



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on the approximation of the laws of the Member States relating to electromagnetic
compatibility**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION

This proposal provides for a revision of Council Directive 89/336/EEC of 3 May 1989 on the approximation of laws of the Member States relating to electromagnetic compatibility (EMC Directive).

Directive 89/336/EEC has been amended by Directives 91/263/EEC, 92/31/EEC and 93/68/EEC. It became applicable on a voluntary basis on 1 January 1992. Since 1 January 1996 all electrical and electronic apparatus concerned must satisfy the requirements of the EMC Directive before being placed on the market within the European Community.

The objective of the EMC Directive is to guarantee the free movement of electrical equipment whilst creating an acceptable electromagnetic environment within the EU. The Directive therefore seeks to ensure that electromagnetic disturbances produced by electrical equipment do not affect the correct functioning of other such equipment, including telecommunication and electricity distribution networks, and that such equipment has an appropriate level of immunity to electromagnetic disturbances so that it can function as intended.

Since 1992 considerable experience has been gained with the application of the EMC Directive. In 1997, due to the need to clarify a number of issues and in order to ensure homogeneous application, the Commission issued an informal guide to the application of the Directive prepared with the assistance of national authorities and other relevant stakeholders.

2. BACKGROUND AND KEY ELEMENTS FOR THE REVISION

2.1. The SLIM process

The EMC Guide has made a substantial contribution towards homogeneous application of the Directive. But it is informal and therefore cannot provide legal certainty to resolve the issues.

In 1997, as a first step towards providing clarity, and giving legal weight to agreed solutions, and also to reduce unnecessary regulatory burdens on industry, the Commission, together with Member States, identified the EMC Directive as a candidate for the SLIM (Simpler Legislation for the Internal Market) initiative.

During 1998 a panel composed of experts from Member States and stakeholders reviewed the Directive. At the end of this process the panel gave their opinion that for certain aspects its application was problematic, and recommended that it should be revised taking due account of the 1997 EMC Guide.

The Recommendations of the SLIM panel focussed on the following aspects:

- basic principles;
- treatment of large machines and installations;

- conformity assessment procedures;
- standards;
- EMC requirements in other Directives;
- consideration of the solutions provided by the EMC Guide.

In its Communication to the European Parliament and the Council (COM(1999)88), the Commission endorsed most of the SLIM panel's recommendations. The Commission then set up a working party consisting of experts from national administrations and relevant stakeholders (industry, network operators, conformity assessment and standardisation bodies, users) to help the Commission draft a proposal for revision of the Directive. During 1999 and 2000 several drafts were considered by this group and, in order to ensure transparency, were placed on the Commission web-site to attract comments from other interested parties. The current proposal for revision of the EMC Directive has been drafted taking due account of comments made during this extensive and wide-ranging consultation.

2.2. Objectives of the revision

In general terms the proposal for revision maintains the objectives of the existing EMC Directive, and its field of application. It follows the regulatory concept of the New Approach and, for the most part, uses concepts already found in the current Directive.

The text of the proposal is recommended in pursuit of the following objectives:

- Clarification of scope by means of improved definitions, more clearly defined exclusions and inclusion of ready-made connecting devices;
- Treatment of fixed installations by means of a more appropriate regulatory regime;
- Enhanced clarity through more detailed essential requirements;
- Clarification of the role of harmonised standards;
- Simplification of the conformity assessment procedure, reduced to a single procedure for apparatus;
- Cutting “red tape” and increasing manufacturers’ choice by abolishing compulsory third-party intervention where harmonised standards have not been applied but allowing in all cases for voluntary involvement of conformity assessment bodies for apparatus;
- Improved market surveillance through better traceability of the manufacturer.

The structure and text of the proposal have been adapted to the state of the art introduced by other New Approach Directives adopted since 1989.

In view of these modifications, it is proposed that Directive 89/336/EEC be replaced by the proposal below.

2.3. Content of the revision

In accordance with the New Approach concept, the proposal for revision lays down the electromagnetic compatibility requirements for electrical equipment which must be satisfied before it is placed on the market and/or put into service.

Equipment is the key term of reference to which the Directive applies. It includes two sub-sets: apparatus and fixed installations. A number of provisions of the Directive apply in common to both apparatus and fixed installations. This is the case for generic electromagnetic protection requirements, and for the principle that these protection requirements can be given technical expression in voluntary harmonised standards. Harmonised standards are to be adopted by the European standardisation bodies CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization) and ETSI (European Telecommunications Standards Institute). Harmonised standards must be elaborated on the basis of remits addressed by the Commission to the European standards bodies in accordance with the procedure laid down in Directive 98/34/EC. Harmonised standards, once published in the Official Journal of the EC, confer presumption of conformity with the essential protection requirements of the Directive, in so far as they are covered by them.

