



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.12.1998
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97/0149 (COD)

OPINION OF THE COMMISSION

pursuant to Article 189 b (2) (d) of the EC Treaty,
on the European Parliament's amendments
to the Council's common position regarding the

proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

ON CONNECTED TELECOMMUNICATIONS EQUIPMENT AND THE MUTUAL RECOGNITION OF

THE CONFORMITY OF EQUIPMENT

AMENDING THE PROPOSAL OF THE COMMISSION

pursuant to Article 189 a (2) of the EC Treaty

SUMMARY

On 6 October 1998, the European Parliament adopted a Decision in which it amended the common position established by the Council with a view to the adoption of a European Parliament and Council Directive on radio and telecommunications terminal equipment and the mutual recognition of their conformity (C4-0342/98 - 97/0149(COD)).

The Directive will create the single market for telecommunications terminal and radio equipment and proposes a substantial relaxation of the regulations governing the placing on the market, the free movement and the putting into service of such equipment. The Directive will replace two Council Directives (91/263/EEC¹ - telecommunications terminal equipment and 93/97/EEC² - satellite earth station equipment), simplify the application of two other Council Directives (93/68/EEC³ - conformity marking and 89/336/EEC⁴ - electromagnetic compatibility) and replace a large number of national regulations.

The issues of concern to the European Parliament are:

- Formal amendments: 1, 2, 3, 6, 8
- Clarification of ambiguities that could lead to misinterpretations detrimental to consumers or manufacturers: 4, 11, 12, 16
- Better definition of essential requirements and procedural aspects to ensure the proper implementation of the latter and deal with emergency problems: 5, 7
- More transparency in the implementation of the Directive, particularly concerning the safeguards and the operation of the TCAM Committee: 9, 10, 18
- Prospective issues for the future assessment and revision of the Directive: 14

Acceptable	All but 1
Acceptable in part or in principle	none
Not acceptable	1

¹ OJ No L 128, 23.5.1991, p. 1.

² OJ No L 290, 24.11.1993, p. 1.

³ OJ No L 220, 30.8.1993, p. 1.

⁴ OJ No L 139, 23.5.1989, p. 19.

EXPLANATORY MEMORANDUM

The Commission hereby presents its opinion on the amendments proposed by the European Parliament as well as a modified proposal for a European Parliament and Council Directive on radio and telecommunications terminal equipment and the mutual recognition of their conformity. The modified proposal incorporates those amendments proposed by the European Parliament in Second Reading which were accepted by the Commission.

INTRODUCTION

a) Background

The Commission adopted its proposal on 4 June 1997 and it was formally transmitted to the EP and the Council on 6 June 1997⁵.

The Economic and Social Committee gave a favourable Opinion on 10 December 1997. The European Parliament adopted a favourable Resolution at its First Reading on 29 January 1998 and proposed 23 amendments to the Commission proposal⁶.

The Council adopted a Common Position for a European Parliament and Council Directive on radio and telecommunications terminal equipment and the mutual recognition of their conformity on 6 June 1998⁷.

b) Purpose of the Directive

The Directive will create the single market for telecommunications terminal and radio equipment and proposes a substantial relaxation of the regulations governing the placing on the market, the free movement and the putting into service of such equipment. The Directive will replace two Council Directives (91/263/EEC⁸ - telecommunications terminal equipment and 93/97/EEC⁹ - satellite earth station equipment), simplify the application of two other Council Directives (93/68/EEC¹⁰ - conformity marking and 89/336/EEC¹¹ - electromagnetic compatibility) and replace a large number of national regulations.

The major elements of the new Directive are:

- Enlargement of the range of equipment covered with the inclusion of radio equipment;

⁵ OJ C 248, 14/08/1997 p. 4

⁶ A4-0023/98, PV 29-01-98

⁷ OJ C 227, 20/07/98 p.37

⁸ OJ No L 128, 23.5.1991, p. 1.

⁹ OJ No L 290, 24.11.1993, p. 1.

¹⁰ OJ No L 220, 30.8.1993, p. 1.

¹¹ OJ No L 139, 23.5.1989, p. 19.

- A set of new definitions which will make the Directive valid well into the future by taking into account the liberalisation of infrastructures and competition between operators;
- The development of the concept of essential requirements specific to telecommunications to take into account technological trends;
- A flexible decision-making process whereby future network infrastructures and systems can be readily covered;
- A less onerous conformity assessment regime based upon the principle of manufacturer's declarations.

The Directive complements other legislative developments in telecommunications and is a response to the inevitable changes to the radio and telecommunications terminal equipment market caused by the liberalisation of the telecommunications infrastructures and services.

EP AMENDMENTS ACCEPTED BY THE COMMISSION

Of the 15 amendments adopted by the European Parliament at Second Reading, the Commission accepted 14 in full:

Amendments accepted in full	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 16, 18
• The Commission accepts amendments 2, 3, 6 and 8 as these amendments render the legal text more coherent.	
• As regards amendments 4,11,12 and 16 the Commission agrees with the European Parliament that they correct a number of ambiguities in the text of the Common Position.	
• Amendment 5 proposes to impose requirements relating to the prevention of non-physical harm to networks only after a Decision of the Commission (deletion of 3.1.c and a new 3.3aa). This approach is supported. The risk is deemed low and general regulation would therefore be disproportionate.	
• Amendment 7, giving operators the right to disconnect terminals without delay is clarifying the provisions of 7.4.	
• The Commission welcomes the amendments 9,10 and 18, which render the decision process, where Member States invoke safeguards more transparent.	
• The Commission can accept amendment 14 for the same reasons it accepted the amendment in first reading.	

EP AMENDMENTS NOT ACCEPTED BY THE COMMISSION

The Commission rejects amendment 1 as with deletion of article 1.5 through amendment 3 the suggested recital would not relate to a provision in the Directive.

