



EMCD 2000.6

Working Document

The present working document contains a draft of the future EMC Directive [reference: 2000.6]. This version reflects the discussions during the meeting of the EMC SLIM Working Group on 21-21 November 2000.

This draft will be further reviewed following consultation with interested parties.

Version control

EMCD 2000.1	Text for discussion during the EMC SLIM WG meeting (24.02.2000)
EMCD 2000.2	Recapitulation of discussions during the EMC SLIM WG meeting (24.02.2000) Presented to the EMC Working Party (25.02.2000)
EMCD 2000.3	Text for discussion during the EMC SLIM WG meeting (03-04.07.2000)
EMCD 2000.4	Recapitulation of discussions during the EMC SLIM WG meeting (03-04.07.2000)
EMCD 2000.5	Text for discussion during the EMC SLIM WG meeting (21-22.11.2000)
EMCD 2000.6	Recapitulation of discussions during the EMC SLIM WG meeting (21-22.11.2000)

All these documents are available at:

http://europa.eu.int/comm/enterprise/electr_equipment/emc/slim/review.htm

List of options

The following table contains a recapitulation of those issues on which it has not been possible to find a common approach - they are indicated between brackets in the main text. Alternative proposals by participants in the EMC SLIM WG are included in footnotes.

FI	FI1	Fixed installation → "...unique combination ... to be used permanently at a predefined location..."
	FI2	Fixed installation → "...it cannot be moved without being, at least partially, disassembled..."
NB	NB0	No Notified Bodies
	NB1	Voluntary role of Notified Bodies
	NB2	Compulsory role of Notified Bodies in the case of non application of harmonised standards
ED	ED1	External devices → "...person technically competent on electromagnetic compatibility matters..."
	ED2	External devices → "...apparatus which requires professional installation..."
ENV	ENV1	Information requirements / Environments → "...compliance with the protection requirements is only ensured in restricted conditions..."
	ENV2	Information requirements / Environments → "...the manufacturer deviates from the electromagnetic compatibility environments defined in the harmonised standards..."
	ENV3	Information requirements / Environments → "...compliance with the harmonised standards is not ensured in residential areas..."
HS	HS1	Scope of harmonised standards → "...demonstration thereof by the methods..."
	HS2	Scope of harmonised standards → "...with reference to the methods..."
	HS3	Scope of harmonised standards → "...in conformity with its provisions ... demonstrated by the methods..."

Preamble

1. Whereas this Directive regulates the electromagnetic compatibility of equipment;
2. Whereas equipment includes both apparatus and fixed installations; whereas different provisions should apply to apparatus and fixed installations;
3. Whereas ready made connecting devices, although unable to generate electromagnetic disturbances in isolation, may generate or transmit electromagnetic disturbance when connected to an apparatus; whereas this justifies to consider ready made connecting devices as apparatus for the purposes of this Directive;
4. Whereas this Directive should not regulate equipment which by the inherent nature of its physical characteristics is not relevant in terms of electromagnetic compatibility;
5. Whereas other Community or national legislation separately addresses the safety of equipment;
6. Whereas Member States are responsible for protecting radiocommunications against electromagnetic disturbance;
7. Whereas electric supply networks and telecommunication networks may be affected by electromagnetic disturbance, which may consequently affect equipment connected to them; whereas Member States are also responsible for protecting electric supply networks and telecom networks against such electromagnetic disturbance;
8. Whereas Member States are also responsible for protecting equipment against the electromagnetic disturbance produced by other equipment;
9. Whereas the national provisions ensuring protection against electromagnetic disturbance must be harmonised in order to guarantee the free movement of electrical and electronic apparatus without lowering existing and justified levels of protection in the Member States;
10. Whereas the protection against electromagnetic disturbance may imply that requirements are imposed to the different economic operators; whereas these requirements shall be applied to the different economic operators in a fair and effective way in order to achieve such protection;

