision of several possible ways, to tie in with several operating levels and likely to be chosen as alternatives by different users;
- use of vocabulary adapted to the tasks and operators;
- minimum use of insignificant codes;
- guarantee that the user can control interaction or stop an action in progress;
- making the effects of the action taken (or orders given) explicit to the user;
- preventing the user from taking inadvertent destructive action, allowing him to cancel previous actions and return to the previous stage;
- step by step guide for new users, while not imposing it on people who do not need it;
- use of special codes (beep, reverse video, brightness, flickering, etc.) only judiciously and consistently;
- menus not the only form of interaction;
- menus not too long;
- no multiple choices for one and the same menu;
- no overlong trees.

404.

Language of software

Another question arises: can English be used for on-screen instructions, despite requirement 1.7.0? User-friendly software means that on-screen instructions should be in a language understood in the country of use. On the other hand, it is of no account that a software program not intended for the user is in a language not understood by him.

Whatever the case, manufacturers must give priority to the translation of ordinary operating instructions over programming instructions. Software programming instructions assume advanced computer skills which requires knowledge of the languages and conventions used in this field at international level, thus making translation probably less necessary. Whether or not software really needs translating will depend on the nature of the machine and the level of operator training planned by the manufacturer. A high-tech machine which can be only operated by highly specialized personnel can run with software using the languages internationally employed in information technology without necessarily using the official language of the country of use. The main thing is that the operator understands the software. The question of language is only one aspect of user-friendliness.

405.

1.3. Protection against mechanical hazards

1.3.1. Stability

Machinery, components and fittings thereof must be so designed and constructed that they are stable enough, under the foreseen operating conditions (if necessary taking climatic conditions into account) for use without risk of overturning, falling or unexpected movement.

If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions.

406.

Stability of the machine

The aim of this requirement is that the machine should keep its position of balance on a permanent basis. This balance must not be compromised by any variation of operating conditions foreseen by the manufacturer.

Normal operating conditions include dynamic physical phenomena resulting from the regular running of the machine: centrifugal force, force due to the inertia of moving parts, vibration causing parts to loosen, break or fall.

The manufacturer must ensure that dismantling a part does not cause the machine to collapse. Where necessary, stays can be provided.

Requirement 1.3.1 also refers to climatic conditions. The manufacturer of machinery designed for use in extreme conditions of cold or heat must provide for integrated preventive measures or the wearing of personal protective equipment to stop operators from leaving go of their machines in the event of movement. He must also take account of the effects of wind and/or snow for exposed machinery.

If the stability of a machine cannot be assured intrinsically or by normal use the manufacturer may provide for additional means of anchorage. Where these means of anchorage are beyond the scope of the manufacturer, e.g. where a sealing is necessary or civil engineering work is necessary, the manufacturer should provide the user with installation guidelines.

407.

1.3.2. Risk of break-up during operation

The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used as foreseen by the manufacturer.

The durability of the materials used must be adequate for the nature of the work place foreseen by the manufacturer, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

The manufacturer must indicate in the instructions the type and frequency of inspection and maintenance required for safety reasons. He must, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration remains despite the measures taken (e.g. as with grinding wheels) the moving parts must be mounted and positioned in such a way that in case of rupture their fragments will be contained.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected against all manner of external stresses and strains; precautions must be taken to ensure that no risk is posed by a rupture (sudden movement, high-pressure jets, etc.).

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to the persons exposed (e.g. tool breakage):

- ***when the workpiece comes into contact with the tool the latter must have attained its normal working conditions,***
- ***when the tool starts and/or stops (intentionally or accidentally) the feed movement and the tool movement must be coordinated.***

408.

(extract)
[1.3.2 Risk of break-up during operation
The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used as foreseen by the manufacturer.
(...)]

409.

Resistance of the machine - an essential aspect of the good engineering practice

Requirement 1.3.2 sets out to ensure that the machine has the capacity to withstand the stresses that it undergoes when operated.

This requirement embraces an important facet of the engineer's fundamental know-how: the capacity to define a product according to a need (safety forming part of the need, whether expressed or not) by combining choice of technology with, in particular, choice of material and method.

The choice of material and characterization of the method of working (drawing, forging, machining, grinding, casting, injection, etc.) will have a significant influence on overall resistance and hence on safety. It is therefore essential that the design offices of manufacturers give a prominent place to safety in their “product-method-material” concepts.

410.

First paragraph: resistance of the parts and linkages

The first paragraph stresses the intrinsic resistance of the parts of the machine and their linkages. It is up to the manufacturer to determine the optimum resistance of the parts according to the functions they fulfil, the lifespan of the equipment and its cost, etc. The "machinery" Directive requires that safety be taken into account in determining resistance.

Two parts are linked as from the moment they come into contact via their surfaces during the operation of the mechanism. This contact may be at a point, in a line or on a surface. Parts may have several degrees of freedom between them. Linkages can be formed by housing, pivot, slide, propeller, sliding pivot, sphere, joint, flat support, linear or circular, and between a sphere and a plane.

The linkage may be elastic or rigid, permanent or detachable. Whatever the production methods are, it is physically impossible to achieve geometrically perfect surfaces. The quality of an assembly depends in particular on the degree of precision in its positioning, on the intensity of the mechanical actions transmissible, and on its deformability. The quality of the assembly components is also decisive for the resistance of the whole. Numerous threaded parts generally make up the assembly of machinery: screws, bolts, pins, set screws. The attention of manufacturers is drawn to the importance of ensuring the correctness of the information found on certain “safety” fixtures.

There are other methods of permanent assembly, such as welding and braze welding. Given that the welded part is a sensitive element from the point of view of safety (e.g. certain steel structure members in large machines), manufacturers often use the international and European standards employed in the field of welding.

Gluing is also a method of linkage which is used a great deal in the mechanical engineering industries. It depends on the materials used and on the stresses withstood by the assembly parts. Gluing allows regular distribution of mechanical actions, ensures sealing, reduces the loads, and does not change the characteristics of the assembly parts. It is, however, sensitive to heat and requires careful surface preparation.

Numerous machines involve relative movement between several parts.

This is often a rotary movement between a shaft and housing. The two rotating parts can be guided by direct contact between the parts, by friction rings or by rolling elements. The choice of type of ball bearing takes account of operational parameters and requirements (loads, couples, speed, rigidity, friction, noise, etc.).

Movement can also be rectilinear (machine-tool carriage, sliding door).

This can be guided by a sliding shaft, by columns, or by guide rails.

Good sealing and good protection of linkages help to meet the principle of prevention of break-up during operation. Sealing is important to prevent contact between two fluid media (oil, ambient air) and for resistance to the surrounding environment (chemical agents, temperature, etc.).

411.

(extract)	
[1.3.2	Risk of break-up during operation (...) The durability of the materials used must be adequate for the nature of the work place foreseen by the manufacturer, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion. (...)]

412.

Second paragraph: choice of materials

The strength of a part or linkage will depend mainly on the choice of material. Requirement 1.1.3 is more general than this requirement. The major families of materials used in machines

are metals, plastics, composites and ceramics. The choice of material depends on its mechanical properties, which condition in particular its elasticity, its weight, its toughness and its fatigue limits. It also takes account of its physico-chemical behaviour vis-à-vis corrosion, ageing and physical and chemical agents. The workability of the material is also very important, along with economic considerations (price, difficulty obtaining it, deadlines).

Knowledge of how materials behave under the effect of mechanical stress governs the choice and size of the part. This knowledge is part of the good engineering practice. For some parts or linkages tests will be useful, if not essential (e.g. tensile, fatigue, hardness and shock-resistance tests). If such tests have been carried out, it will be necessary to show the results in the design and manufacturing record. Resistance to wear through contact between moving parts varies with the hardness of surfaces, the contact pressure and the surface quality of the material. Good lubrication makes for effective reduction of the coefficient of friction.

The strength of materials also depends on their behaviour vis-à-vis chemical agents, especially chemical agents used in the normal operation of the machine. Fire or heat resistance is a major factor in the choice of certain materials (e.g. for furnaces or foundry equipment). Resistance to water or saline environments may be essential for the components of machines used near or in aqueous media.

413.

(extract)
[1.3.2 Risk of break-up during operation
(...)
The manufacturer must indicate in the instructions the type and frequency of inspection and maintenance required for safety reasons. He must, where appropriate, indicate the parts subject to wear and the criteria for replacement.
(...)]

414.

Third paragraph: lifetime, periodic inspection and replacement of parts

The manufacturer evaluates the lifetime of connections (generally in operating hours or million revolutions), and this will vary appreciably according to the type of use: not very frequent, intermittent, eight hours per day, 24 hours continuous. The manufacturer has to provide in the instructions for the timing of inspections and the frequency of replacement of parts. It has to be stressed that the “machinery” Directive only requires maintenance frequencies and replacement criteria to be included where wear has an impact on safety. Indicating inspection or replacement for reasons of performance or productivity is governed by ordinary contract law.

415.

(extract)
[1.3.2 Risk of break-up during operation
(...)
Where a risk of rupture or disintegration remains despite the measures taken (e.g. as with grinding wheels) the moving parts must be mounted and positioned in such a way that in case of rupture their fragments will be contained.
(...)]

416.

Fourth paragraph: containment of rupture

The fourth paragraph introduces a requirement which is not always easy to meet: do, for example, flywheels have to be enclosed in a housing capable of containing the fragments in the event of rupture?

In view of the size of certain flywheels, the answer is no. In many cases, conventional calculations of the resistance of materials, given adequate safety coefficients, are enough to ensure that there is no risk of rupture.

However, resistance calculations are less reliable for heterogeneous materials: the requirement cites the example of grinding wheels, for which a sufficiently strong housing is required.

Whatever lengths the manufacturer goes to in the design of machinery, it is physically impossible to design a machine in which the parts can resist rupture under extreme conditions. An error of programming the machine leading to insufficient clamping of the chuck and too high a speed will automatically lead to the ejection of the part and to the rupture of one or more bodies or guards. Absolute protection cannot be demanded of the manufacturer. The operator also has to use the machinery correctly. He should not make the machine perform operations which are beyond its capacity or can lead to dangerous situations: overheating, excessive speed, etc.

417.

(extract)
[1.3.2 Risk of break-up during operation
(...)
Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected against all manner of external stresses and strains; precautions must be taken to ensure that no risk is posed by a rupture (sudden movement, high-pressure jets, etc.).
(...)]

418.

Fifth paragraph: high-pressure pipes

This essential requirement stresses the risks arising from the rupture of pipes conveying fluids under high pressure. This type of flexible hose can be found on worksite units exposed to bad weather or to stresses. Hydro-electric power stations supplying the machines are also concerned. A conventional preventive measure is to encase the pipe or to make it fast if the flexible hose has to move. Manufacturers might usefully warn users of the precautions to be taken when working with high-pressure pipes. Maintenance of these components generally means compliance with strict consignment procedures.

419.

(extract)
[1.3.2 Risk of break-up during operation
(...)
Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to the persons exposed (e.g. tool breakage):
- when the workpiece comes into contact with the tool the latter must have attained its normal working conditions,

- when the tool starts and/or stops (intentionally or accidentally) the feed movement and the tool movement must be coordinated.]

420.

Sixth paragraph: regulation of speed

The contact between the processed material, metal or wood, for example, and the workpiece requires the latter to reach a certain speed in some cases. Risks of rupture may arise if the speed of the tool is too low or too high.

This paragraph also stipulates that the feeder systems have to stop at the same time as the workpiece. The feeder system must speed up or slow down if the workpiece speeds up or slows down. By way of example, a sheet transport system must stop if the punch press stops.

421.

1.3.3. Risks due to falling or ejected objects

Precautions must be taken to prevent risks from falling or ejected objects (e.g. workpieces, tools, cuttings, fragments, waste, etc.).

422.

Falling or ejected objects

Requirement 1.3.3 is designed to avoid risks posed by falling or ejected objects, such as chippings, tools or bits of tools, white-hot welding products, cutting fluids and abrasive particles.

Mechanisms to prevent objects from being ejected or falling are only necessary where such incidents occur under normal operating conditions or where accidental ejection is foreseeable. By way of example, an accident can be caused by a part being ejected due to insufficient tightening of the chuck bits of a machine tool. A common error among young mechanics is to leave the chuck key in the machine, which is then ejected when the machine starts (there are means to ensure that chuck keys cannot be left in the machine).

423.

Protective shields

Installing a protective shield against breaking up is especially necessary for machines where tools can break due to centrifugal force, pressure or reasonably foreseeable exceptional stresses (shocks, hammering, etc.). Grinding machines and certain rotary tools are particularly affected. Universal milling machines with fixed bench are generally equipped with a protective shield to prevent the operator from being exposed to flying chippings or cutting fluids. This protective shield can be moved and adapted by the operator. It does not, however, have the function of protection against risks connected with the moving parts referred to in requirements 1.3.7 *et seq*.

424.

Organizational measures in workshops

Using a guard to prevent parts from flying off can sometimes prove to be unrealistic. The speed of rotation of the machine and the size of the parts would require too big a guard in relation to the configuration of the machine. The manufacturer can recommend in his instructions additional organizational measures to combat any remaining risk. A permanent

workstation should not be located in an area where dangerous parts can be ejected. Access to areas where there is a risk of ejected or falling objects can be prevented by barriers and/or indicated in some way.

The risk of falling objects can be minimized by mechanization of heavy or cumbersome items. The configuration of the places of storage, stacking and fixing of the parts in the machine is also important. It is useful to provide for a pathway for parts located overhead which can detach from the machine. Personal protective equipment might also be essential.

425.

1.3.4. Risks due to surfaces, edges or angles

In so far as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles, and no rough surfaces likely to cause injury.

426.

Prevention of bruises

These provisions are designed to avoid the risk of an operator bumping into parts of machinery which jut out and injuring himself. This requirement primarily concerns the frame or device of a machine, but it also applies more generally to all components, except of course to tools used for work.

A special risk assessment needs to be made of parts next to passageways, workstations and handling areas.

Particular attention must be paid to the edges of guards, whether fixed or movable, made of sheet metal, which can, if necessary, be rolled or fitted with a protective strip. The radius of the protective strip or roll will depend on whether the guard is movable or not, whether it is controlled or not and whether it can be struck with force or not, etc. This requirement also applies to the internal parts of a machine that the operator can come into contact with during assembly, servicing, etc., as well as to access openings.

The factors to be taken into account when analysing the risk of injury with sharp edges and angles and rough surfaces are mainly:

- their accessibility (within direct reach or not without non-integrated means of access, presence or otherwise of a guard, etc.);
- their situation in respect of regular operating areas, such as workstation, control station, etc.;
- the type of elements concerned (control device, part near a control device, frame, cowling, accessory, etc.);
- the frequency of operations in the area in question;
- the part of the body concerned (special attention must be paid to risks to the head, arms, feet and legs);
- the type of action likely to cause the risk (e.g. deliberate movement, reflex action, freeing movement, stepping back, etc.).

427.

1.3.5. Risks related to combined machinery

Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a danger or risk for the exposed person.

For this purpose, it must be possible to start and stop separately any elements that are not protected.

428.

This requirement supplements requirements 1.2.3 and 1.2.4. In practice, each element must have its own start and stop controls.

429.

1.3.6. Risks relating to variations in the rotational speed of tools

Where the machine is designed to perform operations under different conditions of use (e.g. different speeds or energy supply), it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

430.

Regulation of speed

Machinery must be fitted with a device to allow the operator to regulate the operating conditions and in particular the speed of the machine and the rate of feed. This requirement can also apply to other parameters, such as heat, throughput or pressure. Speed regulation must also be safe. Well-designed controls (e.g. graduated buttons) help to meet this requirement. These controls must be stable enough not to slip.

431.

1.3.7. Prevention of risks related to moving parts

The moving parts of machinery must be designed, built and laid out to avoid hazards or, where hazards persist, fixed with guards or protective devices in such a way as to prevent all risk of contact which could lead to accidents.

All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, specific protection devices or tools, the instruction handbook and possibly a sign on the machinery should be provided by the manufacturer to enable the equipment to be safely unblocked.

432.

(extract)
[1.3.7. Prevention of risks related to moving parts

	The moving parts of machinery must be designed, built and laid out to avoid hazards or, where hazards persist, fixed with guards or protective devices in such a way as to prevent all risk of contact which could lead to accidents. (...)]

433.

First paragraph: prevention of risks related to moving parts

Moving parts in question

Moving parts in a machine act mainly to convey movement.

Requirement 1.3.7 provides for the principle of preventing the risk of contact with the moving parts of a machine. This principle applies equally to moving parts to convey movement (shafts, cylinders, rods, slides, belts, chains, sprockets, etc.) and to work elements (tools, moulds, matrices, rolls, mixing arms).

434.

Risk analysis

A preventive measure is justified where contact with moving parts might pose a risk. Contact with a part actuated by a slow movement or a plain shaft rotating at speed is not necessarily dangerous.

These are mainly risks of entanglement, dragging, crushing, severing, shearing, cutting, pricking and abrasion caused by parts in translation or rotation.

435.

Preventive measures

These risks must be prevented by and large through the relative positioning and configuration of the machine's moving parts. A good illustration of intrinsic hazard prevention is machinery with a body which encloses most of the moving parts and prevents access thereto. Where intrinsic prevention is not sufficient or possible conventional means of protection will consist principally of guards, barriers, enclosures, tubes, gutters and hoods. If necessary, the manufacturer may recommend extra organizational measures (not wearing anything that might catch: rings, bracelets, chains, ties, loose fitting clothes, long hair, gloves).

436.

(extract) [1.3.7.	Prevention of risks related to moving parts All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, specific protection devices or tools, the instruction handbook and possibly a sign on the machinery should be provided by the manufacturer to enable the equipment to be safely unblocked.]

437.

Second paragraph: prevention of the risk of blockage of moving parts

Blockage of the moving parts of a machine may be a source of risk in itself, possibly leading to moving parts breaking or overheating. Operators are often tempted to unblock machines by

improvising on operating methods, and this is often a source of accidents. Even if a machine is disconnected from the power supply residual energy is sometimes likely to continue the movement once the machine is unblocked (e.g. unblocking the cutting blades on lawnmowers).

The risk of jamming is particularly frequent in agricultural machinery. Too much casing on such equipment can increase the risk. This is a typical case of risk transfer. In practice it is very important that the manufacturer should provide for a hazard-free unblocking process. Instructions are indispensable. It will often be useful to post these instructions on the machine itself.

438.

1.3.8. Choice of protection against risks related to moving parts

Guards or protection devices used to protect against the risks related to moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help make the choice.

A. Moving transmission parts

Guards designed to protect exposed persons against the risks associated with moving transmission parts (such as pulleys, belts, gears, rack and pinions, shafts, etc.) must be:

- ***either fixed, complying with requirements 1.4.1 and 1.4.2.1, or***
- ***movable, complying with requirements 1.4.1 and 1.4.2.2.A.***

Movable guards should be used where frequent access is foreseen.

B. Moving parts directly involved in the process

Guards or protection devices designed to protect exposed persons against the risks associated with moving parts contributing to the work (such as cutting tools, moving parts of presses, cylinders, parts in the process of being machined, etc.) must be:

- ***wherever possible fixed guards complying with requirements 1.4.1 and 1.4.2.1,***
- ***otherwise, movable guards complying with requirements 1.4.1 and 1.4.2.2.B or protection devices such as sensing devices (e.g. non-material barriers, sensor mats), remote-hold protection devices (e.g. two-hand controls), or protection devices intended automatically to prevent all or part of the operator's device from encroaching on the danger zone in accordance with requirements 1.4.1 and 1.4.3.***

However, when certain moving parts directly involved in the process cannot be made completely or partially inaccessible during operation owing to operations requiring nearby operator intervention, where technically possible such parts must be fitted with:

- ***fixed guards, complying with requirements 1.4.1 and 1.4.2.1 preventing access to those sections of the parts that are not used in the work,***

-	***adjustable guards, complying with requirements 1.4.1 and 1.4.2.3 restricting access to those sections of the moving parts that are strictly for the work.***

439.

Choice of type of protection

Types of guard

A guard is part of a machine used to provide protection by means of a physical obstacle. The guard can be a casing, a lid, a door, an enclosure, etc.

A locking or interlocking guard is effective only when it is closed.

The guard may have a locking or an interlocking mechanism. In the case of the latter, protection is ensured even if the guard is open (sensitive devices, two-handed controls, etc.).

Requirement 1.3.8 obliges the manufacturer to choose a type of protection mechanism to fit the risk.

The three principal categories of guards are fixed guards, mobile guards and adjustable guards without tools.

It goes without saying that this choice should not increase the risk or make work impossible (see requirement 1.4.1). It is at this choice of mechanism stage that every aspect of the matter needs to be evaluated. Manufacturers may find it worth encouraging a decision not to equip certain moving parts with guards. They must check that the guards or protective devices do not create other risks (e.g. machine jamming, prompting the operator to unlock it under dangerous conditions, etc.).

Requirement 1.3.8 gives guidelines to meeting this requirement, and these should be taken more as guidelines than absolute legal requirements. Requirement 1.3.8 distinguishes between moving transmission parts (point A) and moving parts directly involved in the process (point B). This distinction is justified because it is generally easier to make the moving transmission parts inaccessible, compared to the parts directly involved in the work.

440.

Guide to choice

The guidelines are as follows:

Prevention of risks connected with transmission parts

- installation of a fixed detachable guard with tool,
- for frequent jobs, use of mobile guards with a locking mechanism (type A movable guard).

Prevention of risks connected with moving work parts

- if it is possible to make them inaccessible while moving: use of a fixed or mobile guard or a protective device such as touch-sensitive mats, light barriers, two-handed controls,
- if it is not possible to make them inaccessible: use of a fixed guard preventing access to moving parts to people in areas where they do not work and use of adjustable guards

without tool, restricting access to moving parts in areas where it is not necessary to go for work.

Although the references to the characteristics of the guards recommended for moving transmission parts and moving work parts are different, it is obvious that if, on a given machine, these two types of moving parts are very close to one another and can be protected by one and the same guard, the guard protecting the moving working parts has to be used. A type 1.4.2.2.B guard will thus be used even though it is not referred to in paragraph A for the protection of moving transmission parts.

The choice of guard must be made by the manufacturer as a function of foreseeable risk. The guard chosen must give the highest possible level of safety.

Fixed guards

Preference is given to fixed guards, which must be used wherever possible, except where they would have to be removed frequently to allow access. Because a tool is needed to remove a fixed guard, this operation is considered to be a task for a qualified person (with the appropriate tool). For this purpose, a lock is regarded as a tool.

It is a good idea to store the spanner needed to remove a fixed guard in a device which automatically stops the machine when the spanner is removed.

441.

1.4.	***Required characteristics of guards and protection devices***
1.4.1.	***General requirements***
	Guards and protection devices must: ***- be of robust construction,*** ***- not give rise to any additional risk,*** ***- not be easy to by-pass or render non-operational,*** ***- be located at an adequate distance from the danger zone,*** ***- cause minimum obstruction to the view of the production process,*** ***- enable essential work to be carried out on installation and/or replacement of tools and also for maintenance by restricting access only to the area where the work has to be done, if possible without the guard or protection device having to be dismantled.***

442.

(extract)	
[1.4.	Required characteristics of guards and protection devices
1.4.1.	General requirements
	Guards and protection devices must: - be of robust construction, - not give rise to any additional risk, - not be easy to by-pass or render non-operational, - be located at an adequate distance from the danger zone, - cause minimum obstruction to the view of the production process,

(...)]

443.

Strength, reliability and ergonomics of guards

Guards must resist foreseeable stresses, such as shavings and fragments projected from inside and blows and pressure from outside.

They must meet requirement 1.3.4 and their safety systems must be reliable and designed so that it is difficult to render them non-operational.

The distance between the guard or protection device and the dangerous movement must be such that the time between displacement of the guard or disengagement of the protection device and the stopping of the dangerous movement is less than the time which would be needed for the operator to access the dangerous movement through the opening created by displacement of the guard or activation of the protection device.

Guards must not obstruct the view of the production process. In some cases there may even be the added requirement that guards should not restrict the operator's hearing of the production process. Recommendations for guards which increase the difficulty of the task or make work on the machine practically impossible are contrary to the spirit and the letter of the "machinery" Directive. A guard that has to be detached to allow the operator to work normally serves no purpose.

If it is necessary for the operator to observe the movement, an inspection window must be provided. Whether or not a transparent guard is installed will depend on the risk of cutting oil spray. A guard full of oil will prevent the operator from seeing the working area.

444.

Standards

The literature has abundant references to standards. Standard EN 953 provides the general principles to be met by guards, while EN 294 gives the safety distances for upper limbs and EN 811 gives the same distances for lower limbs. Standard EN 349 defines the space needed for different parts of the body not to be crushed and standard EN 999 helps to calculate the distance at which protective devices need to be placed in respect of moving working parts, taking account of the speed of movement of upper limbs and the actual down time of the machine. The provisions of these standards, which are obviously voluntary, have to be adapted to the particular needs of the machine

445.

(extract)
[1.4. Required characteristics of guards and protection devices

1.4.1. General requirements

Guards and protection devices must:
- (...)
- enable essential work to be carried out on installation and/or replacement of tools and also for maintenance by restricting access only to the area where the work has to be done, if

possible without the guard or protection device having to be dismantled.]

446.

This last indent requires other means of safety integration to be exhausted before resorting to a proliferation of guards. It also means that wherever frequent intervention is anticipated for cleaning, unclogging and unjamming, mobile, non-detachable guards should be preferred to fixed guards which have to detached. Where a fixed guard is used for less frequent action, locking fasteners should be used so as to facilitate refitting (see Directive 89/655/EEC).

447.

1.4.2. Special requirements for guards

1.4.2.1. Fixed guards

Fixed guards must be securely held in place.

They must be fixed by systems that can be opened only with tools.

Where possible, guards must be unable to remain in place without their fixings.

448.

Characteristics of fixed guards

The feature of fixed guards is that they are held in place securely. They can be welded, glued or attached by fixings (bolts, rivets, etc.). They can only be detached with the aid of a tool. If they are not correctly refitted they ought to fall down. However, they cannot fall if they are in a horizontal position. Whatever the case, the spirit of the requirement is that the operator should be aware of the absence of a fixed guard.

This requirement prohibits, for example, a fixed guard which hinges on its upper edge, as it is not possible to check that the operator has reattached such a guard correctly simply by looking at it.

In general, hinged guards are to be avoided. However, they may be used in places where the operator has to work in an awkward position and risks either dropping the guard or having difficulty reattaching it.

449.

1.4.2.2. Movable guards

A. Type A movable guards must:
- ***as far as possible remain fixed to the machinery when open,***
- ***be associated with a locking device to prevent moving parts starting up as long as these parts can be accessed and to give a stop command whenever they are no longer closed.***

B. Type B movable guards must be designed and incorporated into the control system so that:
- ***moving parts cannot start up while they are within the operator's reach,***

- ***the exposed person cannot reach moving parts once they have started up,***
- ***they can be adjusted only by means of an intentional action, such as the use of a tool, spanner, etc.,***
- ***the absence or failure of one of their components prevents starting or stops the moving parts,***
- ***protection against any risk of ejection is provided by means of an appropriate barrier.***

450.

(extract)
[1.4.2.2. Movable guards

A. Type A movable guards must:
- as far as possible remain fixed to the machinery when open,
- be associated with a locking device to prevent moving parts starting up as long as these parts can be accessed and to give a stop command whenever they are no longer closed.

(...)]

451.

Characteristics of movable guards

Movable guards are generally linked mechanically to the frame of the machine or to a fixed part close to the machine. Guards may be attached by hinges or mounted on slides and it is possible to open them without tools.

The Directive distinguishes between type A and type B movable guards. Type A are interlocking guards and type B are interlocking guards with guard locking.

452.

"Interlocking" guards

With type A guards the machine cannot start as long as they are not closed. The machine stops when they are opened. Opening the guard gives the order to stop, although closing the guard does not usually give the order to start.

453.

(extract)
[1.4.2.2. Movable guards
(...)
B. Type B movable guards must be designed and incorporated into the control system so that:
- moving parts cannot start up while they are within the operator's reach,
- the exposed person cannot reach moving parts once they have started up,
- they can be adjusted only by means of an intentional action, such as the use of a tool, spanner, etc.,
- the absence or failure of one of their components prevents starting or stops the moving parts,

	- protection against any risk of ejection is provided by means of an appropriate barrier.[

454.

"Interlocking" guards with guard locking

Type B guards cannot be opened when the machine is in operation. The guard remains locked until the risk of injury due to hazardous functions has been eliminated. Movable guards can be locked by a bolt while unlocking is controlled either by a timed device (timer system) or by a device controlling that the moving parts are stopped.

455.

Locking devices

The locking devices may vary in sophistication as a function of the type of hazard. Type A guards can be made of intrinsically safe components or, where there is frequent access, based on the principle of redundancy through component duplication and/or auto-surveillance. The choice of device must be proportionate to the hazard and to the cost of the machine.

456.

1.4.2.3.	***Adjustable guards restricting access***
	Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must:
	- be adjustable manually or automatically according to the type of work involved,
	- be readily adjustable without the use of tools,
	- reduce as far as possible the risk of ejection.

457.

Using adjustable guards

Requirement 1.4.2.3 concerns adjustable guards.

These guards may be adjusted by the operator or automatically, altogether or only on part of them. The position in which the guard has been adjusted does not move during machine operation. The guard may move along with the worked part (e.g. pieces of wood in surface planing machines).

Adjustable guards are used where access to dangerous areas forming part of the production process cannot be ruled out completely, for example with a drill bit or circular saw blade. Such guards must be readily adjustable so that the operator is not tempted to set the guard to its maximum opening to avoid the need to make adjustments which he finds too complicated. The guard must not be easy to remove.

458.

1.4.3.	***Special requirements for protection devices***
	Protection devices must be designed and incorporated into the control system so that:
	- moving parts cannot start up while they are within the operator's reach,

- ***the exposed person cannot reach moving parts once they have started up,***
- ***they can be adjusted only by means of an intentional action, such as the use of a tool, spanner, etc.,***
- ***the absence or failure of one of their components prevents starting or stops the moving parts.***

459.

Non-physical barriers and sensitive devices

Protection devices perform the same function as type 1.4.2.2.B guards. The requirements are the same accordingly, except as regards the risk of ejection, since protection devices do not present physical obstacles and can therefore be used only where there is no risk of ejection. The various devices available are covered by European standards (EN 574 for two-hand controls, EN 50100 for electro-sensitive devices, etc.). Certain optoelectronic protection systems may be used to control access to automated areas or for machine protection mechanisms such as presses. The detection function is performed by an optoelectronic transmitter and receivers which detect optical radiation interruption by an opaque object. Certain luminous curtains function by area sweeping or by revolving mirror. Other protection mechanisms function by their sensitivity to pressure (mats, floor, sensitive edge, bar).

460.

1.5 Protection against other hazards

1.5.1 Electricity supply

Where machinery has an electricity supply it must be designed, constructed and equipped so that all hazards of an electrical nature are or can be prevented.

The specific rules in force relating to electrical equipment designed for use within certain voltage limits must apply to machinery which is subject to those limits.

461.

Prevention of all electrical hazards

The general rule imposed by essential safety requirement 1.5.1 is that machinery operated by electric power must be designed in such a way as to prevent all hazards of electrical origin. The most frequent electrical hazard is the risk of electrocution. Electrical current can have irreversible nervous and muscular effects as well as heat effects. Fires of electrical origin can also give rise to overcurrent, electric arc or static electricity. Machines have to be equipped to avoid direct contact between a person and an active conductor or a normally live conductive component. The manufacturer must also prevent hazards from indirect contact between a person and a mass or, more generally, a conductive part switched on by accident.

A number of preventive measures among many others commonly used by manufacturers are as follows:

462.

Protection against direct and indirect contact

Obstacles placed between operators and live components should be enclosed to provide a suitable degree of protection. An international standard (EIC 523) defines the indexes of protection of enclosures. The degree of protection varies according to the risks and the nature of the working environment. Conductors themselves should be insulated. Wiring diagrams should be such as to prevent any risk of indirect contact. Machinery controls and resetting devices for protective relays intended for operators should be manoeuvrable without risk of contact with exposed live components. Resetting devices should be outside the enclosure housing live components. It is obviously much more difficult to comply with this rule for specialized maintenance personnel. As far as possible, manufacturers should try to envisage breakdown service procedures from the angle of electrical safety.