CONCLUSIONS

The Commission has accepted 14 of the 15 amendments proposed by the European Parliament at Second Reading in whole.

In accordance with Article 189b paragraph 2(d) of the EC Treaty, the Commission delivers its opinion on the amendments proposed by the European Parliament and amends its initial proposal, incorporating these amendments.

AMENDED PROPOSAL FOR A
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE
ON CONNECTED TELECOMMUNICATIONS EQUIPMENT AND THE MUTUAL RECOGNITION OF
THE CONFORMITY OF EQUIPMENT

(PRESENTED BY THE COMMISSION PURSUANT TO ARTICLE 189 A (2) OF THE EC-TREATY)

THE EUROPEAN PARLIAMENT AND THE
COUNCIL OF THE EUROPEAN UNION,

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

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 ⁽³⁾,

- (1) Whereas the radio equipment and telecommunications terminal equipment sector is an essential part of the telecommunications market, which is a key element of the economy in the Community; whereas the Directives applicable to the telecommunications terminal equipment sector are no longer capable of accommodating the expected changes in the sector caused by new technology, market developments and network legislation;
- (2) Whereas in accordance with the principles of subsidiarity and proportionality referred to in Article 3b of the Treaty, the objective of creating an open competitive single market for telecommunications equipment cannot be sufficiently achieved by the Member States and can therefore be better achieved by the Community; whereas this Directive does not go beyond what is necessary to achieve this aim;
- (3) Whereas Member States may rely upon Article 36 of the Treaty to exclude certain classes of equipment from this Directive;
- (4) Whereas Directive 98/13/EC ⁽⁴⁾ consolidated the provisions relating to telecommunications terminal equipment and satellite earth station equipment, including measures for the mutual recognition of their conformity;
- (5) Whereas that Directive does not cover a substantial proportion of the radio equipment market;
- (6) Whereas dual-use goods are subject to the Community regime of export controls introduced by Council Regulation (EC) No 3381/94 ⁽⁵⁾;
- (7) Whereas the broad scope of this Directive requires new definitions of the expressions "radio equipment" and "telecommunications terminal equipment"; whereas a regulatory regime aimed at the development of a single market for radio equipment and telecommunications terminal equipment should permit investment, manufacture and sale to take place at the pace of technology and market developments;
- (8) Whereas, given the increasing importance of telecommunications terminal equipment and networks using radio transmission besides equipment connected through wired links, any rules governing the manufacturing, marketing and use of radio equipment and telecommunications terminal equipment should cover both classes of such equipment;
- (9) Whereas Directive 98/10/EC of the European Parliament and of the Council of 26 February 1998 on the application of open network provision (ONP) to voice telephony and on universal service for telecommunications in a competitive environment ⁽⁶⁾ calls on national regulatory authorities to ensure the publication of details of technical interface specifications for network access for the purpose of ensuring a competitive market for the supply of terminal equipment;
- (10) Whereas the objectives of 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 ⁽⁷⁾ are sufficient to cover radio equipment and telecommunications terminal equipment, but with no lower voltage limit applying;
- (11) Whereas the electromagnetic compatibility related protection requirements laid down by Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility ⁽⁸⁾ are sufficient to cover radio equipment and telecommunications terminal equipment;

(1) OJ C 248, 14.8.1997, p. 4.

(2) OJ C 73, 9.3.1998, p. 10.

(3) Opinion of the European Parliament of 29 January 1998 (A4-0023/98), Council Common Position of 8 June 1998 (OJ C 227, 20.7.1998, p. 37) and Decision of the European Parliament of 6 October 1998 (A4-0337/98, not yet published in the Official Journal).

(4) OJ L 74, 12.3.1998, p. 1.

(5) OJ L 367, 31.12.1994, p. 1.

(6) OJ L 101, 1.4.1998, p. 24.

(7) OJ L 77, 26.3.1973, p. 29. Directive as amended by Directive 93/68/EEC. (OJ L 220, 30.8.1993, p. 1).

(8) OJ L 139, 23.5.1989, p. 19. Directive as last amended by Directive 93/68/EEC.