11. Whereas manufacturers of equipment intended to be connected to networks shall construct such equipment in a way which prevents networks from suffering an unacceptable degradation of service when used under normal operating conditions; whereas network operators shall construct their networks in a way that does not oblige manufacturers of equipment liable to be connected to networks to take disproportionate measures to prevent networks from suffering an unacceptable degradation of service; whereas the European standardisation organisations should take due account of this objective when developing harmonised standards;
12. Whereas it is in the public interest to have harmonised standards at European level in connection with the electromagnetic compatibility of equipment; whereas compliance with such harmonised standards, once their reference has been published in the Official Journal of the European Communities, gives presumption of conformity to the essential requirements; whereas other means of demonstrating conformity to the essential requirements are permitted;
13. Whereas an electromagnetic compatibility assessment needs to be carried out in order to determine the compliance of an apparatus with the protection requirements set out in this Directive; whereas the correct use of the applicable harmonised standards shall be equivalent to the carrying out of such assessment;
14. Whereas fixed installations, including networks and large machines, are unique combinations of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location; whereas due to their specific characteristics, fixed installations need to be subject to particular rules; whereas the concept of placing on the market and of affixing the CE marking shall not apply to fixed installations;
15. Whereas it is not pertinent to carry out the conformity assessment of apparatus placed on the market for incorporation into a given fixed installation, and otherwise not commercially available, in isolation from the fixed installation into which it will be incorporated; whereas this justifies that such apparatus are exempted from the conformity assessment procedures applicable to apparatus; whereas it should be prevented that such apparatus compromise the conformity of the fixed installation into which they are incorporated;

[Include explanation of article 1.3(b)]

[Include reference to horizontal understanding of key concepts of the New Approach such as "placing on the market", "putting into service" and "manufacturer", as laid down in the New Approach Guide]

[This section will be finalised in EMCD 2000.7]

Article 1 *Scope and definitions*

1. This Directive regulates the electromagnetic compatibility of equipment.
2. For the purposes of this Directive, the following definitions shall apply:

- (a) **Equipment:** any apparatus or fixed installation.
- (b) **Apparatus:** any finished appliance, or combination thereof, intended for the end user, and made commercially available as a single functional unit, liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance.

A **component** or **subassembly** intended for incorporation into an apparatus by the end user, which is liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance, is deemed to be an apparatus for the purposes of this Directive.

A **ready made connecting device** intended for connection to an apparatus by an end user for the transmission of signals, which is marketed separately from such apparatus, and which is liable to generate or transmit electromagnetic disturbance when connected to it, is deemed to be an apparatus for the purposes of this Directive.

- (c) [**Fixed installation** means a unique combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location;]¹
- (d) **Electromagnetic compatibility** means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment
- (e) **Electromagnetic disturbance** means any electromagnetic phenomenon which may degrade the performance of equipment.
- (f) **Immunity** means the ability of equipment to perform without degradation in the presence of an electromagnetic disturbance.

¹ *Option FI2:*

[**Fixed installation** means a combination of several types of apparatus and, where applicable, other devices, which are assembled and installed at the place of use in such a way that it cannot be moved without being, at least partially, disassembled;]

3. This Directive shall not apply to the following equipment:
 - (a) Radio equipment used by radio amateurs within the meaning of Article 1, definition 53, of the radio regulations in the International Telecommunications Convention, which is not available commercially.

Kits of components 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.
 - (b) Aircraft and equipment intended to be fitted into aircraft
4. This Directive shall not apply to equipment for which the inherent nature of its physical characteristics is such that:
 - (a) the electromagnetic emissions it can generate cannot exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
 - (b) it will operate without unacceptable degradation of its intended use in the presence of the electromagnetic disturbances to be expected in its intended use.
5. Insofar as protection requirements specified in this Directive are harmonised, in the case of certain equipment, by specific Directives, this Directive shall not apply or shall cease to apply with regard to such equipment or protection requirements upon the entry into force of those specific Directives.
6. This Directive shall not affect the application of Community or national legislation addressing the safety of equipment.