463.

Protection against overcurrent

Machines should be protected against overcurrent, i.e. against current higher than nominal current. This means any current overload in a regular electrical circuit as well as any short-circuit current with negligible impedance between points of different voltage. Protection against overcurrent is achieved by fuses or circuit breakers. Requirement 1.2.6 does in fact stipulate that an increase in energy supply should not create dangerous situations.

464.

Who is responsible for the provision of protection mechanisms against overcurrent?

The provision of protection mechanisms inside machinery is the responsibility of the manufacturer.

The supply of general protection mechanisms, either in the connection of the electrical equipment of the machine or in the electrical installation of the user site, is the responsibility of the user.

This can obviously be arranged by contract between the supplier or the fitter and the user.

A machine may bear the “CE” marking without being supplied with its general protection mechanism as long as that has been agreed between customer and supplier. Annex B of harmonized standard EN 60204-1 illustrates the customer-supplier dialogue sometimes needed as regards the electrical equipment of machinery. To determine the characteristics of the general protection mechanism to be connected at the place of use, the electrical characteristics of the machine must be established.

It should be remembered at this juncture that the obligation to fit machinery with an isolation of energy sources mechanism, as provided for by essential requirement 1.6.3, must be reflected in the wiring diagram of the machine and its connection.

465.

Earthing

The masses of the various parts of the machine are inter-connected and linked to the general earthing terminal. Earthing is generally provided by means of a protective conductor

incorporated in the connection cable. In the case of high power the earth conductor may be in the immediate vicinity of the electric cable without being incorporated.

These preventive measures are taken when the conductor cannot be replaced by the actual structure of the machine. They do not apply where the electrical equipment is provided with double insulation or reinforced insulation.

466.

Compliance with good wiring practice

The rules governing the methods of wiring electrical installations are set out in national regulations. The code of good practice of electrical fitters is often laid down in standards, and these can vary from one country to another.

For three-phase current, the same conductor can never be used for the neutral and the earth conductor in certain countries, while it can in others. This diversity means that master switches have to be adapted to the rules of the country of use. An important rule to be observed is never to break the conductor used for the earth (except obviously when checking it).

467.

Protection of internal circuits

The internal circuits of machinery powered by separate winding transformers need their own protection mechanisms against indirect contact unless they are powered at very low voltage. This preventive measure concerns internal circuits, generally single-phase, powered by the secondary winding of a transformer. Unless they are powered at very low voltage, these circuits can either be completely isolated from the mass of the frame of the machine or be connected at a given point to the protective circuit of the machine.

468.

Role of standards

The specifications of the EN 60204-1 standard are a good way of meeting this requirement. There is also the EN 60335 standard, which really only covers household electrical appliances; however, to eliminate any ambiguity, CENELEC has started work on the recasting of both standards.

The IEC 523 standard defines what are known as the indices of protection of enclosures (IP).

There are also a number of standards for electrical components and associated conformity marks. It is in the designer's interest to use components meeting these specifications wherever possible.

469.

Reference to rules relating to electrical equipment

The last paragraph of the requirement specifies that the specific rules relating to electrical equipment must apply. In a strict legal sense it may be claimed that the “low-voltage” Directive applies in tandem with the “machinery” Directive. However, the comments on Article 1(5) put this claim in a slightly different light. In practice, household appliances will

always have the "low-voltage" Directive (73/23/EEC, as amended)[79] as the principal Directive. Machinery for professional use will continue to have the "machinery" Directive as the principal Directive. The electrical part of machinery for professional use should be based on standardization in the electrotechnical sector. That said, European standards, including European standards within the scope of the "low-voltage" Directive, are not obligatory. Care must be taken not simply to transpose technical standards which are relevant for household appliances, although not necessarily for industrial equipment.

470.

1.5.2. Static electricity

Machinery must be so designed and constructed as to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

471.

Origin of electrostatic charges

Static electricity is due to an accumulation of electricity generated by the movement of electrified ionizing substances. This might stem in particular from the flow of gas or liquids, the displacement of solids, which can be dust or small particles, the advancement of continuous strip or friction between parts. Electrostatic discharge can cause fires or explosions. It can also cause accidents, especially by causing people to fall over because of its surprise effect.

By way of example, the dangers of static electricity can come from friction between fabrics on the walls of a dyeing machine; from the decomposition of gases in spray painting; from the handling of liquid fuels (petrol); or from dust from flour, sugar, light metal (aluminium). The belts of machines, coated or waxed fabrics, rubber strips, sand paper or paperboard strips on printing machines can also generate electrostatic discharges.

472.

Preventive measures

The fundamental preventive measure is to promote the flow of static charges in such a way that they do not accumulate. Several methods are used: making the atmosphere conductive; making conductors insulating liquids; ensuring the flow of electrostatic charges towards the earth using a suitable conductor.

The atmosphere can be made conductive either by humidification or by ionization. Humidification of the atmosphere can, however, pose other problems: condensation blocking visibility, discomfort to operators. Ionization can be provided by radioactive substances or with a flame if there are no risks for the operators.

The method of making liquid the conductors which are usually insulating, is used in liquid handling operations.

79 Directive 73/23/EEC of 19 February 1973 (OJ No L 77, 26 March 1973, p. 29); as amended by the Directive 93/68/EEC (OJ No L 220, 31 August 1993, p. 1)

The flow of electrostatic charges from machinery is generally achieved by direct earthing or by means of a connection with suitable electric resistance. The main thing is that the continuity of the earthed circuit is ensured.

Semi-conducting rubber with high resistivity can be used, for example, so that the flow of charges does not cause heating. Where electrostatic charges come from a belt drive or from the translation of more or less insulating strip the pulleys and shafts are earthed. Metallic collectors can also be connected to the earth (or similar mechanisms) in contact with the belts, near to the point where they leave the pulleys and if necessary on both sides of the belt. A system of metal wires can also be earthed in the immediate vicinity of both strands of the belt. Belts can be coated with substances which reduce the production of electrostatic charges. The resin sometimes used to keep the belt in position promotes the production of charges and stops them from being collected. Bearing oil and roller bearing oil can compromise even more the continuity of earthed circuits.

Special care must be taken with spray-painting appliances. The metal parts of spray-painting booths, cages, exhaust chambers or systems and any metal objects to be painted should be earthed.

Conveying fine powders sometimes makes it necessary to install detectors to monitor the accumulation of electrostatic charges. Hoppers and excavator belts should be properly earthed and the electric continuity of the belts ensured.

473.

1.5.3. Energy supply other than electricity

Where machinery is powered by an energy other than electricity (e.g. hydraulic, pneumatic or thermal energy, etc.), it must be so designed, constructed and equipped as to avoid all potential hazards associated with these types of energy.

474.

Different forms of energy

Using forms of energy other than electricity needs as rigorous a risk analysis as in the electromechanical sector. Other forms of energy may be chemical energy, thermal energy, physical force to lift a load, wind or tidal energy, nuclear energy, geothermal energy, solar energy or gas, etc.

Hydraulic and pneumatic energy

Machines and their components powered by pressurized fluids (hydraulic and pneumatic transmission systems) are in common use. Manufacturers take a number of design options to prevent hazards arising from this type of energy. Nonetheless, maintenance work on machines often leads to critical situations in terms of safety, due in particular to energy build-up through the pressurized fluids in the machine. Manufacturers should lay down in their instructions how to go about handling this type of system. Rigorous procedures are sometimes indispensable in this respect, generally providing for isolation of any sources of energy (see requirement 1.6.3), immobilization of the machine, dissipation of residual energy and confirmation of the result.

475.

1.5.4. Errors of fitting

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design of such parts or, failing this, by information given on the parts themselves and/or the housings. The same information must be given on moving parts and/or their housings where the direction of movement must be known to avoid a risk. Any further information that may be necessary must be given in the instructions.

Where a faulty connection can be the source of risk, incorrect fluid connections, including electrical conductors, must be made impossible by the design or, failing this, by information given on the pipes, cables, etc. and/or connector blocks.

476.

Design of parts to take account of fitting

Parts should be designed so as to prevent errors of fitting which might be dangerous, e.g. by avoiding symmetrical parts.

Connection errors must be prevented in hydraulic and pneumatic installations with different pressure levels, e.g. by using different diameters for each pressure level.

Likewise, where different gases (oxygen, argon, nitrogen, acetylene, etc.) are used in a machine, connection errors must be made impossible by the design. Colour coding is a good additional precaution, but is in itself insufficient to meet this requirement.

477.

1.5.5. Extreme temperatures

Steps must be taken to eliminate any risk of injury caused by contact with or proximity to machinery parts or materials at high or very low temperatures.

The risk of hot or very cold material being ejected should be assessed. Where this risk exists, the necessary steps must be taken to prevent it or, if this is not technically possible, to render it non-dangerous.

478.

Limit temperatures for hot surfaces are covered by the EN 563 standard.

A separate standard is currently being drawn up to cover limit temperatures for cold surfaces.

479.

1.5.6. Fire

Machinery must be designed and constructed to avoid all risk of fire or overheating posed by the machinery itself or by gases, liquids, dusts, vapours or other substances produced or used by the machinery.

480.

Regulation of sources of fire

Fire hazards are generally prevented by adhering to codes of good practice and the regulations in force on electrical safety. Some machines have mechanisms which make it possible to

maintain the atmosphere outside flammable limits. The internal temperature can be controlled in particular by introducing fresh air. Other machines use techniques which neutralize fire hazards connected with the release of substances.

As an example of preventive measures, standard EN 174-1 on earthmovers proposes fire-resistance values for the floors of the driver's cab and the internal trimmings. On some machines, room has to be found for fire-extinguishers and even an integrated extinguishing system.

481.

1.5.7. Explosion

Machinery must be designed and constructed to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dusts, vapours or other substances produced or used by the machinery.

To that end the manufacturer must take steps to:
- ***avoid a dangerous concentration of products,***
- ***prevent combustion of the potentially explosive atmosphere,***
- ***minimize any explosion which may occur so that it does not endanger the surroundings.***

The same precautions must be taken if the manufacturer foresees the use of the machinery in a potentially explosive atmosphere.

Electrical equipment forming part of the machinery must conform, as far as the risk from explosion is concerned, to the provision of the specific Directives in force.

482.

Prevention of the risk of explosion

Requirement 1.5.7 of the “machinery” Directive deals with the risk of explosion posed by machinery from two aspects.

Explosion of machinery in a normal atmosphere

The first paragraph deals with the risk of explosion of the machine itself without this risk arising from its being in an explosive atmosphere (the fact that the machine is or is not in an explosive atmosphere is not the cause of the explosion). These risks of explosion are intrinsic risks, arising either from the substances worked or produced by the machine or from the operating parameters of the machine itself.

Components located in an explosive atmosphere inside a machine

A machine intended to be operated in a non-explosive atmosphere can contain an explosive atmosphere in one or more of its components. This is the case with a painting cabin, a fully closed machine, a painting system and a ventilation system. The internal components functioning in an explosive atmosphere have to meet the flameproof requirements of Directive 94/9/EC[80]. The entire machine is not subject to Directive 94/9/EC since it is not in an explosive atmosphere.

80 Directive 94/9/CE of 23 March 1994 (OJ No L 100, 19.04.1994, p. 1)

483.

Use of machinery in an explosive atmosphere

The second paragraph of requirement 1.5.7 deals with the risk of explosion posed by the use of machinery in an explosive atmosphere. The ignition of an explosive atmosphere can be caused not only by an explosion from the machine itself but also by an electrical or non-electrical source. Sources of ignition can come from sparks, arcs, high surface temperature, release of acoustic energy, optical radiation, or electromagnetic waves.

Preventive measures will obviously be much more stringent for machinery intended by the manufacturer to be used in an explosive atmosphere. Prevention means limiting electrostatic discharge, avoiding or limiting the creation of an explosive atmosphere by products used in the machine, choosing materials according to their behaviour vis-à-vis such risks, avoiding stray current and leakage in enclosures, providing where possible for operations in closed enclosures, limiting sealing defects, and restricting areas where dust can readily deposit, etc.

484.

The "ATEX" Directive

"New approach" Directive 94/9/EC, as based on Article 100a of the Treaty, on the approximation of the laws concerning equipment and protective systems intended for use in potentially explosive atmospheres and the classification of equipment used in such atmospheres has been adopted by the Council. This Directive is commonly known as the "ATEX" Directive. It is designed to ensure the free movement of products and is addressed to manufacturers. The Member States of the EEA cannot strengthen the provisions of the Directive by national regulations dealing with aspects of safety covered by the Directive.

This Directive follows on from several "old approach" Directives geared primarily to the prevention of risks of explosion due to electricity.

485.

The "ATEX" Directive

Another Directive, based on article 118a of the Treaty, is being prepared with a view to laying down the minimum requirements to be met by users in this field. This future Directive will define explosive areas. It will thus be in the manufacturers' interest to refer to the European definition of explosive areas before setting out the intended uses of their products in their instructions.

The Directive on the prevention of risks of explosion at work is a social Directive. Member States are free to adopt more stringent national regulations since Directives based on Article 118a of the Treaty only set minimum requirements.

486.

Detailed rules for the application of the "machinery" Directive and the "ATEX" Directive

A distinction must be made between several situations:

Machinery intended by the manufacturer to be used in non-explosive atmospheres: exclusive application of the "machinery" Directive.

Directive 94/9/EC does not apply to the prevention of the risk of explosion with machinery intended by the manufacturer to be used in a "normal" atmosphere, i.e. an atmosphere not

created by the machine itself and not involving flammable substances (gases, steam, dust and sprays) where combustion (after ignition) might spread to the surrounding air.

487.

Machinery intended by the manufacturer to be used in explosive atmospheres: joint application of both Directives, save exceptions.

The "machinery" Directive applies to all machinery whether or not intended to be used in explosive atmospheres.

The "ATEX" Directive applies only to equipment and protective systems intended to be used in explosive atmospheres. It also applies to the safety devices and controls which do not work in an explosive atmosphere but which contribute to the safe operating of equipment and protective systems used in explosive atmospheres.

488.

Joint application of both Directives

Machinery intended for use in explosive atmospheres must therefore meet the essential requirements of the "machinery" Directive plus the specific requirements of Directive 94/9/EC. This is a direct consequence of Article 1(4) of the "machinery" Directive. Manufacturers of machinery intended for use in explosive atmospheres must therefore classify their machinery in one of the groups of appliances provided for by Directive 94/9/EC.

489.

Exclusive application of the "machinery" Directive for certain machinery likely to be used in explosive atmospheres

The second paragraph of requirement 1.5.7 states that the manufacturer has to take precautions where the machine is intended for use in an explosive atmosphere. At this point, as we have seen, Directive 94/9/EC takes over from the "machinery" Directive and specifies the content of essential requirements and marketing procedures specific to this risk. Some machines intended for further use in an explosive atmosphere are, however, excluded from Directive 94/9/EC and are therefore covered by the "machinery" Directive instead, in that the "machinery" Directive does not itself exclude them. These are machines where the danger of explosion comes exclusively from the presence of explosive materials or unstable chemical materials.

490.

Equipment and protective systems intended to contribute to the safe operating of equipment in explosive atmospheres

These systems are designed to stop any explosions that occur immediately or, at least, to minimize their effects. It is unlikely that systems of this kind can be comparable to "machinery" within the meaning of the "machinery" Directive. Whether or not these systems work in an explosive atmosphere, they are covered by Directive 94/9/EC.

491.

1.5.8. Noise

Machinery must be so designed and constructed that risks resulting from the emission of airborne noise are reduced to the lowest level taking account of technical progress and the availability of means of reducing noise, in particular at source.

492.

Compliance with codes of good practice to reduce noise

The Directive requires the designer to use all available means to reduce noise by design (e.g. by choosing non-metallic materials, by assembling components of a shape, thickness and size calculated to avoid resonance, by inserting joints to damp vibration, by preventing parts from falling from too high, and by regulating the flow of compressed air exhaust, etc.). It is more effective to take measures to reduce noise at source than to take additional protective measures (such as enclosing the machinery). Additional measures can in fact pose problems (more difficult for the operator to see the requisite information, unwanted heating, smaller openings for supply or removing parts, etc.) and are generally less effective than integrated design measures to reduce noise.

The Directive does not lay down limit values for noise emission. However, the CEN memorandum (CEN/CR 1100) states, with very careful wording, that standards could indicate the average levels achieved at a given date for a type of series-manufactured machinery (where appropriate by power category, technological type, etc.). These standards also clearly state the test codes used and the measuring conditions (materials worked, rate of work, etc.).

493.

The Directive does not cover disturbances in surrounding areas

Moreover, the noise emitted by machinery should not be confused with the noise to which people and the environment are exposed. The latter depends on many factors, such as the number of machines operating in the same room, the noise emitted by the other machines and the siting of the machine (next to a wall, nature of the wall, ceiling height, etc.). Any limit laid down for an individual machine is without prejudice to its influence on the health of operators or environmental quality. The European Commission (Directorate-General for the Environment) is drawing up a proposal for a Directive designed to lay down noise emission limits for machinery used outdoors. The aim of this proposal for a Directive is to extend the scope of existing "old approach" Directives on the matter, targeting in particular construction site equipment and lawnmowers.

494.

1.5.9. Vibration

Machinery must be so designed and constructed that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

495.

The comments on requirement 1.5.8 apply equally to vibration.

496.

1.5.10. Radiation

Machinery must be so designed and constructed that any emission of radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions.

497.

Prevention of risks due to radiation

Certain machinery must emit radiation (X-rays, gamma rays, electromagnetic fields, non-coherent optical radiation, etc.) to operate. Requirement 1.5.10 poses the principle of a general limit on the emission of radiation. Radiation has to be limited to what is necessary for the operation of the machine.

Emission limitation puts a priority on avoiding any harmful effects of radiation on the health of people exposed. This is not the only objective, but requirement 1.5.10 lays emphasis on it. Since the "machinery" Directive also sets out to protect pets and property, emission limitation also takes this dimension into account. The electromagnetic compatibility of machinery is one of the aspects of requirement 1.5.10. Compatibility tests on large or complex machinery pose specific problems. The harmonized standard EN 60204-1 (February 1996, section 20.6) stipulates that these tests can be carried out on suitable control subassemblies of the system rather than on the entire system. Machinery satisfying the requirements of Directive 89/336/EEC, as amended, generally meets requirement 1.5.10 since, in the current state of the art, the levels of exposure to electromagnetic radiation causing dangerous effects to human health are way above levels causing interference to equipment.

498.

Proper execution of what is required of the manufacturer and the user

An important remark has to be made at this point. Limit values for operator exposure are recommended or imposed on users for some types of radiation. It is not possible simply to convert these limits on operator exposure into equipment emission limits at the design stage. It would be nice to combine the two, and in practice it might be possible for certain types of radiation, such as laser radiation. But it is unrealistic in many cases, especially where the radiation emitted obeys diffusion rules which make it possible to lessen its effects. Distance makes it possible to reduce the hazard as regards noise, nuclear radiation or electromagnetic radiation.

Placing a physical obstacle between the radiation and the person exposed is one of the conventional preventive measures. While radiation should be reduced to what is necessary for the operation of the machine, a manufacturer cannot be asked to reduce radiation below the level necessary to maintain the performance of the machine.

499.

1.5.11. External radiation

Machinery must be so designed and constructed that external radiation does not interfere with its operation.

500.

General requirement

Requirement 1.5.11 is a general constraint aimed not only at electromagnetic radiation but also at all other types of radiation. The aim is not to interfere with the operation of the machine. This aim is worded in general terms and obviously sets out to prevent any malfunctioning which might affect operator safety. It also concerns the "safety" of goods either involved in the production process of the machine or being stored nearby. The "safety" of goods and domectic animals is also one of the objectives of the "machinery" Directive even though it comes behind the safety of people. Requirement 1.5.11 can thus be seen as a general requirement of protection against radiation, covering all aspects of the matter, including industrial performance.

This requirement reminds the designer that if the machinery can be used in certain environments or locations, he must select his components in such a way that the foreseeable conditions linked to the environment or location in question do not disrupt the operation of the machinery to the extent that operators or other persons are exposed to danger.

To comply with requirements 1.5.10 and 1.5.11, the designer can take account of the standard EN 954-2 to make a control system safe in the presence of outside radiation of diverse origin.

501.

1.5.12. Laser equipment

Where laser equipment is used, the following provisions should be taken into account:

- ***laser equipment on machinery must be designed and constructed so as to prevent any accidental radiation,***
- ***laser equipment on machinery must be protected so that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health,***
- ***optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by the laser rays.***

502.

This section applies the requirements of section 1.5.10 to laser radiation.

Numerous standards exist, taken from ISO, in particular EN 31252, EN 31253, EN 31145 and EN 31553. Manufacturers can also refer to EN 12626-3.

503.

1.5.13. Emissions of dust, gases, etc.

Machinery must be so designed, constructed and/or equipped that risks due to gases, liquids, dust, vapours and other waste materials which it produces can be avoided.

Where a hazard exists, the machinery must be so equipped that the said substances can be contained and/or evacuated.

Where machinery is not enclosed during normal operation, the devices for containment and/or evacuation must be situated as close as possible to the source emission.

504.

Dust and gas

Machinery must be equipped with the means (appropriately shaped nozzles or dust collectors, etc.) to be readily connected to an exhaust system (the standard EN 626 lays down the principles to be adopted to reduce these risks while the standard EN 1093 sets out the methods of measuring such emissions).

The instructions must specify the main characteristics required of such exhaust systems, including the flow rate.

In the case of portable machinery:

- where the machinery is always used at fixed workstations which can be equipped with an exhaust system, it is sufficient to equip the machinery with a connection nozzle;
- otherwise, the machinery must be equipped with its own collection system (e.g. a sawdust exhaust and collection bag in the case of a sander);
- where collection is technically impossible, the machinery must be designed so that dust, gases or other harmful vapours are not ejected towards the operator.

505.

Requirement 1.5.13 calls for the collection of harmful substances for the protection of operators. These harmful substances must be treated or disposed of. A code of practice on this exists for cabins used for industrial painting[81]. For cabins using liquid paint (cabins closed or with open top, for example), the standard EN 12626-3 relating to this code of practice indicates the following values:

- measured average of air speeds must be no less than 0.30 m/s,
- one-off measured values no less than 0.25 m/s.

These speeds must be measured with directional equipment, giving a value with uncertainty of no more than 0.05 m/s of the measurement in the range from 0.25 m/s to 0.5 m/s.

The "machinery" Directive does not take account of the environmental protection measures to be taken by the manufacturer or the user.

Some Community Directives oblige the manufacturer to keep to emission limits (e.g. for diesel engines). Others oblige users to comply with discharge values into water or the atmosphere. These Directives set minimum limit values which can be stiffened at national or local level.

Striking a balance between the requirement of collecting pollutants at the workplace and environmental protection can lead to delicate technical conflicts. These requirements may turn out to be contradictory where, to satisfy safety at work requirements, high air speeds are needed and filtration techniques do not come up to environmental requirements. It is very important for standards experts to detect this type of contradiction and to try to find solutions by type of machine. Compromises between these two bodies of legislation should be found.

506.

1.5.14. Risk of being trapped in a machine

Machinery must be so designed, constructed or fitted with a means of preventing an exposed person from being enclosed within it or, if that is impossible, with a means of summoning help.

507.

This requirement concerns certain machinery which the operator must enter (e.g. to clean certain food-processing machinery). The operator must be able to get out without outside help. The ideal solution is obviously a mechanism which obviates the need for the operator to enter machinery. Inspecting certain parts of machines, e.g. tannery or brewery installations, can be

81 A painting cabin can be defined as equipment for the application of powdery or liquid organic coating products, including some of following: ventilator, compensation air ducts, air filtration system, air cleaning system (pumps), air heating system, etc.

hazardous if measures are not taken. The presence of noxious gases (hydrogen sulphide, carbon dioxide, etc.) is dangerous.

The risk of being trapped can be avoided by providing manoeuvrable and unlockable exits from inside the machine (e.g. doors big enough to be opened from the inside, even if they have been locked from the outside).

508.

1.5.15. Risk of slipping, tripping or falling

Parts of the machinery where persons are liable to move about or stand must be designed and constructed to prevent persons slipping, tripping or falling on or off these parts.

509.

Guard rails and catwalks

The means of complying with this requirement, particularly as regards guard rails, staircases, ladders, etc., are being studied with a view to the adoption of standards. In the interim there are many national standards.

In the case of equipment used outdoors, the designer may need to take appropriate measures to prevent the accumulation of water, snow or other waste on passages used by operators.

Please refer also to requirement 1.3.4.

510.

1.6. Maintenance

1.6.1. Machinery maintenance

Adjustment, lubrication and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, these operations must be possible without risk (see 1.2.5).

In the case of automated machinery and, where necessary, other machinery, the manufacturer must make provision for a connecting device for mounting diagnostic fault-finding equipment.

Automated machine components which have to be changed frequently, in particular for a change in manufacture or where they are liable to wear or likely to deteriorate following an accident, must be capable of being removed and replaced easily and in safety. Access to the components must enable these tasks to be carried out with the necessary technical means (tools, measuring instruments, etc.) in accordance with an operating mode specified by the manufacturer.

511.

Extent of risks in maintenance operations

In modern machinery there are fewer and fewer accidents during production. The risks are now to be found in operations further down the line (learning, maintenance, control).

The first paragraph indicates that accidents can be prevented by ensuring that parts requiring maintenance are located outside danger zones and are accessible on the level (e.g. lubrication points located outside the housings within which the dangerous movements occur). If this is not possible, the parts in question must be accessible only when the dangerous movements have been disabled.

In choosing these means of access, the manufacturer must remember that maintenance operators need to take their toolboxes with them, which can often rule out vertical ladders or overly steep staircases, for example.

Failing that, he must at least provide for fallback modes to reduce risks to a minimum (slow movement, holding down button or pedal, jerky operation, etc.).

512.

1.6.2. Access to operating position and servicing points

The manufacturer must provide means of access (stairs, ladders, catwalks, etc.) to allow access in safety to all areas used for production, adjustment and maintenance operations.

513.

Standards on the dimensions of access, the resistance of parapets or handrails, the design of ladders and staircases are being prepared. In the meantime, national standards can apply in this case.

For certain very big machinery falling from a height is one of the main risks. Preventive measures for very large machines may be obligatory. Where the design of the machine provides for frequent action by the operator the manufacturer has to provide for safe and effective means of access. He cannot oblige the user to take such measures himself, which will only be breakdown and often dangerous solutions (use of suspended ladders, scaffolding of varying degrees of stability, etc.).

514.

1.6.3. Isolation of energy sources

All machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger exposed persons. In the case of machinery supplied with electricity through a plug capable of being plugged into a circuit, separation of the plug is sufficient.

The isolator must be capable of being locked also where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to exposed persons.

As an exception to the above requirements, certain circuits may remain connected to their energy sources in control, for example, to hold parts, protect information, light interiors, etc. In this case, special steps must be taken to ensure operator safety.

515.

Isolation of the energy source

The purpose of requirement 1.6.3 is to enable the user to isolate the machinery from its energy source(s) before carrying out maintenance, lubrication, cleaning, etc., thereby eliminating the risk of unexpected start-up, accidental electrical contacts, pressurized fluid jets, etc.

Providing a device to isolate energy sources is not an end in itself. It is only justified where it is necessary to prevent a risk. Isolation of the source of energy must not, of course, create a risk itself.

Standard EN 1037 covers the means of isolation and immobilisation regardless of the type of energy used. Electrical energy generally needs a disconnector equipped with pre-break contacts, an isolator switch or a circuit breaker with disconnection function. For hydraulic or pneumatic energy the isolation device will usually be a tap, a valve or a manual control distributor. The manufacturer must provide for dissipation of accumulated energy by including in the design means for discharging capacitors, bleeding accumulators and emptying compressed air reservoirs and pipes.

516.

Small machinery

In the case of small electric machinery of no more than 16 A and less than 3 kW section 5.3.2 of EN 60204-1 of 1992 permits the use of a plug for this isolation function. Higher intensities and powers can result in an electric arc if the plug is pulled out without interrupting the current beforehand, which is why specially designed devices are needed for this function, such as plugs with auxiliary pre-break contacts which guarantee isolation under safe conditions. For low-powered pneumatic machinery “quick release coupling” can also be used as a means of isolation. There is always the risk, however, of a third person plugging the machine back in without the operator’s knowledge. A good preventive measure would be to put the plug where the operator can see it.

On large machinery, it must be possible to lock the isolator.

The dissipation of energy remaining in the circuits of the machinery can cause a problem, particularly in the case of minor maintenance work on machinery with hydropneumatic accumulators which would take too long to recharge before restarting the machinery. In this case the designer can provide an isolation procedure which ensures the operator's safety without draining the accumulators.

517.

1.6.4. Operator intervention

Machinery must be so designed, constructed and equipped that the need for operator intervention is limited.

If operator intervention cannot be avoided, it must be possible to carry it out easily and in safety.

518.

Providing for intervention

Intervention by the operator to regulate the machine or to clean the work area may be a considerable cause of risk if such operations are frequent. As far as possible, manufacturers should design machinery to limit this type of intervention. The ideal situation is to limit them to a minimum number of essential operations. Manufacturers must provide the accessories needed for this kind of intervention (lighting, controls, etc.). It is very important for the intervention procedures to be clearly detailed in the instructions to ensure that operators do not improvise solutions which could prove dangerous. In the absence of instructions the manufacturer may be liable.

519.

1.6.5. Cleaning of internal parts

The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unblocking must also be possible from the outside. If it is absolutely impossible to avoid entering the machinery, the manufacturer must take steps during its construction to allow cleaning to take place with the minimum of danger.

520.

Cleaning

Requirement 1.6.5 applies the principle of safety incorporated into cleaning operations. If despite everything it is impossible to prevent, at the design stage, cleaning operations from being carried out by entering the likes of silos and tanks that have contained dangerous products. If this is not possible, the manufacturer must take every step to make for effective ventilation and emptying, surveillance of the atmosphere inside and, if necessary, an access control device to prevent operators from entering while there is still a hazard.

The standard EN 547 lays down access dimensions.

521.

1.7. Indicators

1.7.0. Information devices

The information needed to control machinery must be unambiguous and easily understood.

It must not be excessive to the extent of overloading the operator.

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

522.

"User friendliness" of the information

This requirement regarding the ergonomics of the information, as laid down earlier for control devices and software, is extended here to all the information needed to control the machinery. See requirements 1.2.2 and 1.2.8.

The last paragraph refers to automatic ventilation, drainage and other systems where a fault could endanger the health and safety of exposed persons, who must be informed immediately of the risk.

523.

1.7.1. Warning devices

Where machinery is equipped with warning devices (such as signals, etc.), 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 Directives concerning colours and safety signals must be complied with.

524.

Ergonomics of signs

Directive 92/58/EEC[82] lays down the minimum requirements for signs at the workplace to be used by employers in the EEA. It does not therefore address manufacturers directly.

The last paragraph of requirement 1.7.1, however, stipulates that manufacturers must comply with this Directive to make for uniformity of safety signs in the EEA. The "machinery" Directive requires only compliance with the technical principles concerning signs laid down in Directive 92/58/EEC, not the social obligations which can only be the responsibility of users (information and training of workers, for example).

The general provisions of this Directive concern the terminology of signs (symbols, pictograms), the types of signs, the interchanging and combining of signs, the effectiveness of signs and safety colours.

It distinguishes between warning signs, alarm signs, mandatory signs, fist-aid signs and information signs. The annexes to the Directive show the graphics of signs. Precise rules exist for the definition of acoustic and luminous signals. For example, an evacuation signal has to be continuous, and an intermittent luminous signal indicates greater danger than a continuous luminous signal.

525.

1.7.2. Warning of residual risks

Where risks remain despite all the measures adopted or in the case of potential risks which are not evident (e.g. electrical cabinets, radioactive sources, bleeding of a hydraulic circuit, hazard in an unseen area, etc.), the manufacturer must provide warnings.

Such warnings should preferably use readily understandable pictograms and/or be drawn up in one of the languages of the country in which the machinery is to be used, accompanied, on request, by the languages understood by the operators.

526.