2.3.1. *Distinction between apparatus and fixed installations*

One of the main reasons for the revision of the EMC Directive is the need for different regulatory regimes tailored for apparatus and for fixed installations. Apparatus means goods which, once they comply with the Directive, can be placed on the market and/or put into service anywhere within the European Union. It is therefore up to the manufacturer to carry out, under his responsibility, a conformity assessment to show that the apparatus complies with the requirements of the Directive. Apparatus which complies must bear the CE marking.

However, the concept of a conformity assessment procedure and the affixation of the CE marking are not felt to be appropriate for fixed installations. Fixed installations are assemblies of various apparatus and other devices installed and intended to be used permanently at a pre-defined location within the EU (e.g. electricity distribution networks, telecommunication networks, large machinery and assemblies of machinery on manufacturing sites). The justification for a different regime is that such fixed installations may be the subject of continuous alterations, coupled with the difficulties experienced in applying a formal conformity assessment procedure to such an installation, due to its size, its complexity, undefined and variable external EMC conditions, operational needs etc...

This viewpoint is given additional weight by the fact that competent authorities can, following the identification of a fixed installation that might be the source of an unacceptable emission, request that the responsible person brings it into compliance.

During the consultation process it was found that stakeholders strongly support the application of a particular regime for fixed installations within the Directive. Such installations, as a source or object of potential electromagnetic disturbances, are part of the electromagnetic environment.

In addition, it is in the interest of the free circulation of equipment to establish a coherent set of harmonised EMC requirements for equipment, including fixed installations, which provide a coherent set of rules defining all the aspects of an acceptable electromagnetic environment.

Furthermore, the rapidly changing technologies used in such installations need to be provided with a solid regulatory base and harmonised standards as tools to ensure that they can be fully exploited throughout the EU.

2.3.2. *Essential requirements*

The proposals lays down in Annex I a coherent and comprehensive regime of essential requirements which equipment, i.e. both apparatus and fixed installations, must comply with.

The essential requirements consist of generic protection requirements covering the emission and immunity characteristics of equipment. In addition, more specific requirements are given separately for apparatus and for fixed installations.

In the case of apparatus the manufacturer will need to perform an electromagnetic compatibility assessment, in which all relevant phenomena are identified and addressed with a view to meeting the protection requirements. If all relevant harmonised EMC standards applicable to a given apparatus are met, it is deemed to have met the obligation for an EMC assessment.

As a general rule, apparatus will be required to meet the protection requirements without recourse to additional external devices (such as filtering or shielding) placed separately on the market. Apparatus must be accompanied by information enabling the product to be clearly identified (e.g. by means of type number, batch code, etc.) and indicating the name and address of the manufacturer. Where the manufacturer or his authorised representative is not established within the EU, the person established within the EU responsible for placing the apparatus on the market will be indicated. These provisions aim at strengthening the means available to market surveillance authorities to verify the compliance of apparatus and to take any enforcement measures considered necessary.

The manufacturer will need to provide information on any specific precautions to be taken before installation, assembly and use of the apparatus to ensure it complies with protection requirements.

In cases where apparatus will not comply with the protection requirements in residential areas, this restriction of use must be indicated. This requirement has its origin in the discussions of the SLIM panel, which came to the conclusion that the revised Directive should define certain classes of EMC environment and the conditions for intended use. The feedback from the consultation process following the SLIM recommendations did not confirm this necessity. Even so, when because of its EMC characteristics an apparatus is not suitable for use in residential areas, it was considered essential to indicate explicitly such a restriction of use.

2.3.3. *Conduct of conformity assessment for apparatus under the sole responsibility of the manufacturer*

In cases where the manufacturer has not applied harmonised standards or has applied them only in part, the current EMC Directive requires a technical construction file including a technical report or certificate issued by a competent body.

Harmonised standards now exist for almost all apparatus. The self-declaration procedure by means of applying harmonised standards is now used in 95% of cases. In practice, bodies which are also competent bodies are often asked to confirm compliance with harmonised standards. The proposal will make the manufacturer's obligations clearer. Experience has also shown that the non-application of harmonised standards cannot be considered as an appropriate criterion for requiring the involvement of a third party. Therefore, the proposal removes the obligation to rely on a competent body. This represents a streamlining of the Directive. However, in accordance with Council Decision 93/465/EEC on the modular concept, the manufacturer must always establish and maintain technical documentation which confirms that the apparatus complies with the essential requirements, whether harmonised standards apply or not.