Article 2

Placing on the market, putting into service

Member States shall take all appropriate measures to ensure that equipment is placed on the market and/or put into service only if it complies with the relevant requirements of this Directive when properly installed, maintained and used for its intended purpose.

Article 3

Essential requirements

The equipment referred to in article 1(1) must meet the essential requirements set out in Annex I which apply to it.

Article 4
Free circulation of equipment

Member States shall not impede for reasons relating to electromagnetic compatibility the placing on the market and/or the putting into service on their territory of equipment in compliance with this Directive.

Article 5
Harmonised standards

1. Where equipment complies with the relevant harmonised standards whose references have been published in the Official Journal of the European Communities, Member States shall presume compliance with the essential requirements referred to in Annex I.

The provisions governing the correct application of harmonised standards are set out in Annex IV.

2. Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements referred to in Annex I, the Member State concerned or the Commission shall bring the matter before the Standing Committee set up by Directive 98/34/EC, hereinafter referred to as "the Committee", giving the reasons thereof. The Committee shall deliver an opinion without delay.
3. Upon receipt of the Committee's opinion, the Commission shall inform the Member States as soon as possible whether or not it is necessary to withdraw this standard from the publication referred to in paragraph 1.

Article 6
Conformity assessment procedure for apparatus

1. This Article sets out the conformity assessment procedure to be used to demonstrate the compliance of apparatus with the provisions of the Directive, with a view to its placing on the market.
2. [The manufacturer or his authorised representative established within the Community must establish a technical documentation which provides evidence of the conformity of the apparatus to the essential requirements of the Directive.

The technical documentation may optionally include a report from a notified body confirming that the electromagnetic compatibility assessment referred to in Annex I has been correctly performed.

This technical documentation shall be held at the disposal of the competent authority for a period ending at least ten years after the last apparatus has been manufactured.]²

3. The compliance of apparatus with all relevant essential requirements shall be attested by a declaration of conformity issued by the manufacturer or his authorised representative established within the Community. The declaration of conformity shall be held at the disposal of the competent authority for a period ending at least ten years after the last apparatus has been manufactured.
4. Apparatus complying with all relevant essential requirements shall bear the CE conformity marking. It shall be affixed under the responsibility of the manufacturer or his authorised representative established within the Community.

Member States shall take the necessary measures to prohibit the affixing to the apparatus, its packaging, the instructions for use or the guarantee certificate of markings which are likely to deceive third parties as to the meaning and/or graphic form of the CE marking. Any other marking may be affixed to the apparatus, its packaging, the instructions for use or the guarantee certificate provided that the visibility and legibility of the CE marking is not thereby reduced.

5. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the declaration of conformity and the technical documentation at the disposal of the competent authority shall be the responsibility of the person who places the apparatus on the Community market.
6. The provisions governing the technical documentation, the declaration of conformity and the CE conformity marking are set out in Annex II.
7. Without prejudice to Article 7, when a competent authority establishes that the CE marking has been unduly affixed, the manufacturer or his authorised representative established within the Community shall be obliged to make

² *Option NB2:*

[The manufacturer or his authorised representative established within the Community must establish a technical documentation which provides evidence of the conformity of the apparatus to the essential requirements of the Directive.

Where the manufacturer has not applied harmonised standards, or has applied them only in part, the technical documentation shall include a report from a notified body confirming that the electromagnetic compatibility assessment referred to in Annex I has been correctly performed.

This technical documentation shall be held at the disposal of the competent authorities for a period ending at least ten years after the last apparatus has been manufactured.]

the product comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State.

Article 7 **Safeguards**

1. Where a Member State ascertains that an apparatus bearing the CE marking does not comply with the provisions of this Directive, it shall take all appropriate measures to withdraw the apparatus from the market, prohibit its placing on the market or restrict its free movement.
2. 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) failure to satisfy the essential requirements referred to in Annex I, when the apparatus does not comply with the standards referred to in Article 5;
 - (b) incorrect application of the standards referred to in Article 5;
 - (c) shortcomings in the standards referred to in Article 5 themselves;
3. The Commission shall consult the parties concerned as soon as possible. If the Commission finds, after such consultations, that the action is justified, it shall inform the Member State that took the action and the other Member States.
4. Where the decision referred to in paragraph 1 is attributed to a shortcoming in the standards, the Commission, after consulting the parties, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to uphold them, and shall initiate the procedures referred to in Article 5.
5. When the apparatus which does not comply is accompanied by the report referred to in Article 6(2), the competent Member State shall take appropriate action in respect of the author of this report, and shall inform the Commission and the other Member States thereof.
6. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Article 8
Decisions in respect of withdrawal, prohibition or restriction

1. Any decision taken pursuant this Directive to withdraw an apparatus from the market, prohibit its placing on the market, or restrict its free movement, shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject.
2. In the event of a decision as referred to in paragraph 1, the manufacturer or his authorised representative shall have the opportunity to put forward his point of view in advance, unless such consultation is not possible because of the urgency of the measure to be taken as justified in particular by public interest requirements.³

Article 9
Notified bodies

1. Member States shall notify the bodies referred to in Article 6, paragraph 1 to the Commission and to the other Member States.

Such notification shall state whether those bodies are competent for all apparatus covered by this Directive or whether their responsibility is limited to certain specific areas.

2. Member States shall apply the criteria listed in Annex III for the assessment of the bodies to be notified.

Bodies which comply with the assessment criteria fixed by the relevant harmonised standards shall be presumed to comply with the aforementioned criteria. The Commission shall publish in the Official Journal of the European Communities the reference of those standards.

3. The Commission shall publish in the Official Journal of the European Communities a list of notified bodies. The Commission shall ensure that this list is kept up to date.

³ *Option NB1:*

Add:

[Where the technical documentation referred to in Annex II does not include a report from a notified body, the manufacturer or his authorised representative shall have the opportunity to produce a report from a notified body confirming that the electromagnetic compatibility assessment referred to in Annex I has been correctly performed.]

4. If a Member State finds that a notified body no longer meets the criteria listed in Annex III, it shall inform the Commission and the other Member States thereof. The reference to this notified body shall be withdrawn from the list referred to in paragraph 3.

Article 10 ***Fixed installations***

1. Apparatus placed on the market which may be incorporated into a fixed installation are subject to all relevant provisions for apparatus as set out in this Directive.

However, this need not apply to apparatus which are specifically designed for incorporation into a given fixed installation and otherwise not commercially available, in which case, the apparatus shall be accompanied, at the moment of its placing on the market by documentation specifying the fixed installation and the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of such installation.

2. Where there are indications of non-compliance of the fixed installation, for example where there are complaints about disturbances being generated by the installation, the competent authorities may request evidence of compliance of the fixed installation, and, when appropriate, initiate an assessment.

Where non-compliance is identified, the competent authorities may impose appropriate measures to bring the installation in compliance with the protection requirements set out in Annex I.

Article 11 ***Transitional provisions***

Member States shall not impede the placing on the market and putting into service of equipment which is in accordance with the provisions of Directive 89/336/EEC 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.

Article 12
Transposition and entry into force

1. Directive 89/336/EEC is hereby repealed as from *[date of application]*.
2. By *[date of application - 1]*, Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall inform the Commission thereof. They shall apply these provisions as from *[date of application]*.
3. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.
4. This Directive shall entry into force on the day of its publication in the Official Journal of the European Communities.

Article 13
Addressees

This Directive is addressed to the Member States.

Annex I

Essential requirements

A) Protection requirements

1. Equipment shall be so designed and manufactured taking into account the state of the art as to ensure that:
 - (a) the electromagnetic disturbances it generates do not exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended;
 - (b) it has a level of immunity to the electromagnetic disturbances to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

B) Specific requirements for apparatus

2. Electromagnetic compatibility assessment

The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, based on the relevant phenomena, with a view to meeting the protection requirements set out in paragraph 1.

The electromagnetic compatibility assessment takes into account all normal intended operating conditions.

