Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC

(2001/C 154 E/15)

(Text with EEA relevance)

COM(2000) 899 final — 2001/0004(COD)

(Submitted by the Commission on 26 January 2001)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee.

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (¹) codified Directive 89/392/EEC (²). Since further substantial amendments are to be made to Directive 98/37/EC, it should be recast in the interests of clarity.
- (2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. 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 installation and maintenance.
- (3) Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery.
- (4) The maintenance or improvement of the level of safety attained in the Member States constitutes one of the essential aims of this Directive. However, unnecessary constraints imposed on undertakings for certain types of machinery should be reduced: machines for the manufacture of pyrotechnics, the main hazard of which is covered by Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in

- (5) In order to ensure legal certainty for users, the scope of this Directive and the concepts relating to its application should be defined as precisely as possible.
- (6) The mandatory provisions governing construction site hoists intended for lifting persons or persons and goods and portable cartridge-operated devices intended for industrial or technical use, which are often supplemented by de facto compulsory technical specifications and/or by voluntary standards, do not necessarily lead to different levels of health and safety but, because of their disparities, do nevertheless constitute barriers to trade within the Community. Moreover, the national systems for the conformity assessment and certification of these machines diverge considerably. It is therefore desirable not to exclude construction site hoists intended for lifting persons or persons and goods, and portable cartridge-operated fixing devices, from the scope of this Directive, since the latter are excluded from the scope of Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons (4).
- (7) Construction site hoists intended for lifting persons or persons and goods, which are but one specific example of devices for lifting persons, should be covered by this Directive. However, the health and safety requirements laid down by this Directive cannot, in view of their specific use, apply to theatre elevators, that is to say devices for lifting persons which are permanently or temporarily installed in auditoria and which permit the movement of persons from the stage to adjacent locations and vice versa.
- (8) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of the provisions of Directives. It is therefore appropriate to put in place the legal framework within which it can proceed harmoniously.

potentially explosive atmospheres (3), roll-over protection structures and falling-object protective structures, which are covered by the declaration of the manufacturer of the complete machinery and logic units which ensure the safety functions of bimanual controls, which are now an integral part of the machinery placed on the market.

⁽¹) OJ L 207, 23.7.1998, p. 1, Directive amended by Directive 98/79/EC (OJ L 331, 7.12.1998, p. 1).

⁽²⁾ OJ L 183, 29.6.1989, p. 9.

⁽³⁾ OJ L 100, 19.4.1994, p. 1.

⁽⁴⁾ OJ L 256, 13.9.1991, p. 51.

- (9) In the context of this market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on machinery and the safeguard clause relating to machinery.
- (10) The putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which can reasonably be foreseen. 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.
- (11) Where the machinery may be used by a consumer, that is to say a non-professional operator, the manufacturer should take account of this in the manufacturing process. The same will apply where a machine is used normally to provide a service to a consumer.
- (12) Although the body of provisions of this Directive may not apply to partly completed machinery, it is nevertheless important that their free movement be guaranteed where they are specifically stated to be intended for incorporation into or assembled with other machinery to form a machine covered by this Directive.
- (13) For trade fairs, exhibitions, etc., it must be possible to exhibit machinery which does not satisfy the requirements of this Directive. However, interested parties should be properly informed that the machinery does not conform and cannot be purchased in that condition.
- (14) 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. In order to help manufacturers to prove conformity to these essential requirements, and to allow inspection of conformity to the essential requirements, it is desirable to have standards that are harmonised at Community level for the prevention of risks arising out of the design and construction of machinery. These standards harmonised at Community level are drawn up by private-law bodies and must retain their non-binding status.
- (15) In view of the nature of the risks involved in the use of machinery covered by this Directive, procedures for assessing conformity to the essential health and safety requirements should be established. These procedures should be devised in the light of the extent of the danger inherent in such machinery. Consequently, each category of machinery should have its appropriate procedure, which is in conformity with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and

- use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (¹) and takes account of the nature of the verification required for such machinery.
- (16) Manufacturers should retain full responsibility for certifying the conformity of their machinery to the provisions of this Directive. Nevertheless, for certain types of machinery having a higher risk factor, a stricter certification procedure is desirable.
- (17) The CE marking should be fully recognised as being the only marking which guarantees that the machinery conforms to the requirements of this Directive. All other markings which are liable to mislead third parties as to the meaning or the form of the CE marking should be prohibited.
- (18) In order to ensure the same quality for the CE marking and the manufacturer's mark, it is important that they be affixed according to the same techniques. In order to avoid confusion between any CE markings which might appear on certain components and the CE marking corresponding to the machinery, it is important that the latter marking be affixed alongside the name of the person who has taken responsibility for it, namely the manufacturer or his authorised representative.
- (19) The manufacturer or his authorised representative should also be obliged to carry out a risk analysis for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures.
- (20) It is essential that, before drawing up the EC declaration of conformity, the manufacturer or his authorised representative established in the Community, should prepare a technical construction file. However, it is not essential that all documentation should be physically produced, but it must be possible to make it available on request. It need not include detailed plans of subassemblies used for the manufacture of machinery, unless knowledge of such plans is essential in order to ascertain conformity with the essential health and safety requirements.
- (21) The addressees of any decision taken under this Directive should be informed of the reasons for such a decision and of the legal remedies open to them.
- (22) In accordance with Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (²), measures for the implementation of this Directive should be adopted by use of the advisory procedure provided for in Article 3 of that Decision or by use of the regulatory procedure provided for in Article 5 of that Decision, as appropriate.

⁽¹⁾ OJ L 220, 30.8.1993, p. 23.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

- (23) Member States should provide for penalties applicable to infringements of the provision of this Directive. The penalties should be effective, proportionate and dissuasive.
- (24) The application of this Directive to a number of machines intended for lifting persons, particularly persons with limited mobility, is conducive to a better definition of the products covered by this Directive in relation to Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (¹). A redefinition of the scope of that Directive was deemed necessary and the Directive should be amended accordingly.
- (25) In accordance with the principle of proportionality, it is necessary and appropriate, in order to implement the fundamental objection of improving the safety of machinery put on the market, to lay down the essential health and safety requirements in relation to its design and manufacture. The Directive confines itself to the minimum required in order to achieve those objectives, in accordance with Article 5 of the Treaty,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Scope

- 1. This Directive applies to:
- (a) the products defined in points (a) to (i) of the second paragraph of Article 2;
- (b) vehicles designed and built to carry out work other than just the transport of persons and used in airports and in the mineral extraction industry.
- 2. The following are excluded from the scope of this Directive:
- (a) components, including safety components, or equipment, including interchangeable equipment, intended to be used as spare parts to replace identical components or equipment supplied by the manufacturer of the original machinery or by a third party in accordance with the manufacturer's instructions;
- (b) specific equipment for use in fairgrounds and amusement parks;
- (c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;
- (d) firearms;
- (e) means of transport, including trailers;
- (1) OJ L 213, 7.9.1995, p. 1.

- (f) mobile offshore units and machinery covered by this Directive installed on board such units;
- (g) machines specially designed and constructed for military or police purposes;
- (h) mine winding gear;
- (i) theatre elevators for persons;
- (j) products falling into the following areas:
 - (i) household appliances,
 - (ii) audio and video equipment,
 - (iii) information technology equipment,
 - (iv) office machinery and equipment,
 - (v) circuit-breakers and switches;
- (k) the following types of high-voltage electrical equipment:
 - (i) switch gear and control gear,
 - (ii) transformers;
- (l) motors of all types;
- (m) industrial sites taken as a whole, such as petrochemical plants or heat or power stations;
- (n) medical devices.

Article 2

Definitions

For the purposes of this Directive, 'machinery' means the products defined in points (a) to (h) of this Article, and the vehicles referred to in point (b) of Article 1(1).

The following definitions shall apply:

- (a) 'machinery stricto sensu'
 - (i) an assembly, fitted with or intended to be fitted with a drive system other than directly applied manual or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,
 - (ii) machinery referred to in (i), missing only the components to connect it on site or to sources of energy and motion,
 - (iii) machinery referred to in (i), ready to be installed and able to function as it stands only if mounted on a vehicle or installed in a building or a structure,

- (iv) lifting apparatus whose only power source is directly applied manual effort;
- (b) 'assembly of machinery' means an assembly of machinery and/or of partly completed machinery which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;
- (c) 'interchangeable equipment' means a device which, after the placing into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function in so far as this equipment is not a spare part or a tool'.
- (d) 'safety component' means a component included in the list below which is independently placed on the market in order to be installed on machinery already in use or on second-hand machinery:
 - (i) components referred to in points 19 and 20 of Annex IV,
 - (ii) safety logic units for an emergency stop or movable guard control circuit,
 - (iii) solenoid valves controlling dangerous movements of machinery,
 - (iv) smoke and dust extraction systems for machinery,
 - (v) guards and protection devices and their locking mechanisms for machinery,
 - (vi) control devices for calling lifting appliances and anti-fall devices for hoists,
 - (vii) devices for preventing lifting appliances from colliding,
 - (viii) safety belts and seat harnesses,
 - (ix) non-return valves for installation on hydraulic circuits,
 - (x) guards for removable mechanical transmission devices;
- (e) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, and placed between the machinery and the load or on the load itself, or constituting an integral part of the load; slings and their components are also regarded as lifting accessories;
- (f) 'removable mechanical transmission device' means a removable component for transmitting power between a

