Official Journal of the European Communities

ISSN 0378-6978

L 100

Volume 37

19 April 1994

English edition

Legislation

Contents

I *Acts whose publication is obligatory*

★ **Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres** 1

★ **Directive 94/10/EC of the European Parliament and the Council of 23 March 1994 materially amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations** 30

★ **Directive 94/11/EC of European Parliament and Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer** 37

★ **Directive 94/12/EC of the European Parliament and the Council of 23 March 1994 relating to measures to be taken against air pollution by emissions from motor vehicles and amending Directive 70/220/EEC** 42

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

I

(Acts whose publication is obligatory)

DIRECTIVE 94/9/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

of 23 March 1994

on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure referred to in Article 189b of the Treaty establishing the European Community,

Whereas it is the duty of Member States to protect, on their territory, the safety and health of persons and, where appropriate, domestic animals and property and, in particular, that of workers, especially against the hazards resulting from the use of equipment and systems providing protection against potentially explosive atmospheres;

Whereas mandatory provisions within the Member States determine the level of safety to be achieved by protective equipment and systems intended for use in potentially explosive atmospheres; whereas these are generally electrical and non-electrical specifications having an effect on the design and structure of equipment which can be used in potentially explosive atmospheres;

Whereas the requirements to be met by such equipment differ from one Member State to another in respect of their extent and differing inspection procedures; whereas these differences are, therefore, likely to raise barriers to trade within the Community;

Whereas harmonization of national legislation is the only way in which to remove these barriers to free trade; whereas this objective cannot be satisfactorily achieved by the individual Member States; whereas this Directive merely lays down the requirements vital to freedom of movement for the equipment to which it applies;

Whereas the regulations intended to remove technical barriers to trade are required to follow the new approach provided for in the Council resolution of 7 May 1985 [3], which requires a definition of the essential requirements regarding safety and other requirements of society without reducing existing, justified levels of protection within the Member States; whereas that resolution provides that a very large number of products be covered by a single Directive in order to avoid frequent amendments and the proliferation of Directives;

Whereas the existing Directives on the approximation of the laws of the Member States to electrical equipment for use in potentially explosive atmospheres have made positive steps towards protection against explosions via measures linked with the structure of the equipment at issue and which have helped to remove barriers to trade in this area; whereas, in parallel, a revision and expansion of the existing Directives is necessary since, more particularly, in an overall context, action must be taken to guard against the potential hazards arising from such equipment. This implies in particular that measures intended to guarantee effective protection of users and third parties must already be contemplated at the design and manufacturing states;

Whereas the form taken by the hazard, the protective measures and the test methods are often very similar, if not identical, for both mining and surface equipment; whereas it is, therefore, absolutely necessary to cover by a single Directive protective equipment and systems falling within both groups;

Whereas the two groups of equipment referred to above are used in a large number of commercial and industrial sectors and possess considerable economic significance;

Whereas compliance with the basic safety and health requirements is essential in order to ensure the safety of

[1] OJ No C 46, 20. 2. 1992, p. 19.
[2] OJ No C 106, 27. 4. 1992, p. 9.
[3] OJ No C 136, 4. 6. 1985, p. 1.

protective equipment and systems; whereas those requirements have been subdivided into general and additional requirements which must be met by protective equipment and systems; whereas, in particular, the additional requirements are intended to take account of existing or potential hazards; whereas protective equipment and systems will, therefore, embody at least one of those requirements where this is necessary for their proper functioning or is to apply to their intended use; whereas the notion of intended use is of prime importance for the explosion-proofing of protective equipment and systems; whereas it is essential that manufacturers supply full information; whereas specific, clear marking of said equipment, stating its use in a potentially explosive atmosphere, is also necessary;

Whereas the intention is to prepare a Directive on operations in potentially explosive atmospheres which is based on Article 118a; whereas that additional Directive will, in particular, aim at explosion hazards which derive from a given use and/or types and methods of installation;

Whereas compliance with essential health and safety requirements is imperative if the safety of equipment is to be ensured; whereas judgment will have to be exercised in the implementation of those requirements in order to take account of both the technology obtaining at the time of manufacture and overriding technical and economic requirements;

Whereas, therefore, this Directive sets out essential requirements only; whereas, in order to facilitate the task of proving compliance with the essential requirements, harmonized European standards are necessary, more especially with regard to the non-electrical aspects of protection against explosions — standards relating to the design, manufacture and testing of equipment, compliance with which enables a product to be presumed to meet such essential requirements; whereas harmonized European standards are drawn up by private bodies and must retain their non-mandatory status; whereas, for this purpose, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the bodies competent to adopt harmonized standards which follow the general guidelines for cooperation between the Commission and those two bodies, signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European Standard or harmonization document) adopted by one or other of those bodies, or by both, at the prompting of the Commission pursuant to Council Directive 83/189/EEC of the 28 March 1983 providing for a procedure governing the provision of information on technical standards and regulations [1] and pursuant to the general guidelines referred to above;

Whereas the legislative framework should be improved in order to ensure that employers and workers make an effective and appropriate contribution towards the standardization process; whereas this should be completed by the time this Directive is implemented;

Whereas, in view of the nature of the risks involved in the use of equipment in potentially explosive atmospheres it is necessary to establish procedures applying to the assessment of compliance with the basic requirements of the Directives; whereas these procedures must be devised in the light of the level of risk which may be inherent in equipment and/or against which systems must protect the immediate environment; whereas, therefore, each category of equipment conformity must be supplemented by an adequate procedure or a choice between several equivalent procedures; whereas the procedures adopted comply fully with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization Directives [2];

Whereas the Council has provided for the affixing of the CE marking by either the manufacturer or his authorized representative within the Community; whereas that marking means that the product complies with all the basic requirements and assessment procedures provided for by the Community law applying to that product;

Whereas it is appropriate that the Member States, as provided for by Article 100a of the Treaty, may take temporary measures to limit or prohibit the placing on the market and the use of equipment and protective systems in cases where they present a particular risk to the safety of persons and, where appropriate, domestic animals or property, provided that the measures are subject to a Community control procedure;

Whereas the recipients of any decision taken as part of this Directive must be aware of the reasons behind that decision and the means of appeal open to them;

Whereas, on 18 December 1985, the Council adopted a framework Directive on electrical equipment for use in potentially explosive atmospheres (76/117/EEC) [3] and, on 15 February 1982, a Directive concerning electrical equipment for use in potentially explosive atmospheres in mines susceptible to fire damp (82/130/EEC) [4]; whereas, from the outset of harmonization work, the conversion into total harmonization of the optional and partial harmonization on which these Directives are based had been contemplated; whereas this Directive fully covers the

[1] OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Directive 88/182/EEC (OJ No L 81, 26. 3. 1988, p. 75).

[2] OJ No L 220, 30. 8. 1993, p. 23.

[3] OJ No L 24, 31. 1. 1976, p. 45. Directive as last amended by Directive 90/487/EEC (OJ No L 270, 2. 10. 1990, p. 23).

[4] OJ No L 59, 2. 3. 1982, p. 10.

scope of the abovementioned Directives and whereas, therefore, these Directives must be repealed;

Whereas the internal market incorporates an area without internal frontiers within which the free movement of goods, persons, services and capital is assured;

Whereas it is necessary to provide for a transitional arrangement enabling equipment manufactured in compliance with the national regulations in force at the date of adoption of this Directive to be marketed and placed in service,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, placing on the market and freedom of movement

Article 1

1. This Directive applies to equipment and protective systems intended for use in potentially explosive atmospheres.

2. Safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion are also covered by the scope of this Directive.

3. For the purposes of this Directive, the following definitions shall apply:

Equipment and protective systems intended for use in potentially explosive atmospheres

(a) 'Equipment' means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material and which are capable of causing an explosion through their own potential sources of ignition.

(b) 'Protective systems' means design units which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures. Protective systems may be integrated into equipment or separately placed on the market for use as autonomous systems.

(c) 'Components' means any item essential to the safe functioning of equipment and protective systems but with no autonomous function.

Explosive atmospheres

Mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture.

Potentially explosive atmosphere

An atmosphere which could become explosive due to local and operational conditions.

Equipment groups and categories

Equipment group I applies to equipment intended for use in underground parts of mines, and to those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust.

Equipment group II applies to equipment intended for use in other places liable to be endangered by explosive atmospheres.

The categories of equipment defining the required levels of protection are described in Annex I.

Equipment and protective systems may be designed for a particular explosive atmosphere. In this case, they must be marked accordingly.

Intended use

The use of equipment, protective systems, and devices referred to in Article 1 (2) in accordance with the equipment group and category and with all the information supplied by the manufacturer which is required for the safe functioning of equipment, protective systems and devices.

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

— medical devices intended for use in a medical environment,

— equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances,

— equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas,

— personal protective equipment covered by Directive 89/686/EEC [1],

— seagoing vessels and mobile offshore units together with equipment on board such vessels or units,

[1] OJ No L 399, 30. 12. 1989, p. 18.

— means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded,

— the equipment covered by Article 223 (1) (b) of the Treaty.

Article 2

1. Member States shall take all appropriate measures to ensure that the equipment, protective systems and devices referred to in Article 1 (2) to which this Directive applies may be placed on the market and put into service only if, when properly installed and maintained and used for their intended purpose, they do not endanger the health and safety of persons and, where appropriate, domestic animals or property.

2. The provisions of this Directive shall not affect Member States' entitlement to lay down, in due observance of the provisions of the Treaty, such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using the equipment, protective systems, and devices referred to in Article 1 (2) in question provided that this does not mean that such equipment, protective systems, or devices are modified in a way not specified in the Directive.

3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of equipment, protective systems, or the devices referred to in Article 1 (2) which do not conform to the provisions of this Directive, provided that a visible sign clearly indicates that such equipment, protective systems, and devices referred to in Article 1 (2) do not conform and that they are not for sale until they have been brought into conformity by the manufacturer or his authorized representative established in the Community. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

Article 3

Equipment, protective systems, and the devices referred to in Article 1 (2) to which this Directive applies must meet the essential health and safety requirements set out in Annex II which apply to them, account being taken of their intended use.

Article 4

1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of equipment, protective systems, or devices referred to in Article 1 (2) which comply with this Directive.

2. Member States shall not prohibit, restrict or impede the placing on the market of components which, accompanied by a certificate of conformity as referred to in Article 8 (3), are intended to be incorporated into equipment or protective systems within the meaning of this Directive.

Article 5

1. Member States shall regard as conforming to all the provisions of this Directive, including the relevant conformity assessment procedures laid down in chapter II:

— equipment, protective systems, and devices referred to in Article 1 (2) accompanied by the EC declaration of conformity referred to in Annex X and bearing the CE marking provided for in Article 10,

— the components referred to in Article 4 (2), accompanied by the certificate of conformity referred to in Article 8 (3).

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

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 health and safety requirements, the equipment, protective system, device referred to in Article 1 (2), or the component referred to in Article 4 (2), constructed in accordance with that standard shall be presumed to comply with the relevant essential health and safety 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 influence the process of preparing and monitoring the harmonized standards at national level.

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 relevant essential health and safety 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, hereinafter referred to as 'the Committee', giving 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. The Commission may adopt any appropriate measure with a view to ensuring the practical application in a uniform manner of this Directive in accordance with the procedure laid down in paragraph 3.

3. The Commission shall be assisted by a Standing Committee, 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.

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.

4. The Standing Committee may furthermore examine any question relating to the application of this Directive and raised by its chairman either on the latter's initiative, or at the request of a Member State.

Article 7

1. Whee a Member State ascertains that equipment, protective systems or devices referred to in Article 1 (2) bearing the CE conformity marking and used in accordance with their intended use are liable to endanger the safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate meaures to withdraw such equipment or protective systems 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).