82 Directive 92/58/EEC of 24 June 1992 (OJ No L 245, 26.08.92, p. 23)

This requirement recalls that pictograms should be used wherever possible. Only residual risks, i.e. risks that remain after all design-integrated safety measures have been exhausted, need the warnings referred to in 1.7.2.

Where pictograms are not available (ISO 7000), the information inscribed on the machinery must be in one of the languages of the country in which the machinery is to be used. The comments made on the translation of instructions are valid here.[83]

The user may ask the supplier for a translation of the warnings in the language of the operators. Providing a warning in a language which is not the language of the country of destination of the machine is governed by contract law and the free negotiation of that service. It is obviously preferable to ask for translations on ordering or when the specifications are drawn up.

The work "preferably" applies to the use of pictograms, but the rest of the requirement is compulsory.

527.

1.7.3. Marking

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

- ***name and address of the manufacturer,***
- ***EC marking,***
- ***designation of series or type,***
- ***serial number, if any,***
- ***year of manufacture.***

Furthermore, where the manufacturer constructs machinery intended for use in a potentially explosive atmosphere, this must be indicated on the machinery.

Machinery must also bear full information relevant to its type and essential to its safe use (e.g. maximum speed of certain rotating parts, maximum diameter of tools to be fitted, mass, etc.).

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

The interchangeable equipment referred to in Article 1(2), third subparagraph must bear the same information.

528.

(extract)
[1.7.3. Marking

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

- name and address of the manufacturer,
- EC marking,
- designation of series or type,

83 See comments on requirement 1.7.4(b) in Annex I

- serial number, if any,
- year of manufacture.

(...)]

529.

Legibility of marking

The way of affixing the marking is left to the discretion of the manufacturer provided that it is legible and indelible. Marking can be by ink jet, machining, a plaque, etc. “Indelible” must be interpreted realistically. Any marking is in itself erasable. It can be erased by machining. The requirement means resistance to normal erasure.

Machinery manufacturers often use engraved metal plates for the serial number and the manufacturer's address. It is best to use an equally tough support to show the “CE” marking. A simple sticker is not enough.

530.

Manufacturer's name

The machine must bear the name of the manufacturer. The declaration of conformity must also mention the name of the manufacturer and any representative of his. The manufacturer's name has to be interpreted in the broadest sense. It means the real name of the manufacturer or the name of the apparent manufacturer. It may be the mark of a distributor if the machine is sold under distributor’s mark. The manufacturer's name may be the same as the user’s where the latter makes a machine for his own use or puts together several machines.

The “machinery” Directive does not require indication of the manufacturer's name so as to know the real manufacturer's identification. This desire for traceability is enshrined in other regulations. The aim is simply to identify the person responsible for placing the machine on the market.

That said, anyone distributing or purchasing machinery cannot delete the name of a manufacturer without taking precautions. Replacing a trademark without the agreement of the original manufacturer is akin to counterfeiting in most Member States.

Manufacturer's ”name” should also mean the manufacturer's company name or trademark. It is not a question of his actual name. The Directive leaves it free to choose between trademark and company name if there is a difference. The address must be shown on the marking. This address can be simplified if there is not really enough room on small machines, as long as the manufacturer can always be identified. In any event, the address on the plaque must be sufficient for mail to reach the company.

531.

Serial number

The number of the machine allotted by the manufacturer has to be found on the machine. This is a common rule in the industry. The choice of number is entirely free. The important thing is to be able to identify with certainty the model of the machine. It may be a number as such (in figures) or codes with letters. However, the Directive does not require an individual number to be given to each machine, although identification of the series or type is obligatory.

532.

Year of manufacture

The year of manufacture must always be shown separately, even if the date of the machine appears in the registration number.

A distinction can be made between
- the year of design during which the design office started work,
- the year of manufacturing during which the machine was put into production,
- the year of marketing during which the machine was first placed on the market, e.g. with a distributor and the year during which the machine was first made available for use in the EEA.

Legally speaking, liability of the manufacturer begins when the machine is first placed on the market.

The "machinery" Directive does not set out to guarantee customer information on the year of the model sold. While a legitimate concern, this is a matter for ordinary contract law. The objective of marking the year is to determine the responsibility of the manufacturer in terms of the technical regulations in force.

A certain latitude exists in fixing the year of manufacture. Literally speaking, the year of manufacture should coincide with the end of production of the machine. But where does the end of production begin exactly? In practice, manufacturers can make the date of manufacture the same as the date of first marketing.

It is doubtlessly preferable that the two dates should coincide. It is also preferable that the date on the marking is the same as on the declaration of conformity.

533.

(extract)
[1.7.3. Marking
(...)

Furthermore, where the manufacturer constructs machinery intended for use in a potentially explosive atmosphere, this must be indicated on the machinery.

Machinery must also bear full information relevant to its type and essential to its safe use (e.g. maximum speed of certain rotating parts, maximum diameter of tools to be fitted, mass, etc.).

(...)]

534.

Explosive atmosphere

Specific markings provided for by the "ATEX" Directive apply here.

Information on safe usage is sometimes indispensable to prevent accidents and is thus obligatory. For grinding machines, for example, the speed of rotation and/or the maximum diameter of the grinding wheel must be known to the user because the choice of grinding wheel depends on it (risk of breaking). The fact that the instructions contain this information was not considered sufficient by the parties involved in drawing up the Directive.

535.

(extract)

[1.7.3. Marking
(...)

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

(...)]

536.

Machine parts handled

The aim is to mark parts which have to be regularly handled when the machine is in use. The operator should not be surprised by the weight of the part to be lifted. These parts are often tools (milling machine head). Marking must enable the operator to choose suitable lifting equipment for the handling operation. In special cases it may be useful to mention the position of jack points.

537.

(extract)
[1.7.3. Marking
(...)

The interchangeable equipment referred to in Article 1(2), third subparagraph, must bear the same information.]

538.

Interchangeable equipment

Interchangeable equipment is like machinery. It must therefore bear all the markings of a machine. The previous paragraph (relating to handling) applies in particular to interchangeable parts which can alter the centre of gravity of the machine to which they are be attached. Marking is essential if there is a risk of overturning.

539.

1.7.4. Instructions

(a) All machinery must be accompanied by instructions including at least the following:

- ***a repeat of the information with which the machinery is marked, except the serial number, (see 1.7.3), together with any appropriate additional information to facilitate maintenance (e.g. addresses of the importer, repairers, etc.),***
- ***foreseen use of the machinery within the meaning of 1.1.2(c),***
- ***workstation(s) likely to be occupied by operators,***
- ***instructions for safe:***
  - ***putting into service,***
  - ***use,***
  - ***handling, giving the mass of the machinery and its various parts where they are regularly to be transported separately,***
  - ***assembly, dismantling,***
  - ***adjustment,***
  - ***maintenance (servicing and repair),***
- ***where necessary, training instructions,***

- *where necessary, the essential characteristics of tools which may be fitted to the machinery.*

Where necessary, the instructions should draw attention to ways in which the machinery should not be used.

(b) The instructions must be drawn up in one of the Community languages by the manufacturer or his authorized representative established in the Community. On being put into service, all machinery must be accompanied by a translation of the instructions in the language or languages of the country in which the machinery is to be used and by the instructions in the original language. This translation must be done either by the manufacturer or his authorized representative established in the Community or by the person introducing the machinery into the language area in question. By way of derogation from this requirement, the maintenance instructions for use by the specialized personnel employed by the manufacturer or his authorized representative established in the Community may be drawn up in only one of the Community languages understood by that personnel.

(c The instructions must contain the drawings and diagrams necessary for putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the machinery, and all useful instructions in particular with regard to safety.

(d) Any literature describing the machinery must not contradict the instructions as regards safety aspects. The technical documentation describing the machinery must give information regarding the airborne noise emissions referred to in (f) and, in the case of hand-held and/or hand-guided machinery, information regarding vibration as referred to in 2.2.

(e) Where necessary, the instructions must give the requirements relating to installation and assembly for reducing noise or vibration (e.g. use of dampers, type and mass of foundation block, etc.).

(f) The instructions must give the following information concerning airborne noise emissions by the machinery, either the actual value or a value established on the basis of measurements made on identical machinery:

- *equivalent continuous A-weighted 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,*
- *peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 mPa),*
- *sound power level emitted by the machinery where the equivalent continuous A-weighted sound pressure level at workstations exceeds 85 dB(A).*

In the case of very large machinery, instead of the sound power level, the equivalent continuous sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonized standards are not applied, sound levels must be measured using the most appropriate mode for the machinery.

The manufacturer must indicate the operating conditions of the machinery during measurement and what modes have been used for the measurement.

Where the workstation(s) are undefined or cannot be defined, sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at height of 1,60 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

(g) ***If the manufacturer foresees that the machinery will be used in a potentially explosive atmosphere, the instructions must give all the necessary information.***

(h) ***In the case of machinery which may also be intended for use by non-professional operators, the wording and layout of the instructions for use, whilst respecting the other essential requirements mentioned above, must take into account the level of general education and acumen that can reasonably be expected from such operators.***

540.

(extract)
[1.7.4. Instructions

(a) All machinery must be accompanied by instructions including at least the following:

- a repeat of the information with which the machinery is marked, except the serial number, (see 1.7.3), together with any appropriate additional information to facilitate maintenance (e.g. addresses of the importer, repairers, etc.),
- foreseen use of the machinery within the meaning of 1.1.2(c),
- workstation(s) likely to be occupied by operators,
- instructions for safe:
  - putting into service,
  - use,
  - handling, giving the mass of the machinery and its various parts where they are regularly to be transported separately,
  - assembly, dismantling,
  - adjustment,
  - maintenance (servicing and repair),
- where necessary, training instructions,
- where necessary, the essential characteristics of tools which may be fitted to the machinery.

Where necessary, the instructions should draw attention to ways in which the machinery should not be used.]

(...)

541.

Primary importance of the instructions

This is an important requirement in terms of safety and legal aspects, which explains why it is so detailed. It must be said, first of all, that all product manufacturers and all service providers have the general obligation of safety and information vis-à-vis their customers under ordinary contract law. The "machinery" Directive merely builds on these principles to formulate concrete applications related to machinery. Instructions provide a kind of "justice of the peace" between the manufacturer and the user, often helping to clarify and share responsibilities. They often play an all-important role in disputes.

542.

General content of the information required by the "machinery" Directive

Manufacturers must supply customers with the information necessary for normal use of the product.

543.

Recommendations and warnings

A distinction is generally made between several types of information provided by the manufacturer. Information provides the basics on the product. A recommendation is information which guides the choice of the customer. And a warning alerts the customer to a snag, a restriction on use, a problem or even a danger and its consequence. The information owed by the manufacturer is information which is objectively "useful" to the customer.

544.

Usefulness of the information

The "usefulness" of the information must be viewed objectively against the capacity for comprehension that the manufacturer can rightfully expect of potential users.[84]

545.

Description of product

Information deals above all with the quality and properties of the product. It is therefore purely descriptive. Information then also analyses the "dynamic" aspects of machinery from first installation to final dismantling, if need be.

546.

Analysis from "cradle to grave"

An analysis of certain stages of the life cycle of a product is a useful way of defining the contents of the instructions. These are mainly the stages of use, maintenance, elimination and destruction. The "machinery" Directive requires only that this information properly handles aspects relating to safety.

547.

Informing the customer of peripheral measures

At this first basic level of information the customer should be informed of any "peripheral measures" that have to taken to operate the machinery safely. The "machinery" Directive requires the provision of peripheral information only insofar as it affects safety of use. Other information is governed by ordinary contract law and fair trading. Some machines require

84 Cf. in particular requirement 1.7.4 (h) of Annex I (points 567 and 568)

prior administrative authorization, e.g. under environmental considerations. It may be useful to inform the customer of this.

548.

Limits on the obligation to provide information

The “machinery” Directive does not impose any special information concerning the performance of the product. Requirement 1.7.4 cannot therefore be invoked to solve an information problem which does not have any link with safety.

549.

Does the manufacturer have to know everything?

Whether or not a manufacturer ought to have mentioned this or that information in the instructions depends on whether he knew that information. If he had the information did he have to pass it on? Was this information objectively useful and essential to the user for safe operation of the machine?

If the seller did not know the information, did he have the right not to know it? Ignorance of the seller on a given aspect of his product is generally considered legitimate if, in the state of the art at the time of the drafting of the instructions, it was impossible for him to know.

The manufacturer is not required to foresee the unforeseeable and, in particular, unknown risks which appear during the industrial development of the product. On the other hand, the manufacturer is obliged to search for information on his product corresponding to the state of the art and good engineering practice of his trade. He must in particular draw the conclusions from the knowledge to which he becomes party.

Manufacturers are not obliged to provide their customers with information of an economic nature, such as the market situation and competitors' prices.

550.

Can the buyer be unaware of everything?

Users obviously do not have the unlimited right to know everything about the machine that is sold to them. The obligation to provide instructions under the “machinery” Directive cannot be used as a pretext to force information which would normally be the subject of a specific service (consultancy or know-how transfer contract).

To determine the content of instructions and the “usefulness” of including information, the question should also be asked as to what the buyer is deemed to know, or, in other words, what he does not have the right not to know. The more the buyer is “in the trade” the less he has the right not to know. Whatever the case, a buyer, whether as an individual or a professional, does not have the right not to know the law. "Ignorance of the law is no excuse". Where the law subjects a machine to restrictions of use, e.g. banning the use of concrete breakers in the middle of town at three in the morning, the buyer is deemed to know this. The manufacturer is not obliged to remind users of their legal obligations which, after all, can vary locally.

Professional users are expected to know the regulations concerning health and safety at work. The European regulation governing the use of machinery is particularly important in this respect. The manufacturer should, of course, indicate the existence of Directive 89/655/EEC, as amended, in the instructions, but, by law, this is not necessary as compliance with the

national transpositions of this Directive on the part of professional users in the EEA is as of right.

Professional users do not have the right not to know the codes of practice of their trades. Compliance with good engineering practice of the user trade is a precondition for the use of some machines. An agri-foodstuffs company never uses simple wood saws to cut frozen meat, for example. The “machinery” Directive does not ask manufacturers to explain to their customers their codes of practice.

On the other hand, attention must be drawn to known ways in which machinery should not be used.

551.

Transmission of information

The “machinery” Directive requires instructions to be transmitted. Some manufacturers who usually sell machinery by catalogue through distributors merely show this information in the catalogue. This is a useful but inadequate measure in terms of the “machinery” Directive. A document must be physically transmitted to each buyer of the machine. This rule is based on common law and exists in most of the Member States.

552.

Proof of transmission

It is generally considered up to the customer who did not receive the instructions to prove that they were not transmitted and not the reverse. Some manufacturers, however, take the trouble to prove transmission of the instructions. Others have the delivery note countersigned by the customer as proof that he has received the instructions. The latter are sometimes attached to this note. The institution by the manufacturer of a formal procedure for the inclusion of the instructions (quality assurance) can make it safe to assume that the instructions have been transmitted. Electronic data interchange is now well established between professionals. The “machinery” Directive is not opposed to instructions being transmitted in this form, but this should be covered by a specific clause in the contract so as to avoid any dispute. Compatibility must be guaranteed between the software used by the manufacturer or his representative and the software used by the buyer.

It is the responsibility of the buyer to ensure the physical availability of the instructions for the end-user. The manufacturer can draw the attention of his customer to this responsibility.

553.

Distributors and suppliers

When a machine is sold through a distributor, the manufacturer's obligation consists of transmitting the instructions to the distributor along with the machine. The obligation of the distributor is to pass on these instructions to the end user along with the machine. The distributor does not have to look for technical information on the machine and often does not have the capacity. On the other hand, if the intermediary, e.g. a supplier, adds to or modifies the technical features of the machine, he must add to or amend the initial information. He obviously does so on his own responsibility and does not commit the manufacturer. Manufacturers may include in their distribution or commercial agency contract the obligation to pass on the instructions to the end user.

554.

Several levels* of *instructions

There is no reason not to separate, in the instructions, the part which has to stop at the supplier and the part which goes to the end user. The instructions given to the end user might also be made up of several separate parts. An operator working on a machine probably does not need to have all the instructions.

555.

Comprehension of information by the customer

While the obligation to draft and transmit instructions is an obligation regarding an end, the obligation to write comprehensible instructions can only be an obligation regarding the means. The comprehension of instructions by a customer obviously depends on his capacity to understand them. This capacity will be greater if the machine is meant to be used by trained professionals rather than the general public.

556.

Instructions for complex assemblies

The manufacturer usually does not manufacture all the components and parts of his machinery, particularly in the case of complex assemblies. Certain components or parts, however, may need instructions regarding the correct use of the machinery, its maintenance, repair, adjustment, etc. The manufacturer is required to obtain all the necessary information from his suppliers and to incorporate it in a logical manner in his own instructions. It is generally not sufficient to juxtapose the various sets of information.

The content of the instructions will vary according to the machine. The more complex the machine and the newer the machine, the more care needs to be taken with the information.

557.

(extract)
[1.7.4. Instructions
(...)

(b) The instructions must be drawn up in one of the Community languages by the manufacturer or his authorized representative established in the Community. On being put into service, all machinery must be accompanied by a translation of the instructions in the language or languages of the country in which the machinery is to be used and by the instructions in the original language. This translation must be done either by the manufacturer or his authorized representative established in the Community or by the person introducing the machinery into the language area in question. By way of derogation from this requirement, the maintenance instructions for use by the specialized personnel employed by the manufacturer or his authorized representative established in the Community may be drawn up in only one of the Community languages understood by that personnel.
(...)

558.

Communication of "original" instructions

The "original" instructions are the instructions on which the manufacturer decides to accept liability. These instructions are definitive. The "original" instructions must come and go with the machine. The manufacturer must draw up these "original" instructions in an official language of the European Union. The "original" instructions are not therefore necessarily

written in the language of the manufacturer. The manufacturer may draw up “original” instructions in several languages. It is recommended that the manufacturer indicates "original" instructions on the versions for which he accepts liability in order to distinguish them from translations which are not definitive.

559.

Instructions have to be translated when put in service

In practice, the translation will be done by the person who introduces the machine into the linguistic area (manufacturer, distributor, importer, user where he is an importer, etc.). Manufacturers are advised to settle this question explicitly in their sales contracts and/or in their offers.

Responsibility for translation in this area is usually the manufacturer’s, the distributor’s or the importer’s, but not the end-user’s.

A user who imports a machine directly performs an act of marketing and may be likened to the manufacturer. He introduces a machine into his linguistic area and must therefore attend to translation of the instructions if the original manufacturer did not do so.

560.

(extract)
[1.7.4. Instructions
(...)

(c) The instructions must contain the drawings and diagrams necessary for putting into service, maintenance, inspection, checking of correct operation and, where *appropriate*, repair of the machinery, and all useful instructions in particular with regard to safety.

(...)]

561.

Description of operating procedures

The manufacturer has to explain to the user how to carry out start-up operations, servicing, maintenance and repairs. It is for the manufacturer to say which of these operations can be carried out by the user. The manufacturer may provide explicitly that some of these operations, especially repairs, should be his exclusive responsibility. This is a technical and/or commercial decision the manufacturer takes for technical (e.g. adjustment to the micron), safety or economic reasons. The “machinery” Directive and the general rules of fair trading require only that information essential to normal and safe operation be transmitted. For certain high-tech machinery which may pose serious safety problems where repairs are concerned the manufacturer might indicate to the customer that he reserves the right to exclusive maintenance. Reserving the right for certain jobs to be performed by specific persons must be written explicitly into the instructions and contracts.

562.

(extract)
[1.7.4. Instructions
(...)

(d) Any literature describing the machinery must not contradict the instructions as regards safety aspects. The technical documentation describing the machinery must give information regarding the airborne noise emissions referred to in (f)

and, in the case of hand-held and/or hand-guided machinery, information regarding vibration as referred to in 2.2.

(...)]

563.

Commercial documents

The aim of this requirement is to avoid contradictions between the commercial documents and the instructions. It is not obligatory to show the level of noise in advertisements. However, it is in the manufacturer's interest to point out that the noise level stated is the noise measured on an equivalent machine using a given test code and a given measuring method. Noise levels can in fact vary from one model to another. The customer might expect that the noise level of the model supplied is exactly as shown in the commercial documents.

564.

Technical documentation

The technical documentation referred to in point 1.7.4 (d) is more detailed than a simple advertisement. It is not, however, the machine's instructions. It will be a data sheet or a page of a catalogue detailing the technical features of the product in order to guide the choice of the buyer (performance, size, pressure, power, etc.). The Directive stipulates that noise must be one of the parameters presented and that vibration information must also be presented for portable and mobile machinery.

565.

(extract)
[1.7.4. Instructions

(...)

(e) Where necessary, the instructions must give the requirements relating to installation and assembly for reducing noise or vibration (e.g. use of dampers, type and mass of foundation block, etc.).

(...)]

566.

The instructions must indicate any compensatory measures to be taken regarding installation or assembly in order to limit the noise or vibration of the machine. These measures supplement design measures and may be, for example, indication of the size of the masonry block to accommodate the machine, the link components (silent block) recommended, etc.

567.

(extract)
[1.7.4. Instructions

(...)

(f) The instructions must give the following information concerning airborne noise emissions by the machinery, either the actual value or a value established on the basis of measurements made on identical machinery:

- equivalent continuous A-weighted 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,

- peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 mPa),
- sound power level emitted by the machinery where the equivalent continuous A-weighted sound pressure level at workstations exceeds 85 dB(A).

In the case of very large machinery, instead of the sound power level, the equivalent continuous sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonized standards are not applied, sound levels must be measured using the most appropriate mode for the machinery.

The manufacturer must indicate the operating conditions of the machinery during measurement and what modes have been used for the measurement.

Where the workstation(s) are undefined or cannot be defined, sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at height of 1,60 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

(...)]

568.

Paragraph (f) requires information concerning noise emissions by the machinery. As mentioned in the comments on section 1.5.8, the Directive does not lay down limit values.

The noise level communicated is the level measured on the machine itself or on an equivalent machine. In the case of a unit machine the level will be that of the model supplied. The manufacturer indicates not only the result of the measurement but also (plus or minus) the uncertainty of measurement of the method used.

The aim of including the noise level in the instructions is to give to the user comparative data to help in the choice of machine. The information in the instructions can also help to decide where to put the machine.

Sound pressure means noise as perceived by the ear of the operator. Sound power is a value which measures the noise level emitted by the machine irrespective of any physiological aspects.

It is essential for all information concerning noise to be accompanied by a statement of the method by which the information was obtained. The methods laid down in European standards will be used once the relevant standards have been adopted. It is not sufficient, for example, to say that the values were obtained by measurement over a reflective plane. The conditions of operation during the measurement must also be given (measuring the noise emissions of machinery when stopped or ticking over does not generally comply with the requirement). European standards have a very important role to play in laying down measuring conditions (reliability, repeatability and reproducibility) to make fair comparisons between machinery of various origins possible.

Large machinery or complex installations built at the customer's site obvious measuring problems. The Directive foresees that this will be on sites specified by the manufacturer and that these will generally be places occupied by operators.

For machinery without a permanent workstation or no workstation at all, noise is evaluated on the assumption that a person is on the machine platform or near it.

Limit values for the sound power level of certain types of construction machinery are laid down in the following specific Directives: 84/533/EEC[85], as amended (compressors), 84/534/EEC[86], as amended (tower cranes), 84/535/EEC[87], as amended (welding generators), 84/536/EEC[88], as amended (power generators), 84/537/EEC[89], as amended (concrete-breakers and picks), 84/538/EEC[90], as amended (lawnmowers), and 86/662/EEC[91], as amended (excavators, bulldozers, loaders and excavator-loaders). These Directives require the maximum sound power level "guaranteed" by the manufacturer to be marked on the machinery. In general, manufacturers simply mark the limit value laid down in the Directive, after checking that the machinery complies therewith, rather than the value actually measured. The "machinery" Directive, however, requires the instructions to give the value actually measured on the machinery in the case of unit machines or on identical machinery in the case of series machines. These Directives are currently the subject of a draft revision designed to generalize their application to all machinery used outdoors.

For the domestic appliances the method of measurement must be as laid down in Directive 86/594/EEC[92].

569.

(extract)
[1.7.4. Instructions
(...)

(g) If the manufacturer foresees that the machinery will be used in a potentially explosive atmosphere, the instructions must give all the necessary information.

(...)]

570.

A machine intended to be used in a potentially explosive atmosphere is generally governed, as seen in the comments on requirement 1.5.7, by Directive 94/9/EC, the "ATEX" Directive. This Directive therefore takes over from the "machinery" Directive for procedural and

85 Directive 84/533/EEC of 17 September 1984 (OJ No L 300, 19.11.84, p.123), as amended by Directive 85/406/EEC (OJ No L 233, 30.08.85, p. 11)
86 Directive 84/534/EEC of 17 September 1984 (OJ No L 300, 19.11.84, p.130), as amended by Directive 87/405/EEC (OJ No L 230, 08.08.87, p. 60)
87 Directive 84/535/EEC of 17 September 1984 (OJ No L 300, 19.11.84, p.142), as amended by Directive 85/407/EEC (OJ No L 233, 30.08.85, p. 16)
88 Directive 84/536/EEC of 17 September 1984 (OJ No L 300, 19.11.84, p.149), as amended by Directive 85/408/EEC (OJ No L 233, 30.08.85, p. 18)
89 Directive 84/537/EEC of 17 September 1984 (OJ No L 300, 19.11.84, p.156), as amended by Directive 85/409/EEC (OJ No L 233, 30.08.85, p. 20)
90 Directive 84/538/EEC of 17 September 1984 (OJ No L 300, 19.11.84, p.171), as amended by Directives 87/252/EEC (OJ No L 117, 05.06.87, p. 22) and 88/180/EEC (OJ No L 81, 26.03.88, p. 69)
91 Directive 86/662/EEC of 22 December 1986 (OJ No L 384, 31.12.86, p.1), as amended by Directives 89/514/EEC (OJ No L 253, 30.08.89, p. 35) and 95/27/EC (OJ No L 168, 18.07.95, p. 14)
92 Directive 86/594/EEC of 1 December 1986 (OJ No L 344, 06.12.86, p.24)

technical aspects to do with the risk of explosion arising from using the machine in a potentially explosive atmosphere.

It is the manufacturer who decides to target the machine for operation in this type of atmosphere, and this decision must be stated quite clearly in the instructions and on the machine. Moreover, indication of potentially explosive atmospheres in which the machine can be used without risk is very important and certainly has to be mentioned. It is also in the manufacturer's interest to include it unequivocally in the contract documents.

The "CE" marking must also be supplemented by the specific marking of the "ATEX" Directive.[93]
Manufacturer liability cannot be invoked if a machine not intended to be used in a potentially explosive atmosphere is put to use in one by the user.

Once the machine is explicitly intended by the manufacturer to be used in a potentially explosive atmosphere, how to use it, any warnings and how not to use it must be contained in the instructions.

571.

(extract)
[1.7.4. Instructions
(...)

(h) In the case of machinery which may also be intended for use by non-professional operators, the wording and layout of the instructions for use, whilst respecting the other essential requirements mentioned above, must take into account the level of general education and acumen that can reasonably be expected from such operators.]

572.

How information concerning a product is presented depends on several factors. The more complex a product is, the more information which has to be provided. The newer the product and the newer the technology, the more explanations have to be given with care. A court decision back in 1894 in one of the Member States found a bicycle manufacturer guilty of not having given instructions on how to use the handlebars! In the final analysis, the main thing is the capacity of the end-user to understand how the product works and, in particular, what precautions have to be taken when using it.

The manufacturer is obviously not required to foresee the capacity of every user to understand! The manufacturer has to consider the characteristics of the customer sector as "reasonably" foreseeable. It is generally thought that ordinary consumers have more limited technical capabilities than professional users.

It also has to be stressed that "consumers" have practically no regulatory obligation as far as using machinery is concerned whereas professionals working in the trade in the EEA generally have to comply with Directive 89/655/EEC, as amended. In most Member States consumers must, however, adhere to elementary rules about disturbing neighbours. It is therefore in the interest of manufacturers of machinery intended totally or partly for general public to draft instructions which are clear, complete and precise from the point of view of safety.

93 See comments on requirements 1.5.7 and 1.7.3

It should be remembered that negligence on the part of the injured person could be a major factor in lessening the civil and penal liability of the manufacturer. Failure to follow carefully constructed instructions may, in certain cases, amount to negligence on the part of the injured person.

The ISO-IEC guide[94] to drafting instructions for products intended for the general public is warmly recommended.

94 ISO-IEC Guide No 37 - Instructions for the use of products of interest to consumers

2 ESSENTIAL HEALTH AND SAFETY REQUIREMENTS *FOR CERTAIN CATEGORIES OF MACHINERY*

573.

2.1. Agri-foodstuffs machinery

Where machinery is intended to prepare and process foodstuffs (e.g. cooking, refrigeration, thawing, washing, handling, packaging, storage, transport or distribution), it must be so designed and constructed as to avoid any risk of infection, sickness or contagion and the following hygiene rules must be observed:

(a) materials in contact, or intended to come into contact, with the foodstuffs must satisfy the conditions set down in the relevant Directives. The machinery must be so designed and constructed that these materials can be clean before each use;

(b) all surfaces including their joinings must be smooth, and must have neither ridges nor crevices which could harbour organic materials;

(c) assemblies must be designed in such a way as to reduce projections, edges and recesses to a minimum. They should preferably be made by welding or continuous bonding. Screws, screwheads and rivets may not be used except where technically unavoidable;

(d) all surfaces in contact with the foodstuffs must be easily cleaned and disinfected, where possible after removing easily dismantled parts. The inside surfaces must have curves of a radius sufficient to allow thorough cleaning;

(e) liquid deriving from foodstuffs as well as cleaning, disinfecting and rinsing fluids should be able to be discharged from the machine without impediment (possibly in a 'clean' position);

(f) machinery must be so designed and constructed as to prevent any liquids or living creatures, in particular insects, entering, or any organic matter accumulating in areas that cannot be cleaned (e.g. for machinery not mounted on feet or casters, by placing a seal between the machinery and its base, by the use of sealed units, etc.);

(g) machinery must be so designed and constructed that no ancillary substances (e.g. lubricants, etc.) can come into contact with foodstuffs. Where necessary, machinery must be designed and constructed so that continuing compliance with this requirement can be checked.

Instructions

In addition to the information required in section 1, the instructions must indicate recommended products and methods for cleaning, disinfecting and rinsing (not only for easily accessible areas but also where areas to which access is impossible or

inadvisable, such as piping, have to be cleaned in situ).

574.

Field of application:

These requirements relate to all agri-foodstuffs equipment. Where a machine is liable to come into contact with products intended for consumption, this is an agri-foodstuffs machine. It must therefore comply with the rules mentioned under this requirement, irrespective of the nature or presentation of the product, i.e. solid, liquid (fruit juice, wine, milk, etc.) or even powder (powdered milk).

All machines in the agri-foodstuffs chain are concerned and taken into account in respect of all the functions which they perform:

- storage (bottle, cardboard package, etc.);
- handling (conveyor belt, etc.);
- mechanical conversion (ham-slicer, meat chopper, etc.);
- thermodynamic conversion (cooking vessel, cooler, freezer, etc.).

In order for the products to maintain their hygienic quality, the agri-foodstuffs machines must therefore preserve the food from any contamination arising from:

- the environment (dust, insects, etc.);
- the machine itself (oils, corrosion products, etc.).

Many European standards are under preparation:

- from a general standpoint, in order to define standards presenting the principles to be complied with;
- from a specific standpoint with respect to the professions involved, in order to draw up C-type standards (for bakers, butchers, delicatessen dealers, milk producers, etc.) allowing production of machines which are presumed to comply with the "machinery" Directive.

It is important to recall that Article 2 (1) of the Directive lays down that the machines must not compromise the safety and health of individuals or of pets and goods where they are used correctly. This means that machines intended for producing pet food must comply with the "machinery" Directive, including the essential requirements under this Point 2.1. In addition, any food product, whether stored, processed or converted in a machine, must not be contaminated or polluted, but must preserve all its properties and characteristics for subsequent use. This is essential if the product is to retain its market value.

