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(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 12 June 1989

on the introduction of measures to encourage improvements in the safety and health of workers at work

(89/391/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 118a thereof,

Having regard to the proposal from the Commission ⁽¹⁾, drawn up after consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament ⁽²⁾,

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

Whereas Article 118a of the Treaty provides that the Council shall adopt, by means of Directives, minimum requirements for encouraging improvements, especially in the working environment, to guarantee a better level of protection of the safety and health of workers;

Whereas this Directive does not justify any reduction in levels of protection already achieved in individual Member States, the Member State being committed, under the Treaty, to encouraging improvements in conditions in this area and to harmonizing conditions while maintaining the improvements made;

Whereas it is known that workers can be exposed to the effects of dangerous environmental factors at the work place during the course of their working life;

Whereas, pursuant to Article 118a of the Treaty, such Directives must avoid imposing administrative, financial and legal constraints which would hold back the creation and development of small and medium-sized undertakings;

Whereas the communication from the Commission on its programme concerning safety, hygiene and health at work ⁽⁴⁾ provides for the adoption of Directives designed to guarantee the safety and health of workers;

Whereas the Council, in its resolution of 21 December 1987 on safety, hygiene and health at work ⁽⁵⁾, took note of the Commission's intention to submit to the Council in the near future a Directive on the organization of the safety and health of workers at the work place;

Whereas in February 1988 the European Parliament adopted four resolutions following the debate on the internal market and worker protection; whereas these resolutions specifically invited the Commission to draw up a framework Directive to serve as a basis for more specific Directives covering all the risks connected with safety and health at the work place;

Whereas Member States have a responsibility to encourage improvements in the safety and health of workers on their territory; whereas taking measures to protect the health and safety of workers at work also helps, in certain cases, to preserve the health and possibly the safety of persons residing with them;

⁽¹⁾ OJ No C 141, 30. 5. 1988, p. 1.

⁽²⁾ OJ No C 326, 19. 12. 1988, p. 102, and OJ No C 158, 26. 6. 1989.

⁽³⁾ OJ No C 175, 4. 7. 1988, p. 22.

⁽⁴⁾ OJ No C 28, 3. 2. 1988, p. 3.

⁽⁵⁾ OJ No C 28, 3. 2. 1988, p. 1.

Whereas Member States' legislative systems covering safety and health at the work place differ widely and need to be improved; whereas national provisions on the subject, which often include technical specifications and/or self-regulatory standards, may result in different levels of safety and health protection and allow competition at the expense of safety and health;

Whereas the incidence of accidents at work and occupational diseases is still too high; whereas preventive measures must be introduced or improved without delay in order to safeguard the safety and health of workers and ensure a higher degree of protection;

Whereas, in order to ensure an improved degree of protection, workers and/or their representatives must be informed of the risks to their safety and health and of the measures required to reduce or eliminate these risks; whereas they must also be in a position to contribute, by means of balanced participation in accordance with national laws and/or practices, to seeing that the necessary protective measures are taken;

Whereas information, dialogue and balanced participation on safety and health at work must be developed between employers and workers and/or their representatives by means of appropriate procedures and instruments, in accordance with national laws and/or practices;

Whereas the improvement of workers' safety, hygiene and health at work is an objective which should not be subordinated to purely economic considerations;

Whereas employers shall be obliged to keep themselves informed of the latest advances in technology and scientific findings concerning work-place design, account being taken of the inherent dangers in their undertaking, and to inform accordingly the workers' representatives exercising participation rights under this Directive, so as to be able to guarantee a better level of protection of workers' health and safety;

Whereas the provisions of this Directive apply, without prejudice to more stringent present or future Community provisions, to all risks, and in particular to those arising from the use at work of chemical, physical and biological agents covered by Directive 80/1107/EEC⁽¹⁾, as last amended by Directive 88/642/EEC⁽²⁾;

Whereas, pursuant to Decision 74/325/EEC⁽³⁾, the Advisory Committee on Safety, Hygiene and Health

Protection at Work is consulted by the Commission on the drafting of proposals in this field;

Whereas a Committee composed of members nominated by the Member States needs to be set up to assist the Commission in making the technical adaptations to the individual Directives provided for in this Directive.

HAS ADOPTED THIS DIRECTIVE:

SECTION I

GENERAL PROVISIONS

Article 1

Object

1. The object of this Directive is to introduce measures to encourage improvements in the safety and health of workers at work.
2. To that end it contains general principles concerning the prevention of occupational risks, the protection of safety and health, the elimination of risk and accident factors, the informing, consultation, balanced participation in accordance with national laws and/or practices and training of workers and their representatives, as well as general guidelines for the implementation of the said principles.
3. This Directive shall be without prejudice to existing or future national and Community provisions which are more favourable to protection of the safety and health of workers at work.

Article 2

Scope

1. This Directive shall apply to all sectors of activity, both public and private (industrial, agricultural, commercial, administrative, service, educational, cultural, leisure, etc.).
2. This Directive shall not be applicable where characteristics peculiar to certain specific public service activities, such as the armed forces or the police, or to certain specific activities in the civil protection services inevitably conflict with it.

In that event, the safety and health of workers must be ensured as far as possible in the light of the objectives of this Directive.

⁽¹⁾ OJ No L 327, 3. 12. 1980, p. 8.

⁽²⁾ OJ No L 356, 24. 12. 1988, p. 74.

⁽³⁾ OJ No L 185, 9. 7. 1974, p. 15.

*Article 3***Definitions**

For the purposes of this Directive, the following terms shall have the following meanings:

- (a) worker: any person employed by an employer, including trainees and apprentices but excluding domestic servants;
- (b) employer: any natural or legal person who has an employment relationship with the worker and has responsibility for the undertaking and/or establishment;
- (c) workers' representative with specific responsibility for the safety and health of workers: any person elected, chosen or designated in accordance with national laws and/or practices to represent workers where problems arise relating to the safety and health protection of workers at work;
- (d) prevention: all the steps or measures taken or planned at all stages of work in the undertaking to prevent or reduce occupational risks.

Article 4

1. Member States shall take the necessary steps to ensure that employers, workers and workers' representatives are subject to the legal provisions necessary for the implementation of this Directive.