- self-propelled machine or a tractor and another machine by joining them at the first fixed bearing. At least one of these two machines must be mobile;
- (g) 'guard for a removable mechanical transmission device' means a device protecting persons exposed from the risk of being dragged along by a removable transmission mechanical device;
- (h) 'portable cartridge-operated device' means a portable device intended for industrial or technical use making use of an explosive charge in the form of a cartridge, for the purposes of:
 - (i) fixing a metal part in a material, or
 - (ii) slaughtering animals, or
 - (iii) marking an object by cold engraving, or
 - (iv) crimping cables;
- (i) 'partly completed machinery' means an assembly, fitted or intended to be fitted with a drive system, of linked parts or mechanical components which are almost a machine but which cannot themselves perform a specific application. Partly completed machinery is intended to be incorporated into or assembled with one or more machines or other partly completed machinery, thereby forming a single machine to which this Directive applies;
- (j) 'placing on the market' means making available for the first time in the Community machinery intended for an end user, whether for reward or free of charge;
- (k) 'manufacturer' means any natural or legal person who designs or manufactures machinery covered by this Directive, with a view to placing it on the market, under his own name or trademark. The manufacturer may also be:
 - (i) any natural or legal person who designs or manufactures a machine covered by this Directive, or who has such a machine designed or manufactured, for his own use,
 - (ii) any natural or legal person who, when a machine covered by this Directive is placed on the market or put into service, is responsible for its conformity to this Directive;
- 'authorised representative' means any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive;

- (m) 'putting into service' means the first use, for its intended purpose, in the Community, of a machine covered by this Directive. Machinery which, prior to its first use, does not require any installation or adjustment by the manufacturer or by a third party designated by him is considered to have been put into service when it is placed on the market:
- (n) 'harmonised standard' means a non-binding technical specification adopted by a standardisation body, namely the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) or the European Telecommunications Standards Institute (ETSI), adopted on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council (¹).

Article 3

Specific Directives

- 1. To the extent that, for a machine, the risks referred to in this Directive are covered more specifically by other Community Directives, this Directive shall not apply, or shall cause to apply, in the case of such machinery and of such risks on the implementation of those Directives.
- 2. In the case of machinery intended to be used by a consumer, as regards the provisions intended to protect health and safety which are not covered either by this Directive or by other specific Community texts, the provisions of Council Directive 92/59/EEC (²) shall apply.

Article 4

Market surveillance

- 1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.
- 2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of the Directive.
- 3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery with the provisions set out in paragraphs 1 and 2.

4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.

Article 5

Placing on the market

- 1. Before placing a machine on the market and/or putting it into service, the manufacturer or his authorised representative must ensure that:
- (a) it satisfies the essential health and safety requirements set out in Annex I:
- (b) the conformity assessment procedures referred to in Article 12 have been completed.
- 2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative must ensure that the procedures referred to in Article 13 have been completed.
- 3. For the purposes of the procedure referred to in Article 12, the manufacturer or his authorised representative must have, or have access to, the necessary means of ensuring that the machine satisfies the essential health and safety requirements set out in Annex I.
- 4. Where machinery is also the subject of other Community Directives relating to other aspects and providing for the affixing of the CE marking, the latter shall indicate that the machinery also conforms to the provisions of those other Directives

However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative.

Particulars of the Directives applied, as published in the Official Journal of the European Communities, must be given on the EC declaration of conformity which accompanies the machine.

Article 6

Freedom of movement

- 1. Member States may not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive in respect of the risks which it covers.
- 2. Member States may not prohibit, restrict or impede the placing on the market of partly completed machinery where the manufacturer or his authorised representative makes a declaration of incorporation, referred to in Annex II, part B, stating that it is to be incorporated into machinery or assembled with other partly completed machinery to form a machine.

 $^(^1)$ OJ L 204, 21.7.1998, p. 37, as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

⁽²⁾ OJ L 228, 11.8.1992, p. 24.

3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of machines which do not conform to this Directive, provided that a visible sign clearly indicates that they do not conform and that they are not available until they have been brought into conformity by the manufacturer or his authorised representative. Furthermore, during demonstrations of such non-conforming machinery, adequate safety measures shall be taken to ensure the protection of persons.

Article 7

Presumption of conformity

- 1. Member States shall consider that machinery bearing the CE marking and accompanied by the EC declaration of conformity, the contents of which are set out in Annex II, part A, comply with the provisions of this Directive.
- 2. Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the *Official Journal of the European Communities*, shall be presumed to comply with the essential health and safety requirements covered by such harmonised standard.
- 3. The Commission shall publish in the Official Journal of the European Communities the references of the harmonised standards.
- 4. Member States shall take the appropriate measures to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonised standards.

Article 8

Specific measures

- 1. The Commission may, acting in accordance with the procedure referred to in Article 22(3), take any appropriate measure to implement the provisions relating to the following points:
- (a) updating of the list of safety components referred to in point (d) of the second paragraph of Article 2;
- (b) arrangements for cooperation between Member States provided for in Article 19;
- (c) updating of the list of machinery referred to in Annex I, point 3.4.2. for which a rollover protective structure is obligatory;
- (d) updating of the list of machinery referred to in Annex I, point 1.6.11.2 for which information on non-ionising radiation must be supplied;
- (e) prohibition of the placing on the market of machinery referred to in Article 9.
- 2. The Commission may, acting in accordance with the procedure referred to in Article 22(2), take any appropriate

measure connected with the implementation and practical application of this Directive.

Article 9

Specific measures to deal with categories of potentially hazardous machinery

Where a Member State considers, with regard to a given category of machinery that it is necessary, in order to protect safety and health, to prohibit or restrict its placing on the market or make it subject to special conditions, it shall take or envisage all necessary and justified transitional measures. It shall then inform the Commission and the other Member States thereof, indicating its reasons.

The Commission shall consult the Member States and other interested parties, indicating to them the measures it intends to take at Community level. The Commission shall adopt, if the national measures are justified and if Community action can ensure a high level of protection of the health and safety of its citizens, the Community measures necessary under the procedure referred to in Article 22(3).

Article 10

Procedure for disputing a harmonised standard

Where a Member State or the Commission considers that a harmonised standard referred to in Article 7(2) does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee instituted by Directive 98/34/EC setting out the reasons therefor. The committee shall deliver an opinion without delay.

In the light of the committee's opinion, the Commission shall decide not to publish, to publish with restriction, to maintain or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Communities.

Article 11

'Product' safeguard clause

1. Where a Member State ascertains that machinery, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under conditions which can reasonably be foreseen, is liable to compromise the health and safety of persons and, where appropriate, domestic animals or property it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service 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 the non-conformity is due to:

(a) failure to satisfy the essential requirements referred to in Article 5(1);

- (b) incorrect application of the harmonised standards referred to in Article 7(2);
- (c) shortcomings in the harmonised standards themselves referred to in 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 measure is not justified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorised representative. Where the decision referred to in paragraph 1 is based on a shortcoming in the harmonised standards, the Commission shall refer the matter to the committee instituted by Directive 98/34/EC if the Member State at the origin of the decision maintains its position, and the Commission or the Member State shall initiate the procedure referred to in Article 10.
- 3. Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission and the other Member States.
- 4. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.

Article 12

Procedures for the conformity assessment of machinery

- 1. Following the risk analysis described in Annex I, point 1.1.2, the manufacturer or his authorised representative shall apply one of the procedures for the assessment of conformity described in paragraphs 2 to 5.
- 2. Where the risk analysis enables the conclusion to be drawn that the Directive has no relevance, the manufacturer or his authorised representative shall apply the simplified procedure described in Annex VIII.
- 3. Where the risk analysis does not enable the conclusion to be drawn that the Directive has no relevance and the machinery is not referred to in Annex IV, the manufacturer or his authorised representative shall, in order to certify its conformity with the provisions of this Directive, apply the procedure for assessment of conformity with internal checks on the manufacture provided for in Annex VII.
- 4. Where the risk analysis does not enable the conclusion to be drawn that the Directive has no relevance and the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2) and provided that those standards cover all of the relevant risks, the manufacturer or his authorised representative shall, in order to certify its conformity with the provisions of this Directive, apply one of the following procedures:
- (a) the procedure for adaptation to harmonised standards provided for in Annex IX;

- (b) the EC type-examination procedure provided for in Annex X;
- (c) the full quality assurance procedure provided for in Annex XI.
- 5. Where the risk analysis does not enable the conclusion to be drawn that the Directive has no relevance and the machinery is referred to in Annex IV and has not been manufactured in accordance with the harmonised standards referred to in Article 7(2), or only partly in accordance with such standards, or if no harmonised standards exist for the machinery in question, the manufacturer or his authorised representative shall, in order to certify its conformity with the provisions of this Directive, apply one of the following procedures:
- (a) the EC type-examination procedure provided for in Annex X:
- (b) the full quality assurance procedure provided for in Annex XI.

Article 13

Procedure for partly completed machinery

The manufacturer of partly completed machinery or his authorised representative must, before placing it on the market:

- (a) draw up a declaration of incorporation described in Annex II, part B, which must accompany the partly completed machinery until it is incorporated into a complete machine and shall then form part of the technical file for that machine.
- (b) prepare a notice of assembly described in Annex V.

Article 14

Notified bodies

- 1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12(4) and (5), 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.
- 2. The Commission shall publish in the Official Journal of the European Communities, for information, a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.
- 3. Member States shall apply the criteria referred to in Annex XII in assessing the bodies to be notified. Bodies meeting the assessment criteria laid down in the relevant harmonised standards, the references of which shall be published in the Official Journal of the European Communities pursuant to this Directive, shall be presumed to fulfil those criteria.

