

EMCD 2000.2/EEO
Working Document
Modified as a result of the proposal agreed by ECACB,
Eurelectric and Orgalime on 19th April, 2000.

Preamble

1. ...
2. ...
3. Whereas fixed installations, including networks, large machines, etc... have specific characteristics that justify another regime in respect of conformity assessment;
4. ...
5. ...

Article 1 *Scope and definitions*

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

(a) **Equipment**: any apparatus or fixed installation.

(b) **Apparatus**: any finished electrical or electronic appliance intended for the end user liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance.

An **electrical or electronic 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 **system** (combination of several apparatus), made commercially available as a single functional unit, is also deemed to be an apparatus for the purposes of this Directive, unless it is a fixed installation.

(c) **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 can not be moved without being, at least partially, disassembled;

(d) **Electromagnetic compatibility** means the ability of electrical or electronic 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 electrical or electronic equipment. An electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself.
- (f) **Immunity** means the ability of electrical or electronic equipment to perform without degradation in the presence of an electromagnetic disturbance.
3. This Directive shall not apply to equipment which, by the inherent nature of its physical characteristics, has an emission level far below the most stringent limits, and for which experience shows that it operates satisfactorily in its intended area of use.
4. 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.
5. This Directive shall not affect the application of Community or national legislation addressing the safety of equipment.

Article 2

Placing in the market, putting into service

Member States shall take all appropriate measures to ensure that equipment may be 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 the purposes for which it is intended.

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 covered by this Directive which satisfies the relevant essential requirements thereof.

Article 5

Harmonised standards

1. Where equipment meets the relevant harmonised standards whose reference numbers 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 procedure for the application of harmonised standards is 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 98/38/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 those standards from the publication referred to in paragraph 1.

Article 6

Conformity assessment procedure for apparatus

1. Apparatus complying with all relevant essential requirements shall bear the CE conformity marking referred to in Annex II. 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.

2. The compliance of apparatus with all relevant essential requirements shall be certified by a declaration of conformity issued by the manufacturer or his authorised representative established within the Community. The declaration shall be held at the disposal of the competent authority for ten years following the placing of the apparatus on the market.
3. 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. This technical documentation shall be held at the disposal of the competent authority for ten years following the placing of the apparatus on the market.

If a manufacturer has not applied or applied only in part, the harmonised standards referred to in Article 5, then he must either;

- obtain a report from a Notified Body or
- document the measures applied to ensure compliance with the essential requirements as defined by Article 3.

4. 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 available shall be the responsibility of the person who places the apparatus on the Community market.
5. The provisions governing the CE conformity marking, the declaration of conformity and the technical documentation are set out in Annex II.
6. 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 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 a CE-marked apparatus does not comply with the essential requirements referred to in Annex I, 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 protection requirements referred to in Annex I, when the apparatus does not meet 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(3), 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. In the event of a challenge the manufacturer may submit a report, drawn up by a body which is notified in accordance with Article 9, on the conformity of the apparatus with the provisions of Article 3.

Article 9

Notified bodies

1. Member States shall notify the Commission and the other Member States the bodies referred to in Article 6(3).

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.

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.

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.

5. Duties of a Notified Body:

When a manufacturer requests a review, in accordance with Article 6.3, for not applying the standards or only applying the standards in part, the Notified Body shall;

- review the technical documentation to ensure that the apparatus demonstrates conformity with the essential requirements as defined by Article 3 and issue a report.

6. In the case of a challenge as stated in Article 8.3, the Notified Body shall;

- at the request of a manufacturer, review the documentation to ascertain that the manufacturer has correctly assessed the conformity with the essential requirements as defined by Article 3 and issue a report.

Article 10
Fixed installations

1. The installer of a fixed installation shall ensure compliance of the fixed installation with the relevant requirements set out in Annex I.
2. Apparatus supplied for a fixed installation and otherwise not commercially available for distribution are exempted from the conformity assessment procedures set out in Article 6.

Documentation shall be produced by the installer [and held by the operator] at the disposal of the Competent Authority, demonstrating that the apparatus used does not compromise the conformity of the installation.

[Need to rephrase (responsibility of Member States)].

3. 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 have to be taken to bring the installation in compliance with the protection requirements set out in Annex I.

Article 11
Special measures

1. The requirements of this Directive shall not prevent the application in any Member State of the following special measures:
 - (a) Measures with regard to the taking into service and use of equipment taken for a specific site in order to overcome an existing or predicted electromagnetic compatibility problem;
 - (b) Measures with regard to the installation of equipment taken in order to protect the public telecommunication networks or receiving or transmitting stations used for safety purposes.
2. Without prejudice to Directive 98/34/EC, Member States shall inform the Commission and the other Member States of the special measures taken pursuant to paragraph 1.

3. Special measures that have been recognised as justified shall be contained in an appropriate notice made by the Commission in the Official Journal of the European Communities.

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 designed and manufactured [in accordance with good engineering practice] 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 function, as might reasonably be expected by the intended user.

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 [corresponding to the state of the art], with a view to meeting the essential requirements set out in paragraph 1.

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

3. External devices

[In the case where apparatus would need additional external devices, such as filtering or shielding, in order to meet the protection requirements referred to in paragraph 1, the instructions for use in the manufacturers' documentation shall include the relevant specifications for such devices.] [*Option EXDEV.1*]

[All apparatus shall meet the protection requirements referred to in paragraph 1 without additional external devices (such as filtering or shielding), unless those devices are either placed on the market together with the apparatus as a functional unit with instructions for use in the manufacturers' documentation or they are commercially available and their required properties are sufficiently described in the instructions for use of the apparatus.] [*Option EXDEV.2*]

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

In the case of apparatus which is not intended to be able to be used in a domestic location, external devices need not be placed on the market together with the apparatus, if they are commercially available. However, their type numbers, manufacturers and conditions of installation shall be clearly identified in the instructions for use of the apparatus.