The proposal will leave with the manufacturer the decision whether to involve a third party, and if so to what extent. As in other New Approach Directives, conformity assessment bodies will be called "Notified Bodies". This change of name will not, however, imply any additional new re-assessment of bodies already designated under the current Directive.

Nor will this change of name affect the current sectoral practice that, under certain conditions, an assessment body owned by a manufacturer may become a Notified Body for the purpose of the EMC Directive.

3. LEGAL BASIS

This proposal is based on Article 95 of the EC Treaty. It aims at ensuring the free circulation of equipment throughout the European Internal Market by laying down harmonised electromagnetic compatibility requirements. Article 95 also covers the EMC requirements for fixed installations. The functioning of the Internal Market can only be ensured if both apparatus and fixed installations are designed and constructed in accordance with a coherent and homogeneous set of EMC requirements.

The proposal has relevance for the European Economic Area.

4. PROPORTIONALITY AND SUBSIDIARITY

The main objective of the proposed action is to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty, this measure is proposed since the objectives laid down above cannot be sufficiently achieved by Member States acting alone and can therefore, by reason of their scale and effects, be better achieved at Community level.

Directive 89/336/EEC follows the principles set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards. In accordance with that approach, the essential requirements laid down in this proposal are given technical expression by harmonised European standards, to be adopted by the various European standardisation bodies. During its ten years of applicability, the directive has proven its accordance with the principle of proportionality as set out in Article 5 of the Treaty. Based on this experience, this proposal follows exactly the same principles, and thus, does not go beyond what is necessary in order to achieve those objectives.

5. CONTENT OF THE PROPOSAL

The main body of the revision proposal consists of four chapters:

- Chapter 1: general provisions;
- Chapter 2: apparatus;
- Chapter 3: fixed installations;
- Chapter 4: final provisions.

The provisions of the proposal are set out in further detail where they substantially deviate from the current Directive.

5.1. Chapter 1: general provisions

5.1.1. Article 1 – Scope

Radio and telecommunication terminal equipment covered by Directive 1999/5/EC is excluded from the scope of the EMC Directive. However, the R&TTE Directive (1999/5/EC) refers explicitly to a number of specific provisions of the EMC Directive and renders them applicable. Due to the modification of the EMC Directive, changes in referencing to the EMC Directive can be identified with the help of the correlation table in Annex VI of the proposal.

Aircraft and equipment fitted into aircraft will be explicitly excluded from the EMC Directive. This exclusion is a result of the conclusions of a study carried out by CENELEC under a mandate from the Commission and with the help of experts on EMC and aircraft specifications. Aircraft can be considered as a very specific environment with regard to EMC. The needs of protection in terms of EMC can be entirely met by specific regulations relating to aircraft.

Furthermore, the EMC Directive shall not apply to equipment which, due to the inherent nature of its physical characteristics, is from an EMC point of view, benign. For example, this might be the case for certain wristwatches or greeting cards incorporating electronic devices.

5.1.2. Article 2

This Article contains legal definitions for the most important technical terms, such as apparatus, fixed installations and electromagnetic compatibility. It should be noted

that only components or sub-assemblies, which are intended to be incorporated by the end-user and are either liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance are deemed to be apparatus in terms of the Directive.

Ready-made connecting devices intended for the transmission of signals are, under certain conditions, deemed to be apparatus and subject to the essential requirements, the conformity assessment regime and the CE marking provisions of the Directive. It should be noted that this does not apply to cables as such but only to ready-made devices placed on the market separately from apparatus. A technical study carried out for the Commission as well as the practical experience of Member States confirmed the need to include ready-made connecting devices within the scope of the Directive. By such an inclusion, national regulations potentially affecting the free circulation of such devices will be avoided.

5.1.3. *Article 6*

This article explains that equipment, to which harmonised standards have been applied, shall benefit from a presumption of conformity to the essential requirements. Harmonised standards become the further technical expression of the essential requirements for equipment falling under their scope. The coverage of fixed installations by the essential requirements and harmonised standards will prevent national regulations on EMC matters, which currently go beyond the level of specification detailed in the Directive.