- 4. A Member State which has designated a body must withdraw its notification if it finds:
- (a) that the body no longer meets the criteria referred to in Annex XII, or
- (b) that certificates have repeatedly been issued to models of machinery which do not satisfy the essential health and safety requirements set out in Annex I.

It shall immediately inform the Commission and the other Member States accordingly.

Article 15

Installation and use of machinery

- 1. This Directive shall not affect Member States' entitlement to lay down, in due observance of Community law, such requirements as they may deem necessary to ensure that persons, and in particular workers, are protected when using machinery, provided that this does not mean that such machinery is modified in a way not specified in this Directive.
- 2. Member States shall take whatever measures they deem necessary to ensure that their laws, regulations and administrative provisions relating to the installation and/or use of machinery are brought to the attention of the parties concerned. They shall inform the Commission thereof.

Article 16

CE marking

- 1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III.
- 2. The CE marking shall be affixed to the machinery distinctly and visibly in accordance with point 1.9 of Annex I.
- 3. The affixing on machinery of markings which are likely to mislead third parties as to the meaning or form of the CE marking shall be prohibited.

Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

Article 17

Non-conformity of marking

Member States shall consider the following marking not to

- (a) the affixing of the CE marking pursuant to this Directive on machinery not covered by this Directive;
- (b) the absence of the CE marking and/or EC declaration of conformity for machinery;

(c) the affixing, on machinery, of a marking other than the CE marking which is prohibited under Article 16.

Where a Member State ascertains that marking does not conform, the manufacturer or his authorised representative shall be obliged to make the machinery conform to the relevant provisions of this Directive and put an end to the infringement under conditions fixed by that Member State.

Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the machinery in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 11.

Article 18

Confidentiality

Without prejudice to existing national provisions and practices in the area of confidentiality, Member States shall ensure that all parties concerned by the application of this Directive are bound to treat as confidential the information obtained in the execution of their tasks which is covered by professional secrecy, unless the divulging of such information is necessary in order to protect the health and safety of persons.

The provisions of the first subparagraph shall not affect the obligations of the Member States and the notified bodies with regard to mutual information and the issuing of warnings, nor the obligations to provide information incumbent on the persons concerned under criminal law.

The decisions taken by the Member States and by the Commission under Articles 9 and 11 must be published.

Article 19

Cooperation between Member States

Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and transmit to each other the information necessary to enable this Directive to be applied uniformly.

Article 20

Right of defence

Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of a machine covered by this Directive shall state the exact grounds on which it is based. Such a measure 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.

Article 21

Dissemination of information

The Commission will take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.

Article 22

Committee

- 1. The Commission shall be assisted by a committee, hereinafter called the 'Machinery Committee', composed of representatives of the Member States and chaired by the representative of the Commission.
- 2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
- 3. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 23

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by the date specified in the first subparagraph of Article 26(1) at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 24

Amendment of Directive 95/16/EC

Directive 95/16/EC is amended as follows:

- 1. In Article 1, paragraphs 2 and 3 are replaced by the following:
 - '2. For the purposes of this Directive, "lift" shall mean an appliance serving specific levels, having a load support moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, intended for the transport of:
 - persons,
 - persons and goods.

Appliances moving along a fixed course even where they do not move along guides which are rigid shall fall within the scope of this Directive.

- 3. This Directive shall not apply to:
- hoists for persons or for persons and goods, whose speed is not greater than 0,15 m/s,
- cableways, including funicular railways,
- lifts specially designed and constructed for military or police purposes,
- platforms intended for raising/lowering persons and from which work can be carried out,
- mine winding gear,
- theatre elevators for persons,
- lifts fitted in means of transport,
- lifts connected to machinery and intended exclusively for access to the workstation,
- appliances for persons with limited mobility, the load support of which moves along the inclined plain of a staircase,
- escalators and mechanical walkways.'
- 2. In Annex I, point 1.2 is replaced by the following:
 - '1.2. Load support

The load support of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer.

Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate their access.'

Article 25

Repeal

Directive 98/37/EC is repealed.

References in Community acts to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XIII.

Article 26

Implementation

1. Member States shall adopt and publish before 30 June 2004 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions with effect from 1 January 2006.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made. 2. 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.

Article 27

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 28

Addressees

This Directive is addressed to the Member States.

ANNEX I

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINES

PRELIMINARY OBSERVATIONS

- 1. The manufacturer of a machine or his authorised representative is under an obligation to assess the hazards in order to identify all of those which apply to his machine; he must then design and construct it taking account of his assessment.
- 2. The obligations laid down by the essential health and safety requirements apply only when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer or his authorised representative but also in foreseeable abnormal situations. In any event, the principle of safety integration (requirement 1.1.2) and the obligations of marking and supplying instructions (requirements 1.9 and 1.10.2) apply to all machinery with the exception of machinery referred to in Article 12, paragraph 2 which present no risks.
- 3. The essential health and safety requirements laid down in this Annex are mandatory. However, taking into account the state of the art and prohibitive economic imperatives, 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.
- 4. The essential health and safety requirements have been grouped according to the categories of machinery. Nevertheless, it is essential to take account of the whole of this Annex in order to be able to meet all the relevant essential requirements. Machinery presents a series of hazards which may be covered under more than one heading of this Annex.
- 1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1. General remarks

1.1.1. Definitions

For the purpose of this Annex:

- '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 moving machinery;
- 4. 'hazardous situation' means any situation in which a person is exposed to one or more risks;
- 5. 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;

- 6. 'guard' means a part of a machine used specifically to provide protection by means of a physical barrier;
- 7. 'protective device' means a device (other than a guard) which eliminates a potential danger or reduces the risk to an acceptable level, alone or in conjunction with a guard.

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 but also in foreseeable abnormal situations.

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, dismantling, disabling and scrapping.

- (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 protective measures in relation to risks that cannot be eliminated,
 - inform users of the residual risks due to any shortcomings of the protective 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 or his authorised representative must envisage not only the normal use of the machinery but also uses of it which could reasonably be expected.

The machinery must be so designed and constructed as to prevent abnormal use if such use would engender a risk. Where appropriate, 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) Machinery must be so designed and constructed as to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.
- (e) Machinery must be supplied with all the essential special equipment and accessories to enable it to be adjusted, maintained and used without risk.

1.1.3. Ergonomics

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.

1.1.4. 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.

1.1.5. Lighting

Machinery must be supplied with integral lighting suitable for the operations concerned where its lack is likely to cause a hazard despite ambient lighting of normal intensity.

Machinery must be so designed and constructed that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects due to the lighting provided by the manufacturer.

The essential requirement described in section 3.1.2 also applies to fixed machinery intended for use outside and for which night work is foreseen.

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

1.1.6. 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.

During the transportation 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 instructions of the manufacturer or of his authorised representative.

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.
- 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 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 hazardous.

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 hazardous 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,
- human error during operation does not lead to hazardous situations.

1.2.2. Manual controls

Manual controls must be:

- clearly visible and identifiable; the use of pictograms is recommended,
- positioned for safe operation without hesitation or loss of time, and without ambiguity,
- designed so that the movement of the manual control is consistent with its effect,
- located outside the danger zones, except where necessary for certain controls, such as the emergency stop and the 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 manual control is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation where necessary.

Manual 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.

Machinery must be fitted with indicators as required for safe operation. The operator must be able to read them from the control position.

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

If this is impossible, the control system must be designed and constructed so that, whenever the machinery is about to start, an acoustic and/or visual warning signal is given which leaves enough time for the exposed person to leave the danger zone or prevent the machinery starting up.

If necessary, means must be provided to ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations.

1.2.3. Starting

It must be possible to start machinery only by voluntary actuation of a manual 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.

However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the manual control provided for the purpose, unless this would lead to a hazardous situation.

As an exception to the above requirements, for automated plant functioning in automatic mode, the starting of the machinery, or restarting after a stoppage, or a change in operating conditions must be possible without intervention, provided this does not lead to a hazardous situation for the operator and/or exposed persons.

1.2.4. Stopping device

1.2.4.1. Normal stopping

Each machine must be fitted with a manual control whereby the machine can be brought safely to a complete stop.

Each workstation must be fitted with a manual control to stop some or all of the moving parts of the machinery, depending on the type of risk, 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.

1.2.4.2. 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 manual controls,
- stop the hazardous process as quickly as possible, without creating additional risks,
- 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.

1.2.4.3. Complex installations

In the case of machinery or parts of machinery designed to work together, the machinery must be so designed and constructed that the stop controls, including emergency stop devices, can stop not only the machinery itself but also all equipment upstream and/or downstream if its continued operation can be dangerous.

1.2.5. Control or operating mode selector

The control mode selected must override all other control or operating modes with the exception of the emergency stop.

If machinery has been designed and built to allow its use in several control or operating modes presenting different safety levels, 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.

If, for certain operations, the machinery must be able to operate with its protection devices neutralised, the control or operating mode selector must simultaneously:

- disable the automatic control mode,
- permit movements only by manual controls requiring sustained action,
- permit the operation of dangerous moving parts only in enhanced safety conditions 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 and any uncontrolled movement.

In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.

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 dangerous situations.

1.2.7. Control circuit failure

A fault in the control circuit logic, or failure of or damage to the control circuit must not lead to dangerous situations.

1.2.8. Software

Any interactive software between the operator and the command or control system of a machine must be user-friendly.

1.3. Protection against mechanical hazards

1.3.1. Stability

Machinery and its components and fittings must be so designed and constructed that they are stable enough for use without risk of overturning, falling or unexpected movement.