The milk sector provides a good example of the points to be considered and may serve as the basis for other examples.
An on-farm milk cooler receiving milk which is newly milked must be able to generate cooled milk which can be used by the dairy industry to manufacture, as required:

- milk for consumption, such as whole milk, semi-skimmed milk, thermized milk, sterilized milk, etc.;
- yoghurts, creams, etc.;
- fresh cheese, cooked cheese, pressed cheese, etc.;
- butter.

These manufactured products must be hygienic and have no unpleasant taste or unpleasant smell, and allow normal production.

In the milk sector, it is therefore accepted that on-farm coolers must:

- preserve the milk from any additional contamination (corrosion products, oil, dust, insects, etc.);
- quickly cool all of the milk coming from milking to the preservation temperature (for the highest-performance equipment, 4°C achieved in less than 2 hours at an external temperature of 38°C) so as to limit the development of initial bacterial flora;
- be well insulated in order to limit temperature rises in the milk in the event of loss of electric power (for the highest-performance equipment, a temperature rise of less than 3°C at any point in the milk, stored at 4°C without stirring and without cooling for 12 hours, at an external temperature of 38°C);
- avoid any physical deterioration of the milk, meaning:
  . no ice formation during cooling, whatever the volume of the milk contained, for ambient temperatures greater than 5°C;
  . effective stirring without foaming and without churning (homogeneous fat at 0.1 g/100 g of sample after 2 minutes of stirring of milk stored at 4°C and left to stand for 1 hour);
- be equipped with an automatic washing device, preventing dirtying, microbial contamination and chemical contamination. Washability test carried out on a standard contaminant, making it possible to verify that:
  . there is no trace of any soiling on the internal walls;
  . residual microbial contamination is less than 10^5 colony-forming organisms per square metre of internal surface;
  . the concentration of detergent diluted in the final rinsing water after washing the milk tank is less than 0.2%.

575.

Materials

With regard to materials, the designer must comply with Directive 89/109/EEC on "Materials and articles intended to come into contact with foodstuffs".[95] This Directive provides for a permanent update of the list of materials and it is possible to obtain information from the Commission where there is any doubt as regards the food-grade quality of a material. In general, stainless steels are materials whose properties allow compliance with the food hygiene requirement.

576.

Surfaces

The standards currently under preparation will be of assistance to the designer, especially in order to define the meaning of a "smooth" surface (Paragraph b) and the meaning of "easily" (in the expression "easily cleanable"); on the other hand, "which can be easily dismantled" simply means that something "can be dismantled without the use of a tool or with a standard tool" (for example, a screwdriver).

Pending the publication of these European standards, the surface condition can be measured with the help of surface comparison samples in accordance with ISO 2632. The surface of zones in direct contact with food must be smoother than for splash zones.

95 Directive No 89/109/EEC of 21 December 1988 (OJ No L 40, 11.02. 89, p. 38)

Manufacturers must also comply with Directives 89/109/EEC and 90/128/EEC concerning plastic materials and articles intended to come into contact with food.[96]
The final paragraph stresses the duty of the manufacturer to indicate in the instructions the cleaning methods and products. In the case of cleaning products, the manufacturer must not merely mention a product brand but must define the products by their physico-chemical characteristics and any contra-indications so that the person using the machine can obtain them easily and in all circumstances.

577.

2.2. Portable hand-held and/or hand-guided machinery

Portable hand-held and/or hand-guided machinery must conform to the following essential health and safety requirements:

- ***according to the type of machinery, it must have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size and arranged to ensure the stability of the machinery under the operating conditions foreseen by the manufacturer,***

- ***except where technically impossible or where there is an independent control, in the case of handles which cannot be released in complete safety, it must be fitted with start and stop controls arranged in such a way that the operator can operate them without releasing the handles,***

- ***it must be designed, constructed or equipped to eliminate the risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,***

- ***portable hand-held machinery must be designed and constructed to allow, where necessary, a visual check of the contact of the tool with the material being processed.***

Instructions

The instructions must give the following information concerning vibrations transmitted by hand-held and hand-guided machinery:

- ***the weighted root mean square acceleration value to which the arms are subjected, if it exceeds 2,5 m/s² as determined by the appropriate test code. Where the acceleration does not exceed 2,5 m/s², this must be mentioned.***

If there is no applicable test code, the manufacturer must indicate the measurement methods and conditions under which measurements were made.

578.

This requirement refers both to portable machines and non-portable machines whose use requires manual guiding of the work tool. This requirement does not deal with the risks associated with the mobility of the machines.

96 Directive No 90/128/EEC of 23 February 1990 (OJ No L 75, 21.03. 90, p. 21), as amended by Directives Nos 92/39/EEC (OJ No L 168, 23.06. 92, p. 21) and 93/9/EEC (OJ No L 90, 14.04 93, p. 26)

We have already mentioned, in the comments on 1.3.1, the requirement of stability of the machine during its operation which is also contained in the present requirement. For some portable machines (circular saws, planes, etc.), the stability of the machine depends on the support area. The size of this area and the manner in which the handles are positioned are solutions to this problem.
The designer must bring all his attention to the means of holding and to their suitability for the weight of the machine. Standards relating to ergonomics will provide information on the weight thresholds which may be taken into account by the manufacturer.
The third indent draws the designer's attention to the design of the control devices. For example, if the machine is put down it must not be possible, whatever the position it adopts, for its weight to activate the starter. This may require, in the case of a trigger-type control device, the installation of a protective guard; however, there are many other possibilities.
This indent also contains another important requirement, namely, that the machine must not be able to continue to operate when the user releases the gripping means. This requirement leads in most cases to eliminating the button allowing the machine to continue rotating after releasing the trigger; this is because, in this case, it would be possible to put the machine down while allowing it to operate, which is counter to the requirement. The "hold-on" button must be connected to a detector which senses the presence of one's hand on the gripping member, this being a sophisticated technical approach.
Other compensatory arrangements are possible, but they will require a great deal of attention. The easiest solution is therefore to provide a trigger which is light enough not to be a nuisance to the operator, who will have to hold it in throughout his work.
Where the portable machine is used as a machine fixed in a jig (for example, a recessing machine used upside down as a mini-shaper or mini-router), it is this jig which has to keep the trigger pressed in. In this case, it will be essential to provide the jig with an on/off switch which will be connected to the electric supply of the portable machine.
As in the case of noise levels, the Directive does not lay down limit values for vibration. However, the CEN memorandum (CEN/CR 1100) provides, with very careful wording, that standards could indicate the average levels achieved at a given date for a type of series-manufactured machinery (where appropriate by power category, technological type, etc.), but these standards would have to clearly state the test codes used and the measuring conditions (materials worked, rate of work, etc.).

579.

2.3. Machinery for working wood and analogous materials

Machinery for working wood and machinery for working materials with physical and technological characteristics similar to those of wood, such as cork, bone, hardened rubber, hardened plastic material and other similar stiff material must conform to the following essential health and safety requirements:

(a) the machinery must be designed, constructed or equipped so that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench the latter must be sufficiently stable during the work and must not impede the movement of the piece;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of pieces of wood, it must be designed, constructed or equipped to eliminate this ejection, or, if this is not the case, so that the ejection does not engender risks for the operator and/or exposed persons;

(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;

(d) where the tool is incorporated into a non-fully automated machine, the latter must be so designed and constructed as to eliminate or reduce the risk of serious accidental injury, for example by using cylindrical cutter blocks, restricting depth of cut, etc.

580.

Woodworking

This requirement refers to the risks and not the processing of a specific material, namely, wood. The concept of similar materials is clearly defined in order to avoid any ambiguity. This is the essence of the first paragraph.
A few explanations should be given in order to meet the requirement of Point c). A motor brake operating by current injection or by polarity reversal is not always the answer.
A controlled stoppage, generally needed and followed by operation on the workpiece or the tool (this is the case in Point c)), for which it is necessary for the tool to stop quickly, should be distinguished from stoppages due to a lack of power, for which the time before the machine has completely stopped is not an essential part of the safety aspect (requirement 1.2.6). The motor brakes mentioned above are acceptable if the interruption to the power supply and the slowing-down of the tool which ensues do not create a particular risk (rejection of the workpiece, breakage of the tool, etc.). The standards should specify these points.
Point c) leads to an automatic brake being imposed for most woodworking machines. Only automatic machines or machines with automatic loading/unloading may be excluded, since the risk of contact with the tool while it is slowing down is virtually zero.
A circular saw blade cannot be allowed to continue rotating for seconds on end (or even minutes) before coming to a stop where the risk of contact is high (especially in machinery combining several tools).
Lastly, the final words in Point d) require an explanation. Apart from the German, all the language versions of the Directive are incorrect: mention is made of "limiting the depth of pass" although it should have said "limiting the thickness of the chipping"; it is in fact possible to work with a very great depth of pass if the feed of the tool is sufficiently low, while too great a chipping thickness leads either to the tool being blocked or, even more dangerously, the worked workpiece being rejected.
Annex IV requires an "EC" type examination for certain machines where they are hand-fed.

When can a machine be said not to be hand-fed?
Essentially when its loading system meets the following two criteria:

- the blank piece is taken from a nearby pile (magazine, pallet, spool, etc.) and guided to the tool automatically;
- it is locked to the machine's control circuit so that the machine cannot operate with the operator feeding pieces one at a time, either because the feed device has broken down or because it has been deliberately turned off.

3. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO THE MOBILITY OF MACHINERY

581.

Machinery presenting hazards due to mobility must be designed and constructed to meet the requirements set out below.

Risks due to mobility always exist in the case of machinery which is self-propelled, towed or pushed or carried by other machinery or tractors, is operated in working areas and whose operation requires either mobility while working, be it continuous or semi-continuous movement, between a succession of fixed working positions.

Risks due to mobility may also exist in the case of machinery operated without being moved, but equipped in such a way as to enable it to be moved more easily from one place to another (machinery fitted with wheels, rollers, runners, etc. or placed on gantries, trolleys, etc.).

In order to verify that rotary cultivators and power harrows do not present unacceptable risks to the exposed persons, the manufacturer or his authorized representative established within the Community must, for each type of machinery concerned, perform the appropriate tests or have such tests performed.

582.

Concept of mobility

The requirements of Chapter 3 are to be considered both when the machine is moving while it is working and when the machine can be moved between phases of the work or between two work sites.

The last paragraph of this preamble may seem incongruous. It is the result of a compromise between the Member States which wanted to submit these two types of machines (rotary cultivators and power hoes) to an "EC" type examination (Annex IV) and those which saw no particular need thereof. It means that the technical file referred to in Article 8 and Annex V is not sufficient; the manufacturer must carry out appropriate tests to check that the essential requirements are met or have them carried out if he does not have the necessary equipment. These tests, the scope of which may be defined by the standards, are to be carried out by type of machinery.
The Directive formally lays down the requirement of carrying out tests only for a very limited number of machines (rotary cultivators and power hoes, on the one hand, and self-propelled trucks, on the other). That being the case, the obligation to evaluate the risks applies to all machines. Evaluating a risk does not always mean carrying out tests. It will be incumbent upon the manufacturer to carry out those tests which seem to him to be necessary.

583.

3.1. General

3.1.1. Definition

"Driver" means an operator responsible for the movement of machinery. The driver may be transported by the machinery or may be on foot, accompanying the

machinery, or may be guiding the machinery by remote control (cables, radio, etc.).

584.

The concept of driver

"Driver" refers only to "competent operators". The responsibility for training drivers obviously is not incumbent upon the supplier of the mobile machine. A "competent operator" driving a machine forms part of the normal conditions of use.

585.

3.1.2. Lighting

If intended by the manufacturer to be used in dark places, self-propelled machinery must be fitted with a lighting device appropriate to the work to be carried out, without prejudice to any other regulations applicable (road traffic regulations, navigation rules, etc.).

586.

Provision of lighting

The machinery being mobile, requirement 1.1.4 no longer suffices since there will not always be ambient lighting. Certain machinery must provide the lighting needed not only for work but also for repair, in accordance with the general principles and comments regarding requirement 1.1.4. Machinery intended to be used for working underground is governed by the special provisions of requirement 5.3.

587.

3.1.3. Design of machinery to facilitate its handling

During the handling of the machine and/or its parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machine and/or its parts are handled in accordance with the manufacturer's instructions.

588.

Safe handling

In addition to the problems mentioned by requirement 1.1.5, this requirement draws attention to the specific hazards which may be associated with fitting interchangeable items of equipment due to sudden movements of the machinery as a result, for example, of ineffective braking or a lack of stability.

This requirement can mean locking certain parts when handling the machine so as to avoid any dangerous movements, e.g. the arms of a detachable crane must be prevented from unfolding before the crane has been fixed in place.

589.

3.2. Work stations

3.2.1. Driving position

The driving position must be designed with due regard to ergonomic principles. There may be two or more driving positions and, in such cases, each driving position must be provided with all the requisite controls. Where there is more than one driving position, the machinery must be designed so that the use of one of them precludes the use of the others, except in emergency stops. Visibility from the driving position must be such that the driver can in complete safety for himself and the exposed persons, operate the machinery and its tools in their intended conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery must be so designed and constructed that, from the driving position, there can be no risk to the driver and operators on board from inadvertent contact with the wheels or tracks.

The driving position must be designed and constructed so as to avoid any health risk due to exhaust gases and/or lack of oxygen.

The driving position of ride-on drivers must be so designed and constructed that a driver's cab may be fitted as long as there is room. In that case, the cab must incorporate a place for the instructions needed for the driver and/or operators. The driving position must be fitted with an adequate cab where there is a hazard due to a dangerous environment.

Where the machinery is fitted with a cab, this must be designed, constructed and/or equipped to ensure that the driver has good operating conditions and is protected against any hazards that might exist (for instance: inadequate heating and ventilation, inadequate visibility, excessive noise and vibration, falling objects, penetration by objects, rolling over, etc.). The exit must allow rapid evacuation. Moreover, an emergency exit must be provided in a direction which is different from the usual exit.

The materials used for the cab and its fittings must be fire-resistant.

590.

Ergonomics of the driving position or positions

The first paragraph, in addition to reminders about ergonomics and the driver's visibility in a dangerous area, requires that, if there is more than one driving position on a machine, using only one of them should render the others non-operational. The control circuit must be designed and constructed accordingly.

The second paragraph mentions "operators on board". Obviously these are operators who are "on board" under the normal conditions intended by the manufacturer. Clearly the manufacturer does not have to take into account in the design of his product the ever-possible presence of operators who are on board "abnormally". There may be an excessive number of operators or a "hidden passenger" clinging to a part of the machine's frame.

591.

The cab

In the fourth paragraph, a cab is only required if the environment of the machine is dangerous, unhealthy or uncomfortable. The environmental conditions in which the machine will operate

must be the subject of a very detailed examination by the manufacturer and the instructions must clearly indicate both authorized conditions and any contra-indications. If an agricultural machine is intended to spray pesticides or other dangerous substances, the cab must be obligatory, and the same applies if there is harmful dust around a work-site machine. In other cases, the requirement is limited to the possibility of equipping the machine with a cab if its dimensions so allow. Attention is drawn to the fact that the machine might actually be too small to provide a cab but not too small to install a standard cab; it is sometimes possible to provide small cabs which are perhaps uncomfortable but which will be preferable to the complete absence of a cab. The only instructions to be stored in the cab are those pertaining to the driver and the operators. It is pointless making arrangements to store in the cab the maintenance manual or the manuals relating to all the interchangeable equipment items that the machine may receive. However, it is necessary to provide enough space to keep some of these manuals.

The fifth paragraph lays down certain characteristics required of the cab, but the detailed requirements will be set out in standards, together with test methods to verify compliance therewith. An emergency exit must be provided in a direction other than the usual exit. This requirement is intended to provide a means of escape from the cab in the event of machinery rolling-over, a fire starting or the usual exit being impractical. This emergency exit may be a window of sufficient size, which can be opened easily without using a tool. Except in cases where it is impossible to provide an emergency exit (in the case of a cab mounted on the top of a tower crane, how can another escape be provided except via the ladder located beneath the cab?), the emergency exit is necessary.
Fire-resistant materials, as mentioned in the sixth paragraph, are defined in the standards (pending European standards, certain national or international standards may be used).

592.

3.2.2. Seating

The driving seat of any machinery must enable the driver to maintain a stable position and be designed with due regard to ergonomic principles.

The seat must be designed to reduce vibrations transmitted to the driver to the lowest level that can be reasonably achieved. The seat mountings must withstand all stresses to which they can be subjected, notably in the event of rollover. Where there is no floor beneath the driver's feet, the driver must have footrests covered with a slip-resistant material.

Where machinery is fitted with provision for a rollover protection structure, the seat must be equipped with a safety belt or equivalent device which keeps the driver in his seat without restricting any movements necessary for driving or any movements caused by the suspension.

593.

Characteristics of the seat or seats

The requirements with regard to this point (driver stability, reduction of vibrations, etc.) must be taken into account in the choice and/or design of the seats fitted on the machine, even if this is not the usual practice in certain professions. The second of the preliminary observations in Annex I states that the essential requirements are imperative. If they cannot be achieved, at any given moment, the machine (in this instance, the seat) must try to get as close as possible.

National or ISO standards deal not only with vibrations or safety belts but also with the ergonomics of the seat. These standards are often intended for public works machinery. They are optional and do not relate, whatever the circumstances, to all machines whose driving position is equipped with a seat.

Very often the manufacturer of the machine is not the manufacturer of the seat, in which case the latter should be asked to supply information on vibrations and anchoring points, especially for inclusion in the technical file referred to in Article 8 and Annex V.

594.

Safety belt

The last paragraph requires all machinery equipped with a rollover protection structure (ROPS), or any machinery for which this structure is intended, also to be equipped with a device which ensures that the driver is held in his seat in the event of rollover. This device may be a safety belt, but devices having the same effect with regard to holding the driver in his seat in the event of rollover are acceptable.

595.

3.2.3. Other places

If the conditions of use provide that operators other than the driver are occasionally or regularly transported by the machinery, or work on it, appropriate places must be provided which enable them to be transported or to work on it without risk, particularly the risk of falling.

Where the working conditions so permit, these work places must be equipped with seats.

Should the driving position have to be fitted with a cab, the other places must also be protected against the hazards which justified the protection of the driving position.

596.

Safety when transporting operators

The same attention as for the safety of operators must be also paid to other places. If risk analysis has led to the designer providing certain protective devices for the driver (ROPS, falling-object protection structures (FOPS), safety belts or similar protection means, etc.), devices protecting against the same risks must be provided at all the workstations.

Likewise, if a dangerous environment (see Point 3.2.1, 4th paragraph) dictates the use of a cab for the driver, there must be room in this cab, or in another cab having the same characteristics, for the operators being transported.

597.

3.3. Controls

3.3.1. Control devices

The driver must be able to actuate all control devices required to operate the

machinery from the driving position, except for functions which can be safely activated only by using control devices located away from the driving position. This refers in particular to working positions other than the driving position, for which operators other than the driver are responsible or for which the driver has to leave his driving position in order to carry out the manoeuvre in safety.

Where there are pedals they must be so designed, constructed and fitted to allow operation by the driver in safety with the minimum risk of confusion; they must have a slip-resistant surface and be easy to clean.

Where their operation can lead to hazards, notably dangerous movements, the machinery's controls, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.

In the case of wheeled machinery, the steering system must be designed and constructed to reduce the force of sudden movements of the steering wheel or steering lever caused by shocks to the guide wheels.

Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked where the machinery is moving.

The last sentence of section 1.2.2 does not apply to the mobility function.

598.

Ergonomics of the control devices

The first paragraph recalls that the driver must have, in his driving position, the control devices necessary for moving his machine and also, without unnecessary movements, any operating devices. Consequently, all the control devices must be within reach of hand or foot. However, for some operations such as manoeuvring the auxiliary crane of a lorry, it is preferable, for the safety of the operation, that the operator leave his driving position. In this case, the control devices must be located clearly at the most appropriate place allowing him a view of the dangerous area, without exposing the operator to other risks for example, to the mechanism activated or road traffic. The Directive obviously does not prevent the control devices, where necessary, from being located outside the cab. The workstation does not necessarily have to be the driving position and may be elsewhere in the cab.

Standards are in preparation concerning the arrangement of the control devices, including the pedals referred to in the second paragraph. Please refer also to requirement 1.2.2 and, in particular, the second and third indents thereof. "Intuitive" controls and consistency with the controls usually found on motor vehicles are particularly recommended for mobile machinery; it is therefore preferable to use these controls. In some cases, other arrangements better adapted to the work to be carried out may be adopted.

599.

3.3.2. Starting/moving

Self-propelled machinery with a ride-on driver must be so equipped as to deter unauthorized persons from starting the engine.

Travel movements of self-propelled machinery with a ride-on driver must be

possible only if the driver is at the controls.

Where, for operating purposes, machinery must be fitted with devices which exceed its normal clearance zone (e.g. stabilizers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary.

Where it is technically and economically feasible, movement of the machinery must depend on safe positioning of the aforementioned parts.

It must not be possible for movement of the machinery to occur which the engine is being started.

600.

Starting

The most common means of complying with the first paragraph in respect of machinery with a ride-on driver is the key. Some companies have proposed using electronic contact key devices to stop the misuse of self-propelled trucks. The system comprises an electronic key incorporating an integrated circuit with a programmable access code as well as an electronic read lock provided with a digital code. It is thus possible to personalize the code and to manage several access levels. The system also comprises a data processing unit. This equipment enables the fleet operator to define the rules for using the trucks and to encode the key. It is even possible to credit a number of hours to each key with a programmable delay. The data processing unit receives the data relating to the use times. Over and above the "security" aspect, such a system helps in planning maintenance operations. This system is only one example. The “machinery” Directive obviously does not insist on so sophisticated a measure.

601.

Presence of the driver

In order to comply with the second paragraph, it is possible to prevent either the engine being switched on or the gear being engaged by a device which detects the presence of the driver. The choice of device must take account of the state of the art, the constraints of the work and the ergonomic design of the driving position and the controls.

The means referred to in the third paragraph may, for example, be acoustic warning devices which cut in when a movement gear is engaged while the authorized clearance is engaged. Warning lights on the dashboard at the driving position are an alternative solution. However, control of the movement of the machine at a safe position from these parts is the best solution.

The final paragraph requires that, where an engine operates the movement of machinery, there be a clutch between the engine and the movement members (wheels, tracks, carrier devices, etc.). In the case of electric motors directly activating movement, it is necessary to ensure that switching the machine on does not produce any movement.

602.

3.3.3. Travelling function

Without prejudice to the provisions of road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilization so as to ensure safety under all the operating, loading, speed, ground and gradient conditions allowed for by the manufacturer and corresponding to conditions encountered in normal use.

The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires in the event of a failure of the main device, or in the absence of the energy supply to actuate the main device, an emergency device with fully independent and easily accessible controls must be provided for slowing down and stopping.

Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical.

Remote-controlled machinery must be designed and constructed to stop automatically if the driver loses control.

603.

Slowing-down and braking of mobile machinery

Requirement 1.2.4 relating to the normal stopping of machines does not apply to the "movement" of mobile machinery.

604.

Highway codes

The first sentence mentions highway codes specific to each Member State. The Commission is studying a proposal for a Directive designed to harmonize the rules to be applied for mobile machinery not intended to cover long distances on the public road network.

605.

Main device and emergency device

To comply with the second paragraph, it is acceptable for the same control device, for example, a pedal, to operate both the main braking control circuit and the emergency system. However, in this case, the control circuits must be independent and the driver must be informed of any failure of the main circuit. This was confirmed by the "89/392" Committee in its reply No 22.

The other paragraphs require no comments, since they are clear enough as written.

606.

3.3.4. Movement of pedestrian-controlled machinery

Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control by the driver. In particular, it must not be possible for movement to occur while the engine is being started.

The control systems for pedestrian-controlled machinery must be designed to minimize the hazards arising from inadvertent movement of the machine towards

the driver. In particular:
(a) crushing;
(b) injury from rotating tools.

Also, the speed of normal travel of the machine must be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate that tool where the reversing control is engaged, except where movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.

607.

Prevention of risks specific to pedestrian-controlled machinery

Self-propelled pedestrian-controlled machinery must remain under the control of the driver. It must not be able to be started and moved without sustained action by the driver.

The speed of the machine when moving forwards must be no faster than a man walking. When reversing, it must be at a reduced speed, particularly if movement is caused by rotation of the tool.

608.

Rotary tools

In principle, a rotary tool must not be able to be actuated when reversing. The Directive allows a derogation where the movement of the machine derives from the tool. The principle and its derogation laid down by the "machinery" Directive must be subjected to risk analysis. This seems to be the case for certain lawn mowers. It is up to the standards bodies to highlight application of this principle and its derogation.

609.

3.3.5. Control circuit failure

A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.

610.

Power-assisted steering

This requirement does not mean that the machine can continue to work without power-assisted steering, merely that it should be possible to remove it from the work area and to park it safely. Power-assisted emergency steering will be necessary if the effort required to control the steering in the event of power-assistance failure is too great.

611.

3.4. Protection against mechanical hazards

3.4.1. Uncontrolled movements

Where a part of a machine has been stopped, any drift away from the stopping position, for whatever reason other than action at the controls, must be such that

it is not a hazard to exposed persons.

Machinery must be so designed, constructed and where appropriate placed on its mobile support as to ensure that where moved the uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

612.

Prevention of shifting and movements

When the machine is stopped and some of the parts are not yet in their rest position, measures have to be taken to reduce the danger of possible movements, e.g. due to leaks in the hydraulic circuits. This requirement does not guarantee that there will be no uncontrolled movement, but that these movements will not be dangerous.

The second paragraph refers, *inter alia*, to machinery with parts which can move independently of the rest of the machine, whether such movements are natural or controlled. Thus, if a manufacturer installs a machine on a lorry chassis, the weight, the position of the centre of gravity and the manner of assembly must be compatible with the speed of the machine (centrifugal force when cornering, for example, unsuitable suspension, strength of the chassis because of excessive constraints, etc.).

613.

Position of the centre of gravity

This requirement means that the manufacturer must also check that, while the machine is moving, too high or too off-centred a position of the centre of gravity does not lead to significant oscillations resulting in loss of stability.

614.

3.4.2. Risk of break-up during operation

Parts of machinery rotating at high speed which, despite the measures taken, may break up or disintegrate, must be mounted and guarded in such a way that, in case of breakage, their fragments will be contained or, if that is not possible, cannot be projected towards the driving and/or operation positions.

615.

Prevention of the risks of shattering

Requirement 3.4.2 makes requirement 1.3.2 less stringent. On certain mobile machinery (especially agricultural machinery), it is clearly impossible to enclose certain rotary parts which are directly linked to the tool, which is itself in the open air. In this case, workstations or driving positions must not lie in the path of fragments produced by fracture.

616.

3.4.3. Rollover

Where, in the case of self-propelled machinery with a ride-on driver and possibly ride-on operators, there is a risk of rolling over, the machinery must be designed for and be fitted with anchorage points allowing it to be equipped with a rollover protective structure (ROPS).

This structure must be such that in case of rolling over it affords the ride-on driver and where appropriate the ride-on operators an adequate deflection-limiting volume (DLV).

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorized representative established within the Community must, for each type of structure concerned, perform appropriate tests or have such tests performed.

In addition, the earth-moving machinery listed below with a capacity exceeding 15 kW must be fitted with a rollover protection structure:
- ***crawler loaders or wheel loaders,***
- ***backhoe loaders,***
- ***crawler tractors or wheel tractors,***
- ***scrapers, self-loading or not,***
- ***graders,***
- ***articulated steer dumpers.***

617.

Rollover prevention

This requirement includes the list of machinery which must be equipped with a rollover protection structure under the old Directive 86/295/EEC, replaced once and for all by the "machinery" Directive as of 1 January 1997. Where the risk of rollover exists for the other types of machinery, requirement 3.4.3 provides that machinery should be fitted with anchorage points allowing it to be equipped with a ROPS. That said, many machinery designers install protection structures from the outset where there is a risk of rollover.

The ROPSs still have to be tested. These tests may be carried out by the manufacturer himself or by any laboratory possessing the necessary facilities. The reference standards include EN 23471 on public works machinery. The manufacturer might use the standard ISO 3411 as a basis for determining the deformation limiting volume of the structure.
When ROPSs are put on the market as individual units, they must comply with the corresponding harmonized European standard or be subject to an "EC" type examination (Annex IV). In the case of ROPS-FOPS structures, supplied as spare parts by the original supplier, these should comply with the general rules governing spare parts. The supply of a spare part by the original manufacturer falls within the initial sales contract. The spare part may be supplied either during or after the contractual guarantee period. The declaration of conformity issued by the manufacturer for the entire machine is deemed to cover the replacement of a component of the machine, where it is a safety component. However, the guarantee provided by the original declaration of conformity covers only spare parts coming from the original manufacturer. There may be no guarantee for a spare part manufactured by another producer.

618.

3.4.4. Falling objects

Where, in the case of machinery with a ride-on driver and possibly ride-on operators, there is a risk due to falling objects or material, the machinery should be designed for, and fitted with, if its size allows, anchorage points allowing it to

be equipped with a falling-object protective structure (FOPS).

This structure must be such that in the case of falling objects or material, it guarantees the ride-on operators an adequate deflection-limiting volume (DLV).

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorized representative established within the Community must, for each type of structure concerned, perform appropriate tests or have such tests performed.

619.

Protection from falling objects

Comments identical to those with regard to the previous requirement may also be made here. As of 1 January 1997 Directive 86/296/EEC,[97] which was based on the ISO 3449 standard, is replaced by the "machinery" Directive.

620.

3.4.5. Means of access

Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the controls for that purpose.

621.

Means of access

The designer must prevent control devices, such as the steering wheels, steering columns, brake levers, handles, etc., from being used as handholds and must prevent tyre treads or protectors not intended for that purpose from being used as footboards. To that end, he must provide a sufficient number of well-placed handholds and steps.

622.

3.4.6. Towing devices

All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged to ensure easy and safe connection and disconnection, and to prevent accidental disconnection during use.

In so far as the towbar load requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.

623.

Coupling

Coupling and uncoupling are performed by an operator, generally on work sites. The designer must therefore make operations easy to carry out, generally without outside assistance, while still ensuring safe handling.

97 Directive No 86/296/EEC of 26 May 1986 (OJ No L 186, 8.07.86, p. 10; as amended by Directive No 91/368/EEC (OJ L 198, 22.0791, p. 16)

If the towbar is heavy, a support must be provided. A support leg with a surface for bearing on the ground may be provided in some cases. A recommendation for putting the towbar down should appear in the instructions.

624.

3.4.7. Transmission of power between self-propelled machinery (or tractor) and recipient machinery

Transmission shafts with universal joints linking self-propelled machinery (or tractor) to the first fixed bearing of recipient machinery must be guarded on the self-propelled machinery side and the recipient machinery side over the whole length of the shaft and associated universal joints.

On the side of the self-propelled machinery (or tractor), the power take-off to which the transmission shaft is attached must be guarded either by a screen fixed to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

On the towed machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machine. The universal-joint transmission shaft must be marked accordingly.

All towed machinery whose operation requires a transmission shaft to connect it to self-propelled machinery or a tractor must have a system for attaching the transmission shaft so that when the machinery is uncoupled the transmission shaft and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the transmission shaft. The guard must cover the transmission shaft to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of "wide-angle" universal joints.

Manufacturers providing means of access to working positions near to the universal joint transmission shaft must ensure that shaft guards as described in the sixth paragraph cannot be used as steps unless designed and constructed for that purpose.

625.

Transmission shafts: legal status

It is because of the frequency of operator interventions and the seriousness of the accidents caused by transmission shafts that these components and their guards are likened to machinery and subject to the requirements of 3.4.7.

626.

Technical aspects

The power transmission of self-propelled machinery must be protected over the entire length of the shaft. Guards must be installed on the self-propelled machinery side and on the towed machinery side. The manufacturer must decide whether or not the transmission shaft and/or its guard can be used as a footboard. If the transmission shaft and/or its guard is used as a footboard, it must be designed for that purpose. If this is not the case, footboards must be installed close by.
The Directive covers the actual transmission shafts and their guards. It is impossible to check a guard without the shaft (or shafts) with which it is associated. The test is carried out on the two parts since there is interaction between these two parts. This does not mean that it is impossible to put isolated guards on the market, but, if they were, the instructions would have to explicitly specify the characteristics of the transmission shafts with which the guard may be safely used. The transmission shaft will, in principle, be sold with its guard; should this not be the case, the instructions should indicate how suitable guards are to be used.