5.2. **Chapter 2: apparatus**

According to [Article 7](#), manufacturers have to assess, under their own responsibility, the compliance of apparatus with the essential requirements, regardless of whether or not products are manufactured in compliance with harmonised standards. The conformity has to be demonstrated through a technical file and attested through the issue of a declaration of conformity. The technical file and the declaration of conformity shall be made available to the Competent Authorities, upon request, during ten years after the last apparatus has been manufactured. The involvement of a notified body is left to the discretion of manufacturers. Notified bodies may issue certificates confirming full compliance with the essential requirements or only in part with given requirements, upon a manufacturer's request (see section 2.3.1). The procedure for the notification of notified bodies and the publication provisions (Article 11) generally follow the requirements to be found in other New Approach Directives.

Given the advent of the R&TTE Directive (1999/5/EC), which now provides the regulatory EMC provisions for almost all radio transmitters, it is considered disproportionate to continue a mandatory third-party regime for those remaining within the scope of the EMC Directive. Residual radio transmitting equipment remaining within the scope will therefore be subject to the same provisions as other apparatus.

5.3. **Chapter 3: fixed installations**

[Article 12](#) provides for a particular regime for fixed installations.

Where such installations are built or modified using apparatus which are generally available on the market, the provisions for such apparatus are detailed in Chapter 2. However, if the apparatus used are specifically designed for a given fixed installation and are otherwise not commercially available, the manufacturer may decide whether or not to follow the provisions of Chapter 2.

However, if the general provisions for apparatus (Articles 5, 7 and 8) are not applied to apparatus designated for a specific installation, such apparatus will need to be accompanied by more specific information indicating the site of intended use and the precautions to be observed in view of the installation.

Article 12 does not require the conduct of a formal conformity assessment procedure for fixed installations prior to their putting into service. As noted above, it was identified by the SLIM panel and during the subsequent consultation process that the application of a conformity assessment procedure may be difficult or even impossible, as well as disproportionate taking account of the technical complexity of installations and the modifications they can be subject to during their lifetime. Where there are indications of non-compliance, for example due to complaints about disturbances being generated by such installations, public authorities may request evidence of compliance and, where appropriate, initiate a proper assessment. Article 12 leaves it to Member States to determine under national law the person(s) to be held responsible for the compliance of the fixed installation with the relevant essential requirements.

5.4. Chapter 4: final provisions

Directive 89/336/EEC will need to be repealed. In accordance with the correlation table of Annex VI, references to Directive 89/336/EEC, for example in harmonised standards, need to be read as referring to the revised Directive.

5.5. Annex I: essential requirements

See Section 2.3.2

5.6. Annexes II to IV

These annexes include standard provisions of the New Approach Directives.

5.7. Annex V

This Annex establishes that the correct application of relevant harmonised standards shall be equivalent to the carrying out of an EMC assessment as referred to in Annex I. Furthermore reference is made to standardisation documents which provide information for manufacturers about the selection and use of harmonised standards. These documents should be of help to manufacturers in particular in cases where the presumption of conformity to the requirements implies the simultaneous applicability of several standards.

6. CONSISTENCY WITH OTHER COMMUNITY POLICIES

The consistency with other Community policies is particularly ensured by the fact that the principles on which this Directive is based are those set out in the Council

Resolution of 7 May 1985 on a new approach to technical harmonisation and standards. Additionally, interface with other Community legislation has been particularly considered, by excluding from the scope of the directive specific equipment, as specified in Article 1, point 2 of this proposal.

7. EXTERNAL CONSULTATIONS

As indicated in section 2.1, the process of revision of the Directive was started following a Communication to the European Parliament and the Council (COM(1999)88), where the Commission endorsed most of the Recommendations of the SLIM panel, composed of independent experts.

The preparation of a proposal for the revision of the EMC Directive was assisted by an EMC SLIM Working Group, made up of Member States and Industry representatives (manufacturers, utility operators, certification bodies, etc).

As a result of the work of this group, several drafts of the future EMC Directive have been prepared for discussion and published on the Internet site of the Commission, in order to reach the widest possible audience of interested parties.

In order to provide the Commission and all other interested parties with the relevant technical information, an independent study was carried out during the year 2000 under contract from the European Commission. Based on the technical findings of this study, the proposal to include ready-made connecting devices within the scope of the Directive and to regulate specifically fixed installations has been added.

Similarly, the evaluation detailed in section 8 was supported by an independent study carried out in 2001 whose objective was to perform a cost benefit analysis on the proposed revision of the Directive.