2. In particular, Member States shall ensure adequate controls and supervision.

SECTION II**EMPLOYERS' OBLIGATIONS***Article 5***General provision**

- 1. The employer shall have a duty to ensure the safety and health of workers in every aspect related to the work.
- 2. Where, pursuant to Article 7 (3), an employer enlists competent external services or persons, this shall not discharge him from his responsibilities in this area.
- 3. The workers' obligations in the field of safety and health at work shall not affect the principle of the responsibility of the employer.
- 4. This Directive shall not restrict the option of Member States to provide for the exclusion or the limitation of employers' responsibility where occurrences are due to unusual and unforeseeable circumstances, beyond the

employers' control, or to exceptional events, the consequences of which could not have been avoided despite the exercise of all due care.

Member States need not exercise the option referred to in the first subparagraph.

*Article 6***General obligations on employers**

1. Within the context of his responsibilities, the employer shall take the measures necessary for the safety and health protection of workers, including prevention of occupational risks and provision of information and training, as well as provision of the necessary organization and means.

The employer shall be alert to the need to adjust these measures to take account of changing circumstances and aim to improve existing situations.

2. The employer shall implement the measures referred to in the first subparagraph of paragraph 1 on the basis of the following general principles of prevention:

- (a) avoiding risks;
- (b) evaluating the risks which cannot be avoided;
- (c) combating the risks at source;
- (d) adapting the work to the individual, especially as regards the design of work places, the choice of work equipment and the choice of working and production methods, with a view, in particular, to alleviating monotonous work and work at a predetermined work-rate and to reducing their effect on health.
- (e) adapting to technical progress;
- (f) replacing the dangerous by the non-dangerous or the less dangerous;
- (g) developing a coherent overall prevention policy which covers technology, organization of work, working conditions, social relationships and the influence of factors related to the working environment;
- (h) giving collective protective measures priority over individual protective measures;
- (i) giving appropriate instructions to the workers.

3. Without prejudice to the other provisions of this Directive, the employer shall, taking into account the nature of the activities of the enterprise and/or establishment:

- (a) evaluate the risks to the safety and health of workers, *inter alia* in the choice of work equipment, the chemical substances or preparations used, and the fitting-out of work places.

Subsequent to this evaluation and as necessary, the preventive measures and the working and production methods implemented by the employer must:

- assure an improvement in the level of protection afforded to workers with regard to safety and health,
 - be integrated into all the activities of the undertaking and/or establishment and at all hierarchical levels;
- (b) where he entrusts tasks to a worker, take into consideration the worker's capabilities as regards health and safety;
- (c) ensure that the planning and introduction of new technologies are the subject of consultation with the workers and/or their representatives, as regards the consequences of the choice of equipment, the working conditions and the working environment for the safety and health of workers;
- (d) take appropriate steps to ensure that only workers who have received adequate instructions may have access to areas where there is serious and specific danger.

4. Without prejudice to the other provisions of this Directive, where several undertakings share a work place, the employers shall cooperate in implementing the safety, health and occupational hygiene provisions and, taking into account the nature of the activities, shall coordinate their actions in matters of the protection and prevention of occupational risks, and shall inform one another and their respective workers and/or workers' representatives of these risks.

5. Measures related to safety, hygiene and health at work may in no circumstances involve the workers in financial cost.

Article 7

Protective and preventive services

1. Without prejudice to the obligations referred to in Articles 5 and 6, the employer shall designate one or more workers to carry out activities related to the protection and prevention of occupational risks for the undertaking and/or establishment.

2. Designated workers may not be placed at any disadvantage because of their activities related to the protection and prevention of occupational risks.

Designated workers shall be allowed adequate time to enable them to fulfil their obligations arising from this Directive.

3. If such protective and preventive measures cannot be organized for lack of competent personnel in the undertaking

and/or establishment, the employer shall enlist competent external services or persons.

4. Where the employer enlists such services or persons, he shall inform them of the factors known to affect, or suspected of affecting, the safety and health of the workers and they must have access to the information referred to in Article 10 (2).

5. In all cases:

- the workers designated must have the necessary capabilities and the necessary means,
- the external services or persons consulted must have the necessary aptitudes and the necessary personal and professional means, and
- the workers designated and the external services or persons consulted must be sufficient in number

to deal with the organization of protective and preventive measures, taking into account the size of the undertaking and/or establishment and/or the hazards to which the workers are exposed and their distribution throughout the entire undertaking and/or establishment.

6. The protection from, and prevention of, the health and safety risks which form the subject of this Article shall be the responsibility of one or more workers, of one service or of separate services whether from inside or outside the undertaking and/or establishment.

The worker(s) and/or agency(ies) must work together whenever necessary.

7. Member States may define, in the light of the nature of the activities and size of the undertakings, the categories of undertakings in which the employer, provided he is competent, may himself take responsibility for the measures referred to in paragraph 1.

8. Member States shall define the necessary capabilities and aptitudes referred to in paragraph 5.

They may determine the sufficient number referred to in paragraph 5.

Article 8

First aid, fire-fighting and evacuation of workers, serious and imminent danger

1. The employer shall:

- take the necessary measures for first aid, fire-fighting and evacuation of workers, adapted to the nature of the

- activities and the size of the undertaking and/or establishment and taking into account other persons present,
- arrange any necessary contacts with external services, particularly as regards first aid, emergency medical care, rescue work and fire-fighting.

2. Pursuant to paragraph 1, the employer shall, *inter alia*, for first aid, fire-fighting and the evacuation of workers, designate the workers required to implement such measures.

The number of such workers, their training and the equipment available to them shall be adequate, taking account of the size and/or specific hazards of the undertaking and/or establishment.

3. The employer shall:

- (a) as soon as possible, inform all workers who are, or may be, exposed to serious and imminent danger of the risk involved and of the steps taken or to be taken as regards protection;
- (b) take action and give instructions to enable workers in the event of serious, imminent and unavoidable danger to stop work and/or immediately to leave the work place and proceed to a place of safety;
- (c) save in exceptional cases for reasons duly substantiated, refrain from asking workers to resume work in a working situation where there is still a serious and imminent danger.

4. Workers who, in the event of serious, imminent and unavoidable danger, leave their workstation and/or a dangerous area may not be placed at any disadvantage because of their action and must be protected against any harmful and unjustified consequences, in accordance with national laws and/or practices.