627.

3.4.8. Moving transmission parts

By way of derogation from section 1.3.8.A, in the case of internal combustion engines, removable guards preventing access to the moving parts in the engine compartment need not have locking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position if the latter is in a fully enclosed cab with a lock to prevent unauthorized access.

628.

Protection against risks associated with the moving parts.

Requirement 1.3.8.A lays down that guards protecting the moving parts of the drive (belts, pulleys, etc.) must either be fixed guards or movable guards which can only be opened with a key or a tool or which have an opening located inside the cab or movable guards which prevent the moving parts from operating when they are open and which stop the machine when they are no longer closed.
A key must be provided in order to open the engine bonnet. For mobile machinery with an enclosed and lockable cab, the bonnet-opening system may be controlled from inside.

629.

3.5. Protection against other hazards

3.5.1. Batteries

The battery housing must be constructed and located and the battery installed so as to avoid as far as possible the chance of electrolyte being ejected on to the operator in the event of rollover and/or to avoid the accumulation of vapours in places occupied by operators.

Machinery must be so designed and constructed that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.

630.

Battery safety

In order to comply with the first paragraph, the manufacturer must carry out a risk analysis of the positioning so as to comply with the various points in the requirement.

The manufacturer must, in order to comply with the second paragraph, either equip the battery with a specific disconnection device or, if the battery terminals are easily accessible, use the disconnection of the terminals with a rapid-action circuit breaker.

631.

3.5.2. Fire

Depending on the hazards anticipated by the manufacturer when in use, machinery must, where its size permits:
- ***either allow easily accessible fire extinguishers to be fitted,***
- ***or be provided with built-in extinguisher systems.***

632.

Fire risk prevention

Taking into account the magnitude of the risk, the environment (confined atmosphere, for example) and the possibility of evacuating the driver, the machine may be equipped with a built-in fire extinguisher system. Machinery intended always to be used in the open air clearly does not need to have a built-in system. On the other hand, size permitting, one or more extinguishers must be able to be installed. It is therefore necessary to provide places and attachment systems for these extinguishers. It is not obligatory to supply extinguishers - it is the responsibility of the user to install them.

633.

3.5.3. Emissions of dust, gases, etc.

Where such hazards exist, the containment equipment provided for in section 1.5.13 may be replaced by other means, for example precipitation by water spraying.

The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products.

634.

Gas and dust

Requirement 1.5.13 lays down that the machines must be designed so as to avoid the risks due to gas, liquids, dust, vapours and other waste products. For this purpose, the machine must be equipped with a collection or suction device. This requirement is not realistic for mobile machines. Requirement 3.5.3 allows derogation from this point. Moreover, the “machinery” Directive does not require sprayers to collect the products which they spray!

635.

3.6. Indications

3.6.1. Signs and warning

Machinery must have means of signalling and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, to ensure the health and safety or exposed persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.

Without prejudice to the requirements to be observed for travelling on the public highway, machinery with a ride-on driver must have the following equipment:

- ***an acoustic warning device to alert exposed persons,***
- ***a system of light signals relevant to the intended conditions of use such as stop lamps, reversing lamps and rotating beacons. The latter requirement does not apply to machinery intended solely for underground working and having no electrical power.***

Remote-controlled machinery which under normal conditions of use exposes persons to the hazards of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect exposed persons against such hazards. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the back of the machine is not directly visible to the driver.

Machinery must be so constructed that the warning and signalling devices cannot all be disabled unintentionally. Where this is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery* while *it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.

636.

Marking, signs and warnings.

This requirement details the markings, signs and instruction plaques specific to mobile machinery. The third paragraph requires the designer to pay special attention to machinery such as road rollers. Devices which considerably reduce this hazard are already available on the market.

The final paragraph concerns hazards which are not immediately obvious to an untrained eye from the external appearance of the machinery. In this case, a warning which is clearly legible at a distance must be affixed to the machinery itself.

637.

3.6.2. Marking

The minimum requirements set out in 1.7.3 must be supplemented by the following:

- ***nominal power expressed in kW,***
- ***mass in kg of the most usual configuration and, where appropriate:***
- ***maximum drawbar pull provided for by the manufacturer at the coupling hook, in N,***
- ***maximum vertical load provided for by the manufacturer on the coupling hook, in N.***

638.

Specific markings

Requirement 1.7.3 applies to mobile machinery, but the points provided for by this requirement should be supplemented.
The specific nature of the hazards associated with the mobility of the machinery requires special markings on the frame of the machinery.

3.6.3. Instruction handbook

Apart from the minimum requirements set out in 1.7.4, the instruction handbook must contain the following information:

(a) regarding the vibrations emitted by the machinery, either the actual value or a figure calculated from measurements performed on identical machinery:
- ***the weighted root mean square acceleration value to which the arms are subjected, if it exceeds 2,5 m/s²; should it not exceed 2,5 m/s², this must be mentioned,***
- ***the weighted root mean square acceleration value to which the body (feet or posterior) is subjected, if it exceeds 0,5 m/s²; should it not exceed 0,5 m/s², this must be mentioned.***

Where the harmonized standards are not applied, the vibration must be measured using the most appropriate method for the machinery concerned.

The manufacturer must indicate the operating conditions of the machinery during measurement and which methods were used for taking the measurements;

(b) in the case of machinery allowing several uses depending on the equipment used, manufacturers of basic machinery to which interchangeable equipment may be attached and manufacturers of the interchangeable equipment must provide the necessary information to enable the equipment to be fitted and used safely.

639.

Additional information for the instructions

One of the additional items of information required for mobile machinery deals with the level of vibrations transmitted by the machinery to the entire body and to the arms. Vibrations transmitted to the ground are not taken into account. Although in the case of portable machinery only information on vibrations transmitted to the arms is required, fuller information is required here.

The manufacturer must carefully draft the information regarding the possibility of fitting and using interchangeable equipment safely. A description of the points and means of attachment with which the machinery is equipped (locations, thread sizes where appropriate, maximum resistance to forces, fluids and pressures used, etc.) is often useful. The manufacturer must also indicate how equipment is to be assembled and, where appropriate, how it should not be used.

It is important to note that the manufacturer of the basic machine (or of the tractor) as well as the manufacturer of the interchangeable equipment must both provide this information.

Accidents may occur if any essential information is lacking; failure to provide this information might make the party in question liable.

640.

4. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO A LIFTING OPERATION

Machinery presenting hazards due to lifting operations - mainly hazards or load falls and collisions or hazards or tipping caused by a lifting operation - must be designed and constructed to meet the requirements set out below.

Risks due to a lifting operation exist particularly in the case of machinery designed to move a unit load involving a change in level during the movement. The load may consist of objects, material or goods.

641.

4.1. General remarks

4.1.1. Definitions

- ***(a) "lifting accessories" means components or equipment not attached to the machine and placed between the machinery and the load or on the load in order to attach it;***
- ***(b) "separate lifting accessories" means accessories which help to make up or use a slinging device, such as eyehooks, shackles, rings, eyebolts, etc.;***
- ***(c) "guided load" means the load where the total movement is made along rigid or flexible guides, whose position is determined by fixed points;***
- ***(d) "working coefficient" means the arithmetic ratio between the load guaranteed by the manufacturer up to which a piece of equipment, an accessory or machinery is able to hold it and the maximum working load marked on the equipment, accessory or machinery respectively;***
- ***(e) "test coefficient" means the arithmetic ratio between the load used to carry out the static or dynamic tests on a piece of equipment, an accessory or machinery and the maximum working load marked on the piece of equipment, accessory or machinery;***
- ***(f) "static test" means the test during which the machinery or the lifting accessory is first inspected and then subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure no damage has occurred;***
- ***(g) "dynamic test" means the test during which the machinery is operated in all its possible configurations at maximum working load with account taken of the dynamic behaviour of the machinery in order to check that the machinery and safety features are functioning properly.***

642.

Importance of the definitions

The “machinery” Directive provides regulations regarding lifting accessories and slinging accessories. Obviously, these components cannot claim to meet the general definition of a machine, an interchangeable item of equipment or even a safety component (the function of this type of component is not exclusively or not at all related to safety).
Together with transmission shafts and their guards, the lifting and slinging accessories are products governed by the Directive, but this does not mean that the other components are.

Using the correct description is the first step towards safety. Furthermore, it is important that manufacturers use these definitions in their instructions without distorting or amending them, and do not use other definitions for the concepts in question. This recommendation also applies to the standards authorities.

643.

Point 4.1.1 b) requires an explanation; various versions, including the French, clearly specify that slinging accessories are lifting accessories with a particular function, namely, to form a sling, i.e. a flexible lifting device to provide a link between the lifting apparatus and the load. Other linguistic versions, including the English, do not make this specific point. The first approach should be adopted, and thus slings should be regarded as particular lifting accessories. In this case, slings should bear the "CE" marking, like all lifting accessories.
Requirement 4.3.2 relating to the marking of lifting accessories also contains a paragraph specifying the marking of slinging accessories. The parties involved in drafting the Directive thus clearly regarded slings as being a special category of lifting accessory. Not adopting this approach could lead to serious discrepancies, some Member States requiring the "CE" marking and others taking the opposite view.

644.

4.1.2. Protection against mechanical hazards

4.1.2.1. Risks due to lack of stability

Machinery must be so designed and constructed that the stability required in 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook.

To that end, the manufacturer or his authorized representative established within the Community must use the appropriate verification methods; in particular, for self-propelled industrial trucks with lift exceeding 1,80 m, the manufacturer or his authorized representative established within the Community must, for each type of industrial truck concerned, perform a platform stability test or similar test, or have such tests performed.

645.

Stability of lifting equipment

Static and dynamic tests are generally performed with increased test coefficients. The designer must take this into account when considering stability. The same applies to stability of the machine when not in service, which cannot always be guaranteed without additional equipment, devices or arrangements.

Industrial trucks were covered up to 1 January 1996 by Directive 86/663/EEC.[98] The latter, which will be repealed pursuant to this Directive, required very strict stability tests. The second paragraph was added so as not to lower the level of safety.

646.

4.1.2.2. Guide rails and rail tracks

Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.

However, if derailment occurs despite such devices, or if there is a failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machine overturning.

647.

Rail tracks and guide rails

This requirement should be read with the first preliminary observation to Annex I in mind. It is clearly not possible to prevent all derailments, but they must be made rare occurrences and, when they do occur in spite of the measures taken, the consequences must be minimized. For example, if a railwheel is equipped with a stirrup encompassing the rail, it will not leave the rail in case of derailment.

The consequences of a rail breakage are harder to mitigate, but rail design and checks during manufacture should make its breakage improbable.

The liability of a manufacturer is clearly limited to what he supplies under contract. For example, in the case of a travelling crane, the manufacturer who does not supply the rails must specify the tolerances which the rails are to meet in order for them to be compatible with what he has supplied. If the supplier of the rails does not comply with these data, the manufacturer would not be liable for an accident where that was cause, as long as the values given by the travelling crane manufacturer are standard and reasonable in terms of the state of the art. A travelling crane without its running track may be regarded as a machine once the manufacturer clearly indicates the limits of what he supplies. Travelling crane manufacturers should not be prevented from affixing the "CE" marking when they have complied with the Directive for the part corresponding to what they supply and there is no safety element missing from their product. Similarly, the travelling crane manufacturer must indicate the anticipated loads, including in the event of overload, to enable the stability of the rail tracks and their supports to be studied.

648.

4.1.2.3. Mechanical strength

Machinery, lifting accessories and removable components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for by the manufacturer, and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling.

98 Directive 86/663/EEC of 22 December 1986 (OJ No L 394, 31.12.86, p. 12); as amended by Directive 91/368/EEC (OJ L 198, 22.07.91, p. 16)

Machinery and lifting accessories must be designed and constructed so as to prevent failure from fatigue or wear, taking due account of their intended use.

The materials used must be chosen on the basis of the working environments provided for by the manufacturer, with special reference to corrosion, abrasion, impacts, cold brittleness and ageing.

The machinery and the lifting accessories must be designed and constructed to withstand the overload in the static tests without permanent deformation or patent defect. The calculation must take account of the values of the static test coefficient chosen to guarantee an adequate level of safety: that coefficient has, as a general rule, the following values:
(a) manually-operated machinery and lifting accessories: 1,5;
(b) other machinery: 1,25.

Machinery must be designed and constructed to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1.

The dynamic tests must be performed on machinery ready to be put into service under normal conditions of use. As a general rule, the tests will be performed at the nominal speeds laid down by the manufacturer. Should the control circuit of the machinery allow for a number of simultaneous movements (for example, rotation and displacement of the load), the tests must be carried out under the least favourable conditions, i.e. as a general rule, by combining the movements concerned.

649.

Materials selection and sizing

The requirements of the first three paragraphs are the subject of many design codes which have the value of good engineering practice. To meet these requirement, the designer may use the harmonized standards or a recognized widely used code. The safety coefficients to be used for this purpose have were discussed at great length when the Directive was being drawn up: would it be possible to use them in the text of the Directive without any risk of ambiguity, given the wide variety of cases?
The decision taken (i.e. the text above) was accompanied by a request from the Council to the Commission to draw up a guide to these coefficients for use by the standards authorities and machinery designers. Here is the full text of the guide, which applies also to requirements 4.1.2.4 and 4.1.2.5.

For the dynamic tests, it may be necessary to ensure stability using certain devices (see the comments relating to 4.1.2.1).

650.

<u>REFERENCE GUIDE FOR THE TEST OR WORKING COEFFICIENTS OF LIFTING GEAR</u>

The Commission departments have prepared this guide after consulting the Standing Committee set up by Article 6(2) of Directive 89/392/EEC.

It is mainly intended for designers of machines or for the supervisory bodies in the absence of standards.

Drafters of harmonized standards should consider the values given in this guide only as general references from which they may deviate where appropriate.

If a harmonized standard, the reference for which has been published in the Official Journal of the European Communities, gives values, the use of these values gives rise to a presumption of conformity to the Directive.

This document can be modified at any time by the Commission, after consulting the Committee set up under Directive 89/392/EEC, in the light of the development of knowledge, standards, materials, etc.

A. ACCESSORIES

1. Separate lifting accessories used for slinging:

- shackles;
- eyehooks;
- eyebolts;
- chains with welded links;
- rings;
- etc.

The static test coefficient is at least:

- 2 for maximum working loads (MWLs) less than or equal to 30 T;
- 1.5 for MWLs greater than 30 T;
- 1 for MWLs equal to or greater than 100 T provided that, during the rise of the load on initial testing, the stresses are measured at the most significant points and compared with the calculated values.

The working coefficient is 4 for all accessories except metallic ropes used to make slings. In that case the working coefficient of the rope/rope-end combination is 5.

2. Metallic ropes other than those used for slinging

In the case of ropes used for lifting loads, other than those used for slinging, account must be taken of several factors, e.g.:

- the ratio between the diameter of the rope and the winding diameter of pulleys, drums or wheels,
- the number of independent ropes used for lifting a load,
- the process and conditions of manufacture,
- the classification of the lifting appliance on which the rope is installed,
- lubrication,
- frequency of inspections,
- etc.

If, for example, calculations, experience or tests make it possible to know, taking into account the first indent above, the maximum stress reached in any one wire, the working coefficient should be chosen, as a first approximation, in such a way as to keep this maximum stress at one-third of the breaking stress. This working coefficient can subsequently be amended up or down to take into account other factors.

If neither calculations nor tests nor the experience embodied in the standards make it possible to determine the working factor, 5 should be taken.
The test coefficient will be that of the lifting appliance on which the rope is installed.
Guying ropes are not subjected to period tests but the rope/rope-end combination should have a working coefficient of 4.
Ropes used in non-permanent installations for the transportation of merchandise guided by rope, whether for guiding, supporting loads or for pulling, should have a working coefficient of 3.5.

3. Metallic chains other than those used for slinging
Chains used for lifting loads can be either with welded links or mechanical chains (roller type or leaf type).
The working coefficient is 4 for chains with welded links and 5 for mechanical chains.
The test coefficient will be that of the lifting appliance on which the chain is installed.

4. Lifting accessories incorporated in machinery, shank hooks, block and tackle, lifting beams, C-hooks, etc.
In workshops or in laboratories, the static test coefficient is 1.5.
Designers should also bear in mind that, when fitted on a lifting appliance, the accessory will be subjected to the periodical dynamic test appropriate to that lifting appliance.
Likewise, the working coefficient depends on the group in which the lifting appliance on which the accessory is fitted is classified.

5. Textile ropes
The static test is not particularly informative and is therefore unnecessary.
The working coefficient is at least 7 for ropes made of synthetic fibres and 8 for ropes made of natural fibres. For the latter, this coefficient will be increased to take into account:

- the kind of fibre (origin, length, etc.);
- the diameter of the rope;
- the process of manufacture (stranded, braided rope, etc.);
- etc.

6. Other accessories
Vacuum or magnetic gripping devices: test and working coefficient: 2.

B. LOAD-LIFTING MACHINERY

1. Static test
The coefficient 1.25 given in the Directive applies to all lifting appliances except that:
- the coefficient is at least 1.5 if the maximum working load is less than or equal to 1 tonne;
- the coefficient is 1 if the maximum working load is greater than 100 tonnes and provided that, during the rise of the load during initial testing, the stresses are measured at the most significant point in the structure and compared with the calculated values.

2. Dynamic test
The coefficient 1.1 given in the Directive applies to all lifting appliances except those for which the maximum working load is greater than or equal to 100 tonnes. For the latter, the coefficient is 1.

651.

4.1.2.4. Pulleys, drums, chains or ropes

Pulleys, drums and wheels must have a diameter commensurate with the size of rope or chains with which they can be fitted.

Drums and wheels must be so designed, constructed and installed that the ropes or chains with which they are equipped can wind round without falling off.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends (splicings are tolerated in installations which are intended from their design to be modified regularly according to needs for use). Complete ropes and their endings have a working coefficient chosen so as to guarantee an adequate level of safety; as a general rule, this coefficient is equal to five.

Lifting chains have a working coefficient chosen so as to guarantee an adequate level of safety; as a general rule, this coefficient is equal to four.

In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorized representative established within the Community must, for each type of chain and rope used directly for lifting the load, and for the rope ends, perform the appropriate tests or have such tests performed.

652.

Cables, wheels, etc.

The dimensional ratios and the compatibility of pulleys, drums and wheels on the one hand and chains and ropes on the other will be specified in harmonized European standards. Manufacturers may also use their current national standards or rules or the rules of the European Federation of Handling Industries.

653.

4.1.2.5. Separate lifting accessories

Lifting accessories must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected lifespan as specified in the operating conditions for a given application.

Moreover:

(a) the working coefficient of the metallic rope/rope-end combination is chosen so as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to five. Ropes must not comprise any splices or loops other than at their ends;

(b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains of any type is chosen so as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to four;

(c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient is chosen so as to guarantee an adequate level of safety; it is, as a general rule, equal to seven, provided the materials used are shown to be of very good quality and the method of manufacture is

appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety.

Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;

(d) all metallic components making up, or used with, a sling must have a working coefficient chosen so as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to four;

(e) the maximum working capacity of a multi-legged sling is determined on the basis of the safety coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;

(f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorized representative established within the Community must, for each type of component referred to in (a), (b), (c) and (d) perform the appropriate tests or have such tests performed.

654.

Whereas in the case of lifting devices, gear and accessories, the contractual relationship between clients and manufacturers enables the conditions of use to be defined and the parameters for fatigue calculations to be set, the same does not apply to lifting accessories sold separately from available stock. In general, the life-span to be taken into consideration for the purposes of the first paragraph must be a standardized lifespan laid down in the standards.

Requirements 4.1.2.1, 4.1.2.3, 4.1.2.4 and 4.1.2.5 above refer to tests which the manufacturer or his authorized representative established within the EEA must perform or have performed. The Directive does not require any of these tests to be performed by a third party. If the manufacturer, or his authorized representative established within the EEA, has the requisite facilities, he should perform the tests himself and keep the test reports in the technical file referred to in Article 8 and Annex V. If he does not have the requisite facilities, he can have the tests performed by a laboratory of his choice. The laboratory chosen does not require any kind of official approval and nor, *a fortiori*, must it belong to a notified body. All it needs is the necessary technical resources.

These tests, to be performed by the manufacturer in advance of placing on the market and putting into service, should not be confused with the periodic tests which may be required by national regulations on the use of machinery and which will in general be performed by a third party under the user's responsibility.

The different coefficients given in the Directive are only valid in the absence of standards, which, in turn, can, as long as justified, provide for higher values as well as lower values. These values amount to "presumption of conformity".[99]

655.

4.1.2.6. Control of movements

Devices for controlling movements must act in such a way that the machinery

99 Council minutes of 14 June 1993: "*The Council and Commission agreed that use of the coefficients contained in the Directive by the manufacturer amounted to presumption of conformity with the essential requirements of the Directive.*"

on which they are installed is kept safe:

(a) machinery must be so designed or fitted with devices that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning;

(b) where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machines must be so designed and constructed as to make it possible to fit systems enabling these risks to be avoided,

(c) the mechanisms of machinery must be so designed and constructed that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine;

(d) it must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way;

(e) holding devices must be so designed and constructed that inadvertent dropping of the loads is avoided.

656.

Prevention of risks due to movements

These requirements may be met, for example:

- point a), by equipping machinery with mechanical stops or movement limiting devices wherever such devices can help to reduce the risk;
- point b), by providing for equipping machinery to be fitted with anti-collision detecting devices. Machinery need not be delivered with such devices fitted, but they must be designed to allow the user to equip the machinery with such devices;
- point c), by equipping machinery with or placing on the market "safety" lifting accessories - self-latching, etc.

- the idea of point c) is not to prevent any shift or downward movement of the load in the case of failure of the power supply, but to limit these movements in terms of amplitude and speed to prevent them from being dangerous.

Lifting apparatus therefore needs to equipped with automatic brakes, and this must be completed by the measures needed to ensure the continuity of the kinematic chain between the brake and the load. Where, for operating reasons, for example, the apparatus is fitted with a slip clutch to allow the load to slide, it must be set well above the maximum load usually acting on it (1.5 to 1.6 times the working load) so that there is no sliding in normal operations.

In the case of hydraulically powered mechanisms the load stopping function can be provided by valves normally closed, pilot-controlled, mounted on the cylinders.

To prevent any shift in the load generated by gravity as the downward movement begins, these devices have to be completed by technical measures limiting the speed to the set value. An engine could play the role of speed limiting device, for example, provided there is no risk of racing, of either mechanical or technical origin, and the brakes are applied as soon as the movement control is in neutral.

The provisions of 4.1.2.6 also apply to apparatus moved manually, which must always allow the position of the load to be controlled without exposing operators to the risk of crank handle return or creeping of the controls. These braking devices therefore need to be equipped with irreversibility and the use of backstops restricted to devices used solely for lifting.

657.

4.1.2.7. Handling of loads

The driving position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons or equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads fixed in one place must be designed and constructed so as to prevent exposed persons from being hit by the load or the counter-weights.

658.

Prevention of the risks of collisions

The first paragraph requires the designer not to put the driving position just anywhere, but to study the best place for viewing the load.
The second paragraph requires access to the space through which the guided loads travel in machinery fixed in one place to be physically impossible (for example, because they are at a height, by providing barriers, etc.).

659.

Definition of guided load

The guided-load machines mentioned in the second paragraph are machines where the load describes an unchanging movement in space (for example, a monorail under which the loads are suspended, a goods lift for transporting goods, etc.).
This does not refer to machines where the movement of the load is free but guided by the operator (for example, overhead travelling cranes, other cranes, etc.).

660.

4.1.2.8. Lightning

Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charges to earth.

661.

Lightning

Some very tall lifting machines are likely to attract lightning when they are working in the open air. This must therefore be taken into account by the manufacturer.

662.

4.2. Special requirements for machinery whose power source is other than manual effort

4.2.1. Controls

4.2.1.1. Driving position

The requirements laid down in section 3.2.1 also apply to non-mobile machinery.

663.

This requirement relates to the work station and, in particular, the obligation of installing a cab or of designing the machine in order for a cab to be installed thereon when the work conditions so require. Please refer back to requirement 3.2.1 and comments thereon.

664.

4.2.1.2. Seating

The requirements laid down in section 3.2.2, first and second paragraphs, and those laid down in section 3.2.3 also apply to non-mobile machinery.

665.

Here, too, machinery with an inherent lifting risk must be fitted with a suitable seat. Requirements 3.2.2 and 3.2.3 do not apply, since the rollover risk does not relate to machinery with only a lifting risk. On the other hand, if the machine with a lifting risk also has a mobility risk, requirements 3.2.2 and 3.2.3 must be applied in their entirety.

666.

4.2.1.3. Movement control devices

The devices controlling movements of the machinery or its equipment must return to their neutral position as soon as they are released by the operator. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by controls authorizing automatic stops at preselected levels without holding a hold-to-run control device.

667.

Specific nature of control devices on lifting machinery

Control devices must generally be of the “hold-to-run” type. This is not the case for:

- guided-load machinery serving specific levels, on condition that requirement 4.1.2.7 is met in full and there is consequently no collision hazard;
- unguided-load machinery, such as tower cranes or travelling cranes, for that part of their movement where there is no collision hazard.

668.

4.2.1.4. Loading control

Machinery with a maximum working load of not less than 1 000 kilograms or an

overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements of the load in the event of:
- ***overloading the machinery***
- ***either as a result of maximum working loads being exceeded, or***
- ***as a result of the moments due to the loads being exceeded,***
- ***the moments conducive to overturning being exceeded as a result of the load being lifted.***

669.

Prevention of the risk of overloading

Any machinery with a lifting capacity of 1 000 kg or more must generally be equipped with a device which warns the driver of overloading and prevents dangerous movements. Moreover, if overloading or certain movements with nominal loading can cause the machinery to tip or overturn, this device or an additional device must warn the driver and prevent movement which could cause the machinery to tip up.

Loading control of tower cranes is generally achieved by a combination of a load limiter and a torque limiter. Indication of the load and radius is indispensable for the operator to apply the correct load curve. This must be completed by indication of nearing activation threshold.

On mobile cranes meeting the limits set out in 4.2.1.4 (1000 kg or 40 000 Nm), the installation of a device using an electronic computer will help to prevent overloading of the apparatus in its various configurations.

Similarly, placing capacity limiters on the vehicle's hydraulic loading arms would preserve the apparatus, once installed on the base chassis, from any overload. Indication of nearing the activation threshold also has to be provided for the operator.

Being lifting apparatus without overhang, such as hoists, winches, travelling cranes, portal cranes, etc., the state of the art can produce a device which provides information in direct correlation with the value of the mass lifted and stops dangerous movements when the maximum working load is exceeded. This kind of device can be installed, for example, to measure a significant effort in:

- the fixed point of block and tackle
- return pulley supports
- the reaction points of lifting winches
- the suspension points of hoists.

However, where, for special applications, the load handled is of known mass and lower than the maximum load capacity of the apparatus and there is never likely to be a case of lifting a load of higher mass (e.g. casting ladles), the absence of risk means that a load limiting device can be dispensed with. The instructions must, of course, state quite clearly the limits of use of the apparatus.

Some machines performing lifting operations have complex operating mechanisms and special working conditions (combination of lifting and mobility, difficult work-site environment due to earth-working and lifting operations performed by the same machine, etc.) which render the devices to prevent dangerous movements ineffective. The current state of the art does not enable this requirement to be met in its entirety.

670.

Industrial trucks with telescopic mast and arm

Application of requirement 4.2.1.4 (Loading control) to industrial trucks with telescopic mast and arm may present problems, as stated in the minutes of the Council meeting of 14 June 1991:
"*The Council and the Commission found that, in the current state of the art, certain machinery, including industrial trucks, might not meet this requirement in its entirety. Any problems in applying this point would be submitted to the "Machinery" Committee for examination."*
However, the second preliminary observation on Annex I does in fact specify that the requirements are obligatory but that there may be derogations on account of the state of the art or the cost of the measures compared with the cost of the product. This observation goes further to say that attempts must be made to comply, as far as possible, with that which the Directive requires.
Although there are currently difficulties which vary, for example, according to the equipment, there are simple and relatively inexpensive methods which can be applied to certain machinery.

By way of example, the problems encountered can be illustrated by the case of industrial trucks with telescopic mast or arm. For these machines the risk of front and side instability needs to be brought under control by integrating the dynamic effects of loading, lifting and lowering.

The parameters involved are the weight and the position of the centre of gravity of the load as a function of its position on the load support, the distribution of weight within the load itself, the inclination of the front/rear mast and the height of the load.

The device should also take account of the various geometries of the trucks and interchangeable equipment, with reconfiguration after any change of equipment.

As regards movement:

- forward or reverse, acceleration, braking and steering are all parameters which involve considerable dynamic effects;
- the ground parameters (variations in terrain or break in slope) cannot be measured by a device; it is only possible to observe the consequences of their variation, without being able to take them into account.

Attention should be drawn to the fact that it is not possible not to apply the Directive by using general texts (for example, standards) which arbitrarily declare that loading control need not be applied to one category of product or another. The manufacturer is still under the obligation to carry out a risk analysis and to find the solution which comes closest to the requirements of the Directive. If he opts for derogation from a requirement, he must indicate in the technical file what analyses have been carried out, what conclusions have been drawn and what measures have been taken to come as close as possible to the requirements.
In the case of industrial trucks, the manufacturer must provide, in the instructions, the information needed to avoid accidents during application.
The tests laid down by the standards (or by Directive 86/663/EEC, as repealed) will be sufficient without further details. They are, after all, static tests which take no account of any dynamic tests that might be necessary.

Requirement 4.2.1.4 in fact covers several aspects:

- the load lifted (1 000 kg),
- the overturning moment (40 000 Nm),

as well as several circumstances:

- too high a load,
- risk of overturning by exceeding the overturning moment.

The manufacturer should consider every case in his analysis and not be limited to just a single aspect, except, of course, if there is no risk.

671.

Use of slip clutches

Since small-sized lifting gear intended to lift loads of more than 1000 kg is relatively inexpensive, slip clutches, which warn the operator and stop the movement, cannot generally be fitted, not least because of the high cost of these slip clutches. Some manufacturers use slip clutches which, when they slip, prevent loads above a given limit from being lifted.

As stated in the comments on requirement 4.1.2.6, to avoid sudden falls a slip clutch must be set at a value well above the maximum working load. A device of this kind cannot therefore be regarded as a device preventing overload.

The manufacturer must therefore carry out a full analysis of all possible situations before choosing the best solution, remembering that the requirement is essential and that it will be necessary in the future to move towards application of that requirement.

672.

4.2.2. Installation guided by cables

Cable carriers, tractors or tractor carriers must be held by counter-weights or by a device allowing permanent control of the tension.

673.

This requirement is designed to prevent the release of guide or hauling cables, which would almost certainly lead to accidents since the load would no longer be correctly guided.

674.

4.2.3. Risks to exposed persons. Means of access to driving position and intervention points

Machinery with guided loads and machinery whose load supports follow a clearly defined path must be equipped with devices to prevent any risks to exposed persons.

Machinery serving specific levels at which operators can gain access to the load platform in order to stack or secure the load must be designed and constructed to prevent uncontrolled movement of the load platform, in particular while being loaded or unloaded.

675.

Safety of workstations

The first paragraph calls for measures to be taken when designing the limits of the levels at which the load supports stop, to prevent operators from falling into the space through which the load travels. It also stresses that an exposed person should not be able to gain access to the space through which it travels.
The second paragraph requires a device which, in order to fulfil the role assigned to it by this requirement, must be controlled either by the opening of the equivalent of a landing door or by the machinery's control devices.

676.

4.2.4. Fitness for purpose

When machinery is placed on the market or is first put into service, the manufacturer or his authorized representative established within the Community must ensure, by taking appropriate measures or having them taken, that lifting accessories and machinery which are ready for use - whether manually or power-operated - can fulfil their specified functions safely. The said measures must take into account the static and dynamic aspects of the machinery.

Where the machinery cannot be assembled in the manufacturer's premises, or in the premises of his authorized representative established within the Community, appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.

677.