- (12) Whereas Community law provides that obstacles to the free movement of goods within the Community, resulting from disparities in national legislation relating to the marketing of products, can only be justified where any national requirements are necessary and proportionate; whereas, therefore, the harmonization of laws must be limited to those requirements necessary to satisfy the essential requirements relating to radio equipment and telecommunications terminal equipment;
- (13) Whereas the essential requirements relevant to a class of radio equipment and telecommunications terminal equipment should depend on the nature and the needs of that class of equipment; whereas these requirements must be applied with discernment in order not to inhibit technological innovation or the meeting of the needs of a free-market economy;
- (14) Whereas care should be taken that radio equipment and telecommunications terminal equipment should not represent an avoidable hazard to health;
- (15) Whereas telecommunications are important to the well-being and employment of people with disabilities who represent a substantial and growing proportion of the population of Europe; whereas radio equipment and telecommunications terminal equipment should therefore in appropriate cases be designed in such a way that disabled people may use it without or with only minimal adaptation;
- (16) Whereas radio equipment and telecommunications terminal equipment can provide certain functions required by emergency services;
- (17) Whereas some features may have to be introduced on the radio equipment and telecommunications terminal equipment in order to prevent the infringement of personal data and privacy of the user and of the subscriber and/or the avoidance of fraud;
- (18) Whereas in some cases interworking via networks with other apparatus within the meaning of this Directive and connection with interfaces of the appropriate type throughout the Community may be necessary;
- (19) Whereas it should therefore be possible to identify and add specific essential requirements on user privacy, features for users with a disability, features for emergency services and/or features for avoidance of fraud;
- (20) Whereas it is recognized that in a competitive market, voluntary certification and marking schemes developed by consumer organizations, manufacturers, operators and other industry actors contribute to quality and are a useful means of improving consumers' confidence in telecommunications products and services; whereas Member States may support such schemes; whereas such schemes should be compatible with the competition rules of the Treaty;
- (21) Whereas unacceptable degradation of service to persons other than the user of radio equipment and telecommunications terminal equipment should be prevented; whereas manufacturers of terminals should construct equipment in a way which prevents networks from suffering harm which results in such degradation, when used under normal operating conditions; whereas network operators should construct their networks in a way that does not oblige manufacturers of terminal equipment to take disproportionate measures to prevent networks from being harmed; whereas the European Telecommunications Standards Institute (ETSI) should take due account of this objective when developing standards concerning access to public networks;
- (22) Whereas effective use of the radio spectrum should be ensured so as to avoid harmful interference; whereas the most efficient possible use, according to the state of the art, of limited resources such as the radio frequency spectrum should be encouraged;
- (23) Whereas harmonized interfaces between terminal equipment and telecommunications networks contribute to promoting competitive markets both for terminal equipment and network services;
- (24) Whereas, however, operators of public telecommunications networks should be able to define the technical characteristics of their interfaces, subject to the competition rules of the Treaty; whereas, accordingly, they should publish accurate and adequate technical specifications of such interfaces so as to enable manufacturers to design telecommunications terminal equipment which satisfies the requirements of this Directive;
- (25) Whereas, nevertheless, the competition rules of the Treaty and Commission Directive 88/301/EEC of 16 May 1988 on competition in the markets in telecommunications terminal equipment⁽⁹⁾ establish the principle of equal, transparent and non-discriminatory treatment of all technical specifications having regulatory implications; whereas therefore it is the task of the Community and the Member States, in consultation with the economic players, to ensure that the regulatory framework created by this Directive is fair;
- (26) Whereas it is the task of the European standardization organizations, notably ETSI, to ensure that harmonized standards are appropriately updated and drafted in a way which allows for unambiguous interpretation; whereas maintenance, interpretation and implementation of harmonized standards constitute very specialized areas of increasing technical complexity; whereas those tasks require the active participation of experts drawn from amongst the economic players; whereas in some circumstances it may be necessary to provide more urgent interpretation of or corrections to harmonized standards than is

(9) OJ L 131, 27.5.1988, p. 73. Directive as amended by Directive 94/46/EC (OJ L 268, 19.10.1994, p. 15).

possible through the normal procedures of the European standardization organizations operating in conformity with 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 ⁽¹⁰⁾;

- (27) Whereas it is in the public interest to have harmonized standards at European level in connection with the design and manufacture of radio equipment and telecommunications terminal equipment; whereas compliance with such harmonized standards gives rise to a presumption of conformity to the essential requirements; whereas other means of demonstrating conformity to the essential requirements are permitted;
- (28) Whereas the assignment of equipment class identifiers should draw on the expertise of CEPT/ERC and of the relevant European standards bodies in radio matters; whereas other forms of cooperation with those bodies is to be encouraged where possible;
- (29) Whereas, in order to enable the Commission to monitor market control effectively, the Member States should provide the relevant information concerning types of interfaces, inadequate or incorrectly applied harmonized standards, notified bodies and surveillance authorities;
- (30) Whereas notified bodies and surveillance authorities should exchange information on radio equipment and telecommunications terminal equipment with a view to efficient surveillance of the market; whereas such cooperation should make the utmost use of electronic means; whereas, in particular, such cooperation should enable national authorities to be informed about radio equipment placed on their market operating in frequency bands not harmonized in the Community;
- (31) Whereas manufacturers should notify Member States of their intention to place radio equipment on the market using frequency bands whose use is not harmonized throughout the Community; whereas Member States therefore need to put in place procedures for such notification; whereas such procedures should be proportionate and should not constitute a conformity assessment procedure additional to those provided for in Annexes IV or V; whereas it is desirable that those notification procedures should be harmonized and preferably implemented by electronic means and one-stop-shopping;
- (32) Whereas radio equipment and telecommunications terminal equipment which complies with the relevant essential requirements should be permitted to circulate freely; whereas such equipment should be permitted to be put into service for its intended purpose; whereas the putting into service may be subject to

authorizations on the use of the radio spectrum and the provision of the service concerned;

- (33) Whereas radio frequencies are allocated nationally and, to the extent that they have not been harmonized, remain within the exclusive competence of the Member States; whereas it is necessary to include a safeguard provision permitting Member States, in conformity with Article 36 of the Treaty, to prohibit, restrict or require the withdrawal from its market of radio equipment which has caused, or which it reasonably considers will cause, harmful interference; whereas interference with nationally allocated radio frequencies constitutes a valid ground for Member States to take safeguard measures;
- (34) Whereas manufacturers are liable for damage caused by defective apparatus according to the provisions of Council Directive 85/374/EEC ⁽¹¹⁾; whereas without prejudice to any liability on the part of the manufacturer, any person who imports apparatus into the Community for sale in the course of his business is liable according to that Directive; whereas the manufacturer, his authorized representative or the person responsible for placing the apparatus on the Community market is liable according to the rules of the law of contractual or non-contractual liability in the Member States;
- (35) Whereas the measures which are appropriate to be taken by the Member States or the Commission where apparatus declared to be compliant with the provisions of this Directive causes serious damage to a network or harmful radio interference shall be determined in accordance with the general principles of Community law, in particular, the principles of objectivity, proportionality and non-discrimination;
- (36) Whereas on 22 July 1993 the Council adopted Decision 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and the use of CE conformity marking which are intended to be used in the technical harmonization directives ⁽¹²⁾; whereas the applicable conformity assessment procedures should preferably be chosen from among the available modules laid down by that Decision;
- (37) Whereas Member States may request that notified bodies they designate and their surveillance authorities be accredited according to appropriate European standards;
- (38) Whereas it is appropriate that compliance of radio equipment and telecommunications terminal equipment with the requirements of Directives 73/23/EEC and 89/336/EEC may be demonstrated using the procedures specified in those Directives where the apparatus is within their scope; whereas, as a result, the procedure

(10) OJ L 109, 26.4.1983, p. 8. Directive as last amended by Commission Decision 96/139/EC (OJ L 32, 10.2.1996, p. 31).