5. The employer shall ensure that all workers are able, in the event of serious and imminent danger to their own safety and/or that of other persons, and where the immediate superior responsible cannot be contacted, to take the appropriate steps in the light of their knowledge and the technical means at their disposal, to avoid the consequences of such danger.

Their actions shall not place them at any disadvantage, unless they acted carelessly or there was negligence on their part.

Article 9

Various obligations on employers

1. The employer shall:

- (a) be in possession of an assessment of the risks to safety and health at work, including those facing groups of workers exposed to particular risks;

- (b) decide on the protective measures to be taken and, if necessary, the protective equipment to be used;
- (c) keep a list of occupational accidents resulting in a worker being unfit for work for more than three working days;
- (d) draw up, for the responsible authorities and in accordance with national laws and/or practices, reports on occupational accidents suffered by his workers.

2. Member States shall define, in the light of the nature of the activities and size of the undertakings, the obligations to be met by the different categories of undertakings in respect of the drawing-up of the documents provided for in paragraph 1 (a) and (b) and when preparing the documents provided for in paragraph 1 (c) and (d).

Article 10

Worker information

1. The employer shall take appropriate measures so that workers and/or their representatives in the undertaking and/or establishment receive, in accordance with national laws and/or practices which may take account, *inter alia*, of the size of the undertaking and/or establishment, all the necessary information concerning:

- (a) the safety and health risks and protective and preventive measures and activities in respect of both the undertaking and/or establishment in general and each type of workstation and/or job;
- (b) the measures taken pursuant to Article 8 (2).

2. The employer shall take appropriate measures so that employers of workers from any outside undertakings and/or establishments engaged in work in his undertaking and/or establishment receive, in accordance with national laws and/or practices, adequate information concerning the points referred to in paragraph 1 (a) and (b) which is to be provided to the workers in question.

3. The employer shall take appropriate measures so that workers with specific functions in protecting the safety and health of workers, or workers' representatives with specific responsibility for the safety and health of workers shall have access, to carry out their functions and in accordance with national laws and/or practices, to:

- (a) the risk assessment and protective measures referred to in Article 9 (1) (a) and (b);

- (b) the list and reports referred to in Article 9 (1) (c) and (d);
- (c) the information yielded by protective and preventive measures, inspection agencies and bodies responsible for safety and health.

Article 11

Consultation and participation of workers

1. Employers shall consult workers and/or their representatives and allow them to take part in discussions on all questions relating to safety and health at work.

This presupposes:

- the consultation of workers,
- the right of workers and/or their representatives to make proposals,
- balanced participation in accordance with national laws and/or practices.

2. Workers or workers' representatives with specific responsibility for the safety and health of workers shall take part in a balanced way, in accordance with national laws and/or practices, or shall be consulted in advance and in good time by the employer with regard to:

- (a) any measure which may substantially affect safety and health;
- (b) the designation of workers referred to in Articles 7 (1) and 8 (2) and the activities referred to in Article 7 (1);
- (c) the information referred to in Articles 9 (1) and 10;
- (d) the enlistment, where appropriate, of the competent services or persons outside the undertaking and/or establishment, as referred to in Article 7 (3);
- (e) the planning and organization of the training referred to in Article 12.

3. Workers' representatives with specific responsibility for the safety and health of workers shall have the right to ask the employer to take appropriate measures and to submit proposals to him to that end to mitigate hazards for workers and/or to remove sources of danger.

4. The workers referred to in paragraph 2 and the workers' representatives referred to in paragraphs 2 and 3 may not be placed at a disadvantage because of their respective activities referred to in paragraphs 2 and 3.

5. Employers must allow workers' representatives with specific responsibility for the safety and health of workers

adequate time off work, without loss of pay, and provide them with the necessary means to enable such representatives to exercise their rights and functions deriving from this Directive.

6. Workers and/or their representatives are entitled to appeal, in accordance with national law and/or practice, to the authority responsible for safety and health protection at work if they consider that the measures taken and the means employed by the employer are inadequate for the purposes of ensuring safety and health at work.

Workers' representatives must be given the opportunity to submit their observations during inspection visits by the competent authority.

Article 12

Training of workers

1. The employer shall ensure that each worker receives adequate safety and health training, in particular in the form of information and instructions specific to his workstation or job:

- on recruitment,
- in the event of a transfer or a change of job,
- in the event of the introduction of new work equipment or a change in equipment,
- in the event of the introduction of any new technology.

The training shall be:

- adapted to take account of new or changed risks, and
- repeated periodically if necessary.

2. The employer shall ensure that workers from outside undertakings and/or establishments engaged in work in his undertaking and/or establishment have in fact received appropriate instructions regarding health and safety risks during their activities in his undertaking and/or establishment.

3. Workers' representatives with a specific role in protecting the safety and health of workers shall be entitled to appropriate training.

4. The training referred to in paragraphs 1 and 3 may not be at the workers' expense or at that of the workers' representatives.

The training referred to in paragraph 1 must take place during working hours.

The training referred to in paragraph 3 must take place during working hours or in accordance with national practice either within or outside the undertaking and/or the establishment.

SECTION III

WORKERS' OBLIGATIONS

Article 13

1. It shall be the responsibility of each worker to take care as far as possible of his own safety and health and that of other persons affected by his acts or Commissions at work in accordance with his training and the instructions given by his employer.

2. To this end, workers must in particular, in accordance with their training and the instructions given by their employer:

- (a) make correct use of machinery, apparatus, tools, dangerous substances, transport equipment and other means of production;
- (b) make correct use of the personal protective equipment supplied to them and, after use, return it to its proper place;
- (c) refrain from disconnecting, changing or removing arbitrarily safety devices fitted, e.g. to machinery, apparatus, tools, plant and buildings, and use such safety devices correctly;
- (d) immediately inform the employer and/or the workers with specific responsibility for the safety and health of workers of any work situation they have reasonable grounds for considering represents a serious and immediate danger to safety and health and of any shortcomings in the protection arrangements;
- (e) cooperate, in accordance with national practice, with the employer and/or workers with specific responsibility for the safety and health of workers, for as long as may be necessary to enable any tasks or requirements imposed by the competent authority to protect the safety and health of workers at work to be carried out;
- (f) cooperate, in accordance with national practice, with the employer and/or workers with specific responsibility for the safety and health of workers, for as long as may be necessary to enable the employer to ensure that the working environment and working conditions are safe and pose no risk to safety and health within their field of activity.