This requirement also applies during transportation, assembly, dismantling, scrapping and any other action involving the machinery.

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.

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.

The durability of the materials used must be adequate for the nature of the workplace.

The manufacturer or his authorised representative must indicate in the instructions the type and frequency of inspections 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, the moving parts must be mounted and positioned in such a way that in case of rupture their fragments will be contained and prevented from reaching workstations.

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.

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to the exposed persons:

- 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.

1.3.3. Risks due to falling or ejected objects

Precautions must be taken to prevent risks from falling or ejected objects.

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.

1.3.5. Risks related to combined machinery

Where the machinery is intended to carry out several different operations with the 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.

1.3.6. Risks relating to variations in the rotational speed of tools

When the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. Prevention of risks related to moving parts

The moving parts of machinery must be designed, built and laid out in such a way as to prevent risk of contact which could lead to accidents or, where risks persist, fitted with guards or protective devices.

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 must be provided to enable the equipment to be safely unblocked.

The instructions and possibly a sign on the machinery should indicate these specific protection devices.

1.3.8. Choice of protection against risks caused by moving parts

Guards or protection devices used to protect against the risks caused by moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help make the choice.

1.3.8.1. Moving transmission parts

Guards designed to protect exposed persons against the risks associated with moving transmission parts must be:

- either fixed guards as referred to in section 1.4.2.1,
- or movable guards of type A as referred to in section 1.4.2.2,

Movable guards should be used where frequent access is foreseen.

1.3.8.2. Moving parts directly involved in the work process

Guards or protection devices designed to protect exposed persons against the risks associated with moving parts directly involved in the process must be:

- either fixed guards as referred to in section 1.4.2.1,
- or movable guards of type B as referred to in section 1.4.2.2,
- or protection devices as referred to in section 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, preventing access to those sections of the parts that are not used in the work,
- adjustable guards as referred to in section 1.4.2.3.

1.3.9. Uncontrolled movements

When 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.

1.4. Required characteristics of guards and protection devices

1.4.1. General requirements

Guards and protection devices must:

- be of robust construction,
- be securely held in place,
- not give rise to any additional risk,
- not be easy to by-pass or render non-operational,
- be unable to remain in place without their fixings,
- 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.

1.4.2. Special requirements for guards

1.4.2.1. Fixed guards

They must be fixed by systems that can be opened only with tools. Their fixing systems must remain attached to the guards when removed.

1.4.2.2. Movable guards

- A. Type A movable guards must:
 - as far as possible remain attached 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:
 - as far as possible remain fixed to the machinery when open,
 - be so designed and constructed that:
 - they can be adjusted only by means of an intentional action,
 - 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,
 - be associated with an interlocking device preventing:
 - moving parts from starting up while they are within the operator's reach,
 - the exposed person from reaching moving parts once they have started up.

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.

1.4.3. Special requirements for protection devices

Protection devices must be designed and constructed so that they can be associated with an interlocking device preventing:

- moving parts from starting up while they are within the operator's reach,
- the exposed person from reaching moving parts once they have started up.

They can be adjusted only by means of an intentional action.

The absence or failure of one of their components prevents starting or stops the moving parts.

1.5. Required characteristics of operating and/or driving positions

1.5.1. Operating and/or driving positions

There may be two or more operating and/or driving positions and, in such cases, each position must be provided with all the requisite manual controls without the operators hindering or endangering each other.

Where there is more than one control position, the machinery must be designed so that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

The operating and/or driving position must be designed and constructed so as to avoid any health risk due to exhaust gases and/or lack of oxygen.

The operating and/or driving position must be fitted with an adequate cab if the machine gives rise to a dangerous environment presenting risks to the health and safety of the operator. The cab must be designed, constructed and/or equipped to ensure that the driver has good operating conditions and is protected against any foreseeable hazards. 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.

1.5.2. Seating

Where the working conditions so permit, work places constituting an integral part of the machinery must be equipped with seats.

Where one exists, the driving seat of the operator or driver must enable the driver or operator to maintain a stable position.

Where the seat is an integral part of the machinery, it must be supplied with it.

If the machinery is subject to vibrations, the seat must be designed in such as way as to reduce the vibrations transmitted to the operator or driver to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the driver or operator, footrests covered with a slip-resistant material must be provided.

1.6. Protection against other hazards

1.6.1. 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. Conformity assessment with regard to electrical hazards is governed by this Directive.

1.6.2. 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.

1.6.3. Lightning

Machinery which is designed for outdoor use and which may be subject to the direct effects of lightning while being used must be fitted with a system for conducting the resultant electrical charges to earth.

1.6.4. Energy supply other than electricity

Where machinery is powered by an energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential hazards associated with these types of energy.

1.6.5. 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.

Where necessary, the instructions must give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections must be made impossible by the design or, failing this, by information given on the pipes, cables, etc. and/or connector blocks.

1.6.6. 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 very 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.

1.6.7. Fire

Machinery must be designed and constructed to avoid all risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

1.6.8. Explosion

Machinery must be designed and constructed to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

Machinery must comply, as far as the risk from explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific directives in force.

1.6.9. 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.

1.6.10. Vibrations

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.

1.6.11. Radiation

1.6.11.1. General

Machinery must be so designed and constructed that any emission of ionising or non-ionising 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.

1.6.11.2. Instructions

Where machinery is likely to emit non-ionising radiation which may endanger exposed persons, in particular persons with active or non-active implantable medical devices, the instructions must give quantitative information concerning the radiation emitted for the operator and exposed persons.

Furthermore, this information is mandatory for the following machinery:

- welding machines,
- induction heaters.
- electro-magnets.

1.6.12. External radiation

Machinery must be so designed and constructed that external radiation does not interfere with its operation.

1.6.13. 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.

1.6.14. Emissions of dangerous substances

Machinery must be so designed, constructed and/or equipped that risks due to dangerous substances which it produces can be avoided.

Where a risk exists, the machinery must be so equipped that the said substances can be contained and/or evacuated in order to prevent the risks related to inhalation or the ingestion of dangerous substances.

During normal operation of the machinery, the devices for containment and/or evacuation referred to in the previous paragraph must be situated as close as possible to the source of emission if the emission is not produced in an enclosed space which is part of the machinery.

1.6.15. Risk of being trapped in a machine

Machinery must be 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.

1.6.16. 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.

1.7. **Maintenance**

1.7.1. Machinery maintenance

Adjustment 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, a connecting device for mounting diagnostic fault-finding equipment must be provided.

Automated machine components which have to be changed frequently 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 in accordance with a specified operating method.

1.7.2. Access to operating positions and servicing points

Machinery must be designed and constructed in such a way as to allow access in safety to all areas used for production, adjustment and maintenance operations.

The movement of exposed persons must be unhindered.

1.7.3. Isolation of energy sources

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 provided that the requirement of the following paragraph is met.

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 requirement laid down in the previous paragraph, certain circuits may remain connected to their energy sources in order, for example, to hold parts, protect information, light interiors, etc. In this case, special steps must be taken to ensure operator safety.

1.7.4. 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.

1.7.5. 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 or his authorised representative must take steps during its construction to allow cleaning to take place with the minimum of danger.

1.8. Information, warnings and warning systems

1.8.1. 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.

1.8.2. Warning devices

Where machinery is equipped with warning devices, these must be unambiguous and easily perceived.

The operator must have facilities to check the operation of such warning devices at all times.

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

1.8.3. Warning of residual risks

Where risks remain despite all the measures adopted or in the case of potential risks which are not evident, the manufacturer or his authorised representative 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 versions in the languages understood by the operators.

1.9. Marking of machinery

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

- the name and address of the manufacturer and, where applicable, his authorised representative (1),
- where applicable, the name and address of the natural or legal person who assumes responsibility for its conformity to this Directive,
- designation of the machinery,
- CE marking,
- designation of series or type,
- serial number, if any,
- the year of construction (2).

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

Machinery must also bear full information relevant to its type and essential to its safe use.

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

All the information must be clearly identifiable by the final user.

⁽¹⁾ Business name and full address; where the marking is established by the authorised representative, the business name and address of the manufacturer must also be shown.

⁽²⁾ The year of construction is the date with which the end of the manufacturing process must coincide stricto sensu. The EC declaration of conformity must be established on that date. It is therefore formally prohibited to pre-date or post-date the machinery when affixing the CE marking.

1.10. Instructions

Every machine must be accompanied by instructions in the official Community language(s) which may be determined in accordance with the Treaty by the Member State in which it is placed on the market and/or put into service.

The instructions accompanying the machine must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.

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

1.10.1. General principles on the drafting of instructions

- (a) The contents of the instructions must be limited to the machine in question and cover not only the normal use of the machinery but also uses which may reasonably be expected of it.
- (b) The manufacturer or his authorised representative must draft the instructions in an official Community language. The words 'Original instructions' should appear on the language version(s) verified by the manufacturer. If the manufacturer or his authorised representative verify versions of the instructions in other official Community languages, these versions should also bear the words 'Original instructions'.
- (c) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be made by the person introducing the machinery into the language area in question. The translations must bear the words 'Translation of the original'.
- (d) In the case of machinery which may be intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.
- (e) By way of exception, the maintenance instructions intended for use by specialist operators employed by the manufacturer or his authorised representative may be drafted in only one Community language which the operators understand.