(11) OJ L 210, 7.8.1985, p. 29.

(12) OJ L 220, 30.8.1993, p. 23.

provided for in Article 10(1) of Directive 89/336/EEC may be used where the application of harmonized standards gives rise to a presumption of conformity with the protection requirements; whereas the procedure provided for in Article 10(2) may be used where the manufacturer has not applied harmonized standards or where no such standards exist;

(39) Whereas Community undertakings should have effective and comparable access to third countries' markets and enjoy treatment in third countries similar to that offered in the Community to undertakings owned wholly, controlled through majority ownership or effectively controlled by nationals of the third countries concerned;

(40) Whereas it is desirable to establish a committee bringing together parties directly involved in the implementation of regulation of radio equipment and telecommunications terminal equipment, in particular the national conformity assessment bodies and national bodies responsible for market surveillance, in order to assist the Commission in achieving a harmonized and proportionate application of the provisions so as to meet the needs of the market and the public at large; whereas representatives of telecommunications operators, users, consumers, manufacturers and service providers should be consulted where appropriate;

(41) Whereas a modus vivendi between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was concluded on 20 December 1994;

(42) Whereas the Commission should keep under review the implementation and practical application of this and other relevant Directives and take steps to ensure coordination of the application of all relevant Directives in order to avoid disturbance to telecommunications equipment which affects the health of humans or is harmful to property;

(43) Whereas the functioning of this Directive should be reviewed in due course in the light of the development of the telecommunications sector and of experience gained from application of the essential requirements and the conformity assessment procedures provided for in this Directive;

(44) Whereas it is necessary to ensure that with the introduction of changes to the regulatory regime there is a smooth transition from the previous regime in order to avoid disruption to the market and legal uncertainty;

(45) Whereas this Directive replaces Directive 98/13/EC, which should accordingly be repealed; whereas Directives 73/23/EEC and 89/336/EEC will no longer apply to apparatus within the scope of this Directive, with the

exception of protection and safety requirements and certain conformity assessment procedures,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

General aspects

Article 1

Scope and aim

1. This Directive establishes a regulatory framework for the placing on the market, free movement and putting into service in the Community of radio equipment and telecommunications terminal equipment.
2. Where apparatus as defined in Article 2(a) incorporates, as an integral part, or as an accessory:
 - (a) a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽¹³⁾; or
 - (b) an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ⁽¹⁴⁾,the apparatus shall be governed by this Directive, without prejudice to the application of Directives 93/42/EEC and 90/385/EEC to medical devices and active implantable medical devices, respectively.
3. Where apparatus constitutes a component or a separate technical unit of a vehicle within the meaning of Council Directive 72/245/EEC ⁽¹⁵⁾ relating to the radio interference (electromagnetic compatibility) of vehicles or a component or a separate technical unit of a vehicle within the meaning of Article 1 of Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles ⁽¹⁶⁾, the apparatus shall be governed by this Directive without prejudice to the application of Directive 72/245/EEC or of Directive 92/61/EEC respectively.
4. This Directive shall not apply to equipment listed in Annex I.

Article 2

Definitions

For the purpose of this Directive the following definitions shall apply:

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- (13) OJ L 169, 12.7.1993, p. 1.
 - (14) OJ L 189, 20.7.1990, p. 17. Directive as amended by Directive 93/68/EC (OJ L 220, 30.8.1993, p. 1).
 - (15) OJ L 152, 6.7.1972, p. 15. Directive as last amended by Commission Directive 95/54/EC (OJ L 266, 8.11.1995, p. 1).
 - (16) OJ L 225, 10.8.1992, p. 72. Directive as amended by the 1994 Act of Accession.

(a) "apparatus" means any equipment that is either radio equipment or telecommunications terminal equipment or both;

(b) "telecommunications terminal equipment" means a product or relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services);

(c) "radio equipment" means a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilizing the spectrum allocated to terrestrial/space radiocommunication;

(d) "radio waves" means electromagnetic waves of frequencies from 9 kHz to 3000 GHz, propagated in space without artificial guide;

(e) "interface" means

(i) a network termination point, which is a physical connection point at which a user is provided with access to public telecommunications network, and/or

(ii) an air interface specifying the radio path between radio equipment

and their technical specifications;

(f) "equipment class" means a class identifying particular types of apparatus which under this Directive are considered similar and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class;

(g) "technical construction file" means a file describing the apparatus and providing information and explanations as to how the applicable essential requirements have been implemented;

(h) "harmonized standard" means a technical specification adopted by a recognized standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 83/189/EEC for the purpose of establishing a European requirement, compliance with which is not compulsory.

(i) "harmful interference" means interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the applicable Community or national regulations.

Article 3

Essential requirements

1. The following essential requirements are applicable to all apparatus:

(a) the protection of the health or the safety of the user or any other person, including objectives with respect to safety requirements contained in Directive 73/23/EEC, but with no voltage limit applying;

(b) the protection requirements with respect to electromagnetic compatibility contained in Directive 89/336/EEC;

2. In addition, radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference.

3. In accordance with the procedure laid down in Article 14, the Commission may decide that apparatus within certain equipment classes or particular types of apparatus shall be so constructed that:

(a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that

(b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that

(c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber is protected; and/or that

(d) it supports certain features ensuring avoidance of fraud; and/or that

(e) it incorporates certain features ensuring access to emergency services; and/or that

(f) it supports certain features in order to facilitate its use by users with a disability.

Article 4

Notification and publication of interface specifications

1. Member States shall notify the interfaces which they have regulated to the Commission insofar as the said interfaces have not been notified under the provisions of Directive 83/189/EEC. After consulting the Committee in accordance with the procedure set out in Article 14, the Commission shall establish the equivalence between notified interfaces and assign an equipment class identifier, details of which shall be published in the Official Journal of the European Communities.

2. Each Member State shall notify to the Commission the types of interface offered in that State by operators of public telecommunications networks. Member States shall ensure that such operators publish accurate and adequate technical specifications of such interfaces before services provided through those interfaces are made publicly available, and regularly publish any updated specifications. The specifications shall be in sufficient detail to permit the design of telecommunications terminal equipment capable of utilizing all services provided through the

corresponding interface. The specifications shall include, inter alia, all the information necessary to allow manufacturers to carry out, at their choice, the relevant tests for the essential requirements applicable to the telecommunications terminal equipment. Member States shall ensure that those specifications are made readily available by the operators.

Article 5

Harmonized standards

1. Where apparatus meets the relevant harmonized standards or parts thereof whose reference numbers have been published in the Official Journal of the European Communities, Member States shall presume compliance with those of the essential requirements referred to in Article 3 as are covered by the said harmonized standards or parts thereof.
2. Where a Member State or the Commission considers that conformity with a harmonized standard does not ensure compliance with the essential requirements referred to in Article 3 which the said standard is intended to cover, the Commission or the Member State concerned shall bring the matter before the Committee.
3. In the case of shortcomings of harmonized standards with respect to the essential requirements the Commission may, after consulting the Committee and in accordance with the procedure laid down in Article 13, publish in the Official Journal of the European Communities guidelines on the interpretation of harmonized standards or the conditions under which compliance with that standard provides presumption of conformity. After consultation of the Committee and in accordance with the procedure laid down in Article 13, the Commission may withdraw harmonized standards by publication of a notice in the Official Journal of the European Communities.

Article 6

Placing on the market

1. Member States shall ensure that apparatus is placed on the market only if it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Directive when it is properly installed and maintained and used for its intended purpose. It shall not be subject to further national provisions in respect of placing on the market.
2. In taking a decision regarding the application of essential requirements under Article 3(3) the Commission shall determine the date of application of the requirements. If it is determined that an equipment class needs to comply with particular essential requirements under Article 3(3), any apparatus of the equipment class in question which is first placed on the market before the date of application of the Commission's determination can continue to be placed on the market for a reasonable period. Both the date of application and the period shall be determined by the Commission

in accordance with the procedure laid down in Article 13.

3. Member States shall ensure that the manufacturer or the person responsible for placing the apparatus on the market provides information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements. Where it concerns radio equipment, such information shall be sufficient to identify on the packaging and the instructions for use of the apparatus the Member States or the geographical area within a Member State where the equipment is intended to be used and shall alert the user by the marking on the apparatus referred to in Annex VII, paragraph 5, to potential restrictions or requirements for authorization of use of the radio equipment in certain Member States. Where it concerns telecommunications terminal equipment, such information shall be sufficient to identify interfaces of the public telecommunications networks to which the equipment is intended to be connected. For all apparatus such information shall be prominently displayed.
4. In the case of radio equipment using frequency bands whose use is not harmonized throughout the Community, the manufacturer or his authorized representative established within the Community or the person responsible for placing the equipment on the market shall notify the national authority responsible in the relevant Member State for spectrum management of the intention to place such equipment on its national market.

This notification shall be given no less than four weeks in advance of the start of placing on the market and shall provide information about the radio characteristics of the equipment (in particular frequency bands, channel spacing, type of modulation and RF-power) and the identification number of the notified body referred to in Annex IV or V.

Article 7

Putting into service and right to connect

1. Member States shall allow the putting into service of apparatus for its intended purpose where it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Directive.
2. Notwithstanding paragraph 1, and without prejudice to conditions attached to authorizations for the provision of the service concerned in conformity with Community law, Member States may restrict the putting into service of radio equipment only for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters relating to public health.
3. Without prejudice to paragraph 4, Member States shall ensure that operators of public telecommunications networks do not refuse to connect telecommunications terminal equipment to appropriate interfaces on technical grounds where

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that equipment complies with the applicable requirements of Article 3.

4. Where a Member State considers that apparatus declared to be compliant with the provisions of this Directive causes serious damage to a network or harmful radio interference or harm to the network or its functioning, the operator may be authorized to refuse connection, to disconnect such apparatus or withdraw it from service. The Member States shall notify each such authorization to the Commission, which shall convene a meeting of the Committee for the purpose of giving its opinion on the matter. After the Committee has been consulted, the Commission may initiate the procedures referred to in Articles 5(2) and 5(3). The Commission and the Member States may also take other appropriate measures.
5. In case of emergency, an operator may disconnect apparatus if the protection of the network requires the equipment to be disconnected without delay, and the user can be offered an alternative solution. The operator shall inform immediately the national authority responsible for the implementation of Articles 7(4) and 8 of this Directive.

Article 8

Free movement of apparatus

1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of apparatus bearing the CE marking referred to in Annex VII, which indicates its conformity with all provisions of this Directive, including the conformity procedures set out in Chapter II. This is without prejudice to Articles 6(4) and 7(2).
2. At trade fairs, exhibitions, demonstrations, etc., Member States shall not create any obstacles to the showing of apparatus which does not comply with this Directive, provided that a visible sign clearly indicates that such apparatus may not be marketed or put into service until it has been made to comply.
3. Where the apparatus is subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that such apparatus also fulfils the provisions of those other Directives. However, should one or more of those Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the apparatus fulfils the provisions only of those Directives applied by the manufacturer. In this case, the particulars of those Directives, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by those Directives and accompanying such products.

Article 9

Safeguards

1. Where a Member State ascertains that apparatus within the scope of this Directive does not comply with the requirements of this Directive, it shall take

all appropriate measures in its territory to withdraw the apparatus from the market or from service, prohibit its placing on the market or putting into service or restrict its free movement.

2. The Member State concerned shall immediately notify the Commission of any such measures indicating the reasons for its decision and whether non-compliance is due to:

- (a) incorrect application of the harmonized standards referred to in Article 5(1);
- (b) shortcomings in the harmonized standards referred to in Article 5(1);
- (c) failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonized standards referred to in Article 5(1).

3. If the measures referred to in paragraph 1 are attributed to incorrect application of the harmonized standards referred to in Article 5(1) or to failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonized standards referred to in Article 5(1), the Commission shall consult the parties concerned as soon as possible. The Commission shall forthwith inform the Member States of its findings and of its opinion as to whether the measures are justified, within two months of notification of the said measures to the Commission.

4. Where the decision referred to in paragraph 1 is attributed to shortcomings in the harmonized standards referred to in Article 5(1), the Commission shall bring the matter before the Committee within two months. The Committee shall deliver an opinion in accordance with the procedure laid down in Article 13. After such consultation, the Commission shall inform the Member States of its findings and of its opinion as to whether the action by the Member State is justified. If it finds that the action is justified it shall forthwith initiate the procedure referred to in Article 5(2).

5. (a) Notwithstanding the provisions of Article 6, a Member State may, acting in conformity with the Treaty, and in particular Articles 30 and 36 thereof, adopt any appropriate measures with a view to

- (i) prohibiting or restricting the placing on its market; and/or

- (ii) requiring the withdrawal from its market

of radio equipment, including types of radio equipment, which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands.

- (b) Where a Member State takes measures in accordance with subparagraph (a) it shall immediately inform the Commission of the said measures, specifying the reasons for adopting them.
6. When a Member State notifies the Commission of a measure referred to in paragraph 1 or 5 the

Commission shall in turn inform other member States and consult the Committee on the matter.

Where, after such consultation, the Commission considers that:

- the measure is justified, it shall immediately so inform the member State which took the initiative and the other member States;
 - the measure is unjustified, it shall immediately so inform the member State and invite the Member State to withdraw the measure.
7. The Commission shall maintain a record of the cases notified by Member States, which shall be made available to them on request.

CHAPTER II

Conformity assessment

Article 10

Conformity assessment procedures

1. The conformity assessment procedures identified in this Article shall be used to demonstrate the compliance of the apparatus with all the relevant essential requirements identified in Article 3.
2. At the choice of the manufacturer, compliance of the apparatus with the essential requirements identified in Articles 3(1)(a) and (b) may be demonstrated using the procedures specified in Directive 73/23/EEC and Directive 89/336/EEC respectively, where the apparatus is within the scope of those directives, as an alternative to the procedures laid out below.
3. Telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial/space radio communication and receiving parts of radio equipment shall be subject to the procedures described in any one of Annexes II, IV or V at the choice of the manufacturer.
4. Where a manufacturer has applied the harmonized standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 shall be subject to the procedures described in any one of Annexes III, IV or V at the choice of the manufacturer.
5. Where a manufacturer has not applied or has only applied in part the harmonized standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 of this Article shall be subject to the procedures described in either of Annexes IV or V at the choice of the manufacturer.
6. Records and correspondence relating to the conformity assessment procedures referred to in paragraphs 2 to 5 shall be in an official language of the Member State where the procedure will be carried out, or in a language accepted by the notified body involved.

Article 11

Notified bodies and surveillance authorities

1. Member States shall notify the Commission of the bodies which they have designated to carry out the relevant tasks referred to in Article 9. Member States shall apply the criteria laid down in Annex VI in determining the bodies to be designated.
2. Member States shall notify the Commission of the authorities established within their territory which are to carry out the surveillance tasks related to the operation of this Directive.
3. The Commission shall publish a list of the notified bodies, together with their identification numbers and the tasks for which they have been notified, in the Official Journal of the European Communities. The Commission shall also publish a list of surveillance authorities in the Official Journal of the European Communities. Member States shall provide the Commission with all information necessary to keep these lists up to date.

CHAPTER III

CE conformity marking and inscriptions

Article 12

CE marking

1. Apparatus complying with all relevant essential requirements shall bear the CE conformity marking referred to in Annex VII. It shall be affixed under the responsibility of the manufacturer, his authorized representative within the Community or the person responsible for placing the apparatus on the market.

Where the procedures identified in Annex III, IV or V are used, the marking shall be accompanied by the identification number of the notified body referred to in Article 10(1). Radio equipment shall in addition be accompanied by the equipment class identifier where such identifier has been assigned. Any other marking may be affixed to the equipment provided that the visibility and legibility of the CE marking is not thereby reduced.
2. No apparatus, whether or not it complies with the relevant essential requirements, may bear any other marking which is likely to deceive third parties as to the meaning and form of the CE marking specified in Annex VII.
3. The competent Member State shall take appropriate action against any person who has affixed marking not in conformity with paragraphs 1 and 2. If the person who affixed the marking is not identifiable, appropriate action may be taken against the holder of the apparatus at the time when non-compliance was discovered.
4. Apparatus shall be identified by the manufacturer by means of type, batch and/or serial numbers and by the name of the manufacturer or the person responsible for placing the apparatus on the market.

CHAPTER IV

The Committee

Article 13

Constitution of the Committee

The Commission shall be assisted by a committee, the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM), composed of representatives of the Member States and chaired by a representative of the Commission.

Article 14

Advisory committee procedure

1. The Committee shall be consulted on the matters covered by Articles 5, 6(2), 7(4), 8(4) and Annex VII(5).
2. The Commission shall consult the Committee periodically on the surveillance tasks related to the application of this Directive, and, where appropriate, issue guidelines on this matter.
3. 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 and decide within one month after having received the opinion of the Committee.

4. The Commission shall periodically consult the representatives of the telecommunications networks providers, the consumers and the manufacturers. It shall keep the Committee regularly informed of the outcome of such consultations.

Article 15

Regulatory committee procedure

1. Notwithstanding the provisions of Article 13, the following procedure shall apply in respect of the matters covered by Articles 3(3) and 4(1).
2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

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

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

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

CHAPTER V

Final and transitional provisions

Article 16

Third countries

1. Member States may inform the Commission of any general difficulties encountered, de jure or de facto, by Community undertakings with respect to placing on the market in third countries, which have been brought to their attention.
2. Whenever the Commission is informed of such difficulties, it may, if necessary, submit proposals to the Council for an appropriate mandate for negotiation of comparable rights for Community undertakings in these third countries. The Council shall decide by qualified majority.
3. Measures taken pursuant to paragraph 2 shall be without prejudice to the obligations of the Community and of the Member States under relevant international agreements.

Article 17

Review and reporting

The Commission shall review the operation of this Directive and report thereon to the European Parliament and to the Council, on the first occasion not later than (*) and every third year thereafter. The report shall cover progress on drawing up the relevant standards, as well as any problems that have arisen in the course of implementation. The report shall also outline the activities of the Committee, and assess progress in achieving an open competitive market for apparatus at Community level and examine how the regulatory framework for placing on the market and putting into service of apparatus should be developed to

- (a) ensure that a coherent system is achieved at Community level for all apparatus;
- (b) allow for convergence of the telecommunications, audiovisual and information technology sectors;
- (c) enable harmonisation of regulatory measures at international level.

(*) 18 months after the entry into force of this Directive.

It shall in particular examine whether essential requirements are still necessary for all categories of apparatus covered and whether the procedures contained in Annex IV, third paragraph, are proportionate to the aim of ensuring that the essential requirements are met for apparatus covered by that Annex. Where necessary, further measures may be proposed in the report for full implementation of the aim of the Directive.

Article 18

Transitional provisions

1. Standards under Directive 73/23/EEC or 89/336/EEC whose references have been published in the Official Journal of the European Communities may be used as the basis for a presumption of conformity with the essential requirements referred to in Article 3(1)(a) and Article 3(1)(b). Common technical regulations under Directive 98/13/EC whose references have been published in the Official Journal of the European Communities may be used as the basis for a presumption of conformity with the other relevant essential requirements referred to in Article 3. The Commission shall publish a list of references to those standards in the Official Journal of the European Communities immediately after this Directive enters into force.
2. Member States shall not impede the placing on the market and putting into service of apparatus which is in accordance with the provisions in Directive 98/13/EC or rules in force in their territory and was placed on the market for the first time before this Directive entered into force or at the latest two years after this Directive entered into force.
3. Apart from the essential requirements referred to in Article 3(1), the Member States may request to continue, for a period of 30 months following the date referred to in the first sentence of Article 18(1), and in conformity with the provisions of the Treaty, continue to require telecommunications terminal equipment not to be capable of causing unacceptable deterioration of a voice telephony service accessible within the framework of the universal service as defined in Directive 98/10/EC. The Member State shall inform the Commission of the reasons for requesting a continuation of such a requirement, the date by which the service concerned will no longer need the requirement, and the measures envisaged in order to meet this deadline. The Commission shall consider the request taking into account the particular situation in the Member State and the need to ensure a coherent regulatory environment at Community level, and shall inform the Member State whether it deems that the particular situation in that Member State justifies a continuation and, if so, until which date such continuation is justified.

Article 19

Transposition

1. Member States shall not later than (*) adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall forthwith inform the Commission thereof. They shall apply these provisions as from (**).

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 Member States.

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

Article 20

Repeal

1. Directive 98/13/EC is hereby repealed as from (*).
2. This Directive is not a specific Directive within the meaning of Article 2(2) of Directive 89/336/EEC. The provisions of Directive 89/336/EEC shall not apply to apparatus falling within the scope of this Directive, with the exception of the protection requirements in Article 4 and Annex III and the conformity assessment procedure in Article 10(1), 10(2) of, and Annex I to, Directive 89/336/EEC, as from (*).
3. The provisions of Directive 73/23/EEC shall not apply to apparatus falling within the scope of this Directive, with the exceptions of the objectives with respect to safety requirements in Article 2 and Annex I and the conformity assessment procedure in Annex III, Section B, and Annex IV to Directive 73/23/EEC, as from (*)

Article 21

Entry into force

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

Article 22

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European
Parliament

The President

For the Council

The President

(*) 12 months after entry into force of this Directive.

(**) Day after the date resulting from footnote (*).

(*) Same date as that referred to in the third sentence of the first subparagraph of Article 18(1).

ANNEX I

Equipment not covered by this Directive as referred to in Article 1(4)

1. Radio equipment used by radio amateurs within Article 1, definition 53, of the International Telecommunications Union (ITU) radio regulations unless the equipment is available commercially. Kits of spare parts to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.
2. Equipment falling within the scope of Council Directive 96/98/EC of 20 December 1996 on marine equipment ⁽¹⁷⁾.
3. Cabling and wiring.
4. Receive only radio equipment intended to be used solely for the reception of sound and TV Broadcasting Services.
5. Products, appliances and components within the meaning of Article 2 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation ⁽¹⁸⁾.
6. Air-traffic-management equipment and systems within the meaning of Article 1 of Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems ⁽¹⁹⁾.