SECTION IV

MISCELLANEOUS PROVISIONS

Article 14

Health surveillance

1. To ensure that workers receive health surveillance appropriate to the health and safety risks they incur at work, measures shall be introduced in accordance with national law and/or practices.

2. The measures referred to in paragraph 1 shall be such that each worker, if he so wishes, may receive health surveillance at regular intervals.

3. Health surveillance may be provided as part of a national health system.

Article 15

Risk groups

Particularly sensitive risk groups must be protected against the dangers which specifically affect them.

Article 16

Individual Directives — Amendments —

General scope of this Directive

1. The Council, acting on a proposal from the Commission based on Article 118a of the Treaty, shall adopt individual Directives, *inter alia*, in the areas listed in the Annex.

2. This Directive and, without prejudice to the procedure referred to in Article 17 concerning technical adjustments, the individual Directives may be amended in accordance with the procedure provided for in Article 118a of the Treaty.

3. The provisions of this Directive shall apply in full to all the areas covered by the individual Directives, without prejudice to more stringent and/or specific provisions contained in these individual Directives.

Article 17

Committee

1. For the purely technical adjustments to the individual Directives provided for in Article 16 (1) to take account of:

- the adoption of Directives in the field of technical harmonization and standardization, and/or
- technical progress, changes in international regulations or specifications, and new findings,

the Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

2. 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.

The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission.

The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of three months from the date of the referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 18

Final provisions

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1992.

They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they have already adopted or adopt in the field covered by this Directive.

3. Member States shall report to the Commission every five years on the practical implementation of the provisions of this Directive, indicating the points of view of employers and workers.

The Commission shall inform the European Parliament, the Council, the Economic and Social Committee and the Advisory Committee on Safety, Hygiene and Health Protection at Work.

4. The Commission shall submit periodically to the European Parliament, the Council and the Economic and Social Committee a report on the implementation of this Directive, taking into account paragraphs 1 to 3.

Article 19

This Directive is addressed to the Member States.

Done at Luxembourg, 12 June 1989.

For the Council

The President

M. CHAVES GONZALES

ANNEX

List of areas referred to in Article 16 (1)

- Work places
- Work equipment
- Personal protective equipment
- Work with visual display units
- Handling of heavy loads involving risk of back injury
- Temporary or mobile work sites
- Fisheries and agriculture

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.

⁽¹⁾ OJ No L 77, 26. 3. 1973, p. 29.

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

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-examination 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. Where 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.

Article 13

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

They shall apply these provisions with effect from 31 December 1992.

2. Member States shall ensure that the texts of the provisions of national law which they adopt in the field covered by this Directive are communicated to the Commission.

Article 14

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1989.

For the Council

The President

P. SOLBES

ANNEX I

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

PRELIMINARY OBSERVATIONS

1. 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. In any event, requirements 1.1.2, 1.7.3 and 1.7.4 apply to all machinery covered by this Directive.
2. The essential health and safety requirements laid down in this Directive are mandatory. However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In this case, the machinery must as far as possible be designed and constructed with the purpose of approaching those objectives.

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1. General remarks

1.1.1. Definitions

For the purpose of this Directive

1. 'danger zone' means any zone within and/or around machinery in which an exposed person is subject to a risk to his health or safety;
2. 'exposed person' means any person wholly or partially in a danger zone;
3. 'operator' means the person or persons given the task of installing, operating, adjusting, maintaining, cleaning, repairing or transporting machinery.

1.1.2. Principles of safety integration

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

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

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

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

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

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

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

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

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

1.1.3. *Materials and products*

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

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

1.1.4. *Lighting*

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

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

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

1.1.5. *Design of machinery to facilitate its handling*

Machinery or each component part thereof must:

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

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

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

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

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

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

1.2. *Controls*

1.2.1. *Safety and reliability of control systems*

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

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

1.2.2. *Control devices*

Control devices must be:

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

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

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

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

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

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

1.2.3. *Starting*

It must be possible to start machinery only by voluntary actuation of a control provided for the purpose.

The same requirement applies:

- when restarting the machinery after a stoppage, whatever the cause,
 - when effecting a significant change in the operating conditions (e.g. speed, pressure, etc.),
- unless such restarting or change in operating conditions is without risk to exposed persons.

This essential requirement does not apply to the restarting of the machinery or to the change in operating conditions resulting from the normal sequence of an automatic cycle.

Where machinery has several starting controls and the operators can therefore put each other in danger, additional devices (e.g. enabling devices or selectors allowing only one part of the starting mechanism to be actuated at any one time) must be fitted to rule out such risks.

It must be possible for automated plant functioning in automatic mode to be restarted easily after a stoppage once the safety conditions have been fulfilled.

1.2.4. *Stopping device*

Normal stopping

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

Each workstation must be fitted with a control to stop some or all of the moving parts of the machinery, depending on the type of hazard, so that the machinery is rendered safe. The machinery's stop control must have priority over the start controls.

Once the machinery or its dangerous parts have stopped, the energy supply to the actuators concerned must be cut off.

Emergency stop

Each machine must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. The following exceptions apply:

- machines in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,
- hand-held portable machines and hand-guided machines.

This device must:

- have clearly identifiable, clearly visible and quickly accessible controls,
- stop the dangerous process as quickly as possible, without creating additional hazards,
- where necessary, trigger or permit the triggering of certain safeguard movements.

The emergency stop control must remain engaged; it must be possible to disengage it only by an appropriate operation; disengaging the control must not restart the machinery, but only permit restarting; the stop control must not trigger the stopping function before being in the engaged position.

Complex installations

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

1.2.5. *Mode selection*

The control mode selected must override all other control systems with the exception of the emergency stop.

If machinery has been designed and built to allow for its use in several control or operating modes presenting different safety levels (e.g. to allow for adjustment, maintenance, inspection, etc.), it must be fitted with a mode selector which can be locked in each position. Each position of the selector must correspond to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator (e.g. access codes for certain numerically controlled functions, etc.).