8. EVALUATION

The assessment of what impact a revision of the Directive will have on the European economy is based on a study carried out by an outside body.

The purpose of the study is to quantify the impact of the changes introduced by the proposed text on the various interested parties. This represents a pilot case of the new orientation of the Commission, whose intention is to use impact assessment as a tool to improve the quality and coherence of the policy development process, as expressed in a recent Communication from the Commission*.

The study was therefore conducted on the basis of an enquiry with interested parties, which included manufacturers, installers, certification bodies, private and professional users and the public authorities responsible for EMC. The final report of the study is available on the web site of the Commission.

The major points considered in this assessment are the following:

* COM(2002)276

- Improving the legal certainty of the text by making available to those responsible for observing and enforcing the Directive a clearer and more detailed text which provides an answer to the varying interpretations of the existing text,
- A coherent and more detailed definition of the aspects covered by the Directive,
- Scope for action by certification bodies,
- Specifying the essential requirements and clarifying the application of harmonised standards,
- Special arrangements for fixed installations.

It emerges from the study that most of those involved in this area believe that the proposal for a Directive will formalise the mechanisms implemented at present, and the study recommends the directive to be revised. At the moment, the Directive is supplemented by a guide. The major qualitative advantage will be to provide a legal basis for the users of this guide. A second qualitative advantage will be the anticipated reduction in the level of electromagnetic interference, chiefly benefiting users and operators of electricity and telecommunication networks.

According to the study, the overall typical net cost for all affected parties in the EU will be € 2.4 billion discounted over the 8 years that the amended Directive is expected to remain in force. This amounts to less than 0.1% of the EU output of EMC products during the same period. This net cost will be mainly (90%) borne by the manufacturers. The sensitivity analysis indicates reasonably stable results: the typical cost coincides with the average and median costs; the lowest estimate is - € 1.3 billion, the 25% quartile - €1.9 billion, the 75% quartile - €2.9 billion and the highest estimate - €3.5 billion. The main uncertainties in the cost/benefit estimates are caused, following the study, by lack of clarity in the use of standards and diverging interpretations of the product scope, product definitions and regime for fixed installations. The Commission is of the opinion that the provisions of Articles 1 and 2 (Scope and definitions) and of Annex V (application of harmonised standards) will reduce the uncertainties. These provisions have received a large support in the consultation process.

At a more detailed level, certain specific points need clarifying:

- (1) **Changing the scope:** The proposal for a Directive excludes from its scope apparatus with a low level of emission but specifically includes ready-made connecting devices intended for connection to an apparatus by an end user for the transmission of signals. The study showed that the inclusion of the latter made up a major cost item (approximately 60% of the overall gross cost), which is largely to be borne by the manufacturers, particularly in the field of information technologies. In the Commission's opinion, however, this must be qualified by the fact that inclusion of this type of equipment, which was also recommended by an independent technical study, will avoid potentially divergent national legislation. As it will ensure the smooth operation of the internal market for the targeted products, this will be a move towards an overall medium-term reduction in costs. On the other hand, the inclusion of this type of ready-made connecting device could increase the workload of the certification bodies, but to a lesser extent. By contrast, both the end users and

the operators identified a gain resulting from the anticipated reduction in electromagnetic interference. The exclusion of low-emission apparatus should not produce any change.

- (2) **Fixed installations:** The proposal for a Directive explicitly covers equipment designed specifically to be incorporated in a fixed installation and requires that fixed installations be constructed in accordance with good engineering practice. As a result, a reduction in manufacturers' costs has been identified, accompanied by a foreseeable reduction in the activities of certification bodies. Nonetheless, complaints may generate substantial costs, since the Directive requires that it be possible to demonstrate conformity with the requirements in this case, which may offset the anticipated benefits.
- (3) **Intervention by notified bodies:** The current Directive requires, in some cases, the intervention of a "Competent Body" which issues a certificate/technical report placed in the technical file which proves conformity with the essential requirements. In the proposed Directive, the name of such bodies has been changed to "Notified Body" to make it consistent with other New Approach Directives. The intervention of such a body is no longer mandatory and the proposal leaves it up to the manufacturer to ask for the intervention of such a body if he considers such an intervention appropriate. The study shows that there might be fewer cases of recourse to notified bodies, thereby reducing the costs borne by manufacturers, whereas the market supervision authorities would have to invest more in technical expertise.
- (4) **Revision of the essential requirements**
 - (a) Electromagnetic compatibility assessment: Some manufacturers in the information technology sector stressed that a maximalist interpretation of the requirement to ensure conformity in all configurations would require the actual testing of all such configurations, thus leading to substantial additional costs. Taking note of this finding of the impact assessment study, the proposal for a Directive has been amended in order to clarify its interpretation by introducing a more reasonable arrangement which does not require the testing of all configurations. Therefore, a possible source of additional social utility loss has been suppressed.
 - (b) Conformity without external devices: The proposal for a Directive requires apparatus to conform to the principal requirements without the aid of external devices. The associated one-off design costs are borne by the manufacturers and limited to the first two years of implementation of the Directive.
 - (c) Making information available: Manufacturers pointed to high costs (approximately 30% of the overall gross cost) due to the requirements for specific information to be provided with the apparatus, as set out in Annex I to the proposal for a Directive, as a result of the need to change the documentation process and, possibly, the production process. This stricter line on documentation compared with the present documentation requirements will fill a gap in the current Directive and

