COUNCIL DIRECTIVE

of 14 June 1989

on the approximation of the laws of the Member States relating to machinery

(89/392/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

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

Whereas, in the Member States, the legislative systems regarding accident prevention are very different; whereas the relevant compulsory provisions, frequently supplemented by *de facto* mandatory technical specifications and/or voluntary standards, do not necessarily lead to different levels of health and safety, but nevertheless, owing to their disparities, constitute barriers to trade within the Community; whereas, furthermore, conformity certification and national certification systems for machinery differ considerably;

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

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

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

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

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

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

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

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

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

(1) OJ No C 29, 3. 2. 1988, p. 1, and OJ No C 214, 16. 8. 1988, p. 23.
(2) OJ No C 326, 19. 12. 1988, p. 143, and OJ No C 158, 26. 6. 1989.
(3) OJ No C 337, 31. 12. 1988, p. 30.

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

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

Whereas, therefore, this Directive defines only the essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery; whereas, in order to help manufacturers to prove conformity to these essential requirements and in order to allow inspection for conformity to the essential requirements, it is desirable to have standards harmonized at European level for the prevention of risks arising out of the design and construction of machinery; whereas these standards harmonized at European level are drawn up by private-law bodies and must retain their non-binding status; whereas for this purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are the bodies recognized as competent to adopt harmonized standards in accordance with the general guidelines for cooperation between the Commission and these two bodies signed on 13 November 1984; whereas, within the meaning of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by either or both of these bodies, on the basis of a remit from the Commission in accordance with the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations [1], as last amended by Directive 88/182/EEC [2], and on the basis of general guidelines referred to above;

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

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

Whereas, for certain types of machinery having a higher risk factor, a stricter certification procedure is desirable; whereas the EC type-examination procedure adopted may result in an EC declaration being given by the manufacturer without any stricter requirement such as a guarantee of quality, EC verification or EC supervision;

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

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

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

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

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

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SCOPE, PLACING ON THE MARKET AND FREEDOM OF MOVEMENT

Article 1

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

2. For the purposes of this Directive, 'machinery' means an assembly of linked parts or components, at least one of

(1) OJ No L 109, 26. 4. 1983, p. 8.
(2) OJ No L 81, 26. 3. 1988, p. 75.

which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material.

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

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

— mobile equipment,

— lifting equipment,

— machinery whose only power source is directly applied manual effort,

— machinery for medical use used in direct contact with patients,

— special equipment for use in fairgrounds and/or amusement parks,

— steam boilers, tanks and pressure vessels,

— machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity,

— radioactive sources forming part of a machine,

— firearms,

— storage tanks and pipelines for petrol, diesel fuel, inflammable liquids and dangerous substances.

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

5. Where, for machinery, the risks are mainly of electrical origin, such machinery shall be covered exclusively by Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits [1].

Article 2

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

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

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

Article 3

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

Article 4

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

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

Article 5

1. Member States shall regard machinery bearing the EC mark and accompanied by the EC declaration of conformity referred to in Annex II as conforming to the essential health and safety requirements referred to in Article 3.

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

2. Where a national standard transposing a harmonized standard, the reference for which has been published in the *Official Journal of the European Communities*, covers one or more of the essential safety requirements, machinery

[1] OJ No L 77, 26. 3. 1973, p. 29.

constructed in accordance with this standard shall be presumed to comply with the relevant essential requirements.

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

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

Article 6

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 (2) do not entirely satisfy the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Committee set up under Directive 83/189/EEC, giving the reasons therefor. The Committee shall deliver an opinion without delay.

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

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

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

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

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

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

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

Article 7

1. Where a Member State ascertains that machinery bearing the EC mark and used in accordance with its intended purpose is liable to endanger the 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, putting into service or use thereof, or to restrict free movement thereof.

The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-conformity is due to:

(a) failure to satisfy the essential requirements referred to in Article 3;

(b) incorrect application of the standards referred to in Article 5 (2);

(c) shortcomings in the standards referred to in Article 5 (2) themselves.

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

3. Where machinery which does not comply bears the EC mark, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall so inform the Commission and the other Member States.

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

CHAPTER II

CERTIFICATION PROCEDURE

Article 8

1. The manufacturer, or his authorized representative established in the Community, shall, in order to certify the conformity of machinery with the provisions of this Directive, draw up an EC declaration of conformity based on the model given in Annex II for each machine manufactured and shall affix to the machinery the EC mark referred to in Article 10.

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

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

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

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

— either draw up the file referred to in Annex VI and forward it to a notified body, which will acknowledge receipt of the file as soon as possible and keep it,

— submit the file referred to in Annex VI to the notified body, which will simply verify that the standards referred to in Article 5 (2) have been correctly applied and will draw up a certificate of adequacy for the file,

— or submit the example of the machinery for the EC type-exmination referred to in Annex VI.

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

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

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

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

5. Whre the machinery is subject to other Community Directives concerning other aspects, the EC mark referred to in Article 10 shall indicate in these cases that the machinery also fulfils the requirements of the other Directives.

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

Article 9

1. Each Member State shall notify the Commission and the other Member States of the approved bodies responsible for carrying out the certification procedures referred to in Article 8 (2) (b) and (c). The Commission shall publish a list of these bodies in the *Official Journal of the European Communities* for information and shall ensure that the list is kept up to date.

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

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

CHAPTER III

EC MARK

Article 10

1. The 'EC' mark shall consist of the EC symbol followed by the last two digits of the year in which the mark was affixed.

Annex III shows the model to be used.

2. The EC mark shall be affixed to machinery distinctly and visibly in accordance with point 1.7.3 of Annex I.

3. Marks or inscriptions liable to be confused with the EC mark shall not be put on machinery.

CHAPTER IV

FINAL PROVISIONS

Article 11

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

Article 12

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