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

- disable the automatic control mode,
- permit movements only by controls requiring sustained action,
- permit the operation of dangerous moving parts only in enhanced safety conditions (e.g. reduced speed, reduced power, step-by-step, or other adequate provision) while preventing hazards from linked sequences,
- prevent any movement liable to pose a danger by acting voluntarily or involuntarily on the machine's internal sensors.

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

1.2.6. *Failure of the power supply*

The interruption; re-establishment after an interruption or fluctuation in whatever manner of the power supply to the machinery must not lead to a dangerous situation.

In particular:

- the machinery must not start unexpectedly,
- the machinery must not be prevented from stopping if the command has already been given,
- no moving part of the machinery or piece held by the machinery must fall or be ejected,
- automatic or manual stopping of the moving parts whatever they may be must be unimpeded,
- the protection devices must remain fully effective.

1.2.7. *Failure of the control circuit*

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

In particular:

- the machinery must not start unexpectedly,
- the machinery must not be prevented from stopping if the command has already been given,
- no moving part of the machinery or piece held by the machinery must fall or be ejected,
- automatic or manual stopping of the moving parts whatever they may be must be unimpeded,
- the protection devices must remain fully effective.

1.2.8. Software

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, components and fittings thereof must be so designed and constructed that they are stable enough, under the foreseen operating conditions (if necessary taking climatic conditions into account) for use without risk of overturning, falling or unexpected movement.

If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions.

1.3.2. Risk of break-up during operation

The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used as foreseen by the manufacturer.

The durability of the materials used must be adequate for the nature of the work place foreseen by the manufacturer, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

The manufacturer must indicate in the instructions the type and frequency of inspection and maintenance required for safety reasons. He must, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration remains despite the measures taken (e.g. as with grinding wheels) the moving parts must be mounted and positioned in such a way that in case of rupture their fragments will be contained.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected against all manner of external stresses and strains; precautions must be taken to ensure that no risk is posed by a rupture (sudden movement, high-pressure jets, etc.).

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to the persons exposed (e.g. tool breakage):

- when the workpiece comes into contact with the tool the latter must have attained its normal working conditions,
- when the tool starts and/or stops (intentionally or accidentally) the feed movement and the tool movement must be coordinated.

1.3.3. Risks due to falling or ejected objects

Precautions must be taken to prevent risks from falling or ejected objects (e.g. workpieces, tools, cuttings, fragments, waste, etc.).

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 machine is designed to perform operations under different conditions of use (e.g. different speeds or energy supply), it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. *Prevention of risks related to moving parts*

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

1.3.8. *Choice of protection against risks related to moving parts*

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

A. *Moving transmission parts*

Guards designed to protect exposed persons against the risks associated with moving transmission parts (such as pulleys, belts, gears, rack and pinions, shafts, etc.) must be:

- either fixed, complying with requirements 1.4.1 and 1.4.2.1, or
- movable, complying with requirements 1.4.1 and 1.4.2.2.A.

Movable guards should be used where frequent access is foreseen.

B. *Moving parts directly involved in the process*

Guards or protection devices designed to protect exposed persons against the risks associated with moving parts contributing to the work (such as cutting tools, moving parts of presses, cylinders, parts in the process of being machined, etc.) must be:

- wherever possible fixed guards complying with requirements 1.4.1 and 1.4.2.1,
- otherwise, movable guards complying with requirements 1.4.1 and 1.4.2.2.B or protection devices such as sensing devices (e.g. non-material barriers, sensor mats), remote-held protection devices (e.g. two-hand controls), or protection devices intended automatically to prevent all or part of the operator's body from encroaching on the danger zone in accordance with requirements 1.4.1 and 1.4.3.

However, when certain moving parts directly involved in the process cannot be made completely or partially inaccessible during operation owing to operations requiring nearby operator intervention, where technically possible such parts must be fitted with:

- fixed guards, complying with requirements 1.4.1 and 1.4.2.1 preventing access to those sections of the parts that are not used in the work,
- adjustable guards, complying with requirements 1.4.1 and 1.4.2.3 restricting access to those sections of the moving parts that are strictly for the work.

1.4. *Required characteristics of guards and protection devices*

1.4.1. *General requirement*

Guards and protection devices must:

- be of robust construction,
- not give rise to any additional risk,
- not be easy to by-pass or render non-operational,
- be located at an adequate distance from the danger zone,
- cause minimum obstruction to the view of the production process,
- enable essential work to be carried out on installation and/or replacement of tools and also for maintenance by restricting access only to the area where the work has to be done, if possible without the guard or protection device having to be dismantled.

1.4.2. *Special requirements for guards*

1.4.2.1. *Fixed guards*

Fixed guards must be securely held in place.

They must be fixed by systems that can be opened only with tools.

Where possible, guards must be unable to remain in place without their fixings.

1.4.2.2. Movable guards

A. Type A movable guards must:

- as far as possible remain fixed to the machinery when open,
- be associated with a locking device to prevent moving parts starting up as long as these parts can be accessed and to give a stop command whenever they are no longer closed.

B. Type B movable guards must be designed and incorporated into the control system so that:

- moving parts cannot start up while they are within the operator's reach,
- the exposed person cannot reach moving parts once they have started up,
- they can be adjusted only by means of an intentional action, such as the use of a tool, key, etc.,
- the absence or failure of one of their components prevents starting or stops the moving parts,
- protection against any risk of ejection is proved by means of an appropriate barrier.

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 incorporated into the control system so that:

- moving parts cannot start up while they are within the operator's reach,
- the exposed person cannot reach moving parts once they have started up,
- they can be adjusted only by means of an intentional action, such as the use of a tool, key, etc.,
- the absence or failure of one of their components prevents starting or stops the moving parts.

1.5. Protection against other hazards

1.5.1. *Electricity supply*

Where machinery has an electricity supply it must be designed, constructed and equipped so that all hazards of an electrical nature are or can be prevented.

The specific rules in force relating to electrical equipment designed for use within certain voltage limits must apply to machinery which is subject to those limits.

1.5.2. *Static electricity*

Machinery must be so designed and constructed as to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3. *Energy supply other than electricity*

Where machinery is powered by an energy other than electricity (e.g. hydraulic, pneumatic or thermal energy, etc.), it must be so designed, constructed and equipped as to avoid all potential hazards associated with these types of energy.

1.5.4. *Errors of fitting*

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design of such parts or, failing this, by information given on the parts themselves and/or the housings. The same information must be given on moving parts and/or their housings where the direction of movement must be known to avoid a risk. Any further information that may be necessary must be given in the instructions.

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

1.5.5. *Extreme temperatures*

Steps must be taken to eliminate any risk of injury caused by contact with or proximity to machinery parts or materials at high or very low temperatures.

The risk of hot or very cold material being ejected should be assessed. Where this risk exists, the necessary steps must be taken to prevent it or, if this is not technically possible, to render it non-dangerous.

1.5.6. *Fire*

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

1.5.7. *Explosion*

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

To that end the manufacturer must take steps to:

- avoid a dangerous concentration of products,
- prevent combustion of the potentially explosive atmosphere,
- minimize any explosion which may occur so that it does not endanger the surroundings.

The same precautions must be taken if the manufacturer foresees the use of the machinery in a potentially explosive atmosphere.

Electrical equipment forming part of the machinery must conform, as far as the risk from explosion is concerned, to the provision of the specific Directives in force.

1.5.8. *Noise*

Machinery must be so designed and constructed that risks resulting from the emission of airborne noise are reduced to the lowest level taking account of technical progress and the availability of means of reducing noise, in particular at source.

1.5.9. *Vibration*

Machinery must be so designed and constructed that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

1.5.10. *Radiation*

Machinery must be so designed and constructed that any emission of radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions.

1.5.11. *External radiation*

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

1.5.12. *Laser equipment*

Where laser equipment is used, the following provisions should be taken into account:

- laser equipment on machinery must be designed and constructed so as to prevent any accidental radiation,
- laser equipment on machinery must be protected so that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health,
- optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by the laser rays.

1.5.13. *Emissions of dust, gases, etc.*

Machinery must be so designed, constructed and/or equipped that risks due to gases, liquids, dust, vapours and other waste materials which it produces can be avoided.

Where a hazard exists, the machinery must be so equipped that the said substances can be contained and/or evacuated.

Where machinery is not enclosed during normal operation, the devices for containment and/or evacuation must be situated as close as possible to the source emission.

1.6. **Maintenance**

1.6.1. *Machinery maintenance*

Adjustment, lubrication and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, these operations must be possible without risk (see 1.2.5).

In the case of automated machinery and, where necessary, other machinery, the manufacturer must make provision for a connecting device for mounting diagnostic fault-finding equipment.

Automated machine components which have to be changed frequently, in particular for a change in manufacture or where they are liable to wear or likely to deteriorate following an accident, must be capable of being removed and replaced easily and in safety. Access to the components must enable these tasks to be carried out with the necessary technical means (tools, measuring instruments, etc.) in accordance with an operating method specified by the manufacturer.

1.6.2. *Access to operating position and servicing points*

The manufacturer must provide means of access (stairs, ladders, catwalks, etc.) to allow access in safety to all areas used for production, adjustment and maintenance operations.

Parts of the machinery where persons are liable to move about or stand must be designed and constructed to avoid falls.

1.6.3. *Isolation of energy sources*

All machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger exposed persons. In the case of machinery supplied with electricity through a plug capable of being plugged into a circuit, separation of the plug is sufficient.

The isolator must be capable of being locked also where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to exposed persons.

As an exception to the above requirements, certain circuits may remain connected to their energy sources in order, for example, to hold parts, protect information, light interiors, etc. In this case, special steps must be taken to ensure operator safety.

1.6.4. *Operator intervention*

Machinery must be so designed, constructed and equipped that the need for operator intervention is limited.

If operator intervention cannot be avoided, it must be possible to carry it out easily and in safety.

1.7. **Indicators**

1.7.0. *Information devices*

The information needed to control machinery must be unambiguous and easily understood.

It must not be excessive to the extent of overloading the operator.

1.7.1. Warning devices

Where machinery is equipped with warning devices (such as signals, etc.), these must be unambiguous and easily perceived.

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

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

1.7.2. Warning of residual risks

Where risks remain despite all the measures adopted or in the case of potential risks which are not evident (e.g. electrical cabinets, radioactive sources, bleeding of a hydraulic circuit, hazard in an unseen area, etc.), the manufacturer must provide warnings.

Such warnings should preferably use readily understandable pictograms and/or be drawn up in one of the languages of the country in which the machinery is to be used, accompanied, on request, by the languages understood by the operators.

1.7.3. Marking

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

- name and address of the manufacturer,
- EC mark, which includes the year of construction (see Annex III),
- designation of series or type,
- serial number, if any.

Furthermore, where the manufacturer constructs machinery intended for use in a potentially explosive atmosphere, this must be indicated on the machinery.

Machinery must also bear full information relevant to its type and essential to its safe use (e.g. maximum speed of certain rotating parts, maximum diameter of tools to be fitted, mass, etc.).

1.7.4. Instructions

(a) All machinery must be accompanied by instructions including at least the following:

- a repeat of the information with which the machinery is marked (see 1.7.3), together with any appropriate additional information to facilitate maintenance (e.g. addresses of the importer, repairers, etc.),
- foreseen use of the machinery within the meaning of 1.1.2 (c),
- workstation(s) likely to be occupied by operators,
- instructions for safe:
 - putting into service,
 - use,
 - handling, giving the mass of the machinery and its various parts where they are regularly to be transported separately,
 - assembly, dismantling,
 - adjustment,
 - maintenance (servicing and repair),
 - where necessary, training instructions.

Where necessary, the instructions should draw attention to ways in which the machinery should not be used.

(b) The instructions must be drawn up by the manufacturer or his authorized representative established in the Community in one of the languages of the country in which the machinery is to be used and should preferably be accompanied by the same instructions drawn up in another Community language, such as that of the country in which the manufacturer or his authorized representative is established. By way of derogation from this requirement, the maintenance instructions for use by the specialized personnel frequently employed by the manufacturer or his authorized representative may be drawn up in only one of the official Community languages.

(c) The instructions must contain the drawings and diagrams necessary for putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the machinery, and all useful instructions in particular with regard to safety.