will align the requirements with those of other New Approach Directives. The proposed regime would enable the market surveillance authorities to identify cases of non-conformity more easily and thus support them in taking measures against manufacturers who do not comply with the Directive.

- (5) **Application of harmonised standards:** The proposal for a Directive clarifies the concept of conformity to standards. Some manufacturers expressed fears that a literal application of the standards might impose further constraints as regards the testing methods and instruments to be used, thereby generating substantial costs. Nevertheless, it is fundamental, in the interests of equity, that standards, whose application remains voluntary, be applied identically by all manufacturers, an aspect which this proposal clarifies.

The Impact Assessment study has proved to be extremely useful. The findings of the study have led to improvement of the text of the directive, avoiding possible sources of social utility losses. According to the study, the proposal of directive involves extremely low costs for those concerned with respect to market volume. The study also concludes that the proposal of directive can bring qualitative benefits that are difficult to quantify, in particular concerning the achieved protection level.

The major cost factors identified should thus be viewed against the benefits brought by the proposal. These benefits will include improved operation of the internal market, greater flexibility for the actors of the market, for given aspects an improved level of protection and the improvement of the tools made available to the competent authorities to perform market surveillance.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the approximation of the laws of the Member States relating to electromagnetic compatibility

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Acting in accordance with the procedure referred to in Article 251 of the Treaty³,

Whereas:

- (1) Council Directive 89/336/EEC of 3 May 1989 on the approximation of laws of the Member States relating to electromagnetic compatibility⁴ has been the subject of a review under the initiative known as Simpler Legislation for the Internal Market (SLIM)⁵. Both the SLIM process⁶ and a subsequent in-depth consultation have revealed the need to complete, reinforce and clarify the framework established by Directive 89/336/EEC.
- (2) Member States are responsible for ensuring that radio-communications, electrical supply and telecommunications networks, as well as equipment connected thereto, are protected against electromagnetic disturbance.
- (3) Provisions of national law ensuring protection against electromagnetic disturbance should be harmonised in order to guarantee the free movement of electrical and electronic apparatus without lowering justified levels of protection in the Member States.
- (4) Protection against electromagnetic disturbance requires obligations to be imposed on the various economic operators. Those obligations should be applied in a fair and effective way in order to achieve such protection.

¹ OJ C , , p. .

² OJ C , , p. .

³ OJ C , , p. .

⁴ OJ L 139, 23.5.1989, p.19, as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993,p.1)

⁵ COM(1996)559

⁶ COM(1999)88

- (5) The electromagnetic compatibility of equipment should be regulated with a view to ensuring the functioning of the internal market, that is to say, of an area without internal frontiers in which the free movement of goods, persons, services and capital is assured.
- (6) The equipment covered by this Directive should include both apparatus and fixed installations. However, separate provision should be made for each. This is so because, whereas apparatus as such is subject to free movement inside the Community, fixed installations on the other hand are installed for permanent use at a predefined location, as assemblies of various types of apparatus and where appropriate other devices. The composition and function of such installations correspond in most cases to the particular needs of their operators.
- (7) Radio equipment and telecommunications terminal equipment should not be covered by this Directive since they are already regulated by Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity⁷. The electromagnetic compatibility requirements in both Directives achieve the same level of protection.
- (8) Aircraft or equipment intended to be fitted into aircraft should not be covered by this Directive, since they are already subject to special Community or international rules governing electromagnetic compatibility.
- (9) This Directive need not regulate equipment which is inherently benign in terms of electromagnetic compatibility.
- (10) The safety of equipment should not be a matter covered by this Directive, since it is dealt with by separate Community or national legislation.
- (11) Where this Directive regulates apparatus, it should refer to finished apparatus commercially available for the first time on the Community market. Certain components or sub-assemblies should, under certain conditions, be considered to be apparatus if they are made available to the end-user. Ready-made connecting devices, although incapable of generating electromagnetic disturbance in isolation, may generate or transmit electromagnetic disturbance when connected to an apparatus and should therefore be considered to be apparatus for the purposes of this Directive.
- (12) The principles on which this Directive is based are those set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards⁸. In accordance with that approach, the design and manufacture of equipment is subject to essential requirements in relation to electromagnetic compatibility. Those requirements are given technical expression by harmonised European standards, to be adopted by the various European standardisation bodies, CEN (European Committee for Standardisation), CENELEC (European Committee for Electro-technical Standardisation) and ETSI (European Telecommunications Standards Institute). CEN, CENELEC and ETSI are recognised as the competent institutions in the field of this Directive for the adoption of harmonised standards, which they draw up in accordance with the general guidelines for co-operation

