



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL

Conformity and standardisation, new approach, industries under new approach

Mechanical and electrical equipment (including telecom terminal equipment)

EMC/WG/5/1

EMC SLIM Working Group – 4th meeting Draft meeting report (v 1.0)

Date: 03-04.07.00
Place: European Commission
DG Enterprise
Rue de la Science / Wetenschapsstraat 15
Brussels, Belgium

Note

The fourth meeting of the EMC SLIM Working Group was devoted to the discussion of draft EMCD 2000.3 (EMC/WG/4/18). The result of these discussions is reflected in a new version of this document: EMCD 2000.4 (EMC/WG/4/32) (see Annex 1).

The text of EMCD 2000.4 has been annotated, where necessary, to reflect the discussions which took place during the meeting. For the sake of simplicity, therefore, this report only contains other relevant issues that have not been included in these annotations.

Procedural items

The list of participants can be found in Annex 2.

The final list of documents can be found in Annex 3. All working documents are available in the EMC Directive Internet Resources Centre [IRC].

Conformity assessment procedures

A proposal by ECACB / ORGALIME / EURELECTRIC to redefine the role of competent bodies was presented (EMC/WG/4/17).

A discussion followed on whether, under the future EMC Directive, the intervention of a competent body should remain compulsory in certain circumstances (as it is presently the case) or should be optional (following, for instance, the approach of the Low Voltage Directive).

The Chairman asked representatives of Member States present in the meeting to give their views on this matter. Austria, United Kingdom, Italy, and Denmark would be in favour of the optional approach. Belgium and the Netherlands too, but on the condition that the procedures are similar to those in the R&TTE Directive. Germany would support the present compulsory regime.

EMC Study

Mr Broyde (EXCEM Consultants) made a report on the progress of the EMC Study. A meeting devoted to the presentation of this study will be convened on 16 October.

Further work – future meetings

The next meeting of the EMC SLIM working Group is scheduled for 21-22 November.

Annex 1: EMC 2000.4



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EMC/WG/4/32

EMCD 2000.4 **Working Document**

The present working document contains a draft of the future EMC Directive [reference: 2000.4]. This version takes into consideration the discussions during the last meeting of the EMC SLIM Working Group.

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 (24.02.00)
EMCD 2000.2	Recapitulation of discussions during the EMC SLIM WG meeting (24.02.00) Presented to the EMC Working Party (25.02.00)
EMCD 2000.3	Text for discussion during the EMC SLIM WG meeting (03-04.07.00)
EMCD 2000.4	Recapitulation of discussions during the EMC SLIM WG meeting (03-04.07.00)

Preamble

[For the sake of simplicity, only relevant paragraphs are included here – their numbering or order are so far irrelevant].

1. ...
2. ...
3. Whereas fixed installations, including networks, large machines, etc... have specific characteristics that justify another regime in respect of conformity assessment;
4. Whereas electric supply networks may be affected by electromagnetic disturbance, which may consequently affect equipment connected to them; whereas the responsibility for the protection against such electromagnetic disturbance shall be shared in a fair and effective way;

[To be redrafted, if necessary, taking into account other “whereas” clauses related to networks – to reconsider the word “responsibility” – to take into account “whereas” clauses in R&TTED]

5. 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 this Directive; whereas the correct use of the applicable harmonised standards shall be equivalent to the carrying out of such assessment;
6. ...
7. ...

[This section will be expanded in version EMCD 2000.5]

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 intended for the end user, or combination thereof 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.

[Consider including the definition of accessory (EMC/WG/4/25rev1)]

- (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 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.
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.
 - (b) [Aircraft and equipment to be fitted into aircraft] [*To be further considered*]
 - (c) [*Other exclusions to be considered*].

4. 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.
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 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 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. 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.] [*Option NB1*]

[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.] [*Option NB2*]

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.

2. 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 ten years following the placing of the apparatus on the market.
3. 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.

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 at the disposal of the competent authority shall be the responsibility of the person who places the apparatus on the Community market.
5. The provisions governing the technical documentation, the declaration of conformity and the CE conformity marking 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 an apparatus bearing the CE marking 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 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(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.

Article 9

Notified bodies

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

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.
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. Member States shall ensure that fixed installations comply with the relevant requirements set out in Annex I.
2. Apparatus placed on the market for incorporation into a fixed installation are subject to all relevant provisions for apparatus as set out in this Directive.

However, this shall not apply to apparatus which are specifically designed for incorporation into a fixed installation and otherwise not commercially available. In this case, documentation shall be kept at the disposal of the Competent Authority, demonstrating that such apparatus does not compromise the conformity of the installation.

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 putting 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 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 additional 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.

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.

[Consider provisions for external devices only intended to be incorporated into the apparatus by professionals].

4. Information requirements

- (a) Each apparatus shall be identified by the manufacturer 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 taken 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.

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 protection requirements set out in paragraph 1.