- (d) Any sales literature describing the machinery must not contradict the instructions as regards safety aspects; it must give information regarding the airborne noise emissions referred to in (f) and, in the case of hand-held and/or hand-guided machinery, information regarding vibration as referred to in 2.2.
- (e) Where necessary, the instructions must give the requirements relating to installation and assembly for reducing noise or vibration (e.g. use of dampers, type and mass of foundation block, etc.).
- (f) The instructions must give the following information concerning airborne noise emissions by the machinery, either the actual value or a value established on the basis of measurements made on identical machinery:
 - equivalent continuous A-weighted sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
 - peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μ Pa),
 - sound power level emitted by the machinery where the equivalent continuous A-weighted sound pressure level at workstations exceeds 85 dB(A).

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

Sound levels must be measured using the most appropriate method for the machinery.

The manufacturer must indicate the operating conditions of the machinery during measurement and what methods have been used for the measurement.

Where the workstation(s) are undefined or cannot be defined, sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at height of 1,60 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

- (g) If the manufacturer foresees that the machinery will be used in a potentially explosive atmosphere, the instructions must give all the necessary information.
- (h) In the case of machinery which may also be intended for use by non-professional operators, the wording and layout of the instructions for use, whilst respecting the other essential requirements mentioned above, must take into account the level of general education and acumen that can reasonably be expected from such operators.

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

2.1. Agri-foodstuffs machinery

In addition to the essential health and safety requirements set out in 1 above, where machinery is intended to prepare and process foodstuffs (e.g. cooking, refrigeration, thawing, washing, handling, packaging, storage, transport or distribution), it must be so designed and constructed as to avoid any risk of infection, sickness or contagion and the following hygiene rules must be observed:

- (a) materials in contact, or intended to come into contact, with the foodstuffs must satisfy the conditions set down in the relevant Directives. The machinery must be so designed and constructed that these materials can be clean before each use;
- (b) all surfaces including their joinings must be smooth, and must have neither ridges nor crevices which could harbour organic materials;
- (c) assemblies must be designed in such a way as to reduce projections, edges and recesses to a minimum. They should preferably be made by welding or continuous bonding. Screws, screwheads and rivets may not be used except where technically unavoidable;
- (d) all surfaces in contact with the foodstuffs must be easily cleaned and disinfected, where possible after removing easily dismantled parts. The inside surfaces must have curves of a radius sufficient to allow thorough cleaning;
- (e) liquid deriving from foodstuffs as well as cleaning, disinfecting and rinsing fluids should be able to be discharged from the machine without impediment (possibly in a 'clean' position);
- (f) machinery must be so designed and constructed as to prevent any liquids or living creatures, in particular insects, entering, or any organic matter accumulating in areas that cannot be cleaned

(e.g. for machinery not mounted on feet or casters, by placing a seal between the machinery and its base, by the use of sealed units, etc.);

- (g) machinery must be so designed and constructed that no ancillary substances (e.g. lubricants, etc.) can come into contact with foodstuffs. Where necessary, machinery must be designed and constructed so that continuing compliance with this requirement can be checked.

Instructions

In addition to the information required in section 1, the instructions must indicate recommended products and methods for cleaning, disinfecting and rinsing (not only for easily accessible areas but also where areas to which access is impossible or inadvisable, such as piping, have to be cleaned *in situ*).

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

In addition to the essential health and safety requirements set out in 1 above, portable hand-held and/or hand-guided machinery must conform to the following essential health and safety requirements:

- according to the type of machinery, it must have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size and arranged to ensure the stability of the machinery under the operating conditions foreseen by the manufacturer,
- except where technically impossible or where there is an independent control, in the case of handles which cannot be released on complete safety, it must be fitted with start and stop controls arranged in such a way that the operator can operate them without releasing the handles,
- it must be designed, constructed or equipped to eliminate the risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,
- portable hand-held machinery must be designed and constructed to allow, where necessary, a visual check of the contact of the tool with the material being processed.

Instructions

The instructions must give the following information concerning vibrations transmitted by hand-held and hand-guided machinery:

- the weighted root mean square acceleration value to which the arms are subjected, if it exceeds $2,5 \text{ m/s}^2$ as determined by the appropriate test code. Where the acceleration does not exceed $2,5 \text{ m/s}^2$, this must be mentioned.

If there is no applicable test code, the manufacturer must indicate the measurement methods and conditions under which measurements were made.

2.3. Machinery for working wood and analogous materials

In addition to the essential health and safety requirements set out in 1 above, machinery for working wood and machinery for working materials with physical and technological characteristics similar to those of wood, such as cork, bone, hardened rubber, hardened plastic material and other similar stiff material must conform to the following essential health and safety requirements:

- (a) the machinery must be designed, constructed or equipped so that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench the latter must be sufficiently stable during the work and must not impede the movement of the piece;
- (b) where the machinery is likely to be used in conditions involving the risk of ejection of pieces of wood, it must be designed, constructed or equipped to eliminate this ejection, or, if this is not the case, so that the ejection does not engender risks for the operator and/or exposed persons;
- (c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;
- (d) where the tool is incorporated into a non-fully automated machine, the latter must be so designed and constructed as to eliminate or reduce the risk of serious accidental injury, for example by using cylindrical cutter blocks, restricting depth of cut, etc.

ANNEX II

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

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorized representative established in the Community ⁽²⁾,
- description of the machinery ⁽³⁾,
- all relevant provisions complied with by the machinery,
- where appropriate, name and address of the notified body and number of the EC type-examination certificate,
- where appropriate, the name and address of the notified body to which the file has been forwarded in accordance with the first indent of Article 8 (2) (c),
- where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of Article 8 (2) (c),
- where appropriate, a reference to the harmonized standards,
- where appropriate, the national technical standards and specifications used,
- identification of the person empowered to sign on behalf of the manufacturer or his authorized representatives.

B. Contents of the declaration by the manufacturer or his authorized representatives established in the Community (Article 4 (2))

The manufacturer's declaration referred to in Article 4 (2) must contain the following particulars:

- name and address of the manufacturer or the authorized representative,
- description of the machinery or machinery parts,
- a statement that the machinery must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive,
- identification of the person signing.