⁷ OJ L 91, 7.4.1999, p.10

⁸ OJ C 136, 4.6.1985, p.1

between themselves and the Commission, and with the procedure laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations⁹.

- (13) It is in the interest of the functioning of the internal market to have standards for the electromagnetic compatibility of equipment which have been harmonised at Community level; once the reference to such a standard has been published in the *Official Journal of the European Communities*, compliance with it should raise a presumption of conformity with the relevant essential requirements, although other means of demonstrating such conformity should be permitted.
- (14) Manufacturers of equipment intended to be connected to networks should construct such equipment in a way that prevents networks from suffering unacceptable degradation of service when used under normal operating conditions. Network operators should construct their networks in such a way that manufacturers of equipment liable to be connected to networks do not suffer a disproportionate burden in order to prevent networks from suffering an unacceptable degradation of service. The European standardisation organisations should take due account of that objective (including the cumulative effects of the relevant types of electromagnetic phenomena) when developing harmonised standards.
- (15) It should be possible to place apparatus on the market or put it into service only if the manufacturers concerned have established that such apparatus has been designed and manufactured in conformity with the requirements of this Directive. Apparatus placed on the market should bear the CE marking attesting to compliance with the Directive. Although conformity assessment should be the responsibility of the manufacturer, without any need to involve an independent conformity assessment body, manufacturers should be free to use the services of such a body.
- (16) The conformity assessment obligation should require the manufacturer to perform an electromagnetic compatibility assessment of apparatus, based on relevant phenomena, in order to determine whether or not it meets the protection requirements under this Directive.
- (17) Where apparatus can take different configurations, the electromagnetic compatibility assessment should confirm that the apparatus meets the protection requirements in the configurations foreseeable by the manufacturer as representative of normal use in the intended applications; in such cases it should be sufficient to perform an assessment on the basis of the configuration most likely to cause maximum disturbance and the configuration most susceptible to disturbance.
- (18) Fixed installations, including large machines and networks, may generate electromagnetic disturbance, or be affected by it. There may be an interface between fixed installations and apparatus, and the electromagnetic disturbances produced by fixed installations may affect apparatus, and vice versa. In terms of electromagnetic compatibility, it is irrelevant whether the electromagnetic disturbance is produced by apparatus or by a fixed installation. Accordingly, fixed installations and apparatus should be subject to a coherent and comprehensive regime of essential requirements. It

⁹ OJ L 204, 21.7.1998, p.37 as last amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18)

should be possible to use harmonised standards for fixed installations in order to demonstrate conformity with the essential requirements covered by such standards.

- (19) Due to their specific characteristics, fixed installations need not be subject to the affixation of the CE marking or to the declaration of conformity.
- (20) 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 is to be incorporated. Such apparatus should therefore be exempted from the conformity assessment procedures normally applicable to apparatus. However, such apparatus should not be permitted to compromise the conformity of the fixed installation into which it is incorporated.
- (21) A transitional period is necessary in order to ensure that manufacturers and other concerned parties are able to adapt to the new regulatory regime.
- (22) Directive 89/336/EEC should therefore be repealed.
- (23) Since the objectives of the proposed action, to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility cannot be sufficiently achieved by Member States acting alone and can therefore, by reason of their scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