(17) OJ L 46, 17. 2.1997, p. 25.

(18) OJ L 373, 31.12.1991, p. 4. Regulation as amended by Commission Regulation (EC) No 2176/96 (OJ L 291, 14.11.1996, p. 15).

(19) OJ L 187, 29. 7.1993, p. 52. Directive as last amended by Commission Directive 97/15/EC (OJ L 95, 10.4.1997, p. 16).

ANNEX II

Conformity assessment procedure referred to in Article 9(3)

Module A (internal production control)

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 point 2, ensures and declares that the products concerned satisfy the requirements of this Directive that apply to them. The manufacturer or his authorized representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.
2. The manufacturer must establish the technical documentation described in point 4 and he or his authorized representative established within the Community must keep it for a period ending at least ten years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes.
3. Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.
4. The technical documentation must enable the conformity of the product with the essential requirements to be assessed. It must cover the design, manufacture and operation of the product, in particular:
 - a general description of the product;
 - 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 product;
 - a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 5 have not been applied or do not exist;
 - results of design calculations made, examinations carried out, etc.;
 - test reports.
5. The manufacturer or his authorized representative must keep a copy of the declaration of conformity with the technical documentation.
6. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

ANNEX III

Conformity assessment procedure referred to in Article 9(4)

(Internal production control plus specific apparatus tests) (*)

This Annex consists of Annex II, plus the following supplementary requirement:

For each type of apparatus, all essential radio test suites must be carried out by the manufacturer or on his behalf. The identification of the test suites that are considered to be essential is the responsibility of a notified body chosen by the manufacturer except where the test suites are defined in the harmonized standards. The notified body must take due account of previous decisions made by notified bodies acting together.

The manufacturer or his authorized representative established within the Community or the person responsible for placing the apparatus on the market must declare that these tests have been carried out and that the apparatus complies with the essential requirements and must affix the notified body's identification number during the manufacturing process.

(*) Annex based on Module A with additional requirements appropriate to the sector.

ANNEX IV

Conformity assessment procedure referred to in Article 9(5)

(Technical construction file)

This Annex consists of Annex III plus the following supplementary requirement:

The technical documentation described in point 4 of Annex II and the declaration of conformity to specific radio test suites described in Annex III must form a technical construction file.

The manufacturer, his authorized representative established within the Community or the person responsible for placing the apparatus on the market, must present the file to one or more notified bodies, each of the notified bodies must be informed of others who have received the file.

The notified body must review the file and if it is considered that it has not been properly demonstrated that the requirements of the Directive have been met, the notified body may issue an opinion to the manufacturer, his representative or the person responsible for placing the apparatus on the market and must inform the other notified bodies who have received the file accordingly. Such an opinion must be given within 4 weeks of receipt of the file by the notified body. On receipt of this opinion, or after the end of the 4-week period, the apparatus may be placed on the market, without prejudice to Articles 6(4) and 8(5).

The manufacturer or his authorized representative established within the Community or the person responsible for placing the apparatus on the market must keep the file for a period ending at least ten years after the last apparatus has been manufactured at the disposal of the relevant national authorities of any Member States for inspection.

ANNEX V

Conformity assessment procedure referred to in Article 9

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 must affix the marks referred to in Article 11(1) to each product and draw up a written declaration of conformity.
2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.
3. Quality system

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

The application must include:

- all relevant information for the products envisaged,
- the quality system's documentation.

3.2. The quality system must 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 must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must 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 5(1) will not be applied in full, the means that 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 that 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 before 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 must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard.

The notified body must 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 must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure must include an assessment visit to the manufacturer's premises.

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

- 3.4. The manufacturer must 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 must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must 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 reassessment is required.

It must notify its decision to the manufacturer. The notification must 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 must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must 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 must carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and must 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 must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, 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 point 3.4 and in points 4.3 and 4.4.

6. Each notified body must make available to the other notified bodies the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

ANNEX VI

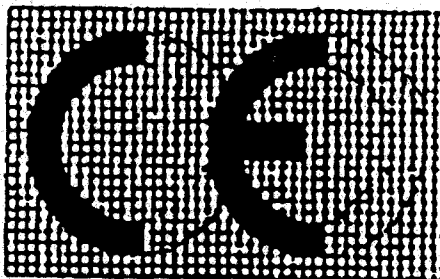
Minimum criteria to be taken into account by Member States when designating notified bodies in accordance with Article 10(1)

1. The notified body, its director and the staff responsible for carrying out the tasks for which the notified body has been designated must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, or a network operator or a service provider, nor the authorized representative of any of such parties. They must be independent and not become directly involved in the design, construction, marketing or maintenance of radio equipment or telecommunications 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 judgement 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 Member 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 Member State in which its activities are carried out) under this Directive or any provision of national law giving effect thereto.

ANNEX VII

Marking of equipment referred to in Article 11(1)

1. The CE conformity marking must consist of the initials "CE" taking the following form:



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

2. The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.
3. The CE marking must be affixed to the product or to its data plate. Additionally it must be affixed to the packaging, if any, and to the accompanying documents.
4. The CE marking must be affixed visibly, legibly and indelibly.
5. The equipment class identifier must take a form to be decided by the Commission in accordance with the procedure laid down in Article 13.

Where appropriate it must include an element intended to provide information to the user that the apparatus makes use of radio frequency bands where their use is not harmonized throughout the Community.

It must have the same height as the initials "CE".

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