1.10.2. Contents of the instructions

Each instruction manual must contain the following information:

- (a) the name and address of the manufacturer and, where applicable, his authorised representative,
- (b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.9).
- (c) the installation and assembly instructions, including the means of attachment,
- (d) the instructions for putting the machinery into service and, if necessary, training instructions,
- (e) where appropriate, the essential characteristics of tools which may be fitted to the machinery,
- (f) instructions on the safety of handling operations, giving the mass of the machinery and its various parts where they are regularly to be transported separately,
- (g) intended conditions of use of the machinery within the meaning of 1.1.2(c),
- (h) where applicable, a statement that the machinery is intended for use in a potentially explosive atmosphere,
- (i) workstation(s) likely to be occupied by operators,
- (j) the operating method to be followed in case of accident or breakdown. If a blockage is likely to occur, the instructions are to specify the operating method to be followed to enable the equipment to be safely deblocked,
- (k) the definition of the adjustment and maintenance operations that should be carried out by the user and the preventive measures that should be observed,
- (l) information to facilitate maintenance,

- (m) instructions on the connecting of fluids, including electrical connections, which may be the source of risk,
- (n) ways in which the machinery should not be used,
- (o) the obligation on the part of the user to comply with the provisions relating to the use of work equipment and in particular Council Directive 89/655/EEC (¹),
- (p) conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling, when out of service, during testing or during foreseeable breakdowns,
- (q) the requirements relating to installation and assembly for reducing noise or vibration,
- (r) the following information on airborne noise emissions:
 - 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 $(130 \text{ dB} \text{ in relation to } 20 \text{ } \mu\text{Pa}),$
 - sound power level emitted by the machinery where the equivalent continuous A-weighted sound pressure level at workstations exceeds 85 dB(A).

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

In the case of very large machinery, instead of the sound power level the equivalent continuous sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery.

The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1.6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

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

2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY

Agri-foodstuffs machinery and machinery for the cosmetics and pharmaceuticals industries, hand-held and/or hand-guided machinery and machinery for working wood and analogous materials must meet all the essential health and safety requirements described in this annex. The following essential requirements therefore relate only to the particular characteristics of these types of machinery.

2.1. Agri-foodstuffs machinery and machinery for the cosmetics and pharmaceuticals industries

2.1.1. General

Agri-foodstuffs machinery and machinery for the cosmetics and pharmaceuticals industries must be so designed and constructed as to avoid any risk of infection, sickness or contagion.

The following hygiene rules must be observed:

(a) materials in contact, or intended to come into contact, with foodstuffs or cosmetic or pharmaceutical products 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 in contact with foodstuffs or cosmetic or pharmaceutical products must:
 - be smooth, and must have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings;
 - be designed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum.
 They should preferably be made by welding or continuous bonding;
 - 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;
- (c) it must be possible to discharge liquids and gases deriving from foodstuffs or cosmetic or pharmaceutical products, as well as cleaning, disinfecting and rinsing fluids from the machine, without impediment (possibly in a 'clean' position);
- (d) 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) machinery must be so designed and constructed that no ancillary substances, including the lubricants used, can come into contact with foodstuffs or cosmetic or pharmaceutical products. Where necessary, machinery must be designed and constructed so that continuing compliance with this requirement can be checked.

2.1.2. Instructions

The instructions for agri-foodstuffs machinery and machinery for the cosmetics and pharmaceuticals industries must indicate recommended products and methods for cleaning, disinfecting and rinsing (not only for easily accessible areas but also for areas to which access is impossible or inadvisable).

2.2. Portable hand-held and/or hand-guided machinery

2.2.1. General

Portable hand-held and/or hand-guided machinery must:

- according to the type of machinery, have a supporting surface of sufficient size and a sufficient number of handles and supports of an appropriate size and arranged to ensure the stability of the machinery under the intended operating conditions;
- except where technically impossible or where there is an independent control, in the case of handles which cannot be released in complete safety, be fitted with manual whenever the machinery is about to 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;
- it must be designed and constructed to allow, where necessary, a visual check of the contact of the tool with the material being processed.

The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

2.2.2. 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.

This value must be actually measured for the machinery in question, or determined on the basis of measurements made on technically comparable machinery representing the intended production.

If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.

The operating conditions during measurement and the methods used for measurement must be described.

2.3. Portable cartridge-operated fixing devices

2.3.1. General

Portable cartridge-operated fixing devices must be designed and constructed in such a way that:

- energy is transmitted from the cartridge to the projectile via an intermediary component and not by direct action.
- the device cannot be used unless it is positioned correctly and with adequate pressure on the workpiece,
- the device cannot be triggered accidentally,
- a shield can be used, if necessary.

Particular precautions must be taken to prevent the chamber from rupturing.

2.3.2. Instructions

The instructions for a given device must give the necessary information regarding:

- suitable cartridges;
- interchangeable equipment that can be used.

2.4. Machinery for working wood and analogous materials

Machinery for working wood and analogous materials must comply with the following rules:

- (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 possible, 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.

3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE HAZARDS DUE TO THE MOBILITY OF MACHINERY

Machinery presenting hazards because of its mobility must meet all the essential health and safety requirements described in this annex. The following essential requirements therefore relate only to the particular characteristics of this type of machinery.

3.1. General

3.1.1. Definitions

Machinery presenting hazards due to mobility:

- machinery operated in working areas and whose operation requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations;
- machinery operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.

Driver: an operator responsible for the movement of a machine. 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

3.1.2. Lighting

If intended to be used in dark places or at night, 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.

3.2. Workstations

3.2.1. Seating

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 relative to the structure caused by the suspension of the seat.

3.2.2. Driving position

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.

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.

3.2.3. Other places

If the conditions of use provide that operators other than the driver may occasionally or regularly be 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.

The second and third paragraphs of 3.2.2 also apply to the places for operators other than the driver.

3.3. **Controls**

If necessary, steps must be taken to prevent unauthorised use of control points.

In the case of remote controls, each control point must clearly identify the machinery to be controlled from that point.

The control system must be designed and constructed in such as way as to affect:

- the machinery in question;
- the functions in question.

Machinery must be designed and constructed in such as way that it will respond only to signals from the intended control points.

3.3.1. Manual controls

The driver must be able to actuate all manual controls required to operate the machinery from the driving position, except for functions which can be safely actuated only by using manual controls 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 manual 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 when the machinery is moving.

The penultimate subparagraph of 1.2.2 applies only in the case of reversing.

3.3.2. Starting/moving

All 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. stabilisers, 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 while the engine is being started.

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 immobilisation so as to ensure safety under all the operating, loading, speed, ground and gradient conditions allowed for.

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 equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

- if the driver loses control, except in the case of machines performing pre-programmed tasks outside the remote-controlled zone when there is no possibility of a dangerous situation arising;
- if it receives a stop signal;

- if a fault is detected in the system;
- if no validation signal is detected within a specified time;
- section 1.2.4.1 does not apply to the travelling function.

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 manual 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 minimise 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 when 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.

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.

3.4. Protection against mechanical hazards

3.4.1. Uncontrolled movements

Machinery must be so designed, constructed and where appropriate placed on its mobile support so as to ensure that, when moved, the uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2. 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 and constructed to take account of this risk 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 authorised representative 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 protective structure:

- crawler loaders or wheel loaders,
- backhoe loaders,
- crawler tractors or wheel tractors,
- scrapers, self-loading or not,

- graders,
- articulated steer dumpers.

3.4.3. 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 and constructed to take account of this risk and fitted, if its size allows, with 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 authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.4. 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.

3.4.5. 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.

3.4.6. Transmission of power between self-propelled machinery (or tractor) and recipient machinery

Removable mechanical transmission components linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length.

On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission component 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 removable mechanical transmission component must be marked accordingly.

All towed machinery whose operation requires a removable mechanical transmission component to connect it to self-propelled machinery or a tractor must have a system for attaching the removable mechanical transmission component so that, when the machinery is uncoupled, the removable mechanical transmission component 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 removable mechanical transmission component. The guard must cover the transmission 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.

If means of access to working positions are provided near to the removable mechanical transmission component, they must be designed and constructed in such a way that the shaft guards cannot be used as steps unless designed and constructed for that purpose.

3.4.7. Moving transmission parts

By way of derogation from section 1.3.8.1, in the case of 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 unauthorised access.

3.5. Protection against other hazards

3.5.1. Batteries

The battery housing must be designed and constructed 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.

3.5.2. Fire

Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:

- either allow easily accessible fire extinguishers to be fitted,
- or be provided with built-in extinguisher systems.

3.5.3. Emissions of dust, gases etc.

The second and third paragraphs of section 1.6.14 do not apply where the main function of the machinery is the spraying of products. The risk of the operator being exposed to emissions must, however, be minimised.

3.6. Indications

3.6.1. Signs and warning

All machinery must have means of signalling and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, to ensure the health and safety of 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. The latter requirement does not apply
 to machinery intended solely for underground working and having no electrical power,
- where appropriate, there must be a connection between a trailer and a machine that presents risks due to mobility.

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.

3.6.2. Marking

The following must be shown legibly and indelibly on all machinery:

- nominal power expressed in kW,
- mass in kg of the most usual configuration and, where appropriate:
 - maximum drawbar pull provided for at the coupling hook, in Newtons (N),
 - maximum vertical load provided for on the coupling hook, in Newtons (N).

3.6.3. Instructions

3.6.3.1. Vibrations

The instructions for machinery that transmits vibrations to the whole body or the upper limbs of the driver must give the following information for the parts of the body concerned:

- 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.

These values must be actually measured for the machinery in question, or determined on the basis of measurements made on technically comparable machinery representing intended production.