In the case where the apparatus can take different configurations, the electromagnetic compatibility assessment must confirm that the apparatus shall meet the protection requirements set out in paragraph 1 in all possible configurations.

3. External devices

All apparatus shall meet the protection requirements referred to in paragraph 1 without external devices such as filtering or shielding, unless those devices, including the necessary instructions for use, are placed on the market together with the apparatus as a functional unit.

[This provision shall not apply to apparatus designed for installation by a person technically competent on electromagnetic compatibility matters, in which case such external devices need not be placed on the market together with the apparatus, provided that those devices are commercially available

and their required electromagnetic compatibility characteristics are sufficiently described in the instructions for use of the apparatus;]⁴

Connecting devices (such as plugs or cables) which have to fulfil specific requirements for the compliance of the apparatus with the protection requirements set out in paragraph 1, need not to be placed on the market together with the apparatus if they are commercially available and their required properties are sufficiently described in the instructions for use of the apparatus.

4. Information requirements

- (a) Each apparatus shall be identified by means of type, batch, serial number or any other information allowing for the identification of the product.
- (b) Each apparatus shall be accompanied by the name and address of the manufacturer, and, if he is not established within the Community, the name and address of his authorised representative or the person established within the Community responsible for placing the apparatus on the Community market.
- (c) The manufacturer shall provide information on any specific precautions that have to be taken when the apparatus is assembled, installed, maintained and used to ensure that the apparatus is in conformity with the protection requirements set out in paragraph 1 when put into service.
- (d) [Apparatus for which compliance with the protection requirements is only ensured in restricted conditions (for instance, when used in a certain environment) shall be accompanied by a clear indication of its restriction of use.]^{5 6}

⁴ *Option ED2:*

[This provision need not apply to apparatus which requires professional installation. In this case such external devices need not be placed on the market together with the apparatus, provided that those devices are commercially available and their required electromagnetic compatibility characteristics are sufficiently described in the instructions for use of the apparatus;]

⁵ *Option ENV2:*

[Where the manufacturer deviates from the electromagnetic compatibility environments defined in harmonised standards, he shall, where appropriate, indicate any restrictions or precautions in relation to the intended use.]

⁶ *Option ENV3:*

[Apparatus for which compliance with the protection requirements is not ensured in residential areas shall be accompanied by a clear indication of its restriction of use.]

5. Ready made connecting devices

- (a) The requirements for apparatus set out in paragraphs 2, 3, 4(c) and 4(d) shall not apply to ready made connecting devices.
- (b) Ready made connecting devices shall be designed and manufactured in such a way that, when connected to the apparatus for which they are intended, following any specific precautions as described below, compliance with the protection requirements set out in paragraph 1 is ensured.
- (c) Ready made connecting devices shall be accompanied by an indication of the type of apparatus they are intended to be connected to, and by information on any specific precautions that need to be taken regarding the connection to such apparatus with a view to meeting the protection requirements set out in paragraph 1.

C) Specific requirements for fixed installations

6. Installation, maintenance and intended use of components

A fixed installation shall be installed and maintained applying good engineering practice and respecting the information on the intended use of its components, with a view to meeting the protection requirements set out in paragraph 1.

Annex II
Technical documentation, EC declaration of conformity,
CE conformity marking

1. [Technical documentation⁷

The technical documentation must enable the conformity of the apparatus with the essential requirements to be assessed. It must cover the design and manufacture of the apparatus, in particular:

- a general description of the apparatus;
- a report of compliance with the harmonised standards, if any, applied in full or in part;
- where the manufacturer has not applied harmonised standards, or has applied them only in part, description and explanation of the solutions adopted to meet the essential requirements of the Directive, including a description of the electromagnetic compatibility assessment set out in Annex I, results of design calculations made, examinations carried out, test reports, etc.;
- optionally, the manufacturer may include in the technical documentation a report from a notified body confirming that the electromagnetic compatibility assessment as referred to in Annex I has been correctly performed.]