Obligation to guarantee safe putting into service

This requirement obliges the manufacturer to ensure that machinery with a lifting risk will operate safely. The manufacturer is free to employ whatever means which he deems appropriate and pertinent to provide this guarantee. The manufacturer may, for example, perform or have performed static and dynamic tests to ensure that the machinery has been correctly manufactured and assembled. The purpose is not to verify the design, but to check that all devices provided for by the designer as necessary for safe working are present and operating correctly. The "appropriate measures" referred to in this requirement (tests or other measures) may be carried out at the time of placing the machinery on the market or putting it into service.

678.

This requirement relates only to placing the product on the market and its being put into service for the first time. Any checks required after each assembly, in the case of equipment that can be dismantled, are not covered by this Directive. These fall within the scope of the use of the equipment, and therefore the Directives based on Article 118a of the Treaty or, failing that, national regulations. These measures in no way affect the freedom of movement of the products.
In addition, periodic checks are laid down by Directive 89/655/EEC, as amended, which must also be taken into account. Once again, freedom of movement is not called into question.

679.

4.3. Marking

4.3.1. Chains and ropes

Each length of lifting chain, rope or webbing not forming part of an assembly

must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorized representative established in the Community and the identifying reference of the relevant certificate.

The certificate should show the information required by the harmonized standards or, should those not exist, at least the following information:

- ***the name of the manufacturer or his authorized representative established within the Community,***
- ***the address within the Community of the manufacturer or his authorized representative, as appropriate,***
- ***a description of the chain or rope which includes:***
- ***its nominal size,***
- ***its construction,***
- ***the material from which it is made, and***
- ***any special metallurgical treatment applied to the material,***
- ***if tested, the standard used,***
- ***a maximum load to which the chain or rope should be subjected in service.***

680.

Sale of chains and ropes
Legal status of lifting chains, ropes and webbing

Chains, ropes and webbing used for lifting are regulated by the “machinery” Directive. It will therefore be necessary to add this new product category to the category of regulated components (transmission shafts and their guards, lifting and slinging accessories, etc.). Here, too, the inclusion in the “machinery” Directive of a component which does not fall within the definition of the "machinery", "interchangeable equipment " or "safety component" is down to expediency, especially as the “machinery” Directive has repealed certain articles of amended Directive 73/361/EEC,[100] as amended, which provide for specific marking for chains, ropes and hooks.

681.

Marking

Chains, ropes and webbing used for lifting must bear a marking. This marking includes the manufacturer's particulars. The Directive also requires identification of the certificate. This might be a number referring to a certificate number.
Is it necessary to affix the "CE" marking on a chain or rope?
In its reply No 33 on the marking of ropes the Commission differentiates between two cases:

- the rope is supplied for use with a machine or in a sling arrangement. In such cases it is often supplied in reels. This is the case in 4.3.1 and “CE” marking is not necessary.
- the rope supplied forms part of an assembly such as a winch or a sling. This is the case referred to in 4.3.2 and the assembly must bear the “CE” marking.

Does this mean that all procedures applicable to machinery are applicable to lifting chains, ropes and webbing? This is probably too hasty a conclusion. Will the chain manufacturer be required a design file when the special certificate already contains the essential information? Will instructions be asked for when buying a length of rope?

100 Directive 73/361/EEC of 19 November 1973 (OJ No L 335, 5.12.73, p. 51), as amended by Directive 76/434/EEC (OJ No L 122, 8.05.76, p. 20)

The legislator has obviously not wanted to put lifting chains, ropes and webbing on a par with machinery, even if he is responsible for regulating them.
When a chain or rope is ordered from a blacksmith, the person placing the order must ask for the marking. The marking may be replaced by a ring or a small plate. In practice, marking or labelling may cause problems when the chains are sold cut-to-length at distributors.

682.

Special certificate

The certificate referred to in requirement 4.3.1 is not the declaration of conformity or referred to in Annex II. The special certificate takes the place of the declaration of conformity. It would therefore be absurd to require both a declaration of conformity and a special certificate, since the latter largely adopts the content of the declarations in Annex II.

There is no explicit mention that the special certificate for lifting chains, ropes and webbing has to go with the products. The special certificate for chains and ropes is not mentioned in Articles 4.2 and 4.3, which oblige the Member States to allow free movement of products "accompanied" by the declaration of conformity. It may be concluded from this that the chain manufacturer can keep this certificate. It is not a condition of freedom of movement of the product.

It is worth noting that the details contained in the harmonized standards have to be reproduced in the special certificate.

The “machinery” Directive therefore makes these standards obligatory. This is the only case in this Directive.

683.

4.3.2. Lifting accessories

All lifting accessories must show the following particulars:
- ***identification of the manufacturer,***
- ***identification of the material (e.g. international classification) where this information is needed for dimensional compatibility,***
- ***identification of the maximum working load,***
- ***EC mark.***

In the case of accessories including components such as cables or ropes, on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or by some other means and securely affixed to the accessory.

The particulars must be legible and located in a place where they are not liable to disappear as a result of machining, wear, etc., or jeopardize the strength of the accessory.

684.

Placing lifting accessories on the market

Lifting accessories are very often placed on the market ready to be used, independently of the machines. The use of a lifting machine requires many and varied lifting accessories which, conversely, are not assigned to a single machine.

Does the lifting accessories have to follow all the procedures required of “machinery”? The same questions raised in the case of chains also arise here. If this were the case, why has the legislator chosen to mention the "CE" marking on lifting accessories? This would was automatic if the accessories were purely and simply treated in the same way as machinery. In contrast, there is no explicit mention of drawing up a file. It is safe to assume that the legislator has considered only the details appearing on the product or on a plate, pad, ring, etc.

685.

Marking of slinging accessories

A sling is made up of various parts; it may consist of a single non-detachable part or of several elements (e.g. hooks, rings, chains or ropes, etc.) put together, as required, by the sling manufacturer.
How should slings be marked? Several suggestions have been put forward (single marking for the complete sling or marking of the various elements).
The most reasonable solution, which is to be recommended, is to mark each of the elements separately; however, it is clear that a chain, consisting of elements which cannot be taken apart without destroying it, need only bear a single marking.
This is because the various parts are not used for the same purpose; they may be used either as a lifting accessory or as a slinging accessory, and therefore must bear the requisite details. Moreover, many slings are manufactured on site from elements originating from different manufacturers; these elements must all be marked so that the assembler does not make any mistakes.

686.

4.3.3. Machinery

In addition to the minimum information provided for in 1.7.3, each machine must bear, legibly and indelibly, information concerning the nominal load:

(i) displayed in uncoded form and prominently on the equipment in the case of machinery which has only one possible value;

(ii) where the nominal load depends on the configuration of the machine, each driving position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the nominal loads for each configuration.

Machinery equipped with a load support which allows access to persons and involves a risk of falling must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.

687.

Warning prohibiting the lifting of persons

The legislator is aware that it is physically impossible to prevent access to the load support.

In the current state of the art, the only requirement separating people-lifting machines from machines which are not authorized for lifting people is the presence or otherwise of control devices on the mobile platform.

688.

4.4. Instruction handbook

4.4.1. Lifting accessories

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied with an instruction handbook setting out at least the following particulars:

- ***normal conditions of use,***
- ***instructions for use, assembly and maintenance,***
- ***the limits of use (particularly for the accessories which cannot comply with 4.1.2.6(e)).***

689.

Instructions for lifting accessories

The final indent relates to accessories such as magnetic or pneumatic grippers for which requirement 4.1.2.6 e) cannot be always met. The manufacturer must specify these cases and inform the user that these devices may be used only above areas where people are not permanently stationed.

690.

4.4.2. Machinery

In addition to section 1.7.4, the instruction handbook must include the following information:

(a) the technical characteristics of the machinery, and in particular:
- ***where appropriate, a copy of the load table described in section 4.3.3 (ii),***
- ***the reactions at the supports or anchors and characteristics of the tracks,***
- ***where appropriate, the definition and the means of installation of the ballast;***

(b) the contents of the logbook, if the latter is not supplied with the machinery;

(c) advice for use, particularly to offset the lack of direct sight of the load by the operator;

(d) the necessary instructions for performing the tests before first putting into service machinery which is not assembled on the manufacturer's premises in the form in which it is to be used.

691.

Supplements to instructions

Point a) reiterates the importance of informing the driver of the machine's loading limits and bearing conditions in order to guarantee stability. Many accidents occurring with lifting equipment are due to stability problems arising from stabilisers which are ill placed or not stable enough.

Point b) does not require the log book to be supplied (periodic maintenance work, whether or not regulated, exceptional maintenance work, major repairs or modifications, etc.) but calls for advice from the manufacturer with regard to its content.
It would be very useful, if not essential, for standards bodies to reflect on this problem, since a standardized form of the content of the log book would enable it to be "deciphered" even where the language in which it is written is not known (e.g. rented machinery or machinery taken with a contractor to another country in the EEA).

692.

5. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK

Machinery intended for underground work must be designed and constructed to meet the requirements set out below.

693.

Concept of "underground work"

The minutes of the Council (Internal Market) of 20 June 1991 state that:
"***It is understood that work carried out in underground car parks, underground shopping malls, cellars, mushroom beds and the like is not regarded as underground work*".** This article has been drawn up for equipment intended to be used in mines and underground quarries, not in "buildings" located below ground.

694.

5.1. Risks due to lack of stability

Powered roof supports must be so designed and constructed as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.

695.

Supports

This requirement is specific to this type of equipment, which is used primarily in mining work. It is sufficiently clear for experts in that area.

696.

5.2. Movement

Powered roof supports must allow for unhindered movement of exposed persons.

697.

Here, too, this requirement is obvious, but it was thought necessary to reiterate it, given the problems encountered in mines.

698.

5.3. Lighting

The requirements laid down in the third paragraph of section 1.1.4 do not apply.

699.

Special case for underground work

This derogation is based on the fact that for underground work the operator carries his own lighting, generally on his helmet.

700.

5.4. Control devices

The accelerator and brake controls for the movement of machinery running on rails must be manual. The deadman's control may be foot-operated, however.

The control devices of powered roof supports must be designed and laid out so that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.

701.

This requirement is clear and requires no further explanation. It covers two different aspects: machinery running on rails and powered roof supports.

702.

5.5. Stopping

Self-propelled machinery running on rails for use in underground work must be equipped with a deadman's control acting on the circuit controlling the movement of the machinery.

703.

"Deadman?"

Standards bodies sometimes use the term "deadman" wrongly. This is a device requiring regular, deliberate action by the operator, at given time intervals, without which the machine will stop.

704.

5.6. Fire

The second indent of 3.5.2 is mandatory in respect of machinery which comprises highly flammable parts.

The braking system of machinery meant for use in underground working must be designed and constructed so as not produce sparks or cause fires.

Machinery with heat engines for use in underground working must be fitted only with internal combustion engines using fuel with a low vaporizing pressure and which exclude any spark of electrical origin.

705.

Flammability

The concept of flammability will be defined in the standards, which should also state the threshold of "high" flammability from which the first paragraph applies.
Given the current state of the art, the third paragraph means in effect that only diesel engines are authorized, but it allows for the possibility of technological developments affecting other types of engines.

706.

5.7. Emissions of dust, gases etc.

Exhaust gases from internal combustion engines must not be discharged upwards.

707.

Gases

This means that standard earth-moving equipment with upwards-pointing exhaust pipes cannot be used in underground working. The main reason for this requirement is to prevent the roof of the roadway from being exposed to thermal stresses which might destabilize the roof.

708.

6. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO THE LIFTING OR MOVING OF PERSONS

Machinery presenting hazards due to the lifting or moving of persons must be designed and constructed to meet the requirements set out below.

709.

The comments on point 4.3.3 state that machinery intended exclusively for lifting loads should not have control devices so to avoid the temptation of their being used as a means of lifting persons.

710.

6.1. General

6.1.1. Definition

For the purposes of this Chapter, "carrier" means the device by which persons are supported in order to be lifted, lowered or moved.

711.

This text provides a definition of "carrier" as used in the following requirements. This is always the place where persons take up position, irrespective of the direction of movement.

712.

6.1.2. Mechanical strength

The working coefficients defined in heading 4 are inadequate for machinery intended for the lifting or moving or persons and must, as a general rule, be doubled. The floor of the carrier must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the maximum working load set by the manufacturer.

713.

This requirement draws attention to the risks run by persons being transported and requires, as a general rule, that the working coefficients be twice that used for loads alone. If a load falls the accident will almost always only have material consequences, whereas if the carrier falls the risk to persons being transported will always be serious. Precautions must therefore be taken to prevent this from happening. Similarly, the floor of the carrier must be carefully designed to take account of any equipment which may be transported in the carrier and which would add to the weight of the persons.

714.

6.1.3. Loading control for types of device moved by power other than human strength

The requirements of 4.2.1.4 apply regardless of the maximum working load figure. This requirement does not apply to machinery in respect of which the manufacturer can demonstrate that there is no risk of overloading and/or overturning.

715.

This requirement reiterates that, when persons are being transported, devices must be installed to prevent overload and, if necessary, exceeding the overturning moment, as required by 4.2.1.4, whatever the maximum working load.

In recent years the increase in the use of lifts has helped to reduce the number of accidents that occur when makeshift scaffolding and ladders are used. But such equipment still presents risks that can be the source of accidents, which are always serious. These accidents have two basic sources: repeated overload, excessive fatigue of the equipment and the breakage of a structural element causing the lift compartment to fall; and overturning of the equipment due to poor installation, overload or catching an obstacle in the vicinity of the equipment.

While the state of the art cannot at present prevent all risks due to overload or exceeding the overturning moment (especially sudden overload in the up position or catching an obstacle), devices exist which, for most equipment, can alert the operator and stop any aggravating movements in the other cases of overload and, if necessary, prevent the overturning moment from being exceeded.

Any derogation from installing such devices will be exceptional and will have to be justified by risk analysis. This might be the case, for example, with small apparatus where the size of the cabin leaves only room for one person and its structures have been calculated to withstand any overload its limited size might permit.

716.

6.2. Controls

6.2.1. Where safety requirements do not impose other solutions:

The carrier must, as a general rule, be designed and constructed so that persons inside have means of controlling movement upwards and downwards and, if appropriate, of moving the carrier horizontally in relation to the machinery.

In operation, those controls must override the other devices controlling the same movement, with the exception of the emergency stop devices.

The controls for these movements must be of the maintained command type, except in the case of machinery serving specific levels.

717.

This requirement is specific to machinery for lifting persons, giving a narrower definition of "lifting of persons". In general the carrier should have controls; this is important since it is often the person being moved who sees the dangers to which he might be exposed and not the operator on the ground. It is therefore essential for him to be able to control the movements.
The final paragraph requires a comment.
It was included in order not to ask too much of the occupants of carriers with a well-defined movement; the drafters of the Directive were thinking in particular of vertical platforms located between two levels.
It could, however, pose problems, and a risk analysis should be carried out in order to take all aspects into account, in particular where risks of jamming or transporting handicapped persons are concerned.
These might be, for example, platforms for wheelchairs or stair-lift seats.
The levels are defined (upper and lower), but what would happen if the chair moved or became jammed? Or if a garment worn by the handicapped person (or person with reduced mobility) using the chair-lift seat got caught? That person would fall down the stairs since he would never be able to "jump off" the seat in order to protect himself.
It is certainly advisable in such cases to use "hold-to-run" controls which will stop the movement as soon as they are released.

718.

6.2.2. If machinery for the lifting or moving of persons can be moved with the carrier in a position other than the rest position, it must be designed and constructed so that the person or persons in the carrier have the means of preventing hazards produced by the movement of the machinery.

719.

The machinery referred to here, used in agricultural or on building sites, is inherently dangerous. When the machinery is in motion the operator in the carrier may notice a danger which the driver is unable to see. According to point 6.2.1, the operator must have the means of controlling movement upwards and downwards. Considering this to be insufficient, the legislator also requires the operator be able to bring the machinery to a stop by means of a control device which interrupts the movement safely or by speaking to the driver.

720.

6.2.3. Machinery for the lifting or moving of persons must be designed, constructed or equipped so that excess speeds of the carrier do not cause hazards.

721.

This article should tie in with the requirement mentioned in point 6.4.1.

722.

6.3. Risks of persons falling from the carrier

6.3.1. If the measures referred to in 1.5.15 are not adequate, carriers must be fitted with a sufficient number of anchorage points for the number of persons possibly using the carrier, strong enough for the attachment of personal protective equipment against the danger of falling.

723.

The "appropriate" height depends on the intended use of the machinery. If the carrier is used as a workstation, it must be possible for the work in question to be carried out from the platform. The guard rails will be at the height needed for this work. If the guard rails are inadequate, anchoring points are recommended.

724.

6.3.2. Any trapdoors in floors or ceiling or side doors must open in a direction which obviates any risk of falling should they open unexpectedly.

725.

This requirement might also seem obvious, but there should be an analysis of any risks and actual situations.
Derogations are possible and the notified bodies must take this into account. A side door, for example, should always open inwards, but this is not for platforms used by fire fighters as it would restrict movement and reduce the possibility of saving life.

726.

6.3.3. Machinery for lifting or moving must be designed and constructed to ensure that the floor of the carrier does not tilt to an extent which creates a risk of the occupants falling, including when moving.

The floor of the carrier must be slip-resistant.

727.

For example, suspended cradles for cleaning façades with more than one powered winch must be equipped with a device which prevents a winch from operating if it is upsetting the horizontal balance of the platform.

728.

6.4. Risks of the carrier falling or overturning

6.4.1 Machinery for the lifting or moving of persons must be designed and constructed to prevent the carrier falling or overturning.

729.

The device referred to, which is linked referred to in point 6.2.3, may be a non-return valve on a hydraulic or pneumatic jack, a mechanical braking system on carriers suspended on ropes or chains, a safety screw on screw equipment, etc.

Where the kinetic energy involved is too great, such devices can be dangerous and must be replaced by other measures to reduce the risk. These must be clearly set out in the instructions.

730.

6.4.2. Acceleration and braking of the carrier or carrying vehicle, under the control of the operator or triggered by a safety device and under the maximum load and speed conditions laid down by the manufacturer, must not cause any danger to exposed persons.

731.

This requirement is obvious; too rapid a movement (sudden stopping, for example) might eject persons from the carrier.

732.

6.5. Markings

Where necessary to ensure safety, the carrier must bear the relevant essential information.

733.

This is information needed for safety, especially the maximum number of persons that can be lifted, etc. If necessary, the function of the control devices may be specified so as to avoid any erroneous manoeuvres.

ANNEX II

734.

A. Contents of the EC declaration of conformity for machinery[1]

The EC declaration of conformity must contain the following particulars:

- ***name and address of the manufacturer or his authorized representative established in the Community,[2]***
- ***description of the machinery,[3]***
- ***all relevant provisions complied with by the machinery,***
- ***where appropriate, name and address of the notified body and number of the EC type-examination certificate,***
- ***where appropriate, the name and address of the notified body to which the file has been forwarded in accordance with the first indent of Article 8(2)(c),***
- ***where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of Article 8(2)(c),***
- ***where appropriate, a reference to the harmonized standards,***
- ***where appropriate, the national technical standards and specifications used,***
- ***identification of the person empowered to sign on behalf of the manufacturer or his authorized representatives.***

B. Contents of the declaration by the manufacturer or his authorized representatives established in the Community (Article 4(2))

The manufacturer's declaration referred to in Article 4(2) must contain the following particulars:

- ***name and address of the manufacturer or the authorized representative,***
- ***description of the machinery or machinery parts,***
- ***where appropriate, the name and address of the notified body and the number of the EC type-examination certificate,***
- ***where appropriate, the name and address of the notified body to which the file has been forwarded in accordance with the first indent of Article 8(2)(c),***
- ***where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of Article 8(2)(c),***
- ***where appropriate, a reference to the harmonized standards.***
- ***a statement that the machinery must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive,***
- ***identification of the person signing.***

C. Contents of the EC declaration of conformity for safety components placed on the market separately[1]

The EC declaration of conformity must contain the following particulars:

- ***name and address of the manufacturer or his authorized representative established in the Community,[2]***
- ***description of the safety component,[4]***
- ***safety function fulfilled by the safety component, if not obvious from the description;***
- ***where appropriate, the name and address of the notified body and the number of the EC type-examination certificate;***

- ***where appropriate, the name and address of the notified body to which the file was forwarded in accordance with the thirst indent of Article 8(2)(c);***
- ***where appropriate, the name and address of the notified body which carried out the verification referred to in the second indent of Article 8(2)(c);***
- ***where appropriate, a reference to the harmonized standards;***
- ***where appropriate, the national technical standards and specifications used;***
- ***identification of the person empowered to sign on behalf of the manufacturer or his authorized representative established in the Community.***

---

1. This declaration must be drawn up in the same language as the original instructions (see Annex I, section 1.7.4(b)) and must be either typewritten or handwritten in block capitals. It must be accompanied by a translation in one of the official languages of the country in which the machinery is to be used. This translation must be done in accordance with the same conditions as for the translation of the instructions.

2 Business name and full address; authorized representatives must also give the business name and address of the manufacturer.

3 Description of the machinery (make, type, serial number, etc.).

4 Description of the safety component (make, type, serial number, if any, etc.).

735.

(Extract)

[A. Contents of the EC declaration of conformity for machinery[1]

The EC declaration of conformity must contain the following particulars:
- name and address of the manufacturer or his authorized representative established in the Community[2],
- description of the machinery[3],
- all relevant provisions complied with by the machinery,
- where appropriate, name and address of the notified body and number of the EC type-examination certificate,
- where appropriate, the name and address of the notified body to which the file has been forwarded in accordance with the first indent of Article 8(2)(c),
- where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of Article 8(2)(c),
- where appropriate, a reference to the harmonized standards,
- where appropriate, the national technical standards and specifications used,
- identification of the person empowered to sign on behalf of the manufacturer or his authorized representatives.

---

1. This declaration must be drawn up in the same language as the original instructions (see Annex I, section 1.7.4(b)) and must be either typewritten or handwritten in block capitals. It must be accompanied by a translation in one of the official languages of the country in which the machinery is to be used. This translation must be done in accordance with the same conditions as for the translation of the instructions.

2	Business name and full address; authorized representatives must also give the business name and address of the manufacturer.
3	Description of the machinery (make, type, serial number, etc.).
(...)]	

736.

Proposed here are a number of declaration models to comply with Annex II. These models are not compulsory. Each heading on each of the declarations to be completed is numbered. This numbering indicates the nature of the statements appearing in a declaration written in a language not or barely understood by the reader. Should it be necessary or useful to draw up a declaration for which there is no model, it is advised that the forms proposed here should be used together with their respective numbers.

737.

Model of an "EC" declaration of conformity of machinery not subject to "EC" type examination (Annex II.A)

01 *"EC" declaration of conformity of a machine with the "machinery" Directive (89/392/EEC, as amended) and the regulations for transposing it into national law*

02 THE MANUFACTURER **(name and address)**

03 THE AUTHORIZED REPRESENTATIVE **(name and address)**
acting on behalf of the MANUFACTURER (name and address)

04 HEREBY DECLARES THAT THE MACHINERY **DESCRIBED BELOW:**
(Description, serial number, brand)

05 **COMPLIES WITH THE PROVISIONS OF THE "MACHINERY" DIRECTIVE (DIRECTIVE 89/392/EEC, as amended) AND THE REGULATIONS TRANSPOSING IT INTO NATIONAL LAW**

06 **ALSO COMPLIES WITH THE PROVISIONS OF THE FOLLOWING EUROPEAN DIRECTIVES:**
(References of the Directives)

07 **COMPLIES WITH THE PROVISIONS OF THE FOLLOWING HARMONIZED STANDARDS:**

08 **ALSO COMPLIES WITH THE FOLLOWING EUROPEAN STANDARDS, NATIONAL STANDARDS AND TECHNICAL PROVISIONS:**

09 **Done at (place),**

10 **On (date),**

11 **Name of the signatory**

12 **Signature**

The numbers appearing in the boxes correspond to the declaration models published in the 1997 issue of the "machinery" Directive application guide. These numbers provide correspondence between the various linguistic versions.

Comments on the model of an "EC" declaration for machinery subject to self-certification (Annex II.A)

738.

01

Each example of the machinery must be accompanied by the "EC" declaration of conformity. The “machinery” Directive is one of the rare European Directives to require the accompaniment of this declaration with the product. The "EC" declaration of conformity is a document which provides information important for the customer. The "EC" marking alone on the machinery is insufficient to provide the buyer with this information.

739.

Provision of the "EC" declaration of conformity

The “machinery” Directive does not specify the manner in which the "EC" declaration of conformity is to be provided to the buyer. It may be in the form of paper in the box in which the machinery is delivered. It may be printed in the instructions. It may be attached to the delivery note. The latter may mention explicitly that the customer certifies having received the "EC" declaration of conformity (and also the instructions).

740.

02

Indication of the name of the manufacturer - The "actual" manufacturer

Indication of the name of the manufacturer means first and foremost the name of the "actual" manufacturer in the ordinary sense of the word. "Manufacturer" is taken to mean: "*The person who assumes responsibility for the design and manufacture of a product covered by the Directive for the purpose of placing it on the market*.[101] The manufacturer may or may not be established in the European Union. The manufacturer is obliged to design relevant equipment and to comply with the procedures for placing it on the market, including in particular the creation of a technical file and the affixing of the "CE" marking. The manufacturer may subcontract certain operations, or indeed the design of the product, as long as he retains control of and responsibility for everything.

741.

What name should be used?

The name of a company is the name which distinguishes it by its purpose, either by means of a made-up name or by the name of a person. It should be distinguished from the corporate name, which only applies to certain companies. It indicates the names of members who are generally, without limit, liable for the company's debts. In some companies, the corporate name is formed by the name of the members followed by the words "and company". The commercial name should also be distinguished from the corporate name or business name. This is the name under which an undertaking carries out its commercial activity. Similarly, the sign is a made-up name which serves to specify a commercial establishment and enables the customer to identify it with ease.

101 Definition taken from the *Guide to the Implementation of Community Harmonization Directives based on the New Approach and the Global Approach* (Office for Official Publications of the European Communities, 1994).

Care should be taken to ensure that the content of the declaration coincides with the name of the manufacturer appearing on the machinery. The marking, it will be recalled, must comprise the name of the manufacturer, his address, the "CE" marking, the description, the serial number, where one exists, and the year of manufacture. Manufacturers of small machinery can simplify this marking (name and town). The marking is done by any means (ink, plaque, etc.) provided that it is legible and indelible.[102]

The marking of the name of the manufacturer of the machinery does not mean having to remove the names of the manufacturers of components appearing on subassemblies.

742.

Machinery manufactured by users for their own use
Where machinery manufactured by a user for his own use, the user must complete and keep the declaration.

743.

"EC" declaration of conformity for complex assemblies
In the case of a complex assembly resulting from the assembly of several machines, the "manufacturer" may be the prime contractor who coordinates and supervises the production of the assembly. The end user will often be this prime contractor. An "EC" declaration of conformity might be signed jointly by several parties. In this case, it is safe to assume that the latter have committed themselves to being jointly and severally liable. They then assume the liability for the whole machine without it being necessary to distinguish between the supply of one assembly or another. It will be very difficult for any one of the signatories to claim that he is not liable because the part he supplied was not involved in the accident.

744.

The address
Nothing is specified with regard to the address. The manufacturer may give his full address, the address of the head office or the address of one of his factories, or even one of its premises in the country of destination.

745.

03

Authorized representative of the "actual" manufacturer
The "authorized representative" of the manufacturer is "the person who, designated expressly by the manufacturer, acts in the name and on behalf of the latter with regard to certain obligations laid down by the Directive, in so far as the Directive so provides".[103]

Delegation must be explicit. The authorized representative of the manufacturer is responsible for the procedures for placing the product on the market. The same applies, in our opinion, to the marking of the machinery. The authorized representative may be a lawyer or any intermediary. The commercial subsidiary of a manufacturer, a commercial representative or a distributor may be designated by the manufacturer as "authorized representative".

102 Cf. the comments on requirement 1.7.3 of Annex I.
103 Case 102/77 Hoffman v La Roche [1978] ECR 1139 and Cases C-427-93, 429/93, 436/93 Bristol-Myers v Squibb [1996]

The authorized representative may therefore complete the "EC" declaration of conformity in the place of the manufacturer. However, he must indicate in this declaration the corporate name and full address of the manufacturer who has given the authorization.

However, the manufacturer who has given the authorization remains free to market the machinery with an "EC" declaration of conformity which makes no reference to any authorized representative in the European Union. This is possible even if this representative has carried out administrative procedures in respect of the equipment in question (submission of the construction file, negotiations with the notified body, etc.). Footnote 2 to Annex II.A requires the authorized representative to mention the name of the manufacturer, but it does not require the manufacturer to mention the name of his authorized representative.

746.

Manufacturer and distributor

Distribution in general

An ordinary distributor (who does not sell under his own brand) cannot be treated in the same way as a manufacturer or the "authorized representative" of a manufacturer (which does not prejudice his civil and criminal liabilities). He markets the product, transferring the "EC" declaration of conformity which he has received from the manufacturer or his authorized representative. A distributor does not therefore have to complete the declaration. He does not have the right to amend it, but there is nothing to prevent him from adding information to the effect that the product is distributed by him and that he has complied with the Directive. However, this will not be an official declaration made under the “machinery” Directive.

747.

Sale under distributor brand

The “machinery” Directive is not incompatible with the widespread practice of selling under a "distributor" brand. The "89/392" Committee indeed stated he following: "*Owners of brand names relating to completed machinery must accept all the obligations that the Directive imposes on the manufacturer. In particular, they must establish and sign the "EC" declaration of conformity, affix the "CE" marking, draw up the instructions and keep the technical file referred to in Annex V*".

The distributor is thus likened to the manufacturer and must act as such.

The "actual" manufacturer's brand may only be replaced by the name of the distributor if he assumes all the manufacturer's obligations. By way of example, the distributor must, on duly reasoned request of the respective national authorities, be able to communicate the parts of the documentation referred to in Annex V. It is to the distributor that customers or the public authorities turn for the purpose of conformity. The "actual" manufacturer is then no more than a mere subcontractor.

748.

The “machinery” Directive does not allow just anyone to remove the mark of the actual manufacturer in order to affix his own. Only someone who is capable of totally assuming the responsibility of the manufacturer may do so. The marking of the name of the manufacturer is a regulatory marking which cannot be replaced simply by a brand name. This ties in with administrative "policing" and "traceability" of the product, the aim being protection of the end user.

It has to be reiterated here that the possibility accorded to the distributor of substituting his brand for that of the actual manufacturer must meet the contractual agreements between the two parties and industrial property rights.[104] Wrongful substitution of one brand name for another in contravention of these rights may amount to deceit of the end-user.

749.

04

Designation of machinery
Designation of the machinery is free and left entirely to the manufacturer's initiative. Numbering of machinery is not compulsory. The manufacturer has to show the information to identify the machinery. In the case of mass-production, an "EC" declaration of conformity drawn up for a batch of identical machines is permissible. In this case, the declaration accompanying the machinery should be a copy on original headed paper, which is more difficult to falsify, rather than a photocopy. It should be identified by serial numbers of the "3501 to 5730" type, the number appearing on the copy of the machinery forming part of this series.

750.

05

Conformity with the “machinery” Directive
Since this is the "EC" declaration of conformity with the “machinery” Directive, it is only natural for it to be indicated.

This will be important when the machinery for which this declaration is drawn up is covered by several Directives. Only certain declarations need to accompany the machinery (including the declaration drawn up under the “machinery” Directive), while others, drawn up under other Directives, might simply be found in the technical documentation.

751.

Mention of the national transposition texts is not necessary but it is possible. Reference to transposition texts is not practised by most manufacturers. To require this would amount to introducing a requirement which is not in the Directive.

752.

06

Conformity with other Directives
The manufacturer should state here what other Community Directives the machinery complies with.