Where the harmonised standards are not applied, the vibration must be measured using the most appropriate method for the machinery concerned.

The operating conditions during measurement and the methods used must be described.

3.6.3.2. Multiple uses

The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safely assembling and using the basic machinery and the interchangeable equipment that can be fitted.

4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO A LIFTING OPERATION

Machinery presenting hazards due to lifting operations must meet all the essential health and safety requirements described in this annex. The following essential requirements therefore relate only to the particular characteristics of this type of machinery.

4.1. General

4.1.1. Definitions

- (a) 'Lifting operation': a movement of loads or persons necessitating, at a given moment, a change of level.
- (b) 'Slinging device': device used to enclose or hook an object and raise it by means of a motor.
- (c) 'Separate lifting accessory': a lifting accessory which helps to make up or use a slinging device.
- (d) 'Guided load': load where the total movement is made along rigid or flexible guides, whose position is determined by fixed points.
- (e) 'Working coefficient': the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a piece of lifting machinery or equipment or an accessory is able to hold it and the maximum working load marked on the machinery, equipment or accessory or respectively.
- (f) 'Test coefficient': means the arithmetic ratio between the load used to carry out the static or dynamic tests on a piece of lifting machinery or equipment or an accessory and the maximum working load marked on the piece of machinery or equipment or accessory.

- (g) 'Static test': the test during which the machinery or the lifting accessory is first inspected and 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.
- (h) 'Dynamic test': the test during which the machinery or lifting accessory is operated in all its possible configurations at maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the machinery in order to check that the machinery or the lifting accessory is functioning properly.
- 4.1.2. Protection against mechanical hazards
- 4.1.2.1. Machinery running on 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 from overturning.

4.1.2.2. 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 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.

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 intended working environments, 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 static and dynamic tests must be performed on all machinery ready to be put into use.

As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, i.e. as a general rule, by combining the movements concerned.

4.1.2.3. Lifting accessories

Pulleys, drums and wheels must have a diameter commensurate with the size of ropes 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, however, tolerated in installations which are intended from their design to be modified regularly according to needs of 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 authorised representative 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.

4.1.2.4. 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 life-span as specified in the operating conditions for a given application.

Moreover:

- (a) the working coefficient of the wire-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 multilegged 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 authorised representative must, for each type of component referred to in (a), (b), (c) and (d) perform the appropriate tests or have such tests performed.

4.1.2.5. Control of movements

Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe.

- (a) Machinery must be designed and constructed or fitted with devices so 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) 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.

4.1.2.6. Movement of loads during handling

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 and machinery whose load supports follow a clearly defined path must be designed, constructed and equipped with devices to prevent any risks to exposed persons.

4.2. Special requirements for machinery whose power source is other than manual effort

4.2.1. Movement controls

Hold-to-run control devices must be used to control the movements of the machinery or its equipment. 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 actuators authorising automatic stops at preselected levels without the operator holding a hold-to-run control device.

4.2.2. Loading control

Machinery with a maximum working load of not less than 1 000 kg or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements 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.

4.2.3. Cables for installations 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.

4.2.4. 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.

4.3. Marking

4.3.1. Chains and rope

Each length of lifting chain, rope or webbing not forming part of an assembly must bear, in addition to the CE marking, a mark showing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate.

If it is not physically possible to show all or part of the information required for lifting accessories, this information must be given on a plate or irremovable ring, or by other means firmly attached to the accessory.

The particulars must be legible, indelible and located in a place where they are not likely to adversely affect the strength of the accessory.

The certificate mentioned above should show the information required by the harmonised standards or, should those not exist, at least the following information:

- the name and address of the manufacturer and, if appropriate, his authorised representative,

- 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,
- the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.

4.3.2. Lifting accessories

All lifting accessories not forming part of an assembly must bear the following marks:

- identification of the material where this information is needed for dimensional compatibility,
- identification of the maximum working load,
- CE marking.

4.3.3. Lifting machinery

Each machine must bear, legibly and indelibly, information concerning the maximum load:

- (a) displayed in uncoded form and prominently in the case of machinery which has only one possible value;
- (b) 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 for 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.

4.4. Instructions

4.4.1. Lifting and separate lifting accessories

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars:

- normal conditions of use,
- the test coefficients,
- instructions for use, assembly and maintenance,
- the limits of use (particularly for accessories such as magnetic or pneumatic pads which cannot comply with 4.1.2.5(e)).

4.4.2. Lifting machinery

All machinery must be accompanied by instructions containing information on:

- (a) the technical characteristics of the machinery, and in particular:
 - where appropriate, a copy of the load table described in section 4.3.3.(b),
 - the reactions at the supports or anchors and, where appropriate, 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 premises of the manufacturer or his authorised representative in the form in which it is to be used.

5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK

Machinery intended for underground work must meet all the essential health and safety requirements described in this annex. The following essential requirements therefore relate only to the particular characteristics of this type of machinery.

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.

5.2. Movement

Powered roof supports must allow for unhindered movement of exposed persons.

5.3. Lighting

The requirements laid down in section 1.1.5 do not apply.

5.4. Manual controls

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 manual controls of powered roof supports must be designed and laid out so that, during displacement operations, operators are sheltered by a support in place. The manual controls must be protected against any accidental release.

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.

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 to 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 vaporising pressure and which exclude any spark of electrical origin.

5.7. Emissions of gases

Exhaust gases from internal combustion engines must not be discharged upwards.

6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OR MOVING OF PERSONS

Machinery presenting hazards due to the lifting or moving of persons must meet all the essential health and safety requirements described in this annex. The following essential requirements therefore relate only to the particular characteristics of this type of machinery.

6.1. General

6.1.1. Definition

'Carrier': the device by which persons are supported in order to be lifted, lowered or moved.

6.1.2. Mechanical strength

The working coefficients defined in heading 4 are inadequate for machinery intended for the lifting or moving of 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.

6.1.3. Loading control for types of device moved by power other than human strength

The requirements of 4.2.2 apply regardless of the maximum working load and the moment conducive to overturning.

6.2. Manual controls

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 movements 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 hold-to-run type.

6.3. Risks to persons in the carrier

6.3.1. Risks of persons falling from the carrier

Where work is performed from the carrier, special precautions must be taken to ensure stability and prevent sudden movements.

If the measures referred to in 1.6.16 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.

Any trapdoors in floors or ceilings or side doors must open in a direction which obviates any risk of falling should they open unexpectedly.

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.

6.3.2. Risks of the carrier falling or overturning

The machinery must be designed and constructed to prevent the carrier falling or overturning.

Machinery for lifting or transporting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for exposed persons. It must be fitted with handles that are fixed relative to the users and that enable them to maintain their stability.

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 which may be produced by the movement of the machinery.

6.4. Markings

Where necessary to ensure safety, the carrier must bear the relevant essential information.

7. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO LIFTING OPERATIONS AND INTENDED FOR PERSONS WITH REDUCED MOBILITY

Machinery presenting particular hazards due to lifting operations and intended for persons with reduced mobility must meet all the essential health and safety requirements described in this annex. The following essential requirements therefore relate only to the particular characteristics of these types of machinery.

7.1. **Definitions**

For the purposes of this chapter, 'support' means any device by which persons of reduced mobility are supported in order to enable them to change level. Supports include platforms, seats or any other device performing the same function.

7.2. Manual controls

The manual controls must be designed and constructed so as to be easily accessible to users, taking account of their handicap.

When a support is bearing a person, the controls must be of the hold-to-run type and must override all other controls. This requirement does not apply to the function of calling a support from a landing.

7.3. Falling of the support

Machinery must be equipped with devices to prevent free falling or uncontrolled upward movements of the support. The device to prevent free falling of the support must be independent of the support's suspension.

This device must be capable of stopping the support under its nominal load and at the maximum speed provided for by the installer. The stopping action must not, irrespective of the load, cause deceleration that is dangerous for the occupants.

Measures must be taken to prevent the support from knocking into the ends of the enclosure.

7.4. Access to the support

Machinery must be designed and constructed so as to minimise the difference in level between the support and each of the levels served.

The approaches to the support must be equipped with protection devices in order to prevent the risk of people falling when the support is not at a landing.

These protection devices must be equipped with an interlocking device controlled by the position of the support so that:

- they cannot be opened unless the support is present,
- the support cannot move until the protection device has been closed.

If the possible vertical drop is less than 0.50 m, a railing is sufficient.

If the possible vertical drop is between $0.50\,$ m and $3\,$ m, the doors and fixed walls protecting the travel zone must be unperforated and at least $1.10\,$ m high,

If the possible vertical drop is more than 3 m, there must be a landing entrance and the fixed walls protecting the travel zone must be unperforated and at least 2 m high.

8. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CONSTRUCTION SITE HOISTS INTENDED FOR LIFTING PERSONS OR PERSONS AND GOODS

Construction site hoists intended for lifting persons or persons and goods must meet all the essential health and safety requirements described in this annex. The following essential requirements therefore relate only to the particular characteristics of these types of machinery.

8.1. **Cab**

Construction site hoists intended for lifting persons or persons and goods must be fitted with an enclosed cab; the walls and roof of the cab may be perforated or unperforated.

Where, for construction site hoists intended for lifting persons or persons and goods, there is a risk of objects falling and endangering persons, the roof of the cab must be suitably protected.

8.2. Protection of the travel zone of the cab

The zone through which the cab travels should not be accessible during normal operation.