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 equipment or a protective system which does not comply bears the CE conformity marking, the competent Member State shall take appropriate action against the person(s) having affixed the marking 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

Conformity assessment procedures

Article 8

1. The procedures for assessing the conformity of equipment, including where necessary the devices referred to in Article 1 (2), shall be as follows:

(a) *equipment-group I and II, equipment-category M 1 and 1*

The manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow the CE type-examination procedure (referred to in Annex III), in conjunction with:

— the procedure relating to production quality assurance (referred to in Annex IV),

or

— the procedure relating to product verification (referred to in Annex V);

(b) *Equipment-group I and II, equipment-category M 2 and 2*

(i) In the case of internal combustion engines and electrical equipment in these groups and categories, the manufacturer or his authorized representative established in the Community shall, in order to affix the CE mark, follow the EC-type examination procedure (referred to in Annex III), in conjunction with:

— the procedure relating to conformity to type referred to in Annex VI, or

— the procedure relating to product quality assurance referred to in Annex VII;

(ii) in the case of other equipment in these groups and categories, the manufacturer or his authorized representative established in the Community must, in order to affix the CE mark, follow the procedure relating to internal control of production (referred to in Annex VIII)

and

communicate the dossier provided for in Annex VIII, paragraph 3, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it.

(c) *equipment-group II, equipment-category 3*

The manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow the procedure relating to internal control of production referred to n Annex VIII;

(d) *equipment-groups I and II*

In addition to the procedures referred to in paragraph 1(a), (b) and (c), the manufacturer or his authorized representative established in the Community may also, in order to affix the CE marking, follow the procedure relating to CE unit verification (referred to in Annex IX).

2. The provisions of 1(a) or 1(d) above shall be used for conformity assessment of autonomous protective systems.

3. The procedures referred to in paragraph 1 shall be applied in respect of components as referred to in Article 4 (2), with the exception of the affixing of the CE marking. A certificate shall be issued by the manufacturer or his authorized representative established in the Community, declaring the conformity of the components with the provisions of this Directive which apply to them and stating their characteristics and how they must be incorporated into equipment or protective systems to assist compliance with the essential requirements applicable to finished equipment or protective systems.

4. In addition, the manufacturer or his authorized representative established in the Community may, in order to affix the CE marking, follow the procedure relating to internal control of production (referred to in Annex VIII) with regard to the safety aspects referred to in point 1.2.7 of Annex II.

5. Notwithstanding the previous paragraphs, the competent authorities may, on a duly justified request, authorize the placing on the market and putting into service on the territory of the Member State concerned of the equipment, protective systems and individual devices referred to in Article 1 (2) in respect of which the procedures referred to in the previous paragraphs have not been applied and the use of which is in the interests of protection.

6. Documents and correspondence relating to the procedures referred to in the abovementioned paragraphs shall be drawn up in one of the official languages of the Member States in which those procedures are being applied or in a language accepted by the notified body.

7. (a) Where the equipment and protective systems are subject to other Community Directives covering other aspects which also provide for the affixing of the CE marking referred to in Article 10, that marking shall indicate that the equipment and protective systems are also presumed to conform with the provisions of those other Directives.

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

Article 9

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

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

2. Member States shall apply the criteria laid down in Annex XI in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relative 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 XI. It shall immediately inform the Commission and the other Member States accordingly.

CHAPTER III

CE conformity marking

Article 10

1. The CE conformity marking shall consist of the initials 'CE'. The form of the marking to be used is shown in Annex X. The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control stage.

2. The CE marking shall be affixed distinctly, visibly, legibly and indelibly to equipment and protective systems, supplementary to the provisions of point 1.0.5. of Annex II.

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

Article 11

Without prejudice to Article 7:

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

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

CHAPTER IV

Final provisions

Article 12

Any decision taken pursuant to this Directive which restricts or prohibits the placing on the market and/or the putting into service or requires the withdrawal from the market of equipment, a protective system, or a device referred to in Article 1 (2) shall state the exact grounds on which it is based. Such a decision shall be notified forthwith 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 13

Member States shall ensure that all the parties involved in the application of the Directive are bound to observe confidentiality in respect of all information obtained in the performance of carrying out their tasks. This does not affect the obligations of the Member States and of the notified bodies regarding reciprocal information and the dissemination of warnings.

Article 14

1. Directive 76/117/EEC, Directive 79/196/EEC [1] and Directive 82/130/EEC shall be repealed as from 1 July 2003.

2. EC certificates of conformity to the harmonized standards obtained in accordance with the procedures laid down in the Directives referred to in paragraph 1 shall continue to be valid until 30 June 2003 unless they expire before that date. Their validity shall continue to be limited to the harmonized standards indicated in the aforementioned Directives.

3. Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 8 (1) to (4) for the assessment of the conformity of electrical equipment placed on the market before 1 July 2003 take account of the results of tests and verifications already carried out under the Directives referred to in paragraph 1.

Article 15

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to

[1] OJ No L 43, 20. 2. 1979, p. 20. Directive as last amended by Directive 90/487/EEC (OJ No L 270, 2. 10. 1990, p. 23).

comply with this Directive before 1 September 1995. They shall forthwith inform the Commission thereof.

The Member States shall apply these measures with effect from 1 March 1996.

When Member States adopt the measures referred to in the first subparagraph, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by Member States.

2. However, Member States shall allow the placing on the market and the putting into service of equipment and protective systems conforming with the national regulations in force in their territory at the date of adoption of this Directive for the period until 30 June 2003.

Article 16

This Directive is addressed to the Member States.

Done at Brussels, 23 March 1994.

For the European Parliament
The President
E. KLEPSCH

For the Council
The President
TH. PANGALOS

ANNEX I

CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES

1. **Equipment-group I**

(a) Category M 1 comprises equipment designed and, where necessary, equipped with additional special means of protection to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines endangered by firedamp and/or combustible dust.

Equipment in this category is required to remain functional, even in the event of rare incidents relating to equipment, with an explosive atmosphere present, and is characterized by means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.0.1.

(b) Category M 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines likely to be endangered by firedamp and/or combustible dust.

This equipment is intended to be de-energized in the event of an explosive atmosphere.

The means of protection relating to equipment in this category assure the requisite level of protection during normal operation and also in the case of more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.0.2.

2. **Equipment-group II**

(a) Category 1 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by mixtures of air and gases, vapours or mists or by air/dust mixtures are present continuously, for long periods or frequently.

Equipment in this category must ensure the requisite level of protection, even in the event of rare incidents relating to equipment, and is characterized by means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.1.

(b) Category 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and of ensuring a high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists or air/dust mixtures are likely to occur.

The means of protection relating to equipment in this category ensure the requisite level of protection, even in the event of frequently occurring disturbances or equipment faults which normally have to be taken into account.

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.2.

(c) Category 3 comprises equipment designed to be capable of functioning in conformity with the operating parameters established by the manufacturer and ensuring a normal level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists, or air/dust mixtures are unlikely to occur or, if they do occur, are likely to do so only infrequently and for a short period only.

Equipment in this category ensures the requisite level of protection during normal operation.

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.3.

ANNEX II

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

Preliminary observations

A. Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilized immediately.

B. For the devices referred to in Article 1 (2), the essential requirements shall apply only in so far as they are necessary for the safe and reliable functioning and operation of those devices with respect to the risks of explosion.

1. COMMON REQUIREMENTS FOR EQUIPMENT AND PROTECTIVE SYSTEMS

1.0. General requirements

1.0.1. *Principles of integrated explosion safety*

Equipment and protective systems intended for use in potentially explosive atmospheres must be designed from the point of view of integrated explosion safety.

In this connection, the manufacturer must take measures:

— above all, if possible, to prevent the formation of explosive atmospheres which may be produced or released by equipment and by protective systems themselves,

— to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition,

— should an explosion nevertheless occur which could directly or indirectly endanger persons and, as the case may be, domestic animals or property, to halt it immediately and/or to limit the range of explosion flames and explosion pressures to a sufficient level of safety.

1.0.2. Equipment and protective systems must be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations.

Any misuse which can reasonably be anticipated must be taken into account.

1.0.3. *Special checking and maintenance conditions*

Equipment and protective systems subject to special checking and maintenance conditions must be designed and constructed with such conditions in mind.

1.0.4. *Surrounding area conditions*

Equipment and protective systems must be so designed and constructed as to be capable of coping with actual or foreseeable surrounding area conditions.

1.0.5. *Marking*

All equipment and protective systems must be marked legibly and indelibly with the following minimum particulars;

— name and address of the manufacturer,

— CE marking (see Annex X, point A),

— designation of series or type,

— serial number, if any,

— year of construction,

— the specific marking of explosion protection  followed by the symbol of the equipment group and category,

— for equipment-group II, the letter 'G' (concerning explosive atmospheres caused by gases, vapours or mists),

and/or

the letter 'D' (concerning explosive atmospheres caused by dust).

Furthermore, where necessary, they must also be marked with all information essential to their safe use.

1.0.6. *Instructions*

(a) All equipment and protective systems must be accompanied by instructions, including at least the following particulars:

— a recapitulation of the information with which the equipment or protective system is marked, except for the serial number (see 1.0.5.), together with any appropriate additional information to facilitate maintenance (e.g. address of the importer, repairer, etc.);

— instructions for safe:

— putting into service,

— use,

— assembling and dismantling,

— maintenance (servicing and emergency repair),

— installation,

— adjustment;

— where necessary, an indication of the danger areas in front of pressure-relief devices;

— where necessary, training instructions;

— details which allow a decision to be taken beyond any doubt as to whether an item of equipment in a specific category or a protective system can be used safely in the intended area under the expected operating conditions;

— electrical and pressure parameters, maximum surface temperatures and other limit values;

— where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;

— where necessary, the essential chracteristics of tools which may be fitted to the equipment or protective system.

(b) The instructions must be drawn up in one of the Community languages by the manufacturer or his authorized representative established in the Community.

On being put into service, all equipment and protective systems must be accompanied by a translation of the instructions in the language or languages of the country in which the equipment or protective system is to be used and by the instructions in the original language.

This translation must be made by either the manufacturer or his authorized representative established in the Community or the person introducing the equipment or protective system into the language area in question.

By way of derogation from this requirement, the maintenance instructions for use by the specialist personnel employed by the manufacturer or his authorized representative established in the Community may be drawn up in a single Community language understood by that personnel.

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

(d) Literature describing the equipment or protective system must not contradict the instructions with regard to safety aspects.

1.1. **Selection of materials**

1.1.1. The materials used for the construction of equipment and protective systems must not trigger off an explosion, taking into account foreseeable operational stresses.

1.1.2. Within the limits of the operating conditions laid down by the manufacturer, it must not be possible for a reaction to take place between the materials used and the constituents of the potentially explosive atmosphere which could impair explosion protection.

1.1.3. Materials must be so selected that predictable changes in their characteristics and their compatibility in combination with other materials will not lead to a reduction in the protection afforded; in particular, due account must be taken of the material's corrosion and wear resistance, electrical conductivity, impact strength, ageing resistance and the effects of temperature variations.

1.2. **Design and Construction**

1.2.1. Equipment and protective systems must be designed and constructed with due regard to technological knowledge of explosion protection so that they can be safely operated throughout their foreseeable lifetime.

1.2.2. Components to be incorporated into or used as replacements in equipment and protective systems must be so designed and constructed that they function safely for their intended purpose of explosion protection when they are installed in accordance with the manufacturer's instructions.

1.2.3. *Enclosed structures and prevention of leaks*

Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only.

If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that developing gases or dusts cannot give rise to explosive atmospheres outside the equipment.

Points where materials are introduced or drawn off must, as far as possible, be designed and equipped so as to limit escapes of flammable materials during filling or draining.

1.2.4. *Dust deposits*

Equipment and protective systems which are intended to be used in areas exposed to dust must be so designed that deposit dust on their surfaces is not ignited.

In general, dust deposits must be limited where possible. Equipment and protective systems must be easily cleanable.

The surface temperatures of equipment parts must be kept well below the glow temperature of the deposit dust.

The thickness of deposit dust must be taken into consideration and, if appropriate, means must be taken to limit the temperature in order to prevent a heat build up.

1.2.5. *Additional means of protection*

Equipment and protective systems which may be exposed to certain types of external stresses must be equipped, where necessary, with additional means of protection.

Equipment must withstand relevant stresses, without adverse effect on explosion protection.

1.2.6. *Safe opening*

If equipment and protective systems are in a housing or a locked container forming part of the explosion protection itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.

1.2.7. Protection against other hazards

Equipment and protective systems must be so designed and manufactured as to:

(a) avoid physical injury or other harm which might be caused by direct or indirect contact;

(b) assure that surface temperatures of accessible parts or radiation which would cause a danger, are not produced;

(c) eliminate non-electrical dangers which are revealed by experience;

(d) assure that foreseeable conditions of overload shall not give rise to dangerous situations.

Where, for equipment and protective systems, the risks referred to in this paragraph are wholly or partly covered by other Community Directives, this Directive shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of those specific Directives.

1.2.8. *Overloading of equipment*

Dangerous overloading of equipment must be prevented at the design stage by means of integrated measurement, regulation and control devices, such as over-current cut-off switches, temperature limiters, differential pressure switches, flowmeters, time-lag relays, overspeed monitors and/or similar types of monitoring devices.

1.2.9. *Flameproof enclosure systems*

If parts which can ignite an explosive atmosphere are placed in an enclosure, measures must be taken to ensure that the enclosure withstands the pressure developed during an internal explosion of an explosive mixture and prevents the transmission of the explosion to the explosive atmosphere surrounding the enclosure.

1.3. **Potential ignition sources**

1.3.1. *Hazards arising from different ignition sources*

Potential ignition sources such as sparks, flames, electric arcs, high surface temperatures, acoustic energy, optical radiation, electromagnetic waves and other ignition sources must not occur.

1.3.2. *Hazards arising from static electricity*

Electrostatic charges capable of resulting in dangerous discharges must be prevented by means of appropriate measures.

1.3.3. *Hazards arising from stray electric and leakage currents*

Stray electric and leakage currents in conductive equipment parts which could result in, for example, the occurrence of dangerous corrosion, overheating of surfaces or sparks capable of provoking an ignition must be prevented.

1.3.4. *Hazards arising from overheating*

Overheating caused by friction or impacts occurring, for example, between materials and parts in contact with each other while rotating or through the intrusion of foreign bodies must, as far as possible, be prevented at the design stage.

1.3.5. *Hazards arising from pressure compensation operations*

Equipment and protective systems must be so designed or fitted with integrated measuring, control and regulation devices that pressure compensations arising from them do not generate shock waves or compressions which may cause ignition.

1.4. **Hazards arising from external effects**

1.4.1. Equipment and protective systems must be so designed and constructed as to be capable of performing their intended function in full safety, even in changing environmental conditions and in the presence of extraneous voltages, humidity, vibrations, contamination and other external effects, taking into account the limits of the operating conditions established by the manufacturer.

1.4.2. Equipment parts used must be appropriate to the intended mechanical and thermal stresses and capable of withstanding attack by existing or foreseeable aggressive substances.

1.5. **Requirements in respect of safety-related devices**

1.5.1. Safety devices must function independently of any measurement or control devices required for operation.

As far as possible, failure of a safety device must be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur.

For electrical circuits the fail-safe principle is to be applied in general.

Safety-related switching must in general directly actuate the relevant control devices without intermediate software command.

1.5.2. In the event of a safety device failure, equipment and/or protective systems shall, wherever possible, be secured.

1.5.3. Emergency stop controls of safety devices must, as far as possible, be fitted with restart lockouts. A new start command may take effect on normal operation only after the restart lockouts have been intentionally reset.

1.5.4. *Control and display units*

Where control and display units are used, they must be designed in accordance with ergonomic principles in order to achieve the highest possible level of operating safety with regard to the risk of explosion.

1.5.5. *Requirements in respect of devices with a measuring function for explosion protection.*

In so far as they relate to equipment used in explosive atmospheres, devices with a measuring function must be designed and constructed so that they can cope with foreseeable operating requirements and special conditions of use.

1.5.6. Where necessary, it must be possible to check the reading accuracy and serviceability of devices with a measuring function.

1.5.7. The design of devices with a measuring function must incorporate a safety factor which ensures that the alarm threshold lies far enough outside the explosion and/or ignition limits of the atmospheres to be registered, taking into account, in particular, the operating conditions of the installation and possible aberrations in the measuring system.

1.5.8. *Risks arising from software*

In the design of software-controlled equipment, protective systems and safety devices, special account must be taken of the risks arising from faults in the programme.

1.6. **Integration of safety requirements relating to the system**

1.6.1. Manual override must be possible in order to shut down the equipment and protective systems incorporated within automatic processes which deviate from the intended operating conditions, provided that this does not compromise safety.

1.6.2. When the emergency shutdown system is actuated, accumulated energy must be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard.

This does not apply to electrochemically-stored energy.

1.6.3. *Hazards arising from power failure*

Where equipment and protective systems can give rise to a spread of additional risks in the event of a power failure, it must be possible to maintain them in a safe state of operation independently of the rest of the installation.

1.6.4. *Hazards arising from connections*

Equipment and protective systems must be fitted with suitable cable and conduit entries.

When equipment and protective systems are intended for use in combination with other equipment and protective systems, the interface must be safe.

1.6.5. *Placing of warning devices as parts of equipment*

Where equipment or protective systems are fitted with detection or alarm devices for monitoring the occurrence of explosive atmospheres, the necessary instructions must be provided to enable them to be provided at the appropriate places.

2. SUPPLEMENTARY REQUIREMENTS IN RESPECT OF EQUIPMENT

2.0. **Requirements applicable to equipment in category M of equipment-group I**

2.0.1. *Requirements applicable to equipment in category M 1 of equipment-group I*

2.0.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in the event of rare incidents relating to equipment.

Equipment must be equipped with means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

Where necessary, this equipment must be equipped with additional special means of protection.

It must remain functional with an explosive atmosphere present.

2.0.1.2. Where necessary, equipment must be so constructed that no dust can penetrate it.

2.0.1.3. The surface temperatures of equipment parts must be kept clearly below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

2.0.1.4. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

If necessary, equipment must be fitted with appropriate additional interlocking systems.

2.0.2. *Requirements applicable to equipment in category M 2 of equipment-group I*

2.0.2.1. Equipment must be equipped with means of protection ensuring that sources of ignition do not become active during normal operation, even under more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

The equipment is intended to be de-energized in the event of an explosive atmosphere.

2.0.2.2. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.0.2.3. The requirements regarding explosion hazards arising from dust applicable to category M 1 must be applied.

2.1. **Requirements applicable to equipment in category 1 of equipment-group II**

2.1.1. *Explosive atmospheres caused by gases, vapours or hazes*

2.1.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in event of rare incidents relating to equipment.

It must be equipped with means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.1.2. For equipment with surfaces which may heat up, measures must be taken to ensure that the stated maximum surface temperatures are not exceeded even in the most unfavourable circumstances.

Temperature rises caused by heat build-ups and chemical reactions must also be taken into account.

2.1.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

If necessary, equipment must be fitted with appropriate additional interlocking systems.

2.1.2. *Explosive atmospheres caused by air/dust mixtures*

2.1.2.1. Equipment must be so designed and constructed that ignition of air/dust mixtures does not occur even in the event of rare incidents relating to equipment.

It must be equipped with means of protection such that

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.2.2. Where necessary, equipment must be so designed that dust can enter or escape from the equipment only at specifically designated points.

This requirement must also be met by cable entries and connecting pieces.

2.1.2.3. The surface temperatures of equipment parts must be kept well below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

2.1.2.4. With regard to the safe opening of equipment parts, requirement 2.1.1.3 applies.

2.2. **Requirements for category 2 of equipment-group II**

2.2.1. *Explosive atmospheres caused by gases, vapours or mists*

2.2.1.1. Equipment must be so designed and constructed as to prevent ignition sources arising, even in the event of frequently occurring disturbances or equipment operating faults, which normally have to be taken into account.

2.2.1.2. Equipment parts must be so designed and constructed that their stated surface temperatures are not exceeded, even in the case of risks arising from abnormal situations anticipated by the manufacturer.

2.2.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.2.2. *Explosive atmospheres caused by air/dust mixtures*

2.2.2.1. Equipment must be designed and constructed so that ignition of air/dust mixtures is prevented, even in the event of frequently occurring disturbances or equipment operating faults which normally have to be taken into account.

2.2.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.2.2.3. With regard to protection against dust, requirement 2.1.2.2 applies.

2.2.2.4. With regard to the safe opening of equipment parts, requirement 2.2.1.3 applies.

2.3. **Requirements applicable to equipment in category 3 of equipment-group II**

2.3.1. *Explosive atmospheres caused by gases, vapours or mists*

2.3.1.1. Equipment must be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.

2.3.1.2. Surface temperatures must not exceed the stated maximum surface temperatures under intended operating conditions. Higher temperatures in exceptional circumstances may be allowed only if the manufacturer adopts special additional protective measures.

2.3.2. *Explosive atmospheres caused by air/dust mixtures*

2.3.2.1. Equipment must be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.

2.3.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.3.2.3. Equipment, including cable entries and connecting pieces, must be so constructed that, taking into account the size of its particles, dust can neither develop explosive mixtures with air nor form dangerous accumulations inside the equipment.

3. SUPPLEMENTARY REQUIREMENTS IN RESPECT OF PROTECTIVE SYSTEMS

3.0. **General requirements**

3.0.1. Protective systems must be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.

3.0.2. Protective systems must be designed and capable of being positional in such a way that explosions are prevented from spreading through dangerous chain reactions or flashover and incipient explosions do not become detonations.

3.0.3. In the event of a power failure, protective systems must retain their capacity to function for a period sufficient to avoid a dangerous situation.

3.0.4. Protective systems must not fail due to outside interference.

3.1. **Planning and design**

3.1.1. *Characteristics of materials*

With regard to the characteristics of materials, the maximum pressure and temperature to be taken into consideration at the planning stage are the expected pressure during an explosion occurring under extreme operating conditions and the anticipated heating effect of the flame.

3.1.2. Protective systems designed to resist or contain explosions must be capable of withstanding the shock wave produced without losing system integrity.

3.1.3. Accessories connected to protective systems must be capable of withstanding the expected maximum explosion pressure without losing their capacity to function.

3.1.4. The reactions caused by pressure in peripheral equipment and connected pipe-work must be taken into consideration in the planning and design of protective systems.

3.1.5. *Pressure-relief systems*

If it is likely that stresses on protective systems will exceed their structural strength, provision must be made in the design for suitable pressure-relief devices which do not endanger persons in the vicinity.

3.1.6. *Explosion suppression systems*

Explosion suppression systems must be so planned and designed that they react to an incipient explosion at the earliest possible stage in the event of an incident and counteract it to best effect, which due regard to the maximum rate of pressure increase and the maximum explosion pressure.

3.1.7. *Explosion decoupling systems*

Decoupling systems intended to disconnect specific equipment as swiftly as possible in the event of incipient explosions by means of appropriate devices must be planned and designed so as to remain proof against the transmission of internal ignition and to retain their mechanical strength under operating conditions.

3.1.8. Protective systems must be capable of being integrated into a circuit with a suitable alarm threshold so that, if necessary, there is cessation of product feed and output and shutdown of equipment parts which can no longer function safely.

ANNEX III

MODULE EC-TYPE EXAMINATION

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen representative of the production envisaged meets the relevant applicable provisions of the Directive.

2. The application for the EC-type examination shall be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

   The application shall include:

   — the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition;

   — a written declaration that the same application has not been lodged with any other notified body;

   — the technical documentation, as described in point 3.

   The applicant shall place at the disposal of the notified body a specimen representative of the production envisaged and hereinafter called 'type'. The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable the conformity of the product with the requirements of the Directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and shall to that extent contain:

   — a general type-description;

   — design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;

   — descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product;

   — a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;

   — results of design calculations made, examinations carried out, etc.;

   — test reports.

4. The notified body shall:

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;

4.2. perform or have performed the appropriate examinations and necessary tests to check whether the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 have not ben applied;

4.3. perform or have performed the appropriate examinations and necessary tests to check whether these have actually been applied, where the manufacturer has chosen to apply the relevant standards;

4.4. agree with the applicant the location where the examinations and necessary tests shall be carried out.

5. Where the type meets the provisions of the Directive, the notified body shall issue an EC-type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination and the necessary data for identification of the approved type.

   A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorized representative established in the Community is denied a type certification, the notified body shall provide detailed reasons for such denial.

Provision shall be made for an appeals procedure.

6. The applicant shall inform the notified body which holds the technical documentation concerning the EC-type-examination certificate of all modifications to the approved equipment or protective system which must receive further approval where such changes may effect conformity with the essential requirements or with the prescribed conditions for use of the product. This further approval is given in the form of an addition to the original EC-type-examination certificate.

7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC-type-examination certificates and additions issued and withdrawn.

8. The other notified bodies may receive copies of the EC-type-examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorized representative established in the Community shall keep with the technical documentation copies of EC-type-examination certificates and their additions for a period ending at least 10 years after the last equipment or protective system was manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

ANNEX IV

MODULE: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the Directive which apply to them. The manufacturer, or his authorized representative established in the Community, shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for EC monitoring, as specified in Section 4.

2. The manufacturer shall operate an approved quality system for production, final equipment inspection and testing as specified in Section 3 and shall be subject to monitoring as specified in Section 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the equipment concerned.

The application shall include:

— all relevant information for the product category envisaged;

— the documentation concerning the quality system;

— technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2. The quality system shall ensure compliance of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the Directive which apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to equipment quality;

— the manufacturing, quality control and quality assurance techniques, processes and systematic actions which will be used;

— the examinations and tests which will be carried out before, during and after manufacture and the frequency with which they will be carried out;

— the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.;

— the means to monitor the achievement of the required equipment quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in Section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard. The auditing team shall have at least one member with experience of evaluation in the equipment technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to uphold the system so that it remains adequate and efficient.

The manufacturer or his authorized representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in Section 3.2 or whether a re-assessment is required.

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

4. **Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular

— the quality system documentation

— the quality records, such as inspection reports and text data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3. The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of Section 3.1;

— the updating referred to in the second paragraph of Section 3.4;

— the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Secton 4.4.

6. Each notified body shall apprise the other notified bodies of the relevant information concerning the quality system approvals issued and withdrawn.

ANNEX V

MODULE: PRODUCT VERIFICATION

1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the equipment subject to the provisions of point 3 are in conformity with the type as described in the EC-type-examination certificate and satisfy the relevant requirements of the Directive.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees conformity of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the Directive which apply to them. The manufacturer or his authorized representative established in the Community shall affix the CE marking to each piece of equipment and shall draw up a declaration of conformity.

3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the equipment, protective system or device referred to in Article 1 (2), with the relevant requirements of the Directive, by examining and testing every product as specified in Section 4.

   The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured.

4. **Verification by examination and testing of each piece of equipment.**

4.1. All equipment shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equipment tests shall be carried out in order to verify their conformity with the type as described in the EC-type-examination certificate and the relevant requirements of the Directive.

4.2. The notified body shall affix or have affixed its identification number to each approved item of equipment and shall draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

ANNEX VI

MODULE: CONFORMITY TO TYPE

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the equipment in question is in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the Directive applicable to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured equipment or protective systems with the type as described in the EC-type-examination certificate and with the relevant requirements of the Directive.

3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured. Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment or protective system on the Community market.

   For each piece of equipment manufactured, tests relating to the anti-explosive protection aspects of the product shall be carried out by the manufacturer or on his behalf. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.

   On the responsibility of the notified body, the manufacturer shall affix the former's identification number during the manufacturing process.

ANNEX VII

MODULE: PRODUCT QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of Section 2 ensures and declares that the equipment is in conformity with the type as described in the EC-type-examination certificate. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.

2. The manufacturer shall operate an approved quality system for the final inspection and testing of equipment as specified in Section 3 below and shall be subject to surveillance as specified in Section 4 below.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system for the equipment and protective systems, with a notified body of his choice.

The application shall include:

— all relevant information for the product category envisaged;

— documentation on the quality system;

— technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2. Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the Directive. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instruments. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality;

— the examinations and tests which will be carried out after manufacture;

— the means to monitor the effective operation of the quality system;

— quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in Section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard.

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in Section 3.2 or whether a re-assessment is required.

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

4. **Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall for inspection purposes allow the notified body access to the inspection, testing and storage premises and shall provide it with all necessary information, in particular:

— quality system documentation;

— technical documentation;

— quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3. The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or arrange for tests to be carried out in order to check the proper functioning of the quality system, where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the third indent of Section 3.1;

— the updating referred to in the second paragraph of Section 3.4;

— the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

ANNEX VIII

MODUL: INTERNAL CONTROL OF PRODUCTION

1. This module describes the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in Section 2, ensures and declares that the equipment satisfy the requirements of the Directive applicable to it. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall establish the technical documentation described in Section 3 and he or his authorized representative established within the Community shall keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last piece of equipment was manufactured.

   Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment on the Community market.

3. Technical documentation shall enable the conformity of the equipment with the relevant requirements of the Directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product. It shall contain:

   — a general description of the equipment,

   — conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

   — descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the equipment,

   — a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the safety aspects of the Directive where the standards have not been applied,

   — results of design calculations made, examinations carried out, etc.,

   — test reports.

4. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity with the technical documentation.

5. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees compliance of the manufactured equipment with the technical documentation referred to in Section 2 and with the requirements of the Directive applicable to such equipment.

ANNEX IX

MODULE: UNIT VERIFICATION

1. This module describes the procedure whereby the manufacturer ensures and declares that the equipment or protective system which has been issued with the certificate referred to in Section 2 conforms to the requirements of the Directive which are applicable to it. The manufacturer or his authorized representative in the Community shall affix the CE marking to the equipment or protective system and draw up a declaration of conformity.

2. The notified body shall examine the individual equipment or protective system and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

   The notified body shall affix, or cause to be affixed, its identification number on the approved equipment or protective system and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of the Directive to be assessed and the design, manufacture and operation of the equipment or protective system to be understood.

   The documentation shall contain:

   — a general description of the product;

   — conceptual design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;

   — descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the equipment or protective system;

   — a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;

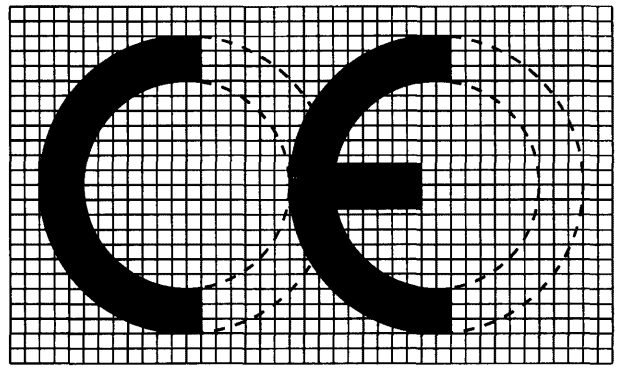
   — results of design calculations made, examinations carried out, etc.;

   — test reports.

ANNEX X

A. **CE Marking**

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



If the marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale equipment, protective systems or devices referred to in Article 1 (2).

B. **Content of the EC declaration of conformity**

The EC declaration of conformity must contain the following elements:

— the name or identification mark and the address of the manufacturer or his authorized representative established within the Community;

— a description of the equipment, protective system, or device referred to in Article 1 (2);

— all relevant provisions fulfilled by the equipment, protective system, or device referred to in Article 1 (2);

— where appropriate, the name, identification number and address of the notified body and the number of the EC-type-examination certificate;

— where appropriate, reference to the harmonized standards;

— where appropriate, the standards and technical specifications which have been used;

— where appropriate, references to other Community Directives which have been applied;

— identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorized representative established within the Community.

ANNEX XI

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 equipment, protective systems, or devices referred to in Article 1 (2) which they inspect, nor the authorized representative of any of these parties. They shall become involved neither directly nor as authorized representatives in the design, construction, marketing or maintenance of the equipment, protective systems or devices referred to in Article 1 (2) in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its inspection 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 may 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 which 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.

DIRECTIVE 94/10/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

of 23 March 1994

materially amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 100A, 213 and 43 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure referred to in Article 189B of the Treaty,

Whereas in order to promote the smooth functioning of the internal market as much transparency as possible should be ensured as regards national initiatives for the establishment of technical standards or regulations by amending the procedure for the provision of information laid down in Directive 83/189/EEC [3];

Whereas in order to remove barriers to the smooth functioning of the internal market the scope of the said Directive should be extended;

Whereas in the light of past experience the procedure for notifying the work programmes of the national standardization bodies should be amended in order to define more clearly the information which has to be notified and to make the procedure more flexible and less cumbersome;

Whereas systematic notification is actually necessary only in the case of new subjects for standardization and in so far as the treatment of these subjects at national level may give rise to differences in national standards which are liable to disturb the functioning of the market as a result; whereas any subsequent notification or communication relating to the progress of national activities must depend on the interest in such activities expressed by those to whom this new subject has already been communicated;

Whereas the Commission must nevertheless be able to request the communication of all or part of the national standardization programmes so that it can review the development of standardization activity in particular economic sectors;

Whereas the European standardization system must be organized by and for the parties concerned, on a basis of coherence, transparency, openness, consensus, independence of special interests, efficiency and decision-making based on national representation;

Whereas the functioning of standardization in the Community must be based on fundamental rights for the national standardization bodies, such as the possibility of obtaining draft standards, being informed of the action taken in response to comments submitted, being associated with national standardization activities or requesting the preparation of European standards in place of national standards; whereas it is for the Member States to take the appropriate measures in their power to ensure that their standardization bodies observe these rights;

Whereas the provisions contained in Directive 83/189/EEC concerning the standstill arrangements applicable to national standardization bodies when a European standard is in preparation must be brought into line with the relevant provisions adopted by the standardization bodies within the framework of the European standardization bodies;

Whereas, as far as technical regulations for products are concerned, the measures designed to ensure the proper functioning or the continued development of the market include greater transparency of national intentions and a broadening of the criteria and conditions for assessing the potential effect of the proposed regulations on the market;

Whereas it is therefore necessary to assess all the requirements laid down in respect of a product and to take account of developments in national practices for the regulation of products;

Whereas requirements, other than technical specifications, referring to the life cycle of a product after it has been placed on the market are liable to affect the free movement of that product or to create obstacles to the proper functioning of the internal market;

Whereas the implementation of Directive 83/189/EEC has revealed the need to clarify the concept of a *de facto* technical regulation; whereas, in particular, the provisions by which the public authority refers to technical specifications or other requirements, or encourages the observance thereof, and the provisions referring to products with which the public authority is associated, in the public interest, have the effect of conferring on such requirements or specifications a more binding value than they would otherwise have by virtue of their private origin;

(1) OJ No C 340, 23. 12. 1992, p. 7.
(2) OJ No C 201, 26. 7. 1993, p. 11.
(3) OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Decision 92/400/EEC (OJ No L 221, 6. 8. 1992, p. 55).

Whereas it is therefore imperative that the urgency procedure be adapted in a way that reflects experience to date.

Whereas experience of the operation of Directive 83/189/EEC has also revealed the need to clarify or explain in more detail certain definitions, rules of procedure or obligations of the Member States under the directive, without prejudice to their obligations concerning the implementation of other Community directives;

Whereas the aim of the internal market is to create an environment that is conducive to the competitiveness of undertakings; whereas increased provision of information is one way of helping undertakings to make more of the advantages inherent in this market; whereas it is therefore necessary to enable economic operators to give their assessment of the impact of the national technical regulations proposed by other Member States by providing for the regular publication of the titles of notified drafts and by amending the provisions relating to the confidentiality of such drafts;

Whereas it is appropriate, in the interests of legal certainty, that Member States publicly announce that a national technical regulation has been adopted in accordance with the formalities laid down in Directive 83/189/EEC as last amended by this Directive;

Whereas it is inherent in the internal market that, in particular where the principle of mutual recognition cannot be implemented by the Member States, the Commission proposes the adoption of binding Community acts; whereas a specific temporary standstill period has been established in order to prevent the introduction of national measures from compromising the adoption, by the Council, of Commission proposals in the same field;

Where experience has shown that, in order to be suited to its purpose, the standstill period must be prolonged in order to make additional allowance for the time taken by discussions in the Council; whereas, also with a view to facilitating the adoption of Community measures by the Council, Member States should refrain from adopting technical regulations once the Council has adopted a common position on a Commission proposal concerning that sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 83/189/EEC is hereby amended as follows:

1. Article 1 shall be amended as follows:

(a) paragraph 7 shall become paragraph 1;

(b) paragraph 1 shall be replaced by the following:

'2. "technical specification", a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;

The term "technical specification" also covers production methods and processes used in respect of agricultural products as referred to in Article 38 (1) of the Treaty, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 65/65/EEC (*), as well as production methods and processes relating to other products, where these have an effect on their characteristics.

3. "other requirement", a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;

(*) OJ No 22, 9. 2. 1965, p. 369/65. Directive as last amended by Directive 93/39/EEC (OJ No L 214, 24. 8. 1993, p. 22).';

(c) paragraph 2 shall be replaced by the following:

'4. "standard", a technical specification approved by a recognized standardization body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:

— international standard: a standard adopted by an international standardization organization and made available to the public,

— European standard: a standard adopted by a European standardization body and made available to the public,

— national standard: a standard adopted by a national standardization body and made available to the public;'

(d) paragraph 3 shall be replaced by the following:

'5. "standards programme", a work programme of a recognized standardization body listing the subjects on which standardization work is being carried out;'

(e) paragraph 4 shall become paragraph 6;

(f) paragraph 7 shall be replaced by the following:

'7. "European standardization body", a body referred to in Annex I';

(g) the following paragraphs shall be added:

'8. "national standardization body", a body referred to in Annex II;

9. "technical regulation", technical specifications and other requirements, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 10, prohibiting the manufacture, importation, marketing or use of a product.

De facto technical regulations include:

— laws, regulations or administrative provisions of a Member State which refer either to technical specifications or other requirements or to professional codes or codes of practice which in turn refer to technical specifications or other requirements and compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions,

— voluntary agreements to which a public authority is a contracting party and which provide, in the public interest, for compliance with technical specifications or other requirements, excluding public procurement tender specifications,

— technical specifications or other requirements which are linked to fiscal or financial measures affecting the consumption of products by encouraging compliance with such technical specifications or other requirements; technical specifications or other requirements linked to national social-security systems are not included.

This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list to be drawn up by the Commission before the entry into force of this Directive in the framework of the Committee referred to in Article 5.

The same procedure shall be used for amending this list;

10. "draft technical regulation",the text of a technical specification or other requirement, including administrative provisions formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made.

This Directive shall not apply to those measures Member States consider necessary under the Treaty for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.'

2. Article 2 shall be replaced by the following:

'Article 2

1. The Commission and the standardization bodies referred to in Annexes I and II shall be informed of the new subjects for which the national bodies referred to in Annex II have decided, by including them in their standards programme, to prepare or amend a standard, unless it is an identical or equivalent transposition of an international or European standard.

2. The information referred to in paragraph 1 shall indicate, in particular, whether the standard concerned:

— will transpose an international standard without being the equivalent,

— will be a new national standard, or

— will amend a national standard.

After consulting the Committee referred to in Article 5, the Commission may draw up rules for the consolidated presentation of this information and a plan and criteria governing the presentation of this information in order to facilitate its evaluation.

3. The Commission may ask for all or part of the standards programmes to be communicated to it.

It shall make this information available to the Member States in a form which allows the different programmes to be assessed and compared.

4. Where appropriate, the Commission shall amend Annex II on the basis of communications from the Member States.

5. The Council shall decide, on the basis of a proposal from the Commission, on any amendment to Annex I.'

3. Article 3 shall be replaced by the following:

'Article 3

The standardization bodies referred to in Annexes I and II, and the Commission, shall be sent all draft standards on request; they shall be kept informed by the body concerned of the action taken on any comments they have made relating to drafts.'

4. Article 4 shall be replaced by the following:

'Article 4

1. Member States shall take all necessary steps to ensure that their standardization bodies:

— communicate information in accordance with Articles 2 and 3,

— publish the draft standards in such a way that comments may also be obtained from parties established in other Member States,

— grant the other bodies referred to in Annex II the right to be involved passively or actively (by sending an observer) in the planned activities,

— do not object to a subject for standardization in their work programme being discussed at European level in accordance with the rules laid down by the European standardization bodies and undertake no action which may prejudice a decision in this regard.

2. Member States shall refrain in particular from any act of recognition, approval or use by reference of a national standard adopted in breach of Articles 2, 3 and 4.'

5. Article 7 (1) shall be replaced by the following:

'1. Member States shall take all appropriate measures to ensure that, during the preparation of a European standard referred to in the first indent of Article 6 (3) or after its approval, their standardization bodies do not take any action which could prejudice the harmonization intended and, in particular, that they do not publish in the field in question a new or revised national standard which is not completely in line with an existing European standard.'

6. Article 8 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. Subject to Article 10, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these have not already been made clear in the draft.

Where appropriate, and unless it has already been sent with a prior communication, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.

Member States shall communicate the draft again under the above conditions if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

Where, in particular, the draft seeks to limit the marketing or use of a chemical substance, preparation or product on grounds of public health or of the protection of consumers or the environment Member States shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10 (4) of Regulation (EEC) No 793/93 (*) in the case of an existing substance or in Article 3 (2) of Directive 92/32/EEC (**) in the case of a new substance.

The Commission shall immediately notify the other Member States of the draft and all documents which have been forwarded to it; it

may also refer this draft, for an opinion, to the Committee referred to in Article 5 and, where appropriate, to the committee responsible for the field in question.

With respect to the technical specifications or other requirements referred to in Article 1 (9), third indent, the detailed comments or opinions of the Commission or the Member States may concern only the aspect which may hinder trade and not the fiscal or financial aspect of the measure.

(*) OJ No L 84, 5. 4. 1993, p. 1.
(**) OJ No L 154, 5. 6. 1992, p. 1.';

(b) paragraphs 3 and 4 shall be replaced by the following:

'3. Member States shall communicate the definitive text of a technical regulation to the Commission without delay.

4. Information supplied under this Article shall not be confidential except at the express request of the notifying Member State. Any such request shall be supported by reasons.

In cases of this kind, if necessary precautions are taken, the Commission and the national authorities may seek expert advice from physical or legal persons in the private sector.';

(c) the following paragraph shall be added:

'5. When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Community act, Member States may make a communication within the meaning of Article 8 (1) of this Directive under that other act, provided that they formally indicate that the said communication also constitutes a communication for the purposes of this Directive.

The absence of a reaction from the Commission under this Directive to a draft technical regulation shall not prejudice any decision which might be taken under other Community acts.'

7. Article 9 shall be replaced by the following:

'Article 9

1. Member States shall postpone the adoption of a draft technical regulation for three months from the date of receipt by the Commission of the communication referred to in Article 8 (1).

2. Member States shall postpone:

— for four months the adoption of a draft technical regulation in the form of a voluntary agreement within the meaning of Article 1 (9), second indent,

— without prejudice to paragraphs 3, 4 and 5, for six months the adoption of any other draft technical regulation,

from the date of receipt by the Commission of the communication referred to in Article 8 (1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of goods within the internal market.

The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.

3. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 8 (1) if, within the three months following that date, the Commission announces its intention to propose or adopt a Directive, Regulation or Decision on the matter in accordance with Article 189 of the Treaty.

4. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 8 (1) if, within the three months following that date, the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a Directive, Regulation or Decision presented to the Council in accordance with Article 189 of the Treaty.

5. If the Council adopts a common position during the standstill period referred to in paragraphs 3 and 4, that period shall, subject to Article 9 (6), be extended to 18 months.

6. The obligations referred to in paragraphs 3, 4 and 5 shall lapse:

— when the Commission informs the Member States that it no longer intends to propose or adopt a binding Community act,

— when the Commission informs the Member States of the withdrawal of its draft or proposal,

— when the Commission or the Council has adopted a binding Community act.

7. Paragraphs 1 to 5 shall not apply in those cases where, for urgent reasons, occasioned by serious and unforeseeable circumstances, relating to the protection of public health or safety, the protection of animals or the preservation of plants, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible. The Member State shall give, in the communication referred to in Article 8, the reasons which warrant the urgency of the measures taken. The Commission shall give its views on the communication as soon as possible. It shall take appropriate action in cases where improper use is made of this procedure. The European Parliament shall be kept informed by the Commission.'

8. Article 10 shall be replaced by the following:

'*Article 10*

1. Articles 8 and 9 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements by means of which Member States:

— comply with binding Community acts which result in the adoption of technical specifications;

— fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications in the Community;

— make use of safeguard clauses provided for in binding Community acts;

— apply Article 8 (1) of Council Directive 92/59/EEC of 29 June 1992 on general product safety (*);

— restrict themselves to implementing a judgment of the Court of Justice of the European Communities;

— restrict themselves to amending a technical regulation within the meaning of Article 1 (9) of this Directive, in accordance with a Commission request, with a view to removing an obstacle to trade.

2. Article 9 shall not apply to the laws, regulations and administrative provisions of the Member States prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9 (3) to (6) shall not apply to the voluntary agreements referred to in Article 1 (9), second indent.

4. Article 9 shall not apply to the technical specifications or other requirements referred to in Article 1 (9), third indent.'

(*) OJ No L 228, 11. 8. 1992, p. 24.'.

9. Article 11 shall be replaced by the following:

'*Article 11*

The Commission shall report every two years to the European Parliament, the Council and the Economic and Social Committee on the results of the application of this Directive. Lists of standardization work entrusted to the European standardization organizations pursuant to this Directive, as well as statistics on the notifications received shall be published on an annual basis in the *Official Journal of the European Communities*.'

10. Article 12 shall be replaced by the following:

'*Article 12*

When Member States adopt a technical regulation, it shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States.'

11. The Annex shall be replaced by Annexes I and II appearing in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1995. They shall forthwith inform the Commission thereof.

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

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

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 23 March 1994.

For the European Parliament
The President
E. KLEPSCH

For the Council
The President
TH. PANGALOS

ANNEX

'ANNEX I

European standardization bodies

CEN
Comité Européen de Normalisation

Cenelec
Comité Européen de Normalisation Electrotechnique

ETSI
European Telecommunications Standards Institute

ANNEX II

National standardization bodies

1. BELGIUM

   IBN/BIN
   Institut belge de normalisation
   Belgisch Instituut voor Normalisatie

   CEB/BEC
   Comité électrotechnique belge
   Belgisch Elektrotechnisch Comité

2. DENMARK

   DS
   Dansk Standardiseringsråd

   DEK
   Dansk Elektroteknisk Komite

3. GERMANY

   DIN
   Deutsches Institut für Normung e.V.

   DKE
   Deutsche Elektrotechnische Kommission im DIN und VDE

4. GREECE

   ELOT
   Hellenic Organization for Standardization

5. SPAIN

   AENOR
   Asociación Española de Normalización y Certificación

6. FRANCE

   AFNOR
   Association française de normalisation

   UTE
   Union technique de l'électricité — Bureau de normalisation auprès de l'AFNOR

7. IRELAND

   NASI
   National Standards Authority of Ireland

   ETCI
   Electro-Technical Council of Ireland

8. ITALY

   UNI
   Ente Nazionale Italiano di Unificazione

   CEI
   Comitato Elettrotecnico Italiano

9. LUXEMBOURG

   ITM
   Inspection du travail et des mines

   SEE
   Service de l'énergie de l'Etat

10. NETHERLANDS

    NNI
    Nederlands Normalisatie Instituut

    NEC
    Nederlands Elektrotechnisch Comité

11. PORTUGAL

    IPQ
    Instituto Português da Qualidade

12. UNITED KINGDOM

    BSI
    British Standards Institution

    BEC
    British Electrotechnical Committee.'

DIRECTIVE 94/11/EC OF EUROPEAN PARLIAMENT AND COUNCIL

of 23 March 1994

on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer

THE EUROPEAN PARLIAMENT AND COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure referred to in Article 189b of the Treaty,

Whereas in certain Member States there exist Regulations on footwear labelling which are designed to protect and inform the public as well as to secure the legitimate interests of industry;

Whereas the disparity of such Regulations risks creating barriers to trade within the Community, thereby prejudicing the functioning of the internal market;

Whereas, in order to avoid problems due to different systems, the items of a common labelling system for footwear should be precisely defined;

Whereas the Council resolution of 9 November 1989 on future priorities for relaunching consumer protection policy [3] calls for efforts to improve consumer information on products;

Whereas it is in the interests of both consumers and the footwear industry to introduce a system reducing the risk of fraud by indicating the exact nature of the materials used in the main components of footwear;

Whereas, in Council resolution of 5 April 1993 on future action on the labelling of products in the interest of the consumer [4], labelling is deemed to be one important means of achieving better information and transparency for the consumer and of ensuring that the internal market functions harmoniously;

Whereas the harmonization of national legislation is the appropriate way of removing these barriers to free trade; whereas that objective cannot be satisfactorily achieved by the individual Member States; whereas this Directive establishes only those requirements which are indispensable for the free movement of the products to which it applies,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to the labelling of the materials used in the main components of footwear for sale to the consumer.

For the purposes of this Directive, 'footwear' shall mean all articles with applied soles designed to protect or cover the foot, including parts marketed separately as referred to in Annex I.

A non-exhaustive list of the products covered by the Directive appears in Annex II.

The following shall be excluded from the Directive:

— second-hand, worn footwear,

— protective footwear covered by Directive 89/686/EEC [5],

— footwear covered by Directive 76/769/EEC [6],

— toy footwear.

2. Information on the composition of footwear shall be conveyed by means of labelling as specified in Article 4.

(i) The labelling shall convey information relating to the three parts of the footwear as defined in Annex I, namely:

(a) the upper;

(b) the lining and sock; and

(c) the outersole.

(ii) The composition of the footwear shall be indicated as specified in Article 4 on the basis either of pictograms or of written indications for specific materials, as stipulated in Annex I.

(iii) In the case of the upper, classification of the materials shall be determined on the basis of the provisions contained in Article 4 (1) and in Annex I, no account being taken of accessories or reinforcements such as ankle patches, edging, ornamentation, buckles, tabs, eyelet stays or similar attachments.

[1] OJ No C 74, 25. 3. 1992, p. 10.
[2] OJ No C 287, 4. 11. 1992, p. 36.
[3] OJ No C 294, 22. 11. 1989, p. 1.
[4] OJ No C 110, 20. 4. 1993, p. 3.
[5] OJ No L 399, 30. 12. 1989, p. 18.
[6] OJ No L 262, 27. 9. 1976, p. 201.

(iv) In the case of the outersole, classification shall be based on the volume of the materials contained therein, in accordance with Article 4.

Article 2

1. Member States shall take all necessary measures to ensure that all footwear placed on the market meets the labelling requirements of this Directive without prejudice to other relevant Community provisions.

2. Where footwear not in conformity with the provisions regarding labelling requirements is placed on the market, the competent Member State shall take appropriate action as specified in its national legislation.

Article 3

Without prejudice to other relevant Community provisions, Member States shall not prohibit or impede the placing on the market of footwear which complies with the labelling requirements of this Directive, by the application of unharmonized national provisions governing the labelling of certain types of footwear or of footwear in general.

Article 4

1. The labelling shall provide information on the material, determined in accordance with Annex I, which constitutes at least 80 % of the surface area of the upper, and the lining and sock, of the footwear, and at least 80 % of the volume of the outersole. If no one material accounts for at least 80 %, information should be given on the two main materials used in the composition of the footwear.

2. The information shall be conveyed on the footwear. The manufacturer or his authorized agent established in the Community may choose either pictograms or written indications in at least the language or languages which may be determined by the Member State of consumption in accordance with the Treaty, as defined and illustrated in Annex I. Member States, in their national provisions shall ensure that consumers are adequately informed of the meaning of these pictograms, while ensuring that such provisions do not create trade barriers.

3. For the purpose of this Directive, labelling shall involve affixing the required information to at least one article of footwear in each pair. This may be done by printing, sticking, embossing or using an attached label.

4. The labelling must be visible, securely attached and accessible and the dimensions of the pictograms must be sufficiently large to make it easy to understand the information contained therein. It must not be possible for the labelling to mislead the consumer.

5. The manufacturer or his authorized agent established in the Community shall be responsible for supplying the label and for the accuracy of the information contained therein. If neither the manufacturer nor his authorized agent is established in the Community, this obligation shall fall on the person responsible for first placing the footwear on the Community market. The retailer shall remain responsible for ensuring that the footwear sold by him bears the appropriate labelling prescribed by this Directive.

Article 5

Additional textual information, affixed, should the need arise, to the labelling may accompany the information required under this Directive. However, Member States may not prohibit or impede the placing on the market of footwear conforming to the requirements of this Directive, in accordance with Article 3.

Article 6

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 23 September 1995 at the latest. They shall forthwith inform the Commission thereof.

2. Member States shall apply the measures referred to in paragraph 1 from 23 March 1995. Stock invoiced or delivered to the retailer before that date shall not be subject to the said measures until 23 September 1997.

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

4. The Commission shall submit to the Council, three years after this Directive has been brought into application, an assessment report taking into consideration any difficulties which may have been encountered by operators where implementing the provisions of this Directive and shall present, should the need arise, appropriate proposals for review.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 23 March 1994.

For the European Parliament
The President
E. KLEPSCH

For the Council
The President
TH. PANGALOS

ANNEX I

1. **Definition and corresponding pictograms or written indications concerning the parts of the footwear to be identified**

Pictograms *Written indications*

(a) **Upper**

This is the outer face of the structural element which is attached to the outersole.

F Tige
D Obermaterial
IT Tomaia
NL Bovendeel
EN Upper
DK Overdel
GR ΕΠΑΝΩ ΜΕΡΟΣ
ES Empeine
P Parte superior

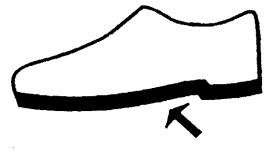
(b) **Lining and sock**

These are the lining of the upper and the insole, constituting the inside of the footwear article.

F Doublure et semelle de propreté
D Futter und Decksohle
IT Fodera e Sottopiede
NL Voering en inlegzool
EN Lining and sock
DK Foring og bindsål
GR ΦΟΔΡΕΣ
ES Forro y plantilla
P Forro e Palmilha

(c) **Outer sole**

This is the bottom part of the footwear article, which is subjected to abrasive wear and attached to the upper.



F Semelle extérieure
D Laufsohle
IT Suola esterna
NL Buitenzool
EN Outer sole
DK Ydersål
GR ΣΟΛΑ
ES Suela
P Sola

2. **Definition and corresponding pictograms of the materials**

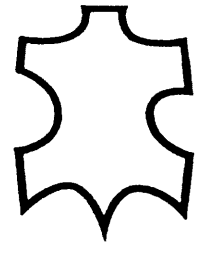
The pictograms concerning the materials should appear on the label beside the pictograms relating to the 3 parts of the footwear as specified in Article 4 and in part 1 of this Annex.

Pictogram *Written indications*

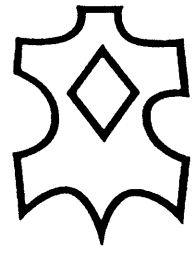
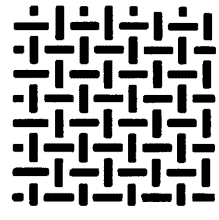
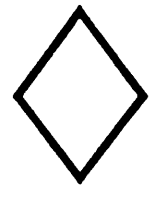
(a) (i) **Leather**

A general term for hide or skin with its original fibrous structure more or less intact, tanned to be rot-proof. The hair or wool may or may not have been removed. Leather is also made from a hide or skin which has been split into layers or segmented either before or after tanning. However, if the tanned hide or skin is disintegrated mechanically and/or chemically into fibrous particles, small pieces or powders and then, with or without the combination of a binding agent, is made into sheets or other forms, such sheets or forms are not leather. If the leather has a surface coating, however applied, or a glued-on finish, such surface layers must not be thicker than 0,15 mm. Thus, all leathers are covered without prejudice to other legal obligations, e.g. the Washington Convention.

Should the term 'full grain leather' be used in the optional additional textual information referred to in Article 5, it will apply to a leather bearing the original grain surface as exposed by removal of the epidermis and with none of the surface removed by buffing, snuffing or splitting.



F Cuir
D Leder
IT Cuoio
NL Leder
EN Leather
DK Læder
GR ΔΕΡΜΑ
ES Cuero
P Couros e peles curtidas

	Pictograms	*Written indications*
(a) (ii) **Coated Leather** leather where the surface coating applied to the leather does not exceed one third of the total thickness of the product but is in excess of 0,15 mm.		F Cuir enduit D Beschichtetes Leder IT Cuoio rivestito NL Gecoat leder EN Coated leather DK Overtrukket læder GR ΕΠΕΝΔΕΔΥΜΕΝΟ ΔΕΡΜΑ ES Cuero untado P Couro revestido
(b) **Natural textile materials and synthetic or non-woven textile materials** 'Textiles' shall mean all products covered by Directive 71/307/EEC and amendments thereof.		F Textile D Textil IT Tessili NL Textiel EN Textile DK Tekstil-materialer GR ΥΦΑΣΜΑ ES Textil P Téxteis
(c) **All other materials**		F Autres matériaux D Sonstiges Material IT Altre materie NL Overige materialen EN Other materials DK Andre materialer GR ΑΛΛΑ ΥΛΙΚΑ ES Otros materiales P Outros materiais

ANNEX II

EXAMPLES OF FOOTWEAR COVERED BY THIS DIRECTIVE

'Footwear' may range from sandals with uppers consisting simply of adjustable laces or ribbons to thigh boots the uppers of which cover the leg and thigh. Among the products included therefore are:

(i) flat or high-heeled shoes for ordinary indoor or outdoor wear;

(ii) ankle-boots, half-boots, knee-boots, and thigh boots;

(iii) sandals of various types, 'espadrilles' (shoes with canvas uppers and soles of plaited vegetable material), tennis shoes, running and other sports shoes, bathing sandals and other casual footwear;

(iv) special sports footwear which is designed for a sporting activity and has, or has provision for the attachment of, spikes, studs, stops, clips, bars or the like and skating boots, ski boots and cross-country ski footwear, wrestling boots, boxing boots and cycling shoes. Also included are composite articles made up of footwear with (ice or roller) skates attached;

(v) dancing slippers;

(vi) footwear formed from a single piece, particularly by moulding rubber or plastics, but excluding disposable articles of flimsy material (paper, plastic film, etc., without applied soles);

(vii) overshoes worn over other footwear, which in some cases are heel-less;

(viii) disposable footwear, with applied soles, generally designed to be used only once;

(ix) orthopaedic footwear.

For reasons of homogeneity and clarity, and subject to the provisions mentioned in the description of the products covered by this Directive, products covered by Chapter 64 of the combined nomenclature ('CN') may, as a general rule, be regarded as falling within the scope of this Directive.

DIRECTIVE 94/12/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

of 23 March 1994

relating to measures to be taken against air pollution by emissions from motor vehicles and amending Directive 70/220/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty,

Whereas measures should be adopted within the framework of the internal market; whereas the internal market comprises an area wihout internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the first programme of action of the European Community on protection of the environment [3], approved by the Council on 22 November 1973, called for account to be taken of the latest scientific advances in combating atmospheric pollution caused by gases emitted from motor vehicles and for Directives adopted previously to be amended accordingly; whereas the fifth programme of action, which in its general approach was approved by the Council in its resolution of 1 February 1993 [4], provides for additional efforts to be made for a considerable reduction in the present level of emissions of pollutants from motor vehicles;

Whereas the objective of reducing the level of pollutant emissions from motor vehicles and the establishment and operation of the internal market for vehicles cannot be sufficiently achieved by individual Member States and can therefore be better achieved by the approximation of the laws of the Member States relating to measures to be taken against air pollution by motor vehicles;

Whereas it is recognized that the development of transport in the Community has entailed significant constraints for the environment; whereas a certain number of official estimates of the increase in traffic density have proved to be lower than the official figures; whereas for that reason stringent emission standards should be laid down for all motor vehicles;

Whereas the Commission has adopted a European programme on emissions, fuels and engine technologies (EPEFE); whereas that programme was established to ensure that proposals for future Directives on pollutant emissions seek the best solutions both for the consumer and for the economy; whereas that programme forms part of the contributions which can be made both by vehicles and the fuels which propel them;

Whereas Council Directive 70/220/EEC [5] which deals with the measures to be taken against air pollution by emissions from motor vehicles, is one of the separate Directives under the type-approval procedure laid down by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers [6];

Whereas Directive 70/220/EEC lays down the limit values for carbon monoxide and unburnt hydrocarbon emissions from the engines of such vehicles; whereas these limit values were first reduced by Directive 74/290/EEC [7] and supplemented, in accordance with Commission Directive 77/102/EEC [8], by limit values for permissible emissions of nitrogen oxides; whereas the limit values for these three types of pollution were successively reduced by Commission Directives 78/665/EEC [9], 83/351/EEC [10] and 88/76/EEC [11]; whereas limit values for particulate pollutant emissions from diesel engines were introduced by Directive 88/436/EEC [12]; whereas more stringent European standards for the emissions of gaseous pollutants of motor vehicles below 1 400 cm^3 were introduced by Directive 89/458/EEC [13]; whereas these standards have been extended to all passenger cars independently of their engine capacity on the basis of an improved European test procedure comprising an extra-urban driving cycle and, whereas requirements relating to the evaporative emissions and to the durability of emission-related vehicle components as well as more stringent particulate pollutant standards for motor vehicles equipped with

(1) OJ No C 56, 26. 2. 1993, p. 34.
(2) OJ No C 201, 26. 7. 1993, p. 9.
(3) OJ No C 112, 20. 12. 1973, p. 1.
(4) OJ No C 138, 17. 5. 1993, p. 1.
(5) OJ No L 76, 6. 4. 1970, p. 1. Directive as last amended by Directive 93/59/EEC (OJ No L 186, 28. 7. 1993, p. 21).
(6) OJ No L 42, 23. 2. 1970, p. 1. Directive as last amended by Commission Directive 93/81/EEC (OJ 264, 23. 10. 1993, p. 49).
(7) OJ No L 159, 15. 6. 1974, p. 61.
(8) OJ No L 32, 3. 2. 1977, p. 32.
(9) OJ No L 223, 14. 8. 1978, p. 48.
(10) OJ No L 197, 20. 7. 1983, p. 1.
(11) OJ No L 36, 9. 2. 1988, p. 1.
(12) OJ No L 214, 6. 8. 1988, p. 1.
(13) OJ No L 226, 3. 8. 1989, p. 1.

diesel engines were introduced by Directive 91/441/EEC [1]; whereas passenger cars designed to carry more than six passengers or having a maximum mass of more than 2 500 kg, light commercial vehicles, and off-road vehicles, covered by the scope of Directive 70/220/EEC, which hitherto have been subject to less stringent standards, are now, under Directive 93/59/EEC, subject to standards as stringent as those for passenger cars, taking into account the specific conditions of such vehicles;

Whereas the work undertaken by the Commission in this field has shown that the best technology currently available to the Community industry can be further improved in order to allow passenger cars to comply with considerably reduced emission limits; whereas the proposed standards will apply both to the approval of new vehicle types and to checks on conformity of production, since the amended method of sampling and statistical evaluation removes the tolerances allowed for the limit values set under previous stages of Directive 70/220/EEC;

Whereas, in the light of the worrying level of pollution caused by vehicle emissions and their role in the formation of the gases responsible for the greenhouse effect, it is necessary to reduce emissions, in particular CO_2 emissions, in accordance with the commitment entered into under the Framework Convention on Climate Change signed in Rio in June 1992; whereas CO_2 results directly from the combustion of carbon-based fuels; whereas CO_2 emissions can principally be reduced by lower fuel consumption; whereas this requires progress in the design of engines and vehicles and in fuel quality; whereas all these elements will be taken into account in a subsequent proposal from the Commission;

Whereas Member States should be allowed to encourage, by means of tax incentives, the introduction of vehicles which satisfy the requirements adopted at Community level; whereas such tax incentives must comply with the provisions of the Treaty and satisfy certain conditions intended to avoid distortions of the internal market; whereas the provisions of this Directive do not affect the Member States' right to include emissions of pollutants and other substances in the basis on which road traffic taxes on motor vehicles are calculated;

Whereas the prior notification requirement of this Directive is without prejudice to notification requirements under other provisions of Community law, notably Article 93 (3) of the Treaty;

Whereas the Council should, by 30 June 1996, adopt the requirements for the stage from the year 2000 on the basis of a proposal to be submitted by the Commission by 31 December 1994 and whereas that proposal is to be aimed at substantially reducing motor vehicle emissions;

Whereas the Commission has held widespread consultations with interested parties, culminating with the Symposium 'Auto Emissions 2000' on 21 and 22 September 1992, which showed that the present approach, focused on exhaust emissions, must be one element in the stage beyond the implementation of the requirements of this Directive, as part of a 'multifaceted' approach comprising all the measures for reducing air pollution due to road traffic; whereas all the parameters which have been identified as having a significant impact on such pollution can at present only be presented in the form of a list; whereas the Commission will undertake the necessary analysis of environmental, technological and cost effectiveness aspects in order to provide before end of December 1994 quantified objectives for Community measures for the year 2000;

Whereas the objective of reducing the level of pollutant emissions from motor vehicles presupposes that, when the Commission makes its proposals for measures to apply after the year 2000 and in the light, *inter alia*, of the preparation of complementary technical measures as provided for in Article 4, it will if necessary put forward target values involving a further substantial reduction in emissions,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 70/220/EEC is hereby amended in accordance with the Annex to this Directive.

Article 2

1. With effect from 1 July 1994 or, should this Directive fail to be published in the *Official Journal of the European Communities* by 31 December 1993 at the latest, six months after it is published, Member States shall accept compliance with the requirements of Directive 70/220/EEC, as amended by this Directive, for the purposes of Articles 4 (1) and 7 (1) of Directive 70/156/EEC.

2. With effect from 1 January 1996, Member States may no longer grant:

— EC type-approval pursuant to Article 4 (1) of Directive 70/156/EEC, or

— national type-approval, unless the provisions of Article 8 (2) of Directive 70/156/EEC are invoked,

for a type of vehicle on grounds relating to air pollution by emissions if it fails to comply with the provisions of Directive 70/220/EEC, as amended by this Directive.

[1] OJ No L 242, 30. 8. 1991, p. 1.

3. With effect from 1 January 1997, Member States shall:

— consider certificates of conformity which accompany new vehicles pursuant to Directive 70/156/EEC as no longer valid for the purposes of Article 7 (1) of that Directive, and

— refuse the registration, sale and entry into service of new vehicles which are not accompanied by a certificate of conformity in accordance with Directive 70/156/EEC, unless the provisions of Article 8 (2) of Directive 70/156/EEC are invoked,

on grounds relating to air pollution by emissions, if the vehicles fail to comply with the provisions of Directive 70/220/EEC, as amended by this Directive.

Article 3

Member States may make provision for tax incentives only in respect of motor vehicles which comply with Directive 70/220/EEC, as amended by this Directive. Such incentives shall comply with the provisions of the Treaty and satisfy the following conditions:

— they shall apply to all new vehicles offered for sale on the market of a Member State which comply in advance with the requirements of Directive 70/220/EEC, as amended by this Directive,

— they shall be terminated with effect from the mandatory application of the emission values laid down in Article 2 (3) for new motor vehicles,

— for each type of motor vehicle, they shall be for an amount lower than the additional cost of the technical solutions introduced to ensure compliance with the values set and of their installation on the vehicle.

The Commission shall be informed in sufficient time of plans to institute or change the tax incentives referred to in the first paragraph, so that it can submit its observations.

Article 4

The Council, acting under the conditions laid down in the Treaty, shall decide before 30 June 1996 on proposals for a further stage of the Community's measures against air pollution caused by emissions from motor vehicles, which the Commission will submit by 31 December 1994. The measures shall apply from the year 2000 onwards.

In these proposals the Commission shall take the following approach:

— the measures shall be designed to produce effects to meet the requirements of the Community's air quality criteria and related objectives,

— an assessment of the cost effectiveness of taking each measure shall be undertaken; in this global assessment full account shall be taken, *inter alia,* of the contributions that:

  — traffic management, for example by spreading the environmental costs appropriately,

  — enhanced urban public transport,

  — new propulsion technologies (e.g. electric transmission),

  — the use of alternative fuels (e.g. biofuels),

  could make to improving air quality,

— the measures shall be proportional and reasonable in the light of the intended objectives.

The proposals, taking account of the methodology outlined above and aimed at a substantial reduction of pollutant emissions as regards the vehicles covered by this Directive, shall comprise in particular the following elements:

1. *Further improvements in the requirements of this Directive:*

based on the assessment of

— the potential of the traditional engine and post-combustion technology,

— possible improvements in the test procedure, e.g. cold-start, starting in low or wintry temperatures, durability (e.g. in the conformity tests), evaporative emissions,

— measures at the level of type-approval supporting strengthened inspection and maintenance requirements, including, for example, on-board diagnostic systems,

— the possibility of checking the conformity of vehicles in circulation,

— the proportional need for:

(i) specific limits for HC and NO_x in addition to a cumulative limit value, and

(ii) measures to cover pollutants not yet regulated.

2. *Complementary technical measures in the framework of specific Directives, including:*

— improvements in fuel quality as far as vehicle emissions of dangerous substances (in particular benzene) are concerned,

— strengthening of the requirements of the inspection and maintenance programme.

The reduced limit values which will be the subject of the new Directive shall not apply before 1 January 2000 for new type-approvals. The Council shall decide on the conditions for granting tax incentives on the basis of these limit values.

Article 5

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1994 or, should the Directive fail to be published in the *Official Journal of the European Communities* by 31 December 1993, six months after it is published. They shall forthwith inform the Commission thereof.

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

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 23 March 1994.

For the European Parliament
The President
E. KLEPSCH

For the Council
The President
TH. PANGALOS

ANNEX

AMENDMENTS TO THE ANNEXES TO DIRECTIVE 70/220/EEC AS AMENDED BY DIRECTIVE 93/59/EEC

ANNEX I

1. Section 3.1 reads as follows:

'3.1. The application for type-approval pursuant to Article 3 of Directive 70/156/EEC of a vehicle type with regard to its tailpipe emissions, evaporative emissions and durability of antipollution devices is submitted by the vehicle manufacturer.'

2. Section 4 reads as follows:

'4. GRANTING OF EC-TYPE-APPROVAL

4.1. If the relevant requirements are satisfied, EEC type-approval shall be granted pursuant to Article 4 (3) of Diretive 70/156/EEC.

4.2. A model for the EC-type-approval certificate is given in Annex IX.'

3. Section 5.3.1.4

The column titles and the first line of the table relating to vehicles of category M are replaced by the following:

'Category of vehicle	Reference mass RM (kg)	Limit values				
		Mass of carbon monoxide L_1 (g/km)		Combined mass of hydrocarbons and oxides of nitrogen L_2 (g/km)		Mass of particulates L_3 (g/km)
		Petrol	Diesel	Petrol	Diesel	Diesel
M (2)	all	2,2	1,0	0,5	0,7 (1)	0,08 (1)

(1) For vehicles fitted with diesel engines of the direct-injection type the value L_2 is 0,9 g/km and the value L_3 is 0,10 g/km until 30 September 1999.
(2) Except: — vehicles designed to carry more than six occupants including the driver,
— vehicles whose maximum mass exceeds 2 500 kilograms.'

4. Section 7 reads as follows:

'7. CONFORMITY OF PRODUCTION

7.1. Measures to ensure the conformity of production must be taken in accordance with the provisions of Article 10 of Directive 70/156/EEC.

Conformity of production is checked on the basis of the description in the type-approval certificate set out in Annex IX to this Directive.

If the authority is not satisfied with the auditing procedure of the manufacturer, then Sections 2.4.2 and 2.4.3 of Annex X to Directive 70/156/EEC are applicable.

7.1.1. If a type I test is to be carried out and a vehicle type-approval has one or several extensions, the tests will be carried out on the vehicle(s) described in the original technical file.

7.1.1.1. Checking the conformity of the vehicle for a type I test.

After selection by the authority, the manufacturer must not undertake any adjustment to the vehicles selected.

7.1.1.1.1. Three vehicles are selected at random in the series and are tested as described in Section 5.3.1 of this Annex. The deterioration factors are used in the same way. The limit values are given in Section 5.3.1.4 of this Annex.

7.1.1.1.2. If the authority is satisfied with the production standard deviation given by the manufacturer in accordance with Annex X to Directive 70/156/EEC, the tests are carried out according to Appendix 1 of this Annex.

If the authority is not satisfied with the production standard deviation given by the manufacturer in accordance with Annex X to Directive 70/156/EEC, the tests are carried out according to Appendix 2 of this Annex.

7.1.1.1.3. The production of a series is deemed to conform or not to conform on the basis of a sampling test of the vehicles once a pass decision is reached for all the pollutants or a fail decision is reached for one pollutant, according to the test criteria applied in the appropriate appendix.

When a pass decision has been reached for one pollutant, that decision will not be changed by any additional tests carried out to reach a decision for the other pollutants.

If no pass decision is reached for all the pollutants and no fail decision is reached for one pollutant, a test is carried out on another vehicle (see Figure I/7).

7.1.1.2. Notwithstanding the requirements of Section 3.1.1 of Annex III, the tests will be carried out on vehicles coming straight off the production line.

7.1.1.2.1. However, at the request of the manufacturer, the tests may be carried out on vehicles which have completed:

— a maximum of 3 000 km for vehicles equipped with a positive ignition engine,

— a maximum of 15 000 km for vehicles equipped with a compression ignition engine,

In both these cases, the running-in procedure will be conducted by the manufacturer, who must undertake not to make any adjustments to these vehicles.

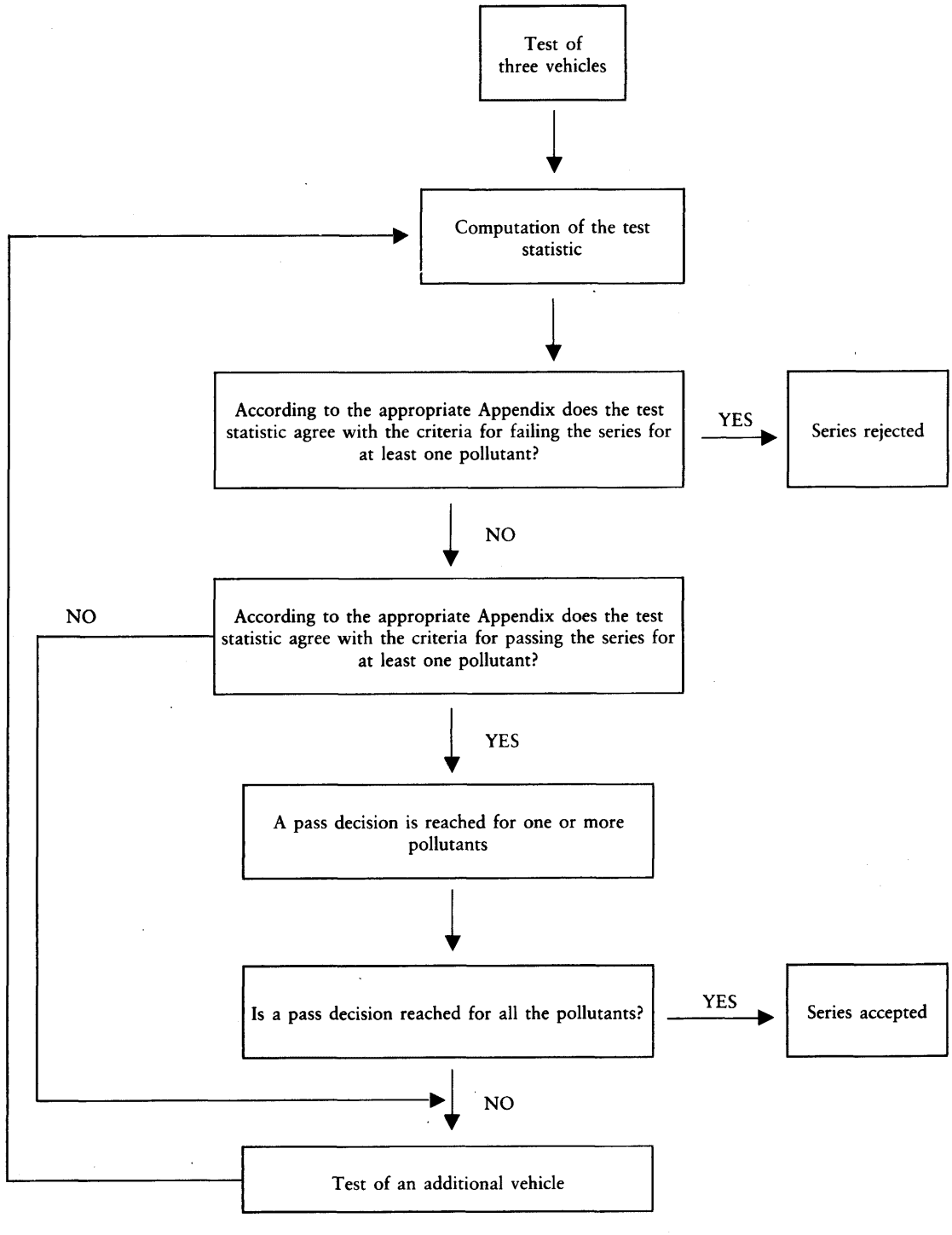

Test of three vehicles
Computation of the test statistic
According to the appropriate Appendix does the test statistic agree with the criteria for failing the series for at least one pollutant?
YES
Series rejected
NO
According to the appropriate Appendix does the test statistic agree with the criteria for passing the series for at least one pollutant?
NO
YES
A pass decision is reached for one or more pollutants
Is a pass decision reached for all the pollutants?
YES
Series accepted
NO
Test of an additional vehicle

Figure I.7

7.1.1.2.2. If the manufacturer wishes to run in the vehicles, ("x" km, where $x \leq 3\,000$ km for vehicles equipped with a positive ignition engine and $x \leq 15\,000$ km for vehicles equipped with a compression ignition engine), the procedure will be as follows:

— the pollutant emissions (type I) will be measured at zero and at "x" km on the first tested vehicle,

— the evolution coefficient of the emissions between zero and "x" km will be calculated for each of the pollutants:

$$\frac{\text{Emissions "x" km}}{\text{Emissions zero km}}$$

This may be less than 1,

— the other vehicles will not be run in, but their zero km emissions will be multiplied by the evolution coefficient.

In this case, the values to be taken will be:

— the values at 'x' km for the first vehicle,

— the values at zero km multiplied by the evolution coefficient for the other vehicles.

7.1.1.2.3. All these tests may be conducted with commercial fuel. However, at the manufacturer's request, the reference fuels described in Annex VIII may be used.

7.1.2. If a type III test is to be carried out, it must be conducted on all vehicles selected for the type I COP test (7.1.1.1.1). The conditions laid down in 5.3.3.2 must be complied with.

7.1.3. If a type IV test is to be carried out, it must be conducted in accordance with Section 7 of Annex VI.'

Appendix 1

1. This Appendix describes the procedure to be used to verify the production conformity for the type I test when the manufacturer's production standard deviation is satisfactory.

2. With a minimum sample size of 3, the sampling procedure is set so that the probability of a lot passing a test with 40 % of the production defective is 0,95 (producer's risk = 5 %) while the probability of a lot being accepted with 65 % of the production defective is 0,1 (consumer's risk = 10 %).

3. For each of the pollutants given in Section 5.3.1.4 of Annex I, the following procedure is used (see Figure I.7).

   Taking:

   L = the natural logarithm of the limit value for the pollutant,

   x_i = the natural logarithm of the measurement for the i-th vehicle of the sample,

   s = an estimate of the production standard deviation (after taking the natural logarithm of the measurements),

   n = the current sample number.

4. Compute for the sample the test statistic quantifying the sum of the standard deviations from the limit and defined as:

$$\frac{1}{s}\sum_{i=1}^{n}(L - x_i)$$

5. Then:

   — if the test statistic is greater than the pass decision number for the sample size given in Table (I.1.5), the pollutant is passed,

   — if the test statistic is less than the fail decision number for the sample size given in Table (I.1.5), the pollutant is failed; otherwise, an additional vehicle is tested according to Section 7.1.1.1 of Annex I and the calculation reapplied to the sample with a sample size one unit greater.

TABLE I.1.5

Cumulative number of tested vehicles (current sample size)	Pass decision threshold	Fail decision threshold
3	3,327	-4,724
4	3,261	-4,790
5	3,195	-4,856
6	3,129	-4,922
7	3,063	-4,988
8	2,997	-5,054
9	2,931	-5,120
10	2,865	-5,185
11	2,799	-5,251
12	2,733	-5,317
13	2,667	-5,383
14	2,601	-5,449
15	2,535	-5,515
16	2,469	-5,581
17	2,403	-5,647
18	2,337	-5,713
19	2,271	-5,779
20	2,205	-5,845
21	2,139	-5,911
22	2,073	-5,977
23	2,007	-6,043
24	1,941	-6,109
25	1,875	-6,175
26	1,809	-6,241
27	1,743	-6,307
28	1,677	-6,373
29	1,611	-6,439
30	1,545	-6,505
31	1,479	-6,571
32	-2,112	-2,112

Appendix 2

1. This Appendix describes the procedure to be used to verify the production conformity requirements for the type I test when the manufacturer's evidence of production standard deviation is either unsatisfactory or unavailable.

2. With a minimum sample size of 3, the sampling procedure is set so that the probability of a lot passing a test with 40 % of the production defective is 0,95 (producer's risk = 5 %) while the probability of a lot being accepted with 65 % of the production defective is 0,1 (consumer's risk = 10 %).

3. The measurements of the pollutants given in Section 5.3.1.4 of Annex I are considered to be log normally distributed and must first be transformed by taking their natural logarithms. Let m_0 and m denote the minimum and maximum sample sizes respectively (m_0 = 3 and m = 32) and let n denote the current sample number.

4. If the natural logarithms of the measurements in the series are $x_1, x_2, \ldots, x_j$ and L is the natural logarithm of the limit value for the pollutant, then define:

$$d_j = x_j - L$$

$$\bar{d}_n = \frac{1}{n} \sum_{j=1}^{n} d_j$$

$$v_n^2 = \frac{1}{n} \sum_{j=1}^{n} (d_j - \bar{d}_n)^2$$

5. Table I.2.5 shows values of the pass (A_n) and fail (B_n) decision numbers against current sample number. The test statistic is the ratio $\bar{d}_n/v_n$ and must be used to determine whether the series has passed or failed as follows:

   For $m_0 \leq n \leq m$:

   — pass the series if $\bar{d}_n/v_n \leq A_n$,

   — fail the series if $\bar{d}_n/v_n \geq B_n$,

   — take another measurement if $A_n < \bar{d}_n/v_n < B_n$.

6. *Remarks*

   The following recursive formulae are useful for computing successive values of the test statistic:

$$\bar{d}_n = \left(1 - \frac{1}{n}\right)\bar{d}_{n-1} + \frac{1}{n}d_n$$

$$v_n^2 = \left(1 - \frac{1}{n}\right) v_{n-1}^2 + \frac{(\bar{d}_n - d_n)^2}{n-1}$$

$$(n = 2, 3, \ldots; \bar{d}_1 = d_1; v_1 = 0)$$

TABLE I.2.5

Minimum sample size = 3

Sample size n	Pass decision threshold A_n	Fail decision threshold B_n
3	-0,80381	16,64743
4	-0,76339	7,68627
5	-0,72982	4,67136
6	-0,69962	3,25573
7	-0,67129	2,45431
8	-0,64406	1,94369
9	-0,61750	1,59105
10	-0,59135	1,33295
11	-0,56542	1,13566
12	-0,53960	0,97970
13	-0,51379	0,85307
14	-0,48791	0,74801
15	-0,46191	0,65928
16	-0,43573	0,58321
17	-0,40933	0,51718
18	-0,38266	0,45922
19	-0,35570	0,40788
20	-0,32840	0,36203
21	-0,30072	0,32078
22	-0,27263	0,28343
23	-0,24410	0,24943
24	-0,21509	0,21831
25	-0,18557	0,18970
26	-0,15550	0,16328
27	-0,12483	0,13880
28	-0,09354	0,11603
29	-0,06159	0,09480
30	-0,02892	0,07493
31	0,00449	0,05629
32	0,03876	0,03876