In its reply to Question No 66 the "89/392" Committee quotes "*that it is absolutely necessary to include in the declaration of conformity a full list of the Directives with which the design of the machinery complies since this makes it indicates:*

104 On this point, see in particular:
- Directive 89/104/EEC of 21 December 1988 on the approximation of the laws of the Member States on marks (1st Directive) (OJ No L 40, 11. 02.89, p. 1), as supplemented by Decision 10/92/EEC (OJ No L 6, 11.01.92, p. 35);
- Regulation (EC) No 40/94 of 20 December 1993 (OJ No L 11, 14.01.94, p. 1; as amended by Regulation (EC) No 3288/94 (OJ No L 349, 31.12.94, p. 83)] and the implementing regulations (Regulation No 2868/95 of 13 December 1995 (OJ L 303, 15.12.95, p. 1; Regulation No 2869/95 of 13 December 1995 (OJ L 303, 15.12.1995, p. 33)

- *during transitional periods, the choice made by the manufacturer (new Directive or old regulation);*
- *outside the transitional periods, whether the manufacturer has followed all the Community legislation (...)*".

The European Directives most likely to involve machinery are electromagnetic compatibility (Directive 89/336/EEC, as amended),[105] electrical safety (Directive 73/23/EEC, as amended),[106] simple pressure vessels (Directive 87/404/EEC, as amended)[107], pressurized equipment (draft Directive),[108] equipment designed for use in potentially explosive atmospheres (Directive 94/9/EEC)[109] and gas appliances (Directive 90/396/EEC, as amended)[110]. The manufacturer must mention the number of the Directive and its name, but not necessarily the national transpositions.

753.

The manufacturer of the machinery must, where appropriate, obtain components in accordance with these Directives. He must require from his supplier in the contract an "EC" declaration of conformity with these Directives which he must keep in the file on the manufacture of the machinery. He must verify statutory markings (for example, on pressurized equipment). The declarations regarding components do not have to be sent to the end customer.

754.

Where a part of the machinery (engines or motors, hydropneumatic accumulators, etc.) is subject to a type examination under another Directive, the manufacturer of the machinery is not obliged, in our opinion, to mention in the declaration the name of the certifying body or the certificate number.

Conversely, if the finished machinery has been subjected to an inspection procedure by a notified body under another Directive, the manufacturer may, if he so wishes, give the name of the body and the certificate number received.

The manufacturer may use the declaration of conformity with the “machinery” Directive as the common declaration of conformity with all the other pertinent Directives applicable to his product. He must then include the points required by each of the Directives which he wishes to take into account.

755.

07

Harmonized standards

Harmonized standards are European standards used to apply the “machinery” Directive; the references are published in the Official Journal of the European Communities and in the official gazettes of the Members States. These standards are not obligatory. The manufacturer is therefore free not to refer to them. It is clearly in the manufacturer's interest to include them

105 Directive 89/336/EEC of 3 May 1989 (OJ No L 139, 23.05.89, p. 19); as amended by Directives 91/263/EEC (OJ No L 128, 23.05.91, p. 1), 92/31/EEC (OJ No L 126, 22.05.92, p. 11), 93/68/EEC (OJ No L 220, 31.08.93, p. 1) and 93/97/EEC (OJ No L 290, 24.11.93, p. 1)

106 Directive 73/23/EEC of 19 February 1973 (OJ No L 77, 26.03.73, p. 29); as amended by Directive 93/68/EEC (OJ No L 220,31.08.93, p. 1)

107 Directive 87/404/EEC of 25 June 1987 (OJ No L 220, 8.08.87, p. 48); as amended by Directives 90/488/EEC (OJ No L 270, 2.10.90, p. 25) and 93/68/EEC (OJ No L 220, 31.08.93, p. 1)

108 Common Position No 22/96 of 29 March 1996 (OJ No C 147, 21.06.96, p. 1)

109 Directive 94/9/EC of 23 March 1994 (OJ No L 100, 19.04.94, p. 1)

110 Directive 90/396/EEC of 29 June 1990 (OJ No L 196, 26.07.90, p. 15); as amended by Directive 93/68/EEC (OJ No L 220, 31.08.93, p. 1)

in the "EC" declaration of conformity since these standards provide the product with a "presumption of conformity" with the Directive in respect of the essential requirements to which they relate. The European standards are available only through the collections of national standards. Since the European standards are adopted in the national collections without any changes, direct reference may be made to the European indication (e.g. EN 294) rather than the national indication (e.g. DIN EN 294).

756.

08

Reference to conformity with other national standards and technical specifications.
The manufacturer may include here compliance with other European standards (the references of which are not published in the OJEC). They are fully valid. European standards are available through the national collections.

Where the European standard has not yet been ratified by the CEN, CENELEC or ETSI, the manufacturer may refer to the draft standard (prEN). Conformity with draft European standards should, in our opinion, be mentioned in the "technical specifications" category, the date and version of the draft. clearly specified. A European draft standard has no other existence in law than that of a private document emanating from a non-profit-making body under Belgian law got the CEN and CENELEC and under French law for ETSI. Under no circumstances does it have the scope of a European standard or, *a fortiori*, a harmonized standard.

757.

National standards of purely national origin (as opposed to national standards which adopt the content of European standards) apply pending the availability of European standards. They have less scope than European standards.

758.

An important role is played by European and national standards in the rules on the awarding of public contracts. Mention of these standards in the "EC" declaration of conformity is an obvious advantage for manufacturers who sell products for this type of contract.

759.

There is nothing to prevent the manufacturer from mentioning voluntary compliance with former regulations repealed by the “machinery” Directive. These former regulations are no longer in force from a legal standpoint.[111] Compliance with their technical content may therefore form part of regular commercial practice.

The manufacturer might also include under this heading compliance with technical specifications which are neither regulations nor standards. These specifications may be documents originating from Engineering Associations (VDE, VDI in Germany) or professional recommendations (e.g. FEM recommendations in the field of handling). They may also be recommendations from private or public insurance companies (for example, the Caisses régionales d'assurance-maladie françaises [*French regional sickness insurance fund*]).

760.

09

Place

111 The Council and the Commission agreed that "technical specifications" also means the "*technical content of regulations existing before the entry into force of the Directive* ", (Council Minutes (Internal market) of 14 June 1989)

The “machinery” Directive does not require mention of where the "EC" declaration of conformity was signed although mentioning where a document is signed is common practice. The signatory is entirely free to indicate a place name. In general, the place name appearing in the declarations of conformity should be that of the registered offices of the company or establishment marketing the product. The place of signature may be different from the manufacturer's address mentioned in Point **02** or **03**.

761.

10

Date of signature

The “machinery” Directive does not require the manufacturer to date the "EC" declaration of conformity. The absence of a date cannot therefore be considered as failure to comply with the Directive. Nevertheless, the fact remains that it is common practice to date documents which have declarations with legal implications.

The date of signature is not explicitly required by the “machinery” Directive, but reference is made to the comments made under point 532 concerning the date of manufacture on the marking of the machinery:
"There is a degree of freedom in fixing the year of manufacture. Taken literally, the year of manufacture should be the same as the end of manufacture of the machinery. But how can the end of manufacture be determined exactly? In practice, manufacturers can make the date of manufacture the same as the date of first placing on the market.”
Without doubt, it is preferable for the two dates to be the same. It is also preferable for the date on the marking to correspond to that on the declaration of conformity.

Manufacturers may be guided by this rule in choosing a date of signature.

There are several options for choosing the date.

The "89/392" Committee states in its reply to question No 66 that the relationship between "*the certificate of conformity and the machinery in question should not give rise to any ambiguity*". This reply confirms that the details shown on the data plate must be repeated in their entirety in the "EC" declaration of conformity. This requirement formulated by the Committee does not, however, appear in the Directive. According to the Committee, the manufacturer would therefore be obliged to indicate the date of manufacture in the "EC" declaration of conformity. Since no date is mentioned in Annex II, it may be assumed that the Committee wishes the date accompanying the signature to be the same as the date of manufacture affixed to the machinery.

The Committee thus seems to require manufacturers of machinery to limit the allocation of a series of numbers to products manufactured in a given calendar year. The series must concern only the numbers of machines produced during the year appearing on the frame and on the declaration. This is obviously a possibility, but probably not a rule of law, under the “machinery” Directive.

The distributor clearly does not have the right to change the date of signature of a declaration of conformity signed by the manufacturer.

762.

11

Name of signatory

The name of the signatory has to be given since the signature is not always legible enough for the name to be recognized. Mention of the name of the signatory is a mark of authenticity.

763.

The signatory

It is not necessary for the signatory to be domiciled in the European Economic Area (EEA). If the manufacturer is outside the EEA and has not deemed it necessary to have an authorized representative therein, he is entitled to carry out all the certification procedures (except for the machinery in Annex IV) at his premises, and therefore to sign the "EC" declaration of conformity.

The signatory must have the authority to make his undertaking liable. Having the authority to make the undertaking liable means that the functions of the signatory enable him to duly carry out the legal act that is the "EC" declaration of conformity. It is rare for the head of an undertaking to be the only natural person having the power to make the undertaking liable. Generally, there is implicit or explicit delegation for decision-taking or for signing legal acts. This delegation may be apparent from simply reading the organization chart of the undertaking.

It is very important to distinguish clearly between the legal responsibilities of the signatory of the declaration and the legal responsibilities under the “machinery” Directive and, more generally, the civil and criminal liabilities associated with the machinery.
The employees of undertakings sign documents daily which make their undertakings liable (for example, cheques made out by an accounting officer) without making themselves personally liable. Any employee in the undertaking may therefore sign the “EC” declaration of conformity from the moment he is empowered through his managerial structure to sign it.
Power of signing is not the same as the general delegation of liability as regards implementation of the Directive. When an employee of an undertaking duly puts his signature to an “EC” declaration of conformity he renders the natural person and, where appropriate, the legal person of the undertaking criminally and morally liable.
The natural person who would have to answer to the courts for non-conformity of the machinery should also be the person who signs the “EC” declaration of conformity.

764.

Liability of authorized representatives established in the European Economic Area

The question of the criminal and civil liability of authorized representatives established in the EEA who sign the declarations of conformity instead of the manufacturer is not as clearcut as the case of employee signatories. Authorized representatives are likened to manufacturers and are natural or legal persons who have been formally authorized by the manufacturer. The division of liabilities regarding a legal-person authorized representative is governed by common law. If the authorized representative is a natural person he must assume the entire liability of the manufacturer. It is therefore difficult to make a distinction between real personal liability and legal liability.

Does the authorized representative have to assume the entire liability of the manufacturer? Should a distinction be made between the different levels of liabilities between the principal and the representative? What are the limits of the authorization given to representatives? To what extent does an authorized representative hold the manufacturer liable with respect to third parties when he exceeds his authority (theory of *prima facie*)? What type of action can an authorized representative bring against the manufacturer and vice versa? All these

questions fall within the scope of the common law of the Member States and would require a study of comparative law.

765.

12

The signature

Fortunately, not every copy of the “EC” declaration of conformity has to have a hand-written signature. The signature may be printed on the declaration. It is possible to affix the stamp of the undertaking above the signature in order to reinforce its authority.

766.

Comment on the language of the declaration

The declaration must be written in the language of the country of use. A translation has to be provided by the manufacturer, his authorized representative or the distributor, or by the person who introduces the instructions into the country (for example, the user).

The “machinery” Directive requires a copy of the declaration in the language of the original instructions to be supplied (this "original" language is not necessarily that of the country of origin of the manufacturer. It is the language which the manufacturer has chosen as the original language) .[112]

112 See Point 1.7.4(b) in Annex I to the "machinery" Directive and comments

767.

Model of an "EC" declaration of conformity of machinery subject to "EC" type examination (Annex II.A)

13 *"EC" declaration of conformity of a machine with the "machinery" Directive (89/392/EEC, as amended) and the regulations for transposing it into national law*

14 THE MANUFACTURER (name and address)

15 THE AUTHORIZED REPRESENTATIVE (name and address)
acting on behalf of the MANUFACTURER (name and address)

16 HEREBY DECLARES THAT THE MACHINERY DESCRIBED BELOW:
(Description, serial number, brand)

17 COMPLIES WITH THE PROVISIONS OF THE "MACHINERY" DIRECTIVE (DIRECTIVE 89/392/EEC, as amended) AND THE REGULATIONS TRANSPOSING IT INTO NATIONAL LAW

18 COMPLIES WITH THE MODEL WHICH HAS OBTAINED AN "EC" TYPE CERTIFICATE, NUMBER ... ISSUED BY THE FOLLOWING NOTIFIED BODY: (name and address of the body)

and, where appropriate

19 COMPLIES WITH THE PROVISIONS OF THE FOLLOWING HARMONIZED STANDARDS:

or

20 COMPLIES WITH THE FOLLOWING HARMONIZED STANDARDS, THE TECHNICAL FILE HAVING BEEN COMMUNICATED TO THE FOLLOWING NOTIFIED BODY: (name and address of the body and, where appropriate, its No)

or

21 COMPLIES WITH THE FOLLOWING HARMONIZED STANDARDS, A CERTIFICATE OF ADEQUACY OF THE FILE WITH RESPECT TO THE SAID STANDARDS HAVING BEEN OBTAINED FROM THE FOLLOWING NOTIFIED BODY (name and address of the body and, where appropriate, its No)

22 ALSO COMPLIES WITH THE PROVISIONS OF THE FOLLOWING EUROPEAN DIRECTIVES: (References of the Directives and, where appropriate, name and address of the notified bodies)

23 ALSO COMPLIES WITH THE FOLLOWING EUROPEAN STANDARDS, NATIONAL STANDARDS AND TECHNICAL PROVISIONS:

24 Done at (place),
25 On (date),
26 Name of the signatory
27 Signature

The numbers appearing in the boxes correspond to the declaration models published in the 1997 issue of the "machinery" Directive application guide. These numbers provide correspondence between the various linguistic versions**.**

Comments on the model of an "EC" declaration for machinery subject to an “EC” type-examination (Annex II.A)

768.

The comments made under the model of “EC” declaration of conformity **01** apply *mutatis mutandis* to this model.
The following comments relate only to the aspects specific to the “EC” type-examination. Machines subject to “EC” type-examination are set out in Annex IV to the “machinery” Directive. A manufacturer cannot obtain “EC” type-examination for machinery not referred to in that annex. The manufacturer may obtain a technical opinion or a private certificate from a third party, but this certificate does not have to appear in the statutory declaration.

769.

18 and, where appropriate, **19**, **20** and **21**

The Directive provides for several cases of procedures for evaluating the conformity of the machinery listed in Annex IV, the model proposed listing all possible cases. To avoid confusion when reading the declaration and one declaration should only use the following:

- **18** possibly accompanied by **19**
- or **20**
- or **21**

770.

18

Mention of “EC” type-examination

This first formula refers to machinery which has obtained an “EC” type-examination certificate from a notified body.
Since 1 January 1997, the number of the notified body may no longer appear on machinery beside the “CE” marking. This was compulsory between 1993 and 1995 and still allowed up to 31 December 1996. Since then it is forbidden. Mention of the notified body is, in fact, a source of barriers to trade. The number of a notified body can only accompany the “CE” marking if, and only if, that body monitors production, which is never the case under the “machinery” Directive, the “EC” type-examination procedure not providing for any monitoring of production. The number of a notified body on a machine would only be justified under a different Directive which explicitly provides therefor. Conversely, there is nothing to prevent the name of the body being followed by its number on the declaration of conformity.

771.

19

Mention of conformity with harmonized standards

Machinery subject to “EC” type-examination which meets the harmonized standards have the option of not being subject to the “EC” type-examination procedure. However, the manufacturer may request this examination voluntarily. He simply has to state the fact that the machinery complies with the harmonized standards.[113]

113 Cf. comments on Article 8 of the Directive

These standards may be standards which dispense with “EC” type-examination, or any other harmonized standard. Attention is drawn to the fact that it is not possible to use **19** without **18**

772.

20

Mention of conformity with standards and submission of the file

The manufacturer of machinery referred to in Annex IV, in line with type "C" harmonized standards, dispensing with the “EC” type-examination, may declare conformity of the machinery himself. He will therefore not use the formula regarding obtaining an “EC” type-examination certificate. He will simply declare that the machinery meets the harmonized standards and that the file has been submitted to an notified body.[114] He is obliged to give the number(s) of the harmonized standard(s) exempting him from the type-examination; he may also indicate any other harmonized standards he has used.

773.

21

Mention of conformity with the standards dispensing with “EC” type-examination and certification of adequacy of the file with respect to the standards

The manufacturer of machinery referred to in Annex IV, in line with harmonized standards, may declare conformity of the machinery himself, requesting the notified body to check that these standards have indeed been met. The body issues a certificate of adequacy of the file.[115] He is obliged to give the number(s) of the harmonized standard(s) exempting him from the type-examination; he may also indicate any other harmonized standards he has used.

774.

25

The date

The problem of the date of signature of the “EC” declaration of conformity is the same as for other types of machinery. Models of machinery subject to “EC” type-examination must be marketed as being in conformity with the initial type, however long placing on the market may be. Where he has made minor modifications the manufacturer must inform the notified body thereof. The latter must check that the modifications do not alter the validity of the initial examination. In the case of a declaration common to a series of models, the manufacturer will continue to market the modified models with the original “EC” declaration of conformity unaltered as long as the notified body has not contested the validity of the certificate.

775.

(Extract)

B. Contents of the declaration by the manufacturer or his authorized representatives established in the Community (Article 4(2))

The manufacturer's declaration referred to in Article 4(2) must contain the following particulars:

114 Cf. comments on Article 8(2)(c), first indent, of the Directive

115 Cf. comments on Article 8(2)(c), second indent, of the Directive

- *name and address of the manufacturer or the authorized representative,*
- *description of the machinery or machinery parts,*
- *where appropriate, the name and address of the notified body and the number of the EC type-examination certificate,*
- *where appropriate, the name and address of the notified body to which the file has been forwarded in accordance with the first indent of Article 8(2)(c),*
- *where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of Article 8(2)(c),*
- *where appropriate, a reference to the harmonized standards.*
- *a statement that the machinery must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive,*
- *identification of the person signing.*

(...)]

776.

Model of a Declaration of incorporation of a subassembly
(Annex II.B)

28 *Declaration of incorporation (Article 4(2) of Directive 89/392/EEC, as amended)*

29 THE MANUFACTURER (name and address)

30 THE AUTHORIZED REPRESENTATIVE (name and address)
acting on behalf of the MANUFACTURER (name and address)

31 HEREBY DECLARES THAT THE MACHINERY OR THE SUBASSEMBLY DESCRIBED BELOW:
(Description, serial number, brand)

32 MAY NOT BE PUT INTO SERVICE BEFORE THE MACHINERY IN WHICH IT WILL BE INCORPORATED IS DECLARED TO COMPLY WITH THE PROVISIONS OF DIRECTIVE 89/392/EEC, as amended, AND WITH THE REGULATIONS TRANSPOSING IT INTO NATIONAL LAW

33 COMPLIES WITH THE PROVISIONS OF THE FOLLOWING HARMONIZED STANDARDS:

34 COMPLIES WITH THE PROVISIONS OF THE FOLLOWING EUROPEAN DIRECTIVES:
(References of Directives and, where appropriate, the name and address of the notified bodies)

35 ALSO COMPLIES WITH THE FOLLOWING EUROPEAN AND NATIONAL STANDARDS AND TECHNICAL PROVISIONS:

36 Done at (place),

37 On (date),

38 Name of signatory

39 Signature

The numbers appearing in the boxes correspond to the declaration models published in the 1997 issue of the “machinery” Directive application guide. These numbers provide correspondence between the various linguistic versions.

Comments on the model of a Declaration of incorporation of a subassembly (Annex II.B)

777.

28

The remarks made regarding the previous declaration models apply *mutatis mutandis* to this model. The following comments relate only to aspects specific to the declaration of incorporation.

This model is not an “EC” declaration of conformity with the “machinery” Directive. It is a warning to the customer that the equipment supplied does not comply with the “machinery” Directive. It is therefore a declaration of non-conformity.

Drawing up an “EC” declaration of conformity with the “machinery” Directive for a subassembly in technical terms may be fraught with legal consequences. The fact of providing an “EC” declaration of conformity and a “CE” marking suggests that the supplier of the subassembly assumes responsibility for the safety of the entire site! The “machinery” Directive does not apply to subassemblies, components (except for safety components) and incomplete machinery. The special reference in this annex to notified bodies which might have been concerned under this Directive should not be found in this declaration model. Since subassemblies are concerned, these notified bodies are not involved.

From a regulatory standpoint, subassemblies do not therefore bear the “CE” marking under the “machinery” Directive. They need not comply with Annex I to the Directive nor accompany the instructions provided for by the Directive.

Like any manufacturer, the manufacturer of subassemblies has the general obligation regarding the safety and information of the customer.

It is incumbent upon the parties to set out in the contract the safety provisions to be applied by the supplier.[116]

778.

To be used, but not abused!
This declaration of incorporation has been specially designed for incomplete machinery. "Incomplete" machinery may be ordinary machinery from which the safety devices have been removed for the purpose of integrating them into a complex assembly. Safety is built in by the manufacturer of the complete machinery or by the acquirer, at the site. Subassemblies, motors, etc., may also be the subject of a declaration of incorporation.
Use should therefore be made of the declaration of incorporation without, however, abusing it. The declaration of incorporation could relate to any component whatsoever (down to a screw)! This is not the spirit of the Directive which refers in this instance to subassemblies and incomplete machinery: "quasi-machinery".

779.

29

Name of the manufacturer

116 Cf. comments on Article 4(2) of the Directive

Although there is no footnote like footnote No 2 to point A of Annex II on details to be included in the “EC” declaration of conformity regarding the name of the company, interpretation of this requirement of point B must be similar: when an authorized representative is involved, the name and address of the manufacturer must be indicated.

780.

32

Declaration of non-compliance with the “machinery” Directive

The "declaration of incorporation" model proposed here is incompatible with a “EC” declaration of conformity with the “machinery” Directive in that this "declaration" is specifically a "declaration of non-compliance" with the Directive. This obviously does not mean that incomplete machinery or a subassembly does not meet a certain number of the essential safety requirements set out in the “machinery” Directive. The declaration of incorporation simply means that, from a regulatory standpoint, the equipment supplied is not subject to the “machinery” Directive.

781.

34

Possible compliance with other Directives

This does not prejudice the application of other European Directives to a subassembly. The subassembly may have the “CE” marking affixed under these other Directives. If deemed worthwhile, this should include the name of any notified bodies and certificate numbers obtained as such.

782.

(Extract)

C. Contents of the EC declaration of conformity for safety components placed on the market separately[1]

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorized representative established in the Community,[2]
- description of the safety component,[3]
- safety function fulfilled by the safety component, if not obvious from the description;
- where appropriate, the name and address of the notified body and the number of the EC type-examination certificate;
- where appropriate, the name and address of the notified body to which the file was forwarded in accordance with the thirst indent of Article 8(2)(c);
- where appropriate, the name and address of the notified body which carried out the verification referred to in the second indent of Article 8(2)(c);
- where appropriate, a reference to the harmonized standards;
- where appropriate, the national technical standards and specifications used;
- identification of the person empowered to sign on behalf of the manufacturer or his authorized representative established in the Community.

.....

1. This declaration must be drawn up in the same language as the original instructions (see Annex I, section 1.7.4(b)) and must be either typewritten or handwritten in block capitals. It must be accompanied by a translation in one of the official languages of the country in which the machinery is to be used. This translation must be done in accordance with the same conditions as for the translation of the

	instructions.
2	Business name and full address; authorized representatives must also give the business name and address of the manufacturer.
3	Description of the security component (make, type, serial number, etc.).

783.

Model of an "EC" declaration of conformity of a safety component not subject to "EC" type examination (Annex II.C)

40 "EC" declaration of conformity of a safety component with the “machinery” Directive (89/392/EEC, as amended) and the regulations for transposing it into national law

41 THE MANUFACTURER (name and address)

42 THE AUTHORIZED REPRESENTATIVE (name and address)
acting on behalf of the MANUFACTURER (name and address)

43 HEREBY DECLARES THAT THE SAFETY COMPONENT DESCRIBED BELOW, PLACED INDIVIDUALLY ON THE MARKET AND PROVIDING THE FOLLOWING SAFETY FUNCTION:
(Description, serial number, brand)

44 SAFETY FUNCTION PROVIDED BY THE COMPONENT (except where this is obvious from the description in Point 43)

45 COMPLIES WITH THE PROVISIONS OF THE “MACHINERY” DIRECTIVE (DIRECTIVE 89/392/EEC, as amended) AND THE REGULATIONS TRANSPOSING IT INTO NATIONAL LAW

46 ALSO COMPLIES WITH THE PROVISIONS OF THE FOLLOWING EUROPEAN DIRECTIVES:
(References of the Directives)

47 COMPLIES WITH THE PROVISIONS OF THE FOLLOWING HARMONIZED STANDARDS:

48 ALSO COMPLIES WITH THE FOLLOWING EUROPEAN STANDARDS, NATIONAL STANDARDS AND TECHNICAL PROVISIONS:

49 Done at (place),

50 On (date),

51 Name of the signatory

52 Signature

The numbers appearing in the boxes correspond to the declaration models published in the 1997 issue of the “machinery” Directive application guide. These numbers provide correspondence between the various linguistic versions.

784.

Comments on the model of an "EC" Declaration of conformity for a safety component not subject to "EC" type-examination (Annex II.C)

The comments made on the previous "EC" declaration of conformity models apply *mutatis mutandis* to this model.

44

Description of product and functions of the safety component
The manufacturer may briefly describe the nature of the safety component or its function where this is not obvious from the description. For some components, it is solely by virtue of the end use ascribed to it by the manufacturer that it can be seen to be a safety component (for example, for certain interlocking electro-mechanical switches).

785.

Model of an "EC" declaration of conformity of a safety component subject to "EC" type examination (Annex II.C)

52 "EC" declaration of conformity of a safety component with the “machinery” Directive (89/392/EEC, as amended) and the regulations for transposing it into national law

53 THE MANUFACTURER (name and address)

54 THE AUTHORIZED REPRESENTATIVE (name and address)
acting on behalf of the MANUFACTURER (name and address)

55 HEREBY DECLARES THAT THE SAFETY COMPONENT DESCRIBED BELOW, PLACED ON THE MARKET INDIVIDUALLY AND PROVIDING THE FOLLOWING SAFETY FUNCTION: (Description, serial number, brand)

56 SAFETY FUNCTION PROVIDED BY THE COMPONENT (except where this is obvious from the description in point 55)

57 COMPLIES WITH THE PROVISIONS OF THE “MACHINERY” DIRECTIVE (DIRECTIVE 89/392/EEC, as amended) AND THE REGULATIONS TRANSPOSING IT INTO NATIONAL LAW

58 COMPLIES WITH THE MODEL WHICH HAS OBTAINED AN “EC” TYPE CERTIFICATE, NUMBER ... ISSUED BY THE FOLLOWING NOTIFIED BODY: (name and address of the body)

and, where appropriate

59 COMPLIES WITH THE PROVISIONS OF THE FOLLOWING HARMONIZED STANDARDS:

or

60 COMPLIES WITH THE FOLLOWING HARMONIZED STANDARDS, THE TECHNICAL FILE HAVING BEEN COMMUNICATED TO THE FOLLOWING NOTIFIED BODY: (name and address of the body)

or

61 COMPLIES WITH THE FOLLOWING HARMONIZED STANDARDS, A CERTIFICATE OF ADEQUACY OF THE FILE WITH RESPECT TO THE SAID STANDARDS HAVING BEEN OBTAINED FROM THE FOLLOWING NOTIFIED BODY (name and address of the body)

62 ALSO COMPLIES WITH THE PROVISIONS OF THE FOLLOWING EUROPEAN DIRECTIVES : (References of the Directives and, where appropriate, name and address of the notified bodies)

63 ALSO COMPLIES WITH THE FOLLOWING EUROPEAN STANDARDS, NATIONAL STANDARDS AND TECHNICAL PROVISIONS:

64 Done at (place),
65 On (date),
66 Name of the signatory
67 Signature

The numbers appearing in the boxes correspond to the declaration models published in the 1997 issue of the “machinery” Directive application guide. These numbers provide correspondence between the various linguistic versions.

786.

Comments on the model of a "EC" Declaration of conformity of a safety component subject to "EC" type examination (Annex II.C)

The comments made on the previous "EC" declaration of conformity models apply *mutatis mutandis* to this model.

The safety component is defined in Articles 1 and 2 of the Directive. Safety components subject to "EC" type examination are listed in full in Annex IV to the Directive.

The "machinery" Directive deals only with safety components placed "separately on the market".[117] A safety component purchased by a manufacturer for the purpose of incorporating it into a machine is not subject to the Directive. It is not subject to an "EC" declaration of conformity (except where the manufacturer so requests in the contract) or to "EC" type examination.

787.

A safety component sold to a user to be incorporated on a machine in service must comply with the "machinery" Directive and be subject to an "EC" declaration of conformity and to an "EC" type examination.[118]
Safety components do not bear the "CE" marking under the "machinery" Directive, but they may under other Directives (for example, the "Electromagnetic compatibility" Directive).

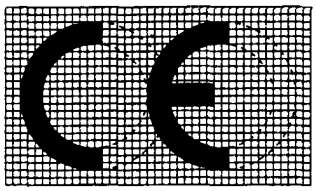
117 Cf. comments on Article 1(2)

118 For safety components sold by a manufacturer as original spare parts, see comments on Article 1(2), point 85

ANNEX III
CE MARKING

788.

The CE marking consists of the symbol shown below and the last two figures of the year in which the mark was affixed.



The proportions of the above symbols for "CE" marking must be kept when reduced or increased in size.

The different elements of the CE marking should have materially the same vertical dimensions, which should not be less than 5 mm. This minimum size may be waived for small machinery.

789.

The "CE" marking is a trade mark which must not be alteration. Flights of fantasy are not permitted. The manufacturer must not, for example, merge the graphical design of the "CE" marking with that of his own brand nor surround the "CE" marking with the stars of Europe, etc. Also to be avoided are "CE" symbols which are flattened, elongated, deformed, framed, etc.

Certain national transpositions have published the "E" symbol using the ordinary block capitals of the Official Journal of the European Communities. This does not prevent the manufacturer from having to comply with the "CE" design shown in this Annex. The sole purpose of the square ruling is to help to define the shape of the design.

The date of affixing of the marking could appear alongside the "CE" marking up to the end of 1996. Thereafter, the manufacturer must affix the year of manufacture on the frame of the machinery. He is not explicitly prevented from placing this next to the "CE", but this date is not part of the symbol itself.

790.

Under the "machinery" Directive, the number of the notified body can never appear alongside the "CE" marking:

- for machinery listed in Annex IV, because Directive 93/68/EEC requires this marking only where the notified body is involved in monitoring manufacture (modules D, E, F, G, H), not for type-examination, as laid down in this Directive (module B);
- for machinery other listed in Annex IV, because there are no notified bodies for such machinery.

791.

It should be borne in mind, however, that the "CE" marking is unique for a given piece of equipment. In the case of a machinery subject to other Directives (e.g. ATEX) which requires

monitoring of the production, the “CE” marking must be followed by the number of the notified body which has carried out this function under the other Directives (this notified body does not have to be the one which carried out the “EC” type of examination under the “machinery” Directive).

792.

The marking must be of the same quality as the other details appearing on the machinery. If the name of the manufacturer has been etched in, the “CE” should be, too.[119]

793.

Another important comment concerns the place on the machinery where the “CE” marking has to be affixed.

When the Directive was written this point was not discussed; it should be recalled that the “machinery” Directive was one of the first "new approach" Directives requiring this type of marking.

Since then other Directives have entered into force which require the same marking on many components (for example, Directive 73/23/EEC ("Low voltage"), as amended, or Directive 89/336/EEC ("Electromagnetic compatibility"), as amended). The machinery will therefore no longer be provided with “CE” marking for the complete machinery, but rather on the components which are incorporated into it. A distinction must be made for “CE” marking on the complete machine. To avoid confusion it is strongly advised that this marking should be on the plaque showing the name and address of the manufacturer and the other details specified in requirement 1.7.3.

119 Cf. comments on point 1.7.3 of Annex I to the "machinery" Directive, points 527 *et seq.*

794.