⁽¹⁾ This declaration must be drawn up in the same language as the instructions (see Annex I, point 1.7.4) and must be either typewritten or handwritten in block capitals.

⁽²⁾ Business name and full address; authorized representatives must also give the business name and address of the manufacturer.

⁽³⁾ Description of the machinery (make, type, serial number, etc.).

ANNEX III

EC MARK

The EC mark consists of the symbol shown below and the last two figures of the year in which the mark was affixed.



The different elements of the EC mark should have materially the same vertical dimensions, which should not be less than 5 mm.

ANNEX IV

**TYPES OF MACHINES FOR WHICH THE PROCEDURE REFERRED TO IN ARTICLE 8 (2) (b) AND (c)
MUST BE APPLIED**

1. Circular saws (single- or multi-blade) for working with wood and meat.
 - 1.1 Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed.
 - 1.2 Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage.
 - 1.3 Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading.
 - 1.4 Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.
 2. Hand-fed surface planing machines for woodworking.
 3. Thicknessers for one-side dressing with manual loading and/or unloading for woodworking.
 4. Band-saws with a mobile bed or carriage and manual loading and/or unloading for working with wood and meat.
 5. Combined machines of the types referred to in 1 to 4 and 7 for woodworking
 6. Hand-fed tenoning machines with several tool holders for woodworking.
 7. Hand-fed vertical spindle moulding machines.
 8. Portable chain saws for woodworking.
 9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
 10. Injection or compression plastics-moulding machines with manual loading or unloading.
 11. Injection or compression rubber-moulding machines with manual loading or unloading.
 12. Cartridge-operated fixing guns.
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ANNEX V

EC DECLARATION OF CONFORMITY

1. The EC declaration of conformity is the procedure by which the manufacturer, or his authorized representative established in the Community declares that the machinery being placed on the market complies with all the essential health and safety requirements applying to it.
2. Signature of the EC declaration of conformity authorizes the manufacturer, or his authorized representative in the Community, to affix the EC mark to the machinery.
3. Before drawing up the EC declaration of conformity, the manufacturer, or his authorized representative in the Community, shall have ensured and be able to guarantee that the documentation listed below is and will remain available on his premises for any inspection purposes:
 - (a) a technical construction file comprising:
 - an overall drawing of the machinery together with drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,
 - a list of:
 - the essential requirements of this Directive,
 - standards, and
 - other technical specifications, which were used when the machinery was designed,
 - a description of methods adopted to eliminate hazards presented by the machinery,
 - if he so desires, any technical report or certificate obtained from a competent body or laboratory ⁽¹⁾,
 - if he declares conformity with a harmonized standard which provides therefor, any technical report giving the results of tests carried out at his choice either by himself or by a competent body or laboratory ⁽¹⁾,
 - a copy of the instructions for the machinery;
 - (b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

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

Failure to present the documentation in response to a duly substantiated request by the competent national authorities may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the Directive.

4. (a) The documentation referred to in 3 above need not permanently exist in a material manner but it must be possible to assemble it and make it available within a period of time commensurate with its importance. It does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the basic safety requirements.
- (b) The documentation referred to in 3 above shall be retained and kept available for the competent national authorities for at least 10 years following the date of manufacture of the machinery or of the last unit produced, in the case of series manufacture.
- (c) The documentation referred to in 3 above shall be drawn up in one of the official languages of the Communities, with the exception of the instructions for the machinery.

⁽¹⁾ A body or laboratory is presumed competent if it meets the assessment criteria laid down in the relevant harmonized standards.

ANNEX VI

EC TYPE-EXAMINATION

1. EC type-examination is the procedure by which a notified body ascertains and certifies that an example of machinery satisfies the provisions of this Directive which apply to it.
2. The application for EC type-examination shall be lodged by the manufacturer or by his authorized representative established in the Community, with a single notified body in respect of an example of the machinery.

The application shall include:

- the name and address of the manufacturer or his authorized representative established in the Community and the place of manufacture of the machinery,
- a technical file comprising at least:
 - an overall drawing of the machinery together with drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,
 - a description of methods adopted to eliminate hazards presented by the machinery and a list of standards used,
 - a copy of the instructions for the machinery,
 - for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

It shall be accompanied by a machine representative of the production planned or, where appropriate, a statement of where the machine may be examined

The documentation referred to above does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the basic safety requirements.

3. The notified body shall carry out the EC type-examination in the manner described below:
 - it shall examine the technical construction file to verify its appropriateness and the machine supplied or made available to it.
 - during the examination of the machine, the body shall
 - (a) ensure that it has been manufactured in conformity with the technical construction file and may safely be used under its intended working conditions;
 - (b) check that standards, if used, have been properly applied;
 - (c) perform appropriate examinations and tests to check that the machine complies with the essential health and safety requirements applicable to it.
4. If the example complies with the provisions applicable to it the body shall draw up an EC type-examination certificate which shall be forwarded to the applicant. That certificate shall state the conclusions of the examination, indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved example.

The Commission, the Member States and the other approved bodies may obtain a copy of the certificate and, on a reasoned request, a copy of the technical construction file and of the reports on the examinations and tests carried out.

5. The manufacturer or his authorized representative established in the Community shall inform the notified body of any modifications, even of a minor nature, which he has made or plans to make to the machine to which the example relates. The notified body shall examine those modifications and inform the manufacturer or his authorized representative established in the Community whether the EC type-examination certificate remains valid.
6. A body which refuses to issue an EC type-examination certificate shall so inform the other notified bodies. A body which withdraws an EC type-examination certificate shall so inform the Member State which notified it. The latter shall inform the other Member States and the Commission thereof, giving the reasons for the decision.
7. The files and correspondence referring to the EC type-examination procedures shall be drawn up in an official language of the Member State where the notified body is established or in a language acceptable to it.

ANNEX VII

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

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 machinery which they inspect, nor the authorized representative of any of these parties. They shall not become either involved directly or as authorized representatives in the design, construction, marketing or maintenance of the machinery. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
 2. The body and its staff 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 judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
 3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.
 4. The staff responsible for inspection shall have:
 - sound technical and professional training,
 - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
 5. The impartiality of inspection staff 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 gained in carrying out its tasks (except *vis-à-vis* the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.
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