External 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.] [*Option EXDEV.3*]

4. Information requirements

(a) Indication of restricted use

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 indication of its restriction of use, issued by the manufacturer or on his behalf by an authorised representative established on the territory of the Community.

(b) Instructions

Each apparatus shall be accompanied by instructions containing all the information required to use it in accordance with its intended purpose in its intended area of use.

The manufacturer shall include in these instructions 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 taken into service.

[*Consider merging (a) with (b)*]

(c) Indication of manufacturer, authorised representative or person responsible for placing the apparatus on the community market

Each apparatus shall be accompanied by a written information stating the full name and address of the manufacturer, and, if he is not established within the Community, the name and address of his authorised representative established within the Community or the person responsible for placing the apparatus on the Community market.

(d) Identification of equipment

Each apparatus shall be identified by the manufacturer by means of type, batch and/or serial number.

C) Specific requirements for fixed installations

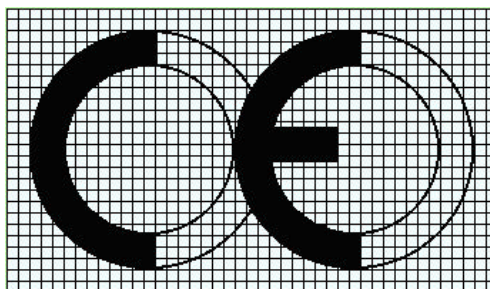
5. Installation, maintenance and intended use of components

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 essential requirements set out in paragraph 1.

Annex II
***CE conformity marking, declaration of conformity,
technical documentation***

1. CE Conformity marking

The CE conformity marking shall 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.

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.

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.

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

2. EC Declaration of conformity

The EC declaration of conformity must contain the following:

- description of the apparatus to which it refers;
- reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of the Directive;
- identification of the signatory empowered to bind the manufacturer or his authorised representative;

3. Technical documentation

the technical documentation shall contain:

- a general description of the apparatus;
- instructions for use;
- list of harmonised standards applied;
- where the harmonised standards are only applied in part or not at all, the description of the measures applied to ensure compliance with the essential requirements as defined by Article 3;
- test or assessment reports;
- design and manufacturing drawings, together with layout diagrams covering components, subassemblies, circuits, etc.;
- descriptions and explanations needed in order to understand the above-mentioned drawings and diagrams as well as the operational aspect of the product;
- the result of design calculations and checks carried out;

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

1. The bodies designated by the Member States must 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 carrying out the tests, preparing the reports, issuing the certificates and performing the verification function provided for in this Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the product in question;
 - (d) maintenance of professional secrecy by personnel;
 - (e) possession of civil liability insurance unless such liability is covered by the State under national law.
2. Fulfilment of the conditions under sections (a) and (b) 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 reference numbers have been published in the Official Journal of the European Communities provides apparatus with presumption of conformity with the relevant essential requirements as set out in Annex I.

[Consider need to be more explicit about essential requirements]

2. The following general conditions apply for the correct application of the aforesaid harmonised standards:
 - (a) Harmonised standards are to be selected according to the following order of precedence: product, product family and generic standards.
 - (b) 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.
 - (c) [Presumption of conformity through a given harmonised standard is limited to the scope covered by this standard.] *[Different considerations on this issue]*
 - (d) Further indications for the use of harmonised standards may be given in the list of harmonised standards published in Official Journal of the European Communities and in guides issued by the standardisation bodies.

Dear Mr Anselmann and Mr Ulzurrun,

At 19th of April an ad-hoc meeting took place in London on the subject EMC Directive, article 10.2 Competent Bodies. The meeting was attended by representatives from the Association of Competent Bodies (Mr O'Dwyer, Mr Imeson and Mr Whaley), EURELECTRIC (Mr Start) and ORGALIME (Mr Bakker-FME-CWM, Mr Huhle-ZVEI, Mr Isnard-FIEEC and Mr Sanhet-CEMEP).

The meeting was held in order to find a solution for the problem on the item "Competent Bodies". Article 10.2 says now that in case that the manufacturer has applied the harmonised standards only in part or not at all, a Competent Body has to draw up a report or a certificate. ORGALIME TCC agreed that it would be worth while to try to remove this obligation.

The result of the meeting is the following: we agreed on a common proposal where art 10.2 is replaced by a choice for the manufacturer. If the standards are only partly applied or not at all, the manufacturer may choose whether he will ask a recognised Body for a report or he will just issue the product and affix the CE-marking on the condition that he has to draw up a Technical Construction File (TCF), which includes the measures that are taken in order to comply with the Directive on the items where the manufacturer is deviating from the standards.

The representatives of the Association of Competent Bodies were willing to give up the obligation for manufacturers to go to a Recognised Body if the measures mentioned above are described. The result is that the Bodies which are now Competent Bodies in the EMCD will remain a Body with legislative support. On the other hand, if a manufacturer wants to apply the harmonised standards only partly or not at all, he only has to mention the measures in the TCF which are taken to comply with the Directive. Therefore, in the view of the ORGALIME representatives, the original goal to remove the red tape is achieved completely. For the ACB the meeting was also completely successful, because their members will remain recognised in the EMCD.

The meeting also agreed to include the possibility for manufacturers if a product is challenged by market surveillance to request for a report from a Notified Body. This was a helpful tool for manufacturers in area of the LVD before 1993 and on the other hand it gives the Bodies concerned more responsibilities.

Further we agreed that it would be worth while to change the name of Competent Bodies into Notified Bodies.

Best regards,

Doede Bakker
ORGALIME Issue manager EMC SLIM