8.3. Suspension system for the load support

Construction site hoists intended for lifting persons or persons and goods must be fitted with a suspension system for the load support, fixings and end pieces designed and constructed in such a way as to ensure an adequate overall level of safety and to minimise the risk of the load support falling.

If cables or chains are used to suspend the load support, at least two independent cables or chains are required, each with its own anchorage. Except when a loop is necessary, the cables or chains must not comprise any knots or splices.

8.4. Falling of the load support

Construction site hoists intended for lifting persons or persons and goods must be fitted with devices to prevent free falling or uncontrolled upward movements of the load support. The device to prevent free falling of the load support must be independent of the load support's suspension.

This device must be capable of stopping the load support under its nominal load and at the maximum speed provided for. The stopping action must not, irrespective of the load, cause deceleration that is dangerous for the occupants.

Measures must be taken to prevent the support knocking into the ends of the enclosure.

8.5. Access to the load support

Construction site hoists intended for lifting persons or persons and goods must be designed and constructed so as to minimise the difference in level between the load support and each of the levels served.

The approaches to the load supports must be equipped with an interlocking device controlled by the position of the load support so that:

- they cannot be opened unless the support is present,
- the support cannot move until the protection device has been closed.

ANNEX II

CONTENTS OF DECLARATIONS

A. Contents of the EC declaration of conformity of the machine (1)

The EC declaration of conformity (2) must contain the following particulars:

- 1. name and address of the manufacturer or his authorised representative (3),
- name and address of the person who is authorised to compile the technical file, who must be established in the Community,
- 3. description and identification of the machine (4),
- 4. a declaration of conformity with the present Directive,
- 5. where appropriate, a declaration of conformity with other European Directives (5) and/or relevant provisions with which the machine complies,
- 6. where appropriate, the name, address and identification number of the notified body which carried out the procedure for ensuring that the machine complies with the harmonised standards provided for in Annex IX,
- 7. where appropriate, the name, address and identification number of the notified body and the number of the EC type-examination certificate provided for in Annex X,
- 8. where appropriate, the name, address and identification number of the notified body which provided the full quality assurance provided for in Annex XI,
- 9. where appropriate, a reference to the harmonised standards used,
- 10. where appropriate, the national technical standards and specifications used,
- 11. the place and date of the declaration,
- 12. the identity and signature of the manufacturer or his authorised representative or of the person empowered to draw up the declaration.

B. Contents of the declaration of incorporation of partly completed machinery (6)

The declaration of incorporation must contain the following particulars:

- 1. name and address of the manufacturer of the partly completed machinery (7) or his authorised representative,
- 2. description and identification of the partly completed machinery (8),
- 3. where appropriate, a declaration of the conformity of the partly completed machinery with other relevant European Directives (9),
- (1) This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, point 1.10.1.(c), and must be either typewritten or handwritten in block capitals.
- (2) This declaration relates exclusively to the machine in the state in which it was delivered, and excludes components which are added and/or operations carried out subsequently by the final user.
- (3) Business name and full address; if the declaration is compiled by an authorised representative, the manufacturer's business name and address must also be given.
- (4) A description of the machine, type, serial number, commercial name, etc.
- (5) These references must be the ones published in the Official Journal of the European Communities.
- (6) This declaration of incorporation must be either typewritten or handwritten in block capitals.
- (7) Business name and full address; if the declaration is compiled by an authorised representative, the manufacturer's business name and address must also be given.
- (8) A description of the partly completed machinery, type, serial number, commercial name, etc.
- (9) These references must be the ones published in the Official Journal of the European Communities.

- 4. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery,
- 5. 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 this Directive,
- 6. the place and date of the declaration,
- 7. the identity and signature of the manufacturer or his authorised representative or of the person empowered to draw up the declaration.

ANNEX III

CE MARKING

The CE conformity marking shall consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, as required in point 1.9 of Annex I, and be applied using the same technique.

ANNEX IV

TYPES OF MACHINERY TO WHICH ONE OF THE PROCEDURES REFERRED TO IN ARTICLE 12(4) AND (5) MUST BE APPLIED

- 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 blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed.
- 1.2. Sawing machines with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage.
- 1.3. Sawing machines with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading.
- 1.4. Sawing machines with movable blade(s) during cutting, having a mechanical feed device for the workpieces, with manual loading and/or unloading.
- 2. Hand-fed surface planing machines for woodworking.
- Thicknessers for one-side dressing having a built-in feed mechanical feed device, with manual loading and/or unloading for woodworking.
- 4. Band-saws with manual loading and/or unloading for working with wood and analogous materials or for working with meat and analogous materials.

- 4.1. Sawing machines with fixed blade during cutting having a fixed or reciprocating-movement bed or support for the workpiece.
- 4.2. Sawing machines with blade assembled on a carriage with reciprocating motion.
- Combined machines of the types referred to in points 1 to 3 and in point 7 for working with food 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 chainsaws 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 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:
 - locomotives and brake-vans,
 - hydraulic-powered roof supports.
- 13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
- 14. Removable mechanical transmission shafts.
- 15. Guards for removable mechanical transmission shafts.
- 16. Vehicle servicing lifts.
- 17. Devices for the lifting of persons or of persons and goods involving a risk of falling from a vertical height of more than three metres.
- 18. Portable cartridge-operated fixing devices.
- 19. Electro-sensitive devices designed to detect persons (non-material barriers, sensor mats, electromagnetic detectors, etc.).
- 20. Automatic mobile screens for protecting the machines referred to in points 9, 10 and 11.

ANNEX V

ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY

These instructions must contain a description of the conditions which must be met with a view to correct incorporation in the final machine, so as not to compromise human safety and health.

They must be written in an official Community language acceptable to the manufacturer of the machine in which the partly completed machinery will be assembled, or to his authorised representative.

ANNEX VI

TECHNICAL FILE FOR MACHINERY

1. This annex must describe the procedure for compiling a technical file. The technical file must demonstrate that the machine complies with the requirements of the Directive. It must cover the design, manufacture and operation of the machine to the extent necessary for this assessment. The technical file must be compiled in one of the official languages of the Community, except for the instructions for the machine, for which the special provisions of Annex I, point 1.10.1 apply.

The technical file shall comprise the following:

- (a) a construction file including:
 - the overall drawing of the machine and drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the
 conformity of the machine with essential safety and health requirements,
 - a list of:
 - the essential health and safety requirements of this Directive which apply to the machine in question,
 - the standards and other technical specifications which were used,
 - a description of methods adopted to eliminate hazards presented by the machine,
 - any technical report or certificate obtained from a body or laboratory selected by the manufacturer or his authorised representative,
 - if a harmonised standard which requires a technical report is used, any technical report giving the results of
 the tests carried out either by the manufacturer or by a body or laboratory chosen by the manufacturer or his
 authorised representative,
 - a copy of the instructions for the machine;
- (b) for series manufacture, the internal measures that will be implemented to ensure that the machines remain in conformity with the provisions of the Directive.

The manufacturer must carry out necessary research and tests on components, fittings or the completed machine to determine whether by its design or construction it is capable of being assembled and put into service safely.

2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States.

This technical file does not have to be located in the territory of the European Union, not does it have to be permanently available in material form. It must be capable of being assembled and made available within a period of time commensurate with its importance by the person designated in the EC declaration of conformity.

3. Failure to present the technical file in response to a duly substantiated request by the competent national authorities may constitute sufficient grounds for doubting the presumption of conformity of the machinery referred to in this technical file with the requirements of this Directive.

ANNEX VII

ASSESSMENT OF CONFORMITY WITH INTERNAL CHECKS ON THE MANUFACTURE OF MACHINERY

- 1. This annex describes the procedure by which the manufacturer or his authorised representative, before placing the machine on the market:
 - compiles a technical file,
 - draws up an EC declaration of conformity for each machine,
 - affixes the CE marking on each machine.
- 2. For each representative example of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VI, point 1.
- 3. The manufacturer or his authorised representative shall affix the CE marking described in Annex III on each machine and shall, for each machine, draw up an EC declaration of conformity, the components of which are set out in Annex II, part A.

The manufacturer or his authorised representative shall keep the technical file described in Annex VI, point 1, together with a copy of the EC declaration of conformity, for a period of at least ten years from the last date of manufacture of the machine.

For series manufacture of identical machines, a copy of the technical file representative of the series in question shall suffice.

ANNEX VIII

ASSESSMENT OF CONFORMITY FOR A MACHINE NOT PRESENTING ANY INTRINSIC RISK TO SAFETY OR HEALTH

Where the analysis of risks performed by the manufacturer or his authorised representative in accordance with Annex I demonstrates that the Directive has no relevance in terms of safety and health, the following procedure shall be applied:

- 1. The manufacturer or his authorised representative shall affix the CE marking on each machine.
- 2. The manufacturer or his authorised representative shall keep the risk analysis for a period of ten years from the date of manufacture of the machine or, in the case of series production, of the last machine manufactured. This analysis must be kept available for inspection by the competent national authorities of the Member States.
- 3. There shall not be any requirement to compile an EC declaration of conformity or keep a complete technical file.