⁷ Option NB2:

[Technical documentation

The technical documentation must enable the conformity of the apparatus with the essential requirements to be assessed. It must cover the design and manufacture of the apparatus, in particular:

- a general description of the apparatus;
- a report of compliance with those harmonised standards, if any, applied in full or in part;
- where the manufacturer has not applied harmonised standards, or has applied them only in part, description and explanation of the solutions adopted to meet the essential requirements of the Directive, including a description of the electromagnetic compatibility assessment set out in Annex I, results of design calculations made, examinations carried out, test reports, etc., and a report from a notified body confirming that the electromagnetic compatibility assessment has been correctly performed.]

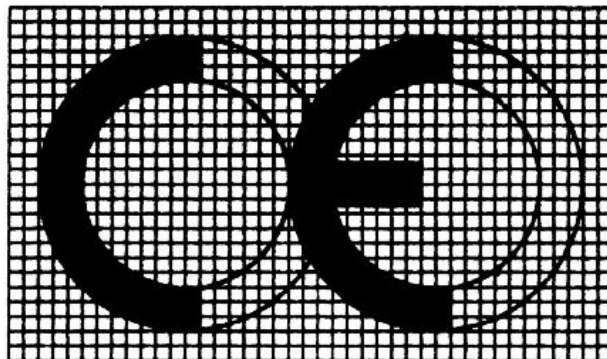
2. EC declaration of conformity

The EC declaration of conformity must contain, at least, the following:

- reference to this Directive;
- identification of the apparatus to which it refers, as set out in Annex I, paragraph 4(a);
- name and address of the manufacturer, and, where applicable, the name and address of his authorised representative within the Community;
- dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of the Directive;
- date and place of issue of the declaration;
- identification and signature of the person empowered to bind the manufacturer or his authorised representative.

3. CE conformity marking

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



The CE marking must have a height of at least 5 mm. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The CE marking must be affixed to the apparatus or to its data plate, unless it is not possible under reasonable technical conditions. Additionally it must be affixed to the packaging, if any, and to the accompanying documents.

Where apparatus is the subject of other Directives covering other aspects and which also provide for the CE conformity marking, the latter shall indicate that the appliances are also presumed to conform to those other Directives.

However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the Directives and accompanying such apparatus.

Annex III
Criteria for the assessment of the bodies to be notified

1. The bodies notified by the Member States shall fulfil the following minimum conditions:
 - (a) availability of personnel and of the necessary means and equipment;
 - (b) technical competence and professional integrity of personnel;
 - (c) independence in preparing the reports and performing the verification function provided for in this Directive
 - (d) independence of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the product in question;
 - (e) maintenance of professional secrecy by personnel;
 - (f) possession of civil liability insurance unless such liability is covered by the State under national law.
2. Fulfilment of the conditions under paragraph 1 shall be verified at intervals by the competent authorities of the Member States.

Annex IV

Application of harmonised standards

1. The correct application of all the relevant harmonised standards whose references have been published in the Official Journal of the European Communities shall be equivalent to the carrying out of the electromagnetic compatibility assessment referred to in Annex I.
2. [Compliance with a harmonised standard means conformity with its provisions (e.g. limits) and demonstration thereof by the methods the harmonised standard describes or refers to.]^{8 9}
3. Presumption of conformity through a harmonised standard or a combination of harmonised standards is limited to the scope of this standard or this combination of standards and to those essential requirements of the Directive covered by this standard or combination of standards.
4. Harmonised standards are to be selected and used according to the provisions of the relevant standardisation documents. The reference to these documents shall be published in the Official Journal of the European Communities.

⁸ *Option HS2:*

[Compliance with a harmonised standard means conformity with its provisions (e.g. limits) with reference to the methods the harmonised standard describes or refers to. If alternative methods are used, their equivalence shall be demonstrated in the technical documentation.]

⁹ *Option HS3:*

[Equipment declared to be compliant with a harmonised standard must be in conformity with its provisions (e.g. limits). Conformity is demonstrated by using the methods the harmonised standard describes or refers to.]