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

1. Technical documentation

The technical documentation must enable the conformity of the product with the essential requirements to be assessed. It must cover the design and manufacture 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 have not been applied;
- where the manufacturer has not applied harmonised standards, or has applied them only in part, a report from a notified body confirming that the electromagnetic compatibility assessment as referred to in Annex I has been correctly performed;] [*Option NB1*]
- [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 have not been applied;
- 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;] [*Option NB2*]
- results of design calculations made, examinations carried out, etc.;
- test reports.

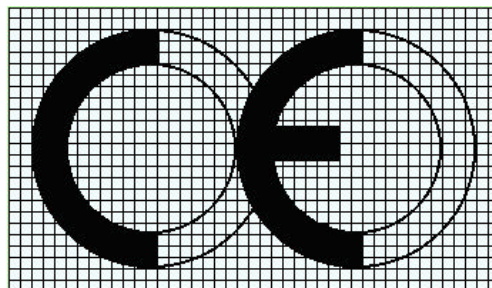
2. EC Declaration of conformity

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 product 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 designated 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 sections (a) and (b) shall be verified at intervals by the competent authorities of the Member States.

[Consider including a reference to the manufacturer's laboratory]

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.
3. Presumption of conformity through a given harmonised standard is limited to the scope covered by this standard.
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.

Annex 2: List of participants

Name: ANSELMANN, Norbert
Organisation: European Commission
Enterprise DG
Country: EU
Email: norbert.anselmann@cec.eu.int

Name: BAKKER, Doede
Organisation: ORGALIME
Country: The Netherlands
Email: dba@fme.nl

Name: BAUMIER, Nathalie
Organisation: EURELECTRIC - UNIPEDE
Country: France
Email: nathalie.baumier@edf.fr

Name: BIRKHAN, Friedrich
Organisation: Bundesministerium für Wirtschaft und Arbeit
Country: Austria
Email: friedrich.birkhan@bmwa.gv.at

Name: BOGERS, Mark
Organisation: European Commission
Enterprise DG
Country: EU
Email: mark.bogers@cec.eu.int

Name: BROYDÉ, Frédéric
Organisation: EXCEM Consultants
Country: France
Email: fredbroyde@excem.fr

Name: BUCKLE, Phil
Organisation: AIE
Country: United Kingdom
Email: PHIL.buckle@eca.co.uk

Name: CELESTE, Franco
Organisation: Ministero Industria, DGSPC

Country: Italy
Email: Celeste@minindustria.it

Name: COENRAADS, Jan
Organisation: Ministry of Transport , Public Works and Water Management- Radiocommunications Agency
Country: The Netherlands
Email: jan.coenraads@rdr.nl

Name: COLPAERT, Eric
Organisation: Belgisch instituut voor post-diensten en telecommunicatie (BIPT)
Country: Belgium
Email: eric.colpaert@bipt.be

Name: COURT, David
Organisation: ECCA
Country: Ireland
Email: dcourt@connogue.com

Name: DE VRÉ, Robert
Organisation: EMC Consultant
Country: Belgium
Email: robert.devre@skynet.be

Name: DOFNAS, Per
Organisation: EICTA
Country: Sweden
Email: per.dofnas@ebc.ericsson.se

Name: EARDLEY, David
Organisation: European Commission Enterprise DG
Country: EU
Email: david.eardley@cec.eu.int

Name: FEDERICI, Emilio
Organisation: Ministero Industria, DGSPC
Country: Italy
Email: federici@minindustria.it

Name: GIESLER, Manfred
Organisation: EICTA
Country: Germany
Email: manfred.giesler@DE.unisys.com

Name: GRAZIANO, Tony
Organisation: EACEM

Country: Belgium
Email: tgo@eacem.be

Name: GUIRADO TORRES, Rafael
Organisation: LCOE

Country: Spain
Email: lcoe.rguirado@inode.es

Name: HABECK, Hans-Johan
Organisation: EACEM
Country: Belgium
Email: hjhabeck@panasonic-tc.de

Name: HANSEN, Erik Anker
Organisation: Danish Telecom Agency
Country: Denmark
Email: eah@tst.dk

Name: HOWICK, Peter
Organisation: Department of Trade and Industry Standards & Technical Regulations Directorate
Country: United Kingdom
Email: peter.howick@dti.gov.uk

Name: IMESON, Dave
Organisation: Chairman of the ECACB
Country: United Kingdom
Email: dimeson@iee.org

Name: ISNARD, Jean-Pierre
Organisation: ORGALIME
Country: France
Email: dirtech@fieec.fr

Name: JEROMIN, Gerd
Organisation: Regulierungsbehörde für Telekommunikation und Post (Reg TP)
Country: Germany
Email: gerd.jeromin@regtp.de

Name: KAISER, Walter
Organisation: ORGALIME
Country: Germany
Email: kaiser@zvei.org

Name: KLAMM, Hubert
Organisation: EACEM
Country: Belgium
Email:

Name: LIGHTFOOT, N.
Organisation: ETSI
Country: United Kingdom
Email: norman.lightfoot@dial.pipex.com

Name: MARCHETTI, Gianpiero
Organisation: Ministero delle Comunicazioni - ISCTI
Country: Italy
Email: gianpiero.marchetti@istsupcti.it

Name: McQUILTON, David
Organisation: Matra BAe Dynamics
Country: United Kingdom
Email: dave.mcquilton@bae.co.uk

Name: NEWMAN, Edel
Organisation: European Commission
Enterprise DG
Country: EU
Email: edel.newman@cec.eu.int

Name: NICOL, Iain
Organisation: Department of Trade and Industry, Standards & Technical Regulations Directorate
Country: United Kingdom
Email: iain.nicol@dti.gov.uk

Name: O'DWYER, Michael
Organisation: Technical Secretary of the ECACB

Country: Ireland
Email: rft@indigo.ie

Name: OCHEL, Gerd
Organisation: ETSI Secretariat

Country: France
Email: Gerd.Ochel@etsi.fr

Name: PRENCIPE, Pier Paolo
Organisation: Ministero Industria

Country: Italy
Email: pierpaolo.prencipe@anie.it

Name: ROED, Jan
Organisation: European Commission
Enterprise DG
Country: EU
Email: jan.roed@cec.eu.int

Name: SANHET, Jean-Louis
Organisation: ORGALIME
Country: France
Email: jean-louis.sanhet@ind.alstom.com

Name: START, D.J.
Organisation: EURELECTRIC / UNIPEDE
Country: United Kingdom
Email: david_start@electricity.org.uk

Name: TALON, Roland
Organisation: AIE
Country: France
Email: r.talon@ffee.fr / rec@ffee.fr

Name: ULZURRUN, Alejandro
Organisation: European Commission
Enterprise DG
Country: EU
Email: alejandro.ulzurrun@cec.eu.int

Name: VEENSTRA, Yvonne
Organisation: Ministry of Transport , Public Works and Water
Management- Radiocommunications Agency
Country: The Netherlands
Email: yvonne.veenstra@rdr.nl

Name: VETSUYPENS, Jean-Paul
Organisation: CENELEC
Country: Belgium
Email: jpvetsuypens@cenelec.be

Name: WINKELMANN, Stephan
Organisation: Reg TP Mainz
Country: Germany
Email: stephan.winkelmann@regtp.de

Annex 3: Final list of working documents

EMC/WG/4/1	Last meeting report (v 1.0)
EMC/WG/4/2	Mr De Vré – Annex IV
EMC/WG/4/3	Mr Scott's comments on EMCD 2000.2
EMC/WG/4/4	Mr Birkhan's comments on EMCD 2000.2
EMC/WG/4/5	Mr Rodriguez's comments on EMCD 2000.2
EMC/WG/4/6	Mr Court's comments on EMCD 2000.2
EMC/WG/4/7	Definition of state of the art
EMC/WG/4/8	Mr Vrolijk's comments on EMCD 2000.2
EMC/WG/4/9	Ms Veenstra's comments on EMCD 2000.2
EMC/WG/4/10	Mr Start's comments on EMCD 2000.2
EMC/WG/4/11	Mr De Vré's comments on EMCD 2000.2 – External devices
EMC/WG/4/12	Mr De Vré's comments on EMCD 2000.2 – Definitions
EMC/WG/4/13	Mr De Vré's comments on EMCD 2000.2 – Apparatus and installations
EMC/WG/4/14	Mr De Vré's comments on EMCD 2000.2 – Competent Bodies
EMC/WG/4/15	Invitation
EMC/WG/4/16rev1	Agenda
EMC/WG/4/17	EMC 2000.2.EEO
EMC/WG/4/18	EMCD 2000.3
EMC/WG/4/19	EMCD 2000.3 (Slides)
EMC/WG/4/20	Mr Birkhan's comment on EMC/WG/4/5
EMC/WG/4/21	Mr Scott's comment on EMCD 2000.2.EEO
EMC/WG/4/22	Mr Rajamäki's comments on EMCD 2000.2
EMC/WG/4/23	ORGALIME expert comments on EMCD 2000.2
EMC/WG/4/24	AIE comments on EMCD 2000.2
EMC/WG/4/25rev1	Mr Jeromin's comments on EMCD 2000.3
EMC/WG/4/26	Mr Sahnet's comments on EMCD 2000.3
EMC/WG/4/27	Mr Scott's comments on EMCD 2000.3
EMC/WG/4/28	Mr Bakker's comments on EMC/WG/4/21
EMC/WG/4/29	Mr Court's comments on EMCD 2000.3
EMC/WG/4/30	Mr Nicol's comments on EMCD 2000.3
EMC/WG/4/31	Mr Colapert's comments on EMCD 2000.3
EMC/WG/4/32	EMCD 2000.4