Chapter I

GENERAL PROVISIONS

Article 1

Subject matter and scope

- 1. This Directive regulates the electromagnetic compatibility of equipment. It aims to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility.
- 2. This Directive shall not apply to:
 - (a) equipment covered by Directive 1999/5/EC;
 - (b) aircraft and equipment intended to be fitted into aircraft;
 - (c) radio equipment which is not commercially available, including kits of components to be assembled by radio amateurs, within the meaning defined in the Radio Regulations adopted in the framework of the Constitution and Convention of the International Telecommunication

Union¹⁰, as well as commercial equipment modified by and for the use of such radio amateurs

3. This Directive shall not apply to equipment the inherent nature of whose physical characteristics is such that:
 - (a) it is incapable of generating electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
 - (b) it will operate without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use.
4. This Directive shall not apply to equipment or requirements in so far as the requirements laid down in this Directive are harmonised by more specific Community legislation.
5. This Directive shall not affect the application of Community or national legislation regulating the safety of equipment.

Article 2 *Definitions*

1. For the purposes of this Directive, the following definitions shall apply:
 - (a) "Equipment" means any apparatus or fixed installation;
 - (b) "Apparatus" means any finished appliance, or combination thereof made commercially available as a single functional unit, intended for the end user, and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;
 - (c) "Fixed installation" means a particular 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;
 - (d) "Electromagnetic compatibility" means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment 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 as intended without degradation in the presence of an electromagnetic disturbance;

¹⁰ Constitution and Convention of the International Telecommunication Union adopted by the Additional Plenipotentiary Conference (Geneva, 1992) as amended by the Plenipotentiary Conference (Kyoto, 1994).

- (g) "Harmonised standard" means a technical specification adopted by a recognised standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement, compliance with which is not compulsory.
2. For the purposes of this Directive the following shall be deemed to be an apparatus within the meaning of paragraph 1(b):
- (a) "components" or "sub-assemblies" intended for incorporation into an apparatus by the end user, which are liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;
 - (b) "ready-made connecting devices" intended for connection to an apparatus by an end user for the transmission of signals, which are placed on the market separately from such apparatus, and which are liable to generate or transmit electromagnetic disturbance when connected to it.

Article 3

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 requirements of this Directive when properly installed, maintained and used for its intended purpose.

Article 4

Free circulation of equipment

1. Member States shall not impede, for reasons relating to electromagnetic compatibility, the placing on the market and/or the putting into service in their territory of equipment which complies with this Directive.
2. The requirements of this Directive shall not prevent the application in any Member State of special measures, concerning the putting into service or use of equipment, which have been taken in respect of a specific site in order to overcome an existing or predicted electromagnetic compatibility problem, or for safety purposes to protect the public telecommunications networks or receiving or transmitting stations used. Member States shall notify those measures in accordance with the procedure laid down in Directive 98/34/EC.
3. Member States shall not create any obstacles to the display at trade fairs, exhibitions, demonstrations or similar events of equipment which does not comply with this Directive provided that a visible sign clearly indicates that such equipment may not be placed on the market or put into service until it has been brought into conformity with this Directive.

Article 5
Essential requirements

The equipment referred to in Article 1 shall meet the essential requirements set out in Annex I.

Article 6
Harmonised standards

1. The compliance of equipment with the relevant harmonised standards whose references have been published in the *Official Journal of the European Communities* shall raise a presumption, on the part of the Member States, of conformity with the essential requirements referred to in Annex I to which such standards relate.
2. The modalities for the application of harmonised standards are set out in Annex V.
3. Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential requirements referred to in Annex I, it shall bring the matter before the Standing Committee set up by Directive 98/34/EC (hereinafter “the Committee”), stating its reasons. The Committee shall deliver an opinion without delay.
4. Upon receipt of the Committee’s opinion, the Commission shall take one of the following decisions with regard to the references to the harmonised standard concerned:
 - (a) not to publish;
 - (b) to publish with restrictions;
 - (c) to maintain the reference in the publication referred to in paragraph 1;
 - (d) to withdraw the reference from the publication referred to in paragraph 1.

The Commission shall inform the Member States of its decision without delay.

Chapter II
APPARATUS

Article 7
Conformity assessment procedure for apparatus

1. For the purposes of demonstrating the compliance of apparatus with the provisions of this Directive, with a view to its placing on the market and/ or putting into service, the conformity assessment procedure set out in paragraphs 2 to 5 shall be used.
2. The manufacturer or his authorised representative established within the Community shall draw up technical documentation which provides evidence of the conformity of the apparatus with the essential requirements of this Directive.

The technical documentation may include a report from the notified body referred to in Article 11 confirming the compliance of the apