II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 29 April 1991

on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity

(91/263/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In cooperation with the European Parliament (2),

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

Whereas Directive 86/361/EEC (4) introduced the initial stage of the mutual recognition of type approval for telecommunications terminal equipment and in particular in its Article 9 envisaged a further stage for full mutual recognition of type approval for terminal equipment;

Whereas Decision 87/95/EEC (5) sets out the measures to be implemented for the promotion of standardization in Europe and the preparation and implementation of standards in the field of information technology and telecommunications;

Whereas the Commission has issued a Green Paper on the development of the common market for telecommunications services and equipment proposing to acclerate the introduction of the full mutual recognition of type approval as the measure vital for the development of a competitive Community-wide terminal market;

Whereas the Council, in its resolution of 30 June 1988 on the development of the common market for telecommunications services and equipment up to 1992 (6), considers as a major goal in the telecommunications policy the full mutual recognition of type approval for terminal equipment on the basis of the rapid development of common European conformity specifications;

Whereas the terminal equipment sector is a vital part of the telecommunications industry, which is one of the industrial mainstays of the economy in the Community;

Whereas harmonizing conditions for the placing on the market of telecommunications terminal equipment will create the conditions for an open and unified market;

(1) OJ No C 211, 17. 8. 1989, p. 12.
(2) OJ No C 113, 7. 5. 1990; and OJ No C 19, 28. 1. 1991, p. 88.
(3) OJ No C 329, 30. 12. 1989, p. 1
(4) OJ No L 217, 5. 8. 1986, p. 21.
(5) OJ No L 36, 7. 2. 1987, p. 31.
(6) OJ No C 257, 4. 10. 1988, p. 1.

Whereas real, comparable access to third country markets for European manufacturers should preferably the achieved through multilateral negotiations within GATT, although bilateral talks between the Community and third countries may also contribute to this process;

Whereas the Council resulution of 7 May 1985 provides for a new approach to technical harmonization and standards (1);

Whereas the scope of the Directive must be based on a general definition of the term 'terminal equipment' so as to allow the technical development of products;

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

Whereas the essential requirements must be satisfied in order to safeguard the general interest; whereas these requirements must be applied with discernment to take account of the state of the art at the time of manufacture and economic requirements;

Whereas Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (2) and Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (3), as amended by Directive 88/182/EEC (4), are applicable, *inter alia,* to the fields of telecommunications and information technology;

Whereas Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility (5) is applicable, *inter alia,* to the fields of telecommunications and information technology; whereas it is, however, appropriate to delete the provisions of Directive 89/336/EEC in so far as they refer to the definition of telecommunications terminal equipment and to the conformity assessment procedures to be applied for such equipment;

Whereas in respect of the essential requirements and in order to help manufacturers to prove conformity to those requirements, it is desirable to have standards harmonized at European level to safeguard the general interest in the design and manufacture of terminal equipment and in order to allow checks of conformity to those requirements; whereas these standards harmonized at European level are drawn up by private-law bodies and must retain their non-binding status; whereas for this purpose the Europen Committee for Standardization (CEN), the European Commttee for Electrotechnical Standardization (Cenelec) and the European Telecommunications Standards Institute (ETSI), are the bodies recognized as competent to adopt harmonized standards; whereas, within the meaning of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by one of these bodies, on the basis of a remit from the Commission in accordance with the provision of Directive 83/189/EEC, and in accordance with the general guidelines referred to above;

Whereas in respect of the essential requirements related to interworking with public telecommunications networks, and in cases where it is justified, through such networks, it is in general not possible to comply with such requirements other than by the application of unique technical solutions; whereas such solutions shall therefore be mandatory;

Whereas the proposals for common technical regulations are, as a general rule, drawn up on the basis of harmonized standards, and, in order to ensure an appropriate technical coordination on a broad European basis, of additional consultations, in particular with the Telecommunications Regulations Application Committee (TRAC) set up by members of the European Conference of Postal and Telecommunications Administrations (CEPT) in a memorandum of understanding signed in 1991;

Whereas it is essential to ensure that notified bodies are of a high standard throughout the Community and meet minimum criteria of competence, impartiality and financial and other independence from clients;

Whereas it is appropriate to set up a committee bringing together parties directly concerned with the implementation

(1) OJ No C 136, 4. 6. 1985, p. 1.
(2) OJ No L 77, 26. 3. 1973, p. 29.
(3) OJ No L 109, 26. 4. 1983, p. 8.
(4) OJ No L 81, 26. 3. 1988, p. 75.
(5) OJ No L 139, 23. 5. 1989, p. 19.

of this Directive, in particular the national bodies designated for certifying conformity, to assist the Commission in executing the tasks entrusted to it by this Directive; whereas representatives from the telecommunication organizations, users, consumers, manufacturers, service providers and the trade unions should have the right to be consulted;

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

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

Whereas measures must be adopted with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER 1

Scope, placing on the market and free circulation

Article 1

1. This Directive shall apply to terminal equipment.

2. For the purpose of this Directive:

— 'public telecommunications network' means the public telecommunications infrastructure which permits the conveyance of signals between defined network termination points by wire, by microwave, by optical means or by other electromagnetic means,

— 'terminal equipment' means equipment intended to be connected to the public telecommunications network, i.e.:

(a) to be connected directly to the termination of a public telecommunications network;

or

(b) to interwork with a public telecommunications network being connected directly or indirectly to the termination of a public telecommunications network

in order to send, process or receive information.

The system of connection may be wire, radio, optical or other electromagnetic system,

— 'technical specification' means 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 terminology, symbols, testing and test methods, packaging, marking and labelling,

— 'standard' means a technical specification adopted by a recognized standards body for repeated or continuous application, compliance with which is not compulsory.

3. The intended purpose of the equipment, shall be declared by the manufacturer or supplier of the equipment. However, terminal equipment within the meaning of paragraph 2 which makes use of a system of communication employing the radio frequency spectrum is presumed to be intended for connection to the public telecommunications network.

Article 2

1. Notwithstanding Article 1, equipment which is capable of being connected to the public telecommunications network, but is not intended for such a purpose, shall be accompanied by a manufacturer's or supplier's declaration, the model of which is to be found in Annex VIII and by the operating manual. At the time of placing the equipment on the market for the first time, a copy of such documentation shall be transmitted to the notified body referred to in Article 10 (1) in the Member State where this first placing on the market takes place. In addition, such equipment shall be subject to the provisions of Article 11 (4).

2. The manufacturer or supplier shall be prepared to justify once, at the request of any notified body referred to in Article 10 (1), the intended purpose of such equipment on the basis of its relevant technical characteristics, its functions and indications of the market segment it is intended for.

Article 3

1. Member States shall take all appropriate measures to ensure that terminal equipment may be placed on the market and put into service only if it complies with the requirements laid down in this Directive when it is properly installed and maintained and used for its intended purpose.

2. Member States shall also take all appropriate measures to ensure that equipment referred to in Article 2 may be placed and allowed to remain on the market only if it complies with the requirements laid down by this Directive for this equipment and may not be connected to the public telecommunications network within the meaning of Article 1 (2).

3. Member States shall also take all appropriate measures to ensure that terminal equipment or equipment referred to in Article 2 is disconnected from the public telecommunications network if it is not used for its intended purpose. Member States may moreover take all appropriate measures, according to their national laws, to prevent connection to the public telecommunications network of terminal equipment that is not used in conformity with its intended purpose.

Article 4

Terminal equipment shall satisfy the following essential requirements:

(a) user safety, in so far as this requirement is not covered by Directive 73/23/EEC;

(b) safety of employees of public telecommunications networks operators, in so far as this requirement is not covered by Directive 73/23/EEC;

(c) electromagnetic compatibility requirements in so far as they are specific to terminal equipment;

(d) protection of the public telecommunications network from harm;

(e) effective use of the radio frequency spectrum, where appropriate;

(f) interworking of terminal equipment with public telecommunications network equipment for the purpose of establishing, modifying, charging for, holding and clearing real or virtual connection;

(g) interworking of terminal equipment via the public telecommunications network, in justified cases.

The cases where terminal equipment supports:

(i) reserved service according to Community law;

or

(ii) a service which the Council has decided that there should be Community-wide availability,

are considered as justified cases and the requirements concerning this interworking are determined in accordance with the procedure provided for in Article 14.

In addition, after consultation of representatives of the bodies referred to in Article 13 (3) and taking due account of the result of these consultations, the Commission may propose that this essential requirement is recognized as being justified for other terminal equipment in accordance with the procedure provided for in Article 14.

Article 5

Member States shall not impede the placing on the market and the free circulation and use on their territory of terminal equipment which complies with the provisions of this Directive.

Article 6

1. Member States shall presume compliance with the essential requirements referred to in Article 4 (a) and (b) in respect of terminal equipment which is in conformity with the national standards implementing the relevant harmonized standards, the references of which have been published in the *Official Journal of the European Communities*. Member States shall publish the references of such national standards.

2. The Commission shall, in accordance with the procedure laid down in Article 14, adopt:

— as a first step, the measure identifying the type of terminal equipment for which a common technical regulation is required, as well as the associated scope statement for that regulation, with a view to its transmission to the relevant standardization bodies,

— ás a second step, once they have been prepared by the relevant standardization bodies, the corresponding harmonized standards, or parts thereof, implementing the essential requirements referred to in Article 4 (c) to (g) which shall be transformed into common technical regulations, compliance with which shall be mandatory and the reference of which shall be published in the *Official Journal of the European Communities*.

Article 7

Where a Member State or the Commission considers that the harmonized standards referred to in Article 6 exceed or

do not entirely meet the essential requirements referred to in Article 4, the Commission or the Member State concerned shall bring the matter before the Committee referred to in Article 13, hereinafter referred to as 'the Committee', giving the reasons therefor. The Committee shall deliver an opinion as soon as possible.

In the light of the Committee's opinion and after consultation of the standing Committee set up by Directive 83/189/EEC, the Commission shall inform the Member States whether or not it is necessary to withdraw reference to those standards and any related technical regulations from the *Official Journal of the European Communities* and shall take the necessary steps to correct the shortcomings noted in the standards.

Article 8

1. Where a Member State finds that terminal equipment bearing the markings under the provision laid down in Chapter III does not comply with the relevant essential requirements when properly used in accordance with the purpose intended by the manufacturer, it shall take all appropriate measures to withdraw such products from the market or to prohibit or restrict their being placed on the market.

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

(a) incorrect application of the harmonized standards or common technical regulations referred to in Article 6;

(b) shortcomings in the harmonized standards or common technical regulations referred to in Article 6 themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified it shall immediately so inform the Member State that took the action and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the harmonized standards or common technical regulations, the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measure intends to maintain them, and shall initiate the procedure referred to in Article 7.

3. Where terminal equipment which does not comply with the relevant essential requirements bears the CE mark the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall keep the Member State informed of the progress and outcome of this procedure

CHAPTER II

Conformity assessment

Article 9

1. According to the choice of the manufacturer or his authorized representative established within the Community, terminal equipment shall be subject to either the EC type-examination, as described in Annex I, or to the EC delcaration of conformity, as described in Annex IV.

2. An EC type-examination as described in Annex I shall be accompanied by a declaration issued according to the EC declaration of conformity to type procedure as described in Annex II or Annex III.

3. The records and correspondence relating to the procedure referred to in this Article shall be in an official language of the Member State where the said procedure will be carried out, or in a language acceptable to the notified body involved

4. Article 10 (4) of Directive 89/336/EEC is hereby deleted.

Article 10

1. Member States shall notify to the Commission the bodies established in the Community and their identifying symbols, which they have designated for carrying out the certification, product checks, and associated surveillance tasks pertaining to the procedures referred to in Article 9. Member States shall apply the minimum criteria, set out in Annex V, for the designation of such bodies. Bodies that satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the criteria set out in Annex V.

2. Member States shall inform the Commission of test laboratories established in the Community which they have designated for carrying out tests pertaining to the procedures referred to in Article 9. Notified bodies shall apply the criteria fixed by the appropriate parts of the

relevant harmonized standards for the designation of such laboratories.

3. The Commission shall publish the list of notified bodies and the list of test laboratories together with the tasks for which they have been designated in the *Official Journal of the European Communities* and shall ensure that this list is kept up to date.

4. A Member State has designated a notified body or a test laboratory under paragraph 1 or 2 shall annul the designation if the notified body or the test laboratory no longer meets the relevant cirteria for designation. It shall immediately inform the other Member States and the Commission accordingly and withdraw the notification. Where a Member State or the Commission considers that a notified body or a test laboratory designated by a Member State does not meet the relevant criteria the matter shall be brought before the Committee referred to in Article 13, which shall give its opinion within three months; in the light of the Committee's opinion the Commission shall inform the Member State concerned of any changes needed if that notified body or test laboratory is to retain its recognized status.

5. In order to facilitate the determination of conformity of terminal equipment with technical regulations and standards, the notified bodies shall recognize documentation issued by third country relevant bodies, when agreements between the Community and the third country concerned have been concluded on the basis of a mutually satisfactory understanding.

6. The notified bodies referred to in Article 10 (1), when issuing an EC type-examination certificate as referred to in Annex I, followed by the appropriate document referred to in Annex II or III, or a decision on quality assurance assessment as referred to in Annex IV, issue at the same time an administrative approval for the connection of the concerned terminal equipment to the public telecommunications network.

CHAPTER III

CE mark of conformity and inscriptions

Article 11

1. The marking of terminal equipment complying with this Directive shall consist of the CE mark consisting of the symbol 'CE', followed by the identifying symbol of the notified body responsible and a symbol indicating that the equipment is intended and is suitable to be connected to the public telecommunications network. The CE mark and these two symbols are shown in Annex VI.

2. The affixing of marks which are likely to be confused with the marks of conformity specified in Annex VI shall be prohibited.

3. Terminal equipment shall be identified by the manufacturer by means of type, batch and/or serial numbers and by the name of the manufacturer and/or supplier responsible for placing it on the market.

4. Equipment manufacturers or suppliers who place on the market equipment as referred to in Article 2 shall affix the symbol specified in Annex VII in such a way that it follows the CE mark and visually forms an integral part of the total marking.

Article 12

Where it is established that the marking referred to in Article 11 (1) has been affixed to terminal equipment which:

— does not conform to an approved type,

— conforms to an approved type which does not meet the essential requirements applicable to it,

or, where the manufacturer has failed to fulfil his obligations under the relevant EC declaration of conformity,

the notified body shall withdraw the EC type-examination certificate referred to in Annex I, the EC quality system approval decision referred to in Annex III or the EC quality system approval decision as referred to in Annex IV, notwithstanding any decisions taken under Article 8.

CHAPTER IV

Committee

Article 13

1. The Commission shall be assisted by a Committee of an advisory nature composed of the representatives of the Member States and chaired by the representative of the Commission. The Committee shall be called the Approvals Committee for Terminal Equipment (ACTE).

2. The representative of the Commission shall submit to the Committee a draft of the measure 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.

3. The Commission will periodically consult the representative of the telecommunications organizations, the consumers, the manufacturers, the service providers and trade unions and will inform the Committee on the outcome of such consultations, with a view to taking due account of the outcome.

Article 14

1. Notwithstanding Article 13 (1) and (2), the following procedure shall apply for matters covered by Articles 4 (g) and 6 (2).

2. The representative of the Commission shall submit to the Committee established in Article 13 a draft of the measures to be taken as referred to in Articles 4 (g) and 6 (2). The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

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

4. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measure to be taken. The Council shall act by qualified majority. If, within three months from the date of referral to it, the Council has not acted, the proposed measure shall be adopted by the Commission.

CHAPTER V

Final and transitional provisions

Article 15

The Commission shall draw up every second year a report on the implementation of this Directive, including progress on drawing up the relevant harmonized standards and on transforming them into technical regulations, as well as any problems that have arisen in the course of implementation. The report will also outline the activities of the Committee, and assess progress in achieving an open competitive market for termimal equipment at Community level consistent with the essential requirements referred to in Article 4.

Article 16

1. Directive 86/361/EEC is hereby repealed, with effect from 6 November 1992. References made to the repealed Directive shall be construed as being made to this Directive.

2. Notwithstanding paragraph 1 and Article 10 (2), Member States may designate as test laboratories such bodies which have been notified under Directive 86/361/EEC, without applying the criteria of Article 10 (2) for a period of 18 months after the effective date of repeal of Directive 86/361/EEC, it being understood that these laboratories will continue to observe the criteria for which they were notified.

3. Notwithstanding paragraph 1, any type approval granted by Member States in accordance with Directive 86/361/EEC may remain valid under the legislation of the Member States within the criteria of validity appropriate to the original approval.

4. Notwithstanding paragraph 1, measures adopted under Directive 86/361/EEC shall be submitted to the Committee under the procedure of Article 14 for possible transposition into common technical regulations.

Article 17

1. Member States shall take the measure necessary to comply with this Directive not later than 6 November 1992. They shall fortwith inform the Commission thereof.

When Member States adopt these measure, 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 inform the Commission of the main provisions of domestic law which they adopt in the field governed by this Directive.

Article 18

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1991.

For the Council

The President

R. GOEBBELS

ANNEX I

EC TYPE-EXAMINATION

1. EC type-examination is that part of the procedure whereby a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of the Directive that apply to it.

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' (1). 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 essential requirements of the Directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the product.

For example, the documentation shall contain as far as is relevant for assessment:

— a general type-description sufficient to identify the product preferably by provision of photographs,

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

— descriptions and explanations necessary for the understanding of said drawings and lists and the operation of the product,

— a list of the standards referred to in Article 6, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive when the standards referred to in Article 6 have not been applied,

— results of examinations carried out, etc.,

— test reports,

— proposed user information or handbook.

4. The notified body shall:

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with it and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 6 (1), as well as the components 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 which are specified in Article 4 (a) and (b);

(1) A type may cover several versions of the product provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product.

4.3. perform, or have performed, the appropriate examinations and necessary tests to check that the type meets the relevant common technical regulations specified in Article 6 (2);

4.4. agree with the applicant on the location where the examinations and necessary tests are to 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, conditions for its validity 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.

6. The applicant shall inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional 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 request copies of the EC tpye-examination certificates and/or their additions. The Annexes to the certificate shall be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorized representative 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 product has been 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 II

CONFORMITY TO TYPE

1. Conformity to type is that part of the procedure whereby the manufacturer or his authorized representative established within the Community 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 that applies to them. The manufacturer shall affix the marks referred to in Article 11 (1) to each product and draw up a written declaration of conformity to type.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate and with the requirements of the Directive that apply to them.

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 product has been manufactured.

   Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the declaration of conforming to type available shall be the responsibility of the preson who places the product on the Community market.

4. A notified body chosen by the manufacturer shall carry out, or have carried out, product checks at random intervals. An adequate sample of the final products, which may be taken on site by the notified body or on its behalf, shall be examined and appropriate tests shall be carried out to check the conformity of products with the relevant requirements of the Directive. In those cases where one or more of the products checked do not conform, the notified body shall take appropriate measures.

ANNEX III

PRODUCTION QUALITY ASSURANCE

1. Production quality assurance is 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 that apply to them. The manufacturer shall affix the marks referred to in Article 11 (1) to each product and draw up a written declaration of conformity to type.

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in point 3 and shall be subject to monitoring as specified in point 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 products concerned.

The application shall inlcude:

— all relevant information for the product category envisaged,

— the documentation concerning the quality system,

— if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

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

All the element, 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 the quality programmes, plan, 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 manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests 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, qualification reports of the personnel concerned, etc.,

— the means to monitor the achievement of the required product 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 point 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (1).

The auditing team shall have at least one member with experience of evaluation in the product 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.

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(1) This harmonized standard will be EN 29002, supplemented, if necessary, to take into account the specific nature of the procedure for which it is implemented.

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

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed 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 point 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 allow the notified body access for inspection purpose to the locations of manufacture, inspection and testing, and storage and shall provide it with all necessary information, in particular:

— the quality system documentation,

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

4.3. The notified body shall carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

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

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

— the documentation referred to in the second indent of point 3.1.,

— the updating referred to in the second paragraph of point 3.4.,

— the decisions and reports from the notified body which are referred to in the final paragraph of points 3.4., 4.3. and 4.4.

6. Each notified body referred to in Article 10 (1) shall make available to the other notified bodies referred to in that Article the relevant information concerning the quality system approvals issued and withdrawn.

ANNEX IV

FULL QUALITY ASSURANCE

1. Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer shall affix the marks referred to in Article 11 (1) to each product and draw up a written declaration of conformity.

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include:

— all relevant information for the products envisaged,

— the quality system's documentation.

3.2. The quality system shall ensure compliance of the products with the requirements of the Directive that 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. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as a 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 design and product quality,

— the technical specifications, including the harmonized standards and technical regulations as well as relevant test specifications that will be applied and, where the standards referred to in Article 6 (1) will not be applied in full, the means will be used to ensure that the essential requirements of the Directive that apply to the products will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests will be carried out before, during and after manufacture, and the frequency with which they will be carried out; as well as the results of the tests carried out befor manufacture where appropriate,

— the means by which it is ensured that the test and examination facilities respect the appropriate requirements for the performance of the necessary test,

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

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

3.3. The notified body shall asses the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard (1).

(1) This harmonized standard shall be EN 29001, supplemented, if necessary, to take into account the specific nature of the products for which it is implemented.

The notified body shall assess in particular whether the quality control system ensures conformity of the products with the requirements of the Directive in the light of the relevant documentation supplied in respect of points 3.1. and 3.2. including, where relevant, test results supplied by the manufacturer.

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The evaluation 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 fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed 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 point 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. **EC 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 allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.