ANNEX IV

TYPES OF MACHINERY AND SAFETY COMPONENTS FOR WHICH THE PROCEDURE REFERRED TO IN ARTICLE 8(2)(b) AND (c) MUST BE APPLIED

A. Machinery

1. ***Circular saws (single or multi-blade) for working with wood and analogous materials or for working with meat and analogous materials.***
   - ***1.1 Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed.***
   - ***1.2 Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage.***
   - ***1.3 Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading.***
   - ***1.4 Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.***
2. ***Hand-fed surface planing machines for woodworking.***
3. ***Thicknessers for one-side dressing with manual loading and/or unloading for woodworking.***
4. ***Band-saws with a fixed or mobile bed and band-saws with a mobile carriage, with manual loading and/or unloading, for working with wood and analogous materials or for working with meat and analogous materials.***
5. ***Combined machines of the types referred to in 1 to 4 and 7 for working with wood and analogous materials.***
6. ***Hand-fed tenoning machines with several tool holders for woodworking.***
7. ***Hand-fed vertical spindle moulding machines for working with wood and analogous materials.***
8. ***Portable chain saws for woodworking.***
9. ***Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.***
10. ***Injection or compression plastics-moulding machines with manual loading or unloading.***
11. ***Injection or compression rubber-moulding machines with manual loading or unloading.***
12. ***Machinery for underground working of the following types:***
    - ***machinery on rails: locomotives and brake-vans,***
    - ***hydraulic-powered roof supports,***
    - ***internal combustion engines to be fitted to machinery for underground working.***
13. ***Manually-loaded trucks for the collection of household refuse incorporating a compression mechanism.***
14. ***Guards and detachable transmission shafts with universal joints as described in section 3.4.7.***
15. ***Vehicles servicing lifts.***
16. ***Devices for the lifting of persons involving a risk of falling from a vertical height of more than 3 metres.***

17. Machines for the manufacture of pyrotechnics.

B. Safety components

1. Electro-sensitive devices designed specifically to detect persons in order to ensure their safety (non-material barriers, sensor mats, electromagnetic detectors, etc.).
2. Logic units which ensure the safety functions of bi-manual controls.
3. Automatic movable screens to protect the presses referred to in 9, 10 and 11.
4. Roll-over protective structures (ROPS).
5. Falling-object protective structures (FOPS).

795.

During the negotiations on Directive 89/392/EEC some Member States expressed the need to subject certain machines to prior inspection. Regulations did in fact already exist which required manufacturers to carry out prior inspections.

The above list is exhaustive and should be taken literally. In legal terms this is a text of a “special" rather than “general" nature. The list should be interpreted in the strict sense. It can be changed only by decision of the Council and the European Parliament, i.e. by a new Directive.

This is also confirmed by the Commission’s answer, after consultation with the "89/392" Committee,[120] to Question 43 on plastics moulding machines, in which the reply was that "*the list in Annex IV must be read in the strict sense (...)*".

796.

Some were concerned at the freedom given to notified bodies to define the content of type-examination and at the risks that uncontrolled competition might inflict on the security of this content. The Commission has helped to put in place a loose structure ("European Coordination") responsible for harmonizing these examinations and thus achieving uniform application of the Directive.

Once this "European Coordination" has adopted "harmonization" certificates, competition will come into play and help in their implementation: if a body wishes to go further, it will be more expensive and it will gradually lose its customers, whereas if it requires less, the Member State which has notified it will be entitled to ask it why.

These harmonization certificates will obviously be brought to the attention of manufacturers.

797.

(Extract)
[A. MACHINERY
(...)]

798.

There are no general criteria which immediately allow machinery to be classified as relating to Annex IV or not.

On reading Annex IV, it is apparent that many of the machines listed require manual loading, moving or unloading rather than automated operation.

120 "89/392" Committee, 17 July 1994, Question/Answer No 43, confirmed by Question/Answer No 24 and Question/Answer No 25, "89/392" Committee, April 1995

The "89/392" Committee[121] felt it necessary to express its opinion on what should be understood by the words "automatic loading device". The question was posed for woodworking machines, but it can be applied equally to other types of machinery.

According to Answer No 35, "*a loading device can be called automatic where it satisfies the following two criteria:*

- *it takes the blank to be worked from a pile nearby and brings it automatically to the tool of the machine;*
- *it is locked to the machine's control circuit in such a way that it cannot operate with the operator feeding it workpiece by workpiece, except when the feed device breaks down or is intentionally taken out of service.*

All other loading systems are regarded as being manual".

If the machinery is designed in such a way that the automatic loading device can be neutralized (disengaged or moved), it must be regarded as manual-loading machinery. The possibility of neutralizing the loading system must only be taken into consideration for standard production functions. Neutralizing the loading device for maintenance operations is not enough for the machinery to be called manual-loading machinery.

799.

(Extract)
[A. MACHINERY
(...)

[1. Circular saws (single or multi-blade) for working with wood and analogous materials or for working with meat and analogous materials.

1.1 Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed.

1.2 Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage.

1.3 Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading.

1.4 Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.

2. Hand-fed surface planing machines for woodworking.

3. Thicknessers for one-side dressing with manual loading and/or unloading for woodworking.

(...)]

800.

121 "89/392" Committee, April 1995, Question/Answer No 35

What the machines mentioned in point 1 have in common is that they are circular saws. Some of them are designed for woodworking, others for cutting meat. In no event can machinery be designed to both types of work.

It should also be noted that the machines referred to in points 2 and 3 are solely woodworking machines and do not concern "similar materials".

801.

(Extract)
[A. MACHINERY
(...)

[4. Band-saws with a fixed or mobile bed and band-saws with a mobile carriage, with manual loading and/or unloading, for working with wood and analogous materials or for working with meat and analogous materials.

(...)]

802.

Band-saws with fixed or mobile bed

Certain comments on the “machinery” Directive express the view that there are differences between the various linguistic versions of point 4 of Annex IV.

Although the word "bed" is used in the English version, this point actually refers to work tables and not part of the machine's frame supporting certain mechanisms. The machines in question are also machines where the inclinable table remains fixed during the machining operation, once the inclination has been set.

Although this does not yet appear in the Swedish version, band-saws with fixed or mobile bed form part of this point 4 of Annex IV.

803.

(Extract)
[A. MACHINERY
(...)

[5. Combined machines of the types referred to in 1 to 4 and 7 for working with wood and analogous materials.

6. Hand-fed tenoning machines with several tool holders for woodworking.

7. Hand-fed vertical spindle moulding machines for working with wood and analogous materials.

8. Portable chain saws for woodworking.

9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

(...)]

804.

The presses referred to in point 9 are conventional presses for the cold-working of metals with a travel greater than 6 mm (below this value it is impossible to insert one's finger and be injured) and a speed of movement greater than 30 mm/sec. Folding presses with the same characteristics are also meant. All other types of press (for example, presses for the hot-working of metals, presses for sintering metal powders, punching machinery, guillotine shears, etc.) are not mentioned in Annex IV and are therefore not subject to obligatory type-examination.

(Extract)
[A. MACHINERY
(...)

10. Injection or compression plastics-moulding machines with manual loading or unloading.

11. Injection or compression rubber-moulding machines with manual loading or unloading.

(...)]

805.

The plastics-moulding machines referred to in point 10 are simply machines which work plastics in the technical sense of plastics. Plastics are taken to be derived from synthetic materials (thermoplastics, such as polyurethanes or styrenes, or thermosettings, such as polyesters or silicones).

Chocolate is a malleable and shapable material, but it is not a plastic material within the meaning of the Directive.

Nor is "plastic" as an explosive based on penthrite and a plasticizer a plastic material within the meaning of the Directive.

806.

(Extract)
[A. MACHINERY
(...)

12. Machinery for underground working of the following types:
    - machinery on rails: locomotives and brake-vans,
    - hydraulic-powered roof supports,
    - internal combustion engines to be fitted to machinery for underground working.

13. Manually-loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Guards and detachable transmission shafts with universal joints as described in section 3.4.7.

15. Vehicles servicing lifts.

16. Devices for the lifting of persons involving a risk of falling from a vertical height of more than 3 metres.

17. Machines for the manufacture of pyrotechnics.
(...)]

807.

The Council and the Commission[122] take the view that the term "pyrotechnic machinery" "*relates exclusively to machinery handling"* "pyrotechnic materials", *namely, a material (or a mixture of materials) intended to produce a heat, light, sound, gaseous or smoke-generating effect or a combination of such effects, by virtue of non-detonating, self-sustaining exothermic chemical reactions*".

808.

(Extract)
[A. MACHINERY
(...)
B. Safety components

1. Electro-sensitive devices designed specifically to detect persons in order to ensure their safety (non-material barriers, sensor mats, electromagnetic detectors, etc.).

2. Logic units which ensure the safety functions of bi-manual controls.

3. Automatic movable screens to protect the presses referred to in 9, 10 and 11.

4. Roll-over protective structures (ROPS).

5. Falling-object protective structures (FOPS).
(...)]

809.

122 Council Minutes of 14 June 1993

Bringing machinery in service into conformity, as laid down by Directive 89/655/EEC, as amended, means that users have to acquire additional safety devices. Supply in this area is vast and of highly variable quality. The components listed in Annex IV are those which, in the event of failure, are the most likely to have serious of consequences for the safety of persons exposed. Moreover, it is difficult for a user who is not a specialist to assess the reliability of such components. The example of logic systems for electrical two-hand control units (point 2) is taken to illustrate the choice of submitting certain safety components to type-examination.

810.

Two-hand controls occupy both the operator’s hands during the dangerous phases of machinery operation. They consist of a fixed or mobile console generally equipped with push buttons arranged so that they cannot be actuated except using both hands. The operator must not be able to "cheat" by pressing, for example, on one of the buttons with his elbow. The electronic part consists of a circuit in the form of a logic system. It is only the electronic part which is subject to type-examination. This circuit is designed in such a way that the activating order can only be given by pressing both push buttons. Releasing one button is enough to countermand the operation. Action on the controls must be synchronous and continuous action on the controls must not allow a cycle to be repeated. A delay of a few tenths of a second is permitted. It is important for the logic systems to be well designed to ensure that the circuit is sufficiently reliable.

ANNEX V
"EC" DECLARATION OF CONFORMITY

811.

For the purposes of this Annex, "machinery" means either "machinery" or "safety component" as defined in Article 1(2).

1. The EC declaration of conformity is the procedure by which the manufacturer, or his authorized representative established in the Community, declares that the machinery being placed on the market complies with all the essential health and safety requirements applying to it.

2. Signature of the EC declaration of conformity authorizes the manufacturer, or his authorized representative in the Community, to affix the EC mark to the machinery.

3. Before drawing up the EC declaration of conformity, the manufacturer, or his authorized representative in the Community, must have ensured and be able to guarantee that the documentation listed below is and will remain available on his premises for any inspection purposes:

(a) a technical construction file comprising:

- ***an overall drawing of the machinery together with drawings of the control circuits,***
- ***full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,***
- ***a list of:***
  - ***the essential requirements of this Directive,***
  - ***standards, and***
  - ***other technical specifications which were used when the machinery was designed,***
- ***a description of methods adopted to eliminate hazards presented by the machinery,***
- ***if he so desires, any technical report or certificate obtained from a competent body or laboratory[1],***
- ***if he declares conformity with a harmonized standard which provides therefor, any technical report giving the results of tests carried out at his choice either by himself or by a competent body or laboratory,[1]***
- ***a copy of the instructions for the machinery;***

(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

The manufacturer must carry out necessary research or tests on components, fittings or the completed machinery to determine whether by its design or construction, the machinery is capable of being erected and put into service safely.

Failure to present the documentation in response to a duly substantiated request by the competent national authorities may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the Directive.

4. (a) The documentation referred to in 3 above need not permanently exist in a material manner but it must be possible to assemble it and make it available within a period of time commensurate with its importance. It does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the basic safety requirements.

(b) The documentation referred to in 3 above must be retained and kept available for the competent national authorities for at least 10 years following the date of manufacture of the machinery or of the last unit produced, in the case of series manufacture.

(c) The documentation referred to in 3 above must be drawn up in one of the official languages of the Communities, with the exception of the instructions for the machinery.

.....

[1] A body or laboratory is presumed competent if it meets the assessment criteria laid down in the relevant harmonized standards.

812.

This annex gives details of the technical file. Justification of the declaration by the manufacturer himself, without intervention by a third party, is partly based on this file: the manufacturer must be able to retrace, in his file, the design steps taken. It must provide a kind of "type-examination". The result of this must be recorded, point by point, in a file.

813.

Paragraph (a) of Point 3 details the content of this file.
The only drawings and calculations which must be included in the file (second indent of point 3(a)) are those which are necessary to understand how the designer has met the essential requirements. Where the designer has followed a standard which covers one or more essential requirements, he obviously does not need to give other explanations in the file of how these requirements have been dealt with other than to quote the standard. If this standard is not a harmonized European standard, compliance with it, even if it does not entail automatic presumption of conformity with the Directive, nevertheless confirms the manufacturer's efforts to meet a recognized preventive measure. It is in the interest of the manufacturer to quote all the external sources which have guided or prompted him to choose a given solution.

814.

Point 3(b) specifies that a manufacturer cannot pass on liability to the manufacturer of a part or component. The choice of these must therefore be justified in the file, insofar as they have a bearing on compliance with one or more requirements.

The file can be kept on the manufacturer's premises, even if the manufacturer is outside the European Union.

The last paragraph of point 3(b) draws attention to the fact that failure to present the file at the request of a competent national authority casts doubt on conformity with the requirements of the Directive. This must be qualified by two comments regarding section 4(a):

- part of the file may be kept on an electronic support or may be located in another file which is common to several types of machinery. In some cases it may not be feasible for a manufacturer to keep paper files of all the technical documents concerning a type of machinery. A manufacturer cannot therefore be reproached for not being able to hand over the file immediately on request: he must be given sufficient time to assemble the file,
- the Council has asked the Commission to take appropriate measures to avoid abuses (minutes of the Council meeting of 14 June 1989). The file cannot be demanded without justification. Where a national authority has doubts about the fulfilment of a particular requirement, it cannot demand the whole file but only the part which indicates how the designer has dealt with that requirement. The obligation to submit the file (or the pertinent part of the file) to the authorities responsible for market control means the holder of the file has to take positive action to make it actually available to those authorities (send a copy of the file, e-mail, etc.). The control authorities, who have limited geographical jurisdiction, cannot be expected to go beyond their frontiers to examine the file at the manufacturer's. Submission of the files to the authorities has to be direct, not through diplomatic channels.

815.

It is also important to take account of the technical file on the subassemblies which the manufacturer has used and which were manufactured by other manufacturers. As a rule, the final manufacturer does not have these technical files. However, he is the one who must supply them upon request by the competent national authorities. The comments made on Article 4(2) highlight the various options open to the final manufacturer.

816.

Point 4(b) requires the file to be kept for 10 years after the date of final manufacture of the machinery. Some people think this period is too short, but the legislator considered that if a type of machinery has not caused any safety problems for 10 years, it can be considered to be safe and it is unlikely that a competent national authority will subsequently need to consult the file.

817.

It has to stressed quite strongly that the technical construction file does not have to accompany the machinery. Manufacturers are not obliged to accept requests for the file from their customers. This file is neither the declaration of conformity referred to in Annex II nor the instruction handbook.

818.

Some technical control bodies asked by users to help them with the approval of machinery tell their customers to demand the construction file from the supplier. This is an abusive practice and amounts to "misuse" of the "machinery" Directive. Experts, which is what the staff at technical control bodies are, should be capable of assessing machinery without having this file. Testers and users who do obtain the technical file cannot claim to be unaware of the slightest safety defect or even a "hidden fault" in the machinery. They have the same information as the manufacturers, which can only increase their liability.

819.

The file is an administrative authorities instrument to which only the Member States have access.

When a manufacturer responds to a request by the authorities for part of the file, the Directive stipulates no requirement regarding language, except that it should be one of the languages of

the Community. There seems little point in advising manufacturers to come to an understanding with the authorities on this point.

The information communicated by the manufacturer is covered by professional secrecy. The State is liable if information disclosed to a third party should prejudice the manufacturer.

820.

ANNEX VI
EC TYPE-EXAMINATION

For the purposes of this Annex, "machinery" means either "machinery" or "safety component" as defined in Article 1(2).

1. EC type-examination is the procedure by which a notified body ascertains and certifies that an example of machinery satisfies the provisions of this Directive which apply to it.

2. The application for EC type-examination must be lodged by the manufacturer or by his authorized representative established in the Community, with a single notified body in respect of an example of the machinery.

The application must include:
- ***the name and address of the manufacturer or his authorized representative established in the Community and the place of manufacture of the machinery,***
- ***a technical file comprising at least:***
  - ***an overall drawing of the machinery together with drawings of the control circuits,***
  - ***full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,***
  - ***a description of methods adopted to eliminate hazards presented by the machinery and a list of standards used,***
  - ***a copy of the instructions for the machinery,***
  - ***for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.***

It must be accompanied by a machinery representative of the production planned or, where appropriate, a statement of where the machinery may be examined.

The documentation referred to above does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the basic safety requirements.

3. The notified body must carry out the EC type-examination in the manner described below:
- ***it must examine the technical construction file to verify its appropriateness and the machinery supplied or made available to it.***
- ***during the examination of the machinery, the body must***
  - ***(a) ensure that it has been manufactured in conformity which the technical construction file and may safely be used under its intended working conditions;***
  - ***(b) check that standards, if used, have been properly applied;***
  - ***(c) perform appropriate examinations and tests to check that the machinery complies with the essential health and safety requirements applicable to it.***

4. If the example complies with the provisions applicable to it the body must draw up an EC type-examination certificate which must be forwarded to the applicant. That certificate must state the conclusions of the examination, indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved example.

The Commission, the Member States and the other approved bodies may obtain a copy of the certificate and, on a reasoned request, a copy of the technical construction file and of the reports on the examinations and tests carried out.

5. The manufacturer or his authorized representative established in the Community must inform the notified body of any modifications, even of a minor nature, which he has made or plans to make to the machinery to which the example relates. The notified body must examine those modifications and inform the manufacturer or his authorized representative established in the Community whether the EC type-examination certificate remains valid.

6. A body which refuses to issue an EC type-examination certificate must so inform the other notified bodies. A body which withdraws an EC type-examination certificate must so inform the Member State which notified it. The latter must inform the other Member States and the Commission thereof, giving the reasons for the decision.

7. The files and correspondence referring to the EC type-examination procedures must be drawn up in an official language of the Member State where the notified body is established or in a language acceptable to it.

821.

The application may be lodged only by the manufacturer or his authorized representative established in the EEA, and not by the user or an unauthorized importer. This is because the result of the examination forms part of the certification procedure, which can be carried out only by the manufacturer or his authorized representative.

The provision in Article 8(6) for the manufacturer's responsibilities to be taken over by a third party applies to machinery manufactured by a company established outside the EEA and not represented in the EEA. It is basically intended to regularize an illegal situation.

822.

A manufacturer cannot set notified bodies in competition with each other on technical questions by requesting an EC type-examination certificate from several notified bodies in the hope that at least one of them will issue such a certificate. However, this does not prohibit competition on the grounds of cost. A manufacturer located in one Member State may select a body notified by another Member State.

823.

The file to be presented to the body responsible for carrying out the examination is very similar to that referred to in Annex V. The only major difference is that in this case the file referred to in Annex V will also contain the EC type-examination certificate.

824.

The notified body may require the manufacturer to make adjustments or changes. Such demands must be discussed and negotiated between the manufacturer and the body, as the manufacturer is subject to economic and commercial constraints, and he needs to know how far he must go. In case of doubt, the Commission and the Article 6(2) Committee should be consulted. Clearly, over the years the body will build up a kind of technical case-law which can be of use to the standards authorities. The “European Coordination of notified bodies” can also help.

825.

The fact that a manufacturer has received an EC type-examination certification does not relieve him of any of his obligations. He retains full responsibility for the conformity of the machinery to the provisions of the Directive and a competent national authority can still demand to see the file if it has reason to doubt that one of the requirements is fulfilled.

826.

The withdrawal of an EC type-examination certificate referred to in paragraph 6 does not have retroactive effect: machinery already placed on the market and previously deemed to comply continues to comply. Clearly, if the defect which led to withdrawal of the certificate is a latent defect, the manufacturer must take action in respect of machinery already on the market. Who bears the cost of such measures? It is not possible to give a general answer here.

827.

Certificates issued by the notified bodies are not for a defined period. A manufacturer can therefore market a model of machinery based on certification dating back several years. However, commercial pressure from customers and developments in the state of the art will very likely oblige him, in practice, to modify his model.

828.

The notified body can withdraw an EC type-examination, especially for a reason connected with an accident. The notified body does of course have to exercise care when so doing as such a decision is tantamount to prohibiting the manufacturer from placing the product on the market. However, point 6 of Annex VI provides explicitly for the possibility of a notified body to withdraw the EC type-examination certificate, and this point warrants comment. This possibility exists for essential safety needs, in particular as a result of a safeguard clause subscribed to by a Member State, a serious accident or a near miss which could have been serious. Where the machine obtaining an EC type-examination certificate proves to be dangerous, either because the body has been alerted by the market surveillance authorities that the machinery places on the market does not correspond in any way to the approved model, because the machine has a hidden defect, because the body has committed an obvious error of judgement, or because the state of the art has advanced to such an extent that the previous expert opinion is no longer valid a number of years after issue of the certificate, the notified body must withdraw the EC type-examination certificate.
In the event of an obvious error of judgement by a notified body, the notifying Member State must take appropriate steps in respect of the said body and, if necessary, withdraw its notification status. The body may be liable in respect of any person (user or manufacturer) suffering damage as a result of this error of judgement.

829.

Insofar as a notified body believes that it taking on too much of a risk by granting certificates for an unlimited period, it might reasonably be asked to give up its public service status.

830.

Point 5 states that the manufacturer must inform the notified body of any modifications made to the machinery. It further provides that even minor modifications must be notified. Acting on the basis of these modifications, the notified body cannot withdraw its certificate, but it can declare that the certificate is no longer valid because the "current" machinery is no longer

identical to the one that underwent "EC" type-examination. It can therefore request that the procedures to obtain a new certificate be carried out again, or be supplemented. A succession of minor modifications can, after all, lead to machinery which is very different from the original machinery.

831.

The Directive gives no indication about the length of time the notified body should keep the file submitted for "EC" type-examination or for compliance with Article 8(2)(c) in the case of conformity with harmonized standards. By analogy with what is requested of the manufacturer, it may be argued that the notified body should keep it for a minimum of 10 years. However, for the manufacturer this is 10 years after final production, a date which is unknown to the approved body and which the manufacturer is not obliged to divulge. To take account of the foreseeable duration of normal manufacture, it might be advisable for the approved bodies to keep files for 15 years.

832.

ANNEX VII
MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY THE MEMBER STATES FOR THE NOTIFICATION OF BODIES

For the purposes of this Annex, "machinery" means either "machinery or "safety component" as defined in Article 1(2).

1. ***The body, its director and the staff responsible for carrying out the verification tests must not be the designer, manufacturer, supplier or installer of machinery which they inspect, nor the authorized representative of any of these parties. They must not become either involved directly or as authorized representatives in the design, construction, marketing or maintenance of the machinery. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.***

2. ***The body and its staff must carry out the verification tests with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.***

3. ***The body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it must also have access to the equipment required for special verification.***

4. ***The staff responsible for inspection must have:***
   - ***sound technical and professional training,***
   - ***satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,***
   - ***the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.***

5. ***The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.***

6. ***The body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.***

7. ***The staff of the body must be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.***

833.

The European Commission has entered into international negotiations for mutual recognition agreements to be concluded with certain third countries. These agreements would allow bodies in such countries to issue "EC" type-examination certificates.

Any challenge on the part of a manufacturer as regards meeting the minimum criteria in this annex can be communicated directly to the Commission and to the Member State which notified the body.

LEGAL STATUS OF SECOND-HAND AND RECONDITIONED MACHINERY

NB: the opinions expressed in this section are part of a more detailed study. It is not possible to justify all the proposed legal analyses here. As this study has not yet been completed, this section must be read with reservation. The final decision concerning application of the “machinery” Directive to certain second-hand machines will have to be taken later.

1. INTRODUCTION: General definitions

1.1. Concept of "machinery in service"

Machinery " in service" refers to machinery which has already been used in a country of the European Economic Area (EEA) and continues to be used within the same company.
Machinery in service in companies is sometimes termed "used machinery", as opposed to new machinery which has not yet been put into service. The term "used" does not say anything about the generation or actual wear and tear of the machinery.
The same goes for changes which affect the legal circumstances of the company itself, especially as a result of a take-over, sale of the business, merger, conversion of assets, incorporation, etc. A change in the capital of the business or a change in the general management does not mean that the machinery in service is newly "placed on the market".
Physical transfer of the machinery from one establishment to another is not to be taken as "placing it on the market". This is because there is only one legal person in question, namely, the company which owns the machinery. As an employer, the company that owns the machinery must comply with the safety rules arising out of Directive 89/655/EEC,123 as amended. On the other hand, when the machinery is transferred from the parent company to a subsidiary, it must be regarded as being placed on the market since there is a distinction between the legal personalities of the two companies.
Machinery put into service in companies before 1 January 1993 and still in service on 1 January 1997 and thereafter must be made to comply with the technical provisions set out in Directive 89/655/EEC, as amended. Work equipment transferred from one establishment to another within the same company is regarded as being "kept in service" and thus conformity is not required until after the date of conformity laid down by Directive 89/655/EEC, as amended.

1.1.1. Concept of second-hand machinery

Second-hand applies to work equipment and protective means which have already been used in a country of the EEA and are once again being placed on the EEA market. The fact of being placed once again on the market assumes that the second-hand machinery has passed the stage of first being placed on the market and first being put into service in the EEA.

1.1.2. Concept of "reconditioned" machinery

In most languages spoken in the European Union the words describing reconditioned machinery start with a prefix which indicates the repetition of an action or the return to a prior

123 Directive 89/655/EEC of 30 November 1989 (OJ No L 393, 30.12.89, p. 13). This Directive was amended by Directive 95/63/EC (OJ No L 335, 30.12.95, p. 28).

situation (retro). Reconditioned machinery is existing machinery which has undergone technical work designed to modify its condition, its performance, its safety, etc. This work may consist of modifying the machinery to a greater or lesser extent.
Superficial reconditioning consists of modifying certain parts of the machinery and of changing worn parts.

1.1.3. Concept of “reconstructed” or “rebuilt” machinery

“Reconstructed” or “rebuilt” machinery is new machinery consisting, entirely or in part, of parts taken from old machinery.

2. Can European technical regulations be applied to second-hand or reconditioned machinery?

"New approach" Directives were designed exclusively for new products or for products regarded as new.
Application of “new approach” Directives to second-hand products might result in a loss of credibility for the "CE" marking. It might also affect fair trading and cause unacceptable distortion of competition.
A new general approach would be needed to make the technical harmonization Directives applicable to this type of product.
From the technical standpoint, application of the Directives to second-hand machinery is generally unrealistic.
Although there is no legal obstacle to regulating second-hand machinery through a European Directive based on Article 100a of the Treaty, it is difficult to see how technical harmonization could be implemented for machinery belonging to different generations.
The “machinery” Directive is very difficult to comply with where the reconditioning or sale of old second-hand machinery are concerned because it stipulates the concept of integrated safety and not just added safety. Moreover, the type-examination procedure concerning the machinery listed in Annex IV to the Directive is completely unsuited to the problem of second-hand machinery.

3. What law is applicable to second-hand or reconditioned machinery?

3.1. Very limited application of “new approach” Directives to second-hand machinery

3.1.1. Second-hand machinery from third countries

Machinery in service in a third country has never been placed on the market in the EEA. When such machinery leaves the third country and crosses the frontier of the EEA it counts as being placed on the market in the EEA for the first time. As such, all European Directives are applicable, and the machinery must meet all the obligations of new machinery.

3.1.2. "Reconstructed" or “rebuilt” machinery is regarded as ecological "new" machinery!

Where existing machinery is completely "stripped down" and only a few original parts remain, the question arises as to whether this is reconditioned machinery or new machinery consisting partly of "recovered" components. In our opinion, the "reconditioner" can decide to consider this machinery as "new". This machinery has undergone effective "reconstruction". It is

"rebuilt". It is ecological "new" machinery in a way in that it consists, entirely or in part, of recovered parts. "Reconstructed" machinery ties in well with clean and recycled products.
In other words, the original machinery has not been used by the renovator as initial machinery, but as a source of spare parts in order to make something new.

3.2. Problem of "maintaining" the conformity of machinery

The “machinery” Directive does not apply anew to machinery placed on the market subsequent to first being put into service. The obligation of "maintaining the conformity of machinery" falls to the vendor when the machinery is sold to a user. It falls to the purchaser when it is sold to someone in the trade. In all cases, it falls to the vendor when a specific national regulation lays this down explicitly.

4. Directive on the general safety of products.[124] Common law applicable to second-hand machinery sold to consumers

This Directive covers products sold to users, including second-hand products. It is "subsidiary" to “new approach” Directives and national regulations. "Hybrid" products intended for general users and for the trade are concerned. All types of availability are concerned.
Content of the obligations imposed by the Directive on the general safety of products:
The supplier has the general obligation to inform the consumer. He may be obliged to recall products. He must meet the general obligation of safety deemed to be met by complying with the technical annexes of the respective technical harmonization Directives, with national regulations, with the state of the art, with standards and with codes of good practice.

5. Application of national regulations on second-hand goods

These regulations are possible under Articles 30 and 36 of the Treaty. They could add to the Directive on the "general safety of products" for sales to consumers.

6. In the absence of regulations, what level of safety can "reasonably" be expected of second-hand or reconditioned machinery?

6.1. Distinction between ordinary second-hand and reconditioned machinery

A distinction must be made between second-hand machinery and reconditioned machinery. The standard of reconditioned machinery is normally higher than that of second-hand machinery of comparable generation.
The distinction is made by a number of factors:
Possibility of identifying the original machine. Directive 89/104/EEC125 to approximate the laws of the Member States relating to trade marks provides invaluable information.
Criterion associated with the skill of the reconditioner.
Fiscal criteria (Directive 94/5/EC126).
Integrated safety and "added" safety.
Price criterion.
Work done on the machinery's geometry and wearing pieces.

124 Directive 92/59/EEC of 29 June 1992 (OJ No L 228, 11.08.92, p. 24)
125 Directive 89/104/EEC of 21 December 1988 (OJ No L 40, 11.02.89, p. 1)
126 Directive 94/5/EC (OJ No L 060, 3.03.94, p. 16)

Criterion of change of function of the machinery.
Criterion of improvement in performance.
Criterion of changed safety conditions.
Criterion of intention of the parties.
Customs criteria: "last substantial working" and change in tariff heading.

6.2. What would be the normal commercial practice with regard to safety?

For ordinary second-hand machinery, the requirement would be application of the Annex to Directive 89/655/EEC, as amended, or maintenance of conformity with the original European Directive or the national regulations.
As regards reconditioning, practice would seem to be as follows: at the very least, compliance with the rules of good practice applicable to second-hand machinery and compliance, as far as possible, with the technical rules governing new products for the parts which have been reconditioned.
There is no "CE" marking, except of course if it was already on the machinery when it was new.

7. Problem of providing services on machinery in service

7.1. Distinction between placing on the market and provision of services

A distinction must be made between "placing on the market" and "provision of services" on machinery in use.
The law governing availability, sale and leasing is not the same as for contract work.
A reconditioner who places nothing on the market is under no obligation to comply with the technical regulations other than where expressly stated in the contract. Liability is the user's in his function as employer. A reconditioner who sells parts outside the main work contract is under the obligation to comply with any regulations which apply thereto.
The service supplier is civilly and criminally liable under common law for the "service" part. He may sometimes be criminally liable for the "parts supplied" part.

7.2. Special case of work carried out by the manufacturer

A manufacturer carrying out work as part of his contractual guarantee applies the "machinery" Directive if he works on the product which he sold before it was first put into service.
He may still apply it after it is first put into service, but he is no longer obliged to do so.
When a manufacturer does work outside the contractual guarantee, he must be treated in the same way as an ordinary service supplier. His statutory liability as manufacturer no longer applies in this case.
Statutory liability is for the user only.
There is no application of the "machinery" Directive.

A service supplier who puts together a subassembly must provide a declaration of incorporation with the subassembly. He is under no obligation to comply with the "machinery" Directive for subassemblies. However, other Directives may apply.

7.3. Problem of international provision of services

Machinery leaving the EEA for reconditioning, and then returning, cannot be regarded as being placing on the market anew. This is a cross-frontier provision of services.