ANNEX IX

ADEQUACY IN RESPECT OF THE HARMONISED STANDARDS FOR MACHINERY REFERRED TO IN ANNEX IV

- 1. This annex describes the conformity assessment for a machine referred to in Annex IV and manufactured in accordance with one or more harmonised standards. It describes the procedure by which:
 - the manufacturer or his authorised representative, before placing the machine on the market:
 - compiles the technical file referred to in Annex VI, point 1,
 - lodges an application for approval of this technical file with a notified body,
 - the notified body:
 - ascertains and certifies that the technical file satisfies the provisions of this Directive,
 - draws up a certificate of adequacy,

- the manufacturer or his authorised representative, before placing the machine on the market:
 - draws up an EC declaration of conformity for each machine,
 - affixes the CE marking on each machine.
- 2. Before taking any other action, the manufacturer or his authorised representative must, for each representative example of the series in question, draw up the technical file referred to in Annex VI, point 1.
- 3. The application for a certificate of adequacy shall be lodged by the manufacturer or his authorised representative with a notified body of its choice, for each representative example of the series in question.

Files and correspondence concerning the inspection procedures by the notified body shall be written in an official language of the Member State in which the notified body is established or in a language acceptable to it.

The application must contain:

- the name and address of the manufacturer or his authorised representative,
- a written declaration that the application has not been lodged with another notified body,
- the technical file referred to in Annex VI, point 1.
- 4. The notified body shall examine the technical file and ascertain whether the harmonised standards which are referred to in it have been applied correctly.
- 5. If the technical file satisfies the provisions of the Directive, the notified body shall issue the applicant with a certificate of adequacy. The certificate shall include the name and address of the manufacturer or his authorised representative, the data necessary for identifying the machine described in the file, the conclusion of the examination and the conditions to which its issue may be subject.

The notified body shall retain a copy of the certificate, the technical file and all other relevant documents for a period of 15 years from the date of the issue of the certificate.

6. If it refuses to issue the manufacturer or his authorised representative with a certificate of adequacy, the notified body shall give detailed reasons for the refusal. It shall inform the applicant and the other notified bodies accordingly. An appeal procedure must be available.

If it withdraws a certificate of adequacy from the manufacturer or his authorised representative, the notified body shall give detailed reasons for the withdrawal. It shall inform the applicant and the Member State which notified it, stating the reasons for its decision. It shall inform the Commission and the other Member States. An appeal procedure must be available.

- 7. The applicant shall inform the notified body which retains the technical file relating to the certificate of adequacy of all modifications to the approved machine. The notified body shall examine these modifications and either confirm the validity of the existing certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or with the intended conditions of use of the machine.
- 8. The Commission, Member States and the other approved bodies may obtain, on request, a copy of the certificates of adequacy. On reasoned request, the Commission and Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.
- 9. On receipt of the certificate of adequacy, the manufacturer or his authorised representative shall ensure and certify that the machines manufactured in accordance with the technical file are in conformity with it and satisfy the provisions of this Directive.

The manufacturer or his authorised representative shall affix the CE marking described in Annex III on each machine and shall, for each machine, draw up an EC declaration of conformity, the components of which are set out in Annex II, part A.

The manufacturer or his authorised representative shall, for each machine manufactured, retain the components of the technical file, together with a copy of the EC declaration of conformity, for a period of at least ten years from the last date of manufacture of the machine.

For series manufacture of identical machines, a copy of the technical file representative of the series in question shall suffice.

ANNEX X

EC TYPE-EXAMINATION OF A MACHINE REFERRED TO IN ANNEX IV

- 1. This annex describes the conformity assessment of a machine referred to in Annex IV following a type-examination performed by a notified body. It describes the procedure by which:
 - the manufacturer or his authorised representative, before placing the machine on the market
 - compiles the technical file referred to in Annex VI, point 1,
 - lodges an application for a type-examination with a notified body,
 - the notified body
 - ascertains and declares that a representative example of the series in question satisfies the provisions of this
 Directive.
 - draws up an EC type-examination certificate,
 - the manufacturer or his authorised representative, before placing the machine on the market
 - draws up an EC declaration of conformity for each machine,
 - affixes the CE marking on each machine.
- 2. Before taking any other action, the manufacturer or his authorised representative must, for each specimen representative of the series in question, draw up the technical file referred to in Annex VI, point 1.
- 3. For each example representative of the series in question, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of its choice.

Files and correspondence referring to the type-examination procedures of the notified body shall be written in an official language of the Member State where the notified body is established or in a language acceptable to it.

The application shall include:

- the name and address of the manufacturer or his authorised representative,
- a written declaration that the application has not been lodged with another notified body,
- the technical file described in Annex VI, point 1.

Moreover, the applicant shall place at the disposal of the notified body an example which is representative of the series in question, hereafter named the 'type' (1). The notified body may ask for further copies if the test programme so requires.

- 4. The notified body shall:
- 4.1. examine the technical file, check that the type was manufactured in accordance with it and establish which components have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those components whose design is not based on the relevant provisions of those standards;
- 4.2. carry out or have carried out appropriate inspections and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of the Directive where the standards referred to in Article 7(2) were not applied;
- 4.3. where harmonised standards were used, carry out or have carried out appropriate inspections and tests to verify that those standards were actually applied;
- 4.4. agree with the applicant as to the place where the necessary inspections and tests will be carried out.

⁽¹⁾ The type may comprise several versions of the machine in so far as the differences between those versions do not affect the level of safety or other performance-related requirements of the machine.

5. If the type satisfies the provisions of the Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer or his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.

The notified body shall retain a copy of this certificate, the technical file and all relevant documents, for a period of 15 years from the date of issue of the certificate.

6. If it refuses to issue the manufacturer or his authorised representative with an EC type-examination certificate, the notified body shall give detailed reasons for its refusal. It shall inform the applicant and the other notified bodies. An appeal procedure must be available.

If it withdraws an EC type-examination certificate from the manufacturer or his authorised representative, the notified body shall give detailed reasons for the withdrawal. It shall inform the applicant and the Member State which notified it, stating the reasons for its decision. This Member State shall inform the other Member States and the Commission. An appeal procedure must be available.

- 7. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved machine. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential safety and health requirements or the intended working conditions of the machine.
- 8. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.
- 9. After receipt of the EC type-examination certificate, the manufacturer or his authorised representative shall ascertain and declare that the machines in question conform to the type described in the certificate and that they satisfy the provisions of this Directive.

The manufacturer or his authorised representative shall affix on each machine the CE marking described in Annex III and shall, for each machine, draw up an EC declaration of conformity, the elements of which are set out in Annex II, part A.

The manufacturer or his authorised representative shall retain the technical file, together with a copy of the EC declaration of conformity, for at least ten years from the last date of manufacture of the machine.

For series manufacture of identical machines, a copy of the technical file representative of the series in question shall suffice.

ANNEX XI

FULL QUALITY ASSURANCE FOR A MACHINE REFERRED TO IN ANNEX IV

- 1. This annex describes the conformity assessment of a machine whose manufacture is subject to full quality assurance. It describes the procedure by which:
 - the manufacturer
 - implements a system of full quality assurance described in section 3 of this annex,
 - compiles a technical file,
 - the notified body evaluates and supervises this quality assurance system,
 - the manufacturer or his authorised representative
 - draws up an EC declaration of conformity for each machine
 - affixes the CE marking, together with the identification number of the notified body, on each machine.
- 2. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 3, and shall be subject to the surveillance referred to in point 4.
- 3. Quality system
- 3.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.

The application shall contain:

- the name and address of the manufacturer,
- the places of design, manufacture, inspection, testing and storage of the machinery,
- the technical file described in Annex VI, point 1, for one of the machinery which he intends to manufacture,
- documentation on the quality system,
- a written declaration that the application has not been lodged with another notified body.
- 3.2. The quality system must ensure conformity of the machinery with the provisions of this Directive.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. This documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

It must contain, in particular, an adequate description of:

- the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery;
- the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are met;
- the design inspection and design verification techniques, processes and systematic actions that will be used when designing machines covered by this Directive;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

- the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications
 of the personnel concerned;
- the means of monitoring the achievement of the required design and quality of the machines, as well as the effective operation of the quality system.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 3.2. The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 3.2.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machines covered by this Directive. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.

The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 3.2, or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 4. Surveillance under the responsibility of the notified body
- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:
 - documentation concerning the quality system,
 - the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,
 - the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.
- 4.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.
- 4.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:
 - the results of previous surveillance visits;
 - the need to monitor remedial measures;
 - where appropriate, special conditions attaching to approval of the system;
 - significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.

5. The manufacturer or his authorised representative shall ascertain and declare that the machines in question are in conformity with and satisfy the requirements of this Directive.

The manufacturer or his authorised representative shall affix the CE marking described in Annex III on each machine, together with the identification number of the notified body, and shall, for each machine, draw up an EC declaration of conformity, the components of which are set out in Annex II, part A.

The manufacturer or his authorised representative shall keep the components of the technical file described in Annex VI, point 1, together with a copy of the EC declaration of conformity, for a period of at least ten years from the last date of manufacture of the machine.

For series manufacture of machinery, a representative example of the machine in question shall suffice.

- 6. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:
 - the documentation referred to in point 3.1, second subparagraph, second indent,
 - the decisions and reports of the notified body referred to in point 3.3, final subparagraph, and point 3.4, final subparagraph, and in points 4.3 and 4.4.
- 7. If the notified body refuses to approve a manufacturer's quality system or withdraws approval of such a system, it shall give detailed reasons for its refusal. It shall inform the applicant and the other notified bodies. An appeal procedure must be available.

ANNEX XII

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF RODIES

- 1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become either involved directly or as authorised representatives in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
- 2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
- 3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.
- 4. The staff responsible for inspection shall have:
 - sound technical and vocational 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 shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
- 6. The body shall 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 shall be bound to observe professional secrecy with regard to all information obtained 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.

ANNEX XIII

CORRELATION TABLE

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Article 1(1)	Article 1(1)
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