— the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them 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 product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of point 3.1.,

— the updating referred to in the second paragraph of point 3.4.,

— the decisions and reports from the notified body which are referred to in the final paragraph of points 3.4., 4.3. and 4.4.

6. Each notified body referred to in Article 10 (1) shall make available to the other notified bodies referred to in that Article the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

ANNEX V

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN DESIGNATING NOTIFIED BODIES IN ACCORDANCE WITH ARTICLE 10 (1)

1. The notified body, its director and the staff responsible for carrying out the tasks for which the notified body has been designated shall not be a designer, manufacturer, supplier or installer of terminal equipment, or a network operator or a service provider, nor the authorized representative of any of such parties. They shall not become directly involved in the design, construction, marketing or maintenance of terminal equipment, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its staff must carry out the tasks for which the notified body has been designated with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of any inspection, especially from persons or groups of persons with an interest in such results.

3. The notified body must have at its disposal the necessary staff and facilities to enable it to perform properly the administrative and technical work associated with the tasks for which it has been designated.

4. The staff responsible for inspections must have:

   — sound technical and professional training,

   — satisfactory knowledge of the requirements of the tests or inspections that are carried out and adequate experience of such tests or inspections,

   — the ability to draw up the certificates, records and reports required to authenticate the performance of the inspections.

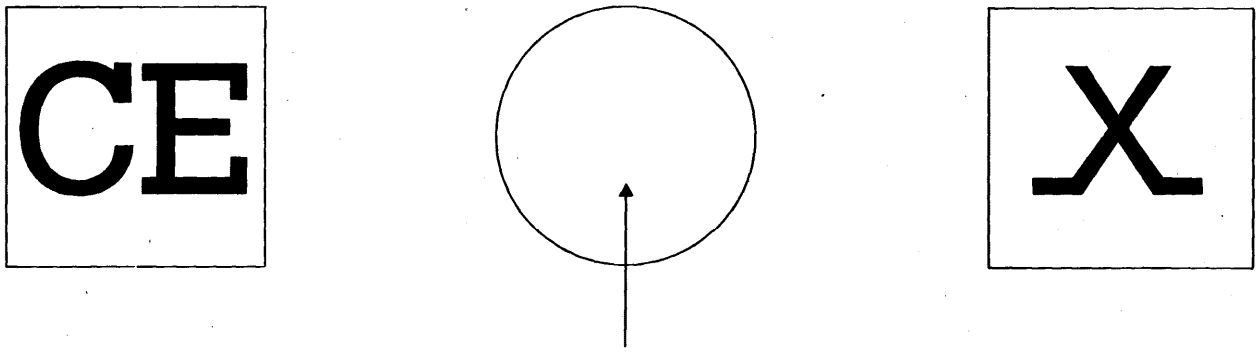
5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such inspections.

6. The notified body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible.

7. The staff of the notified body is 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 thereto.

ANNEX VI

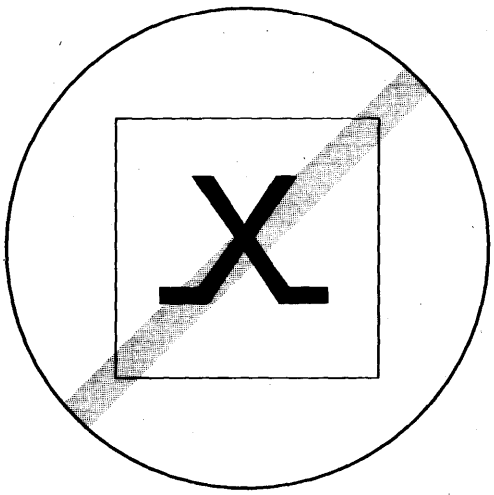
MARKING FOR TERMINAL EQUIPMENT REFERRED TO IN ARTICLE 11 (1)



Symbol of the notified body

ANNEX VII

MARKING FOR EQUIPMENT REFERRED TO IN ARTICLE 11 (4)



ANNEX VIII

MODEL OF A DECLARATION REFERRED TO IN ARTICLE 2 (1)

The manufacturer/supplier (1) .....

.....

.....

Declares that (2).....

.....

is not intended to be connected to a public telecommunications network.

The connection of such equipment to a public telecommunications network in the Community Member State will be in violation of the national law implementing Directive 91/263/EEC on the approximation of the laws of the Member States concerning telecommunication terminal equipment, including the mutual recognition of their conformity.

DATE, PLACE AND SIGNATURE

(1) Name and address.
(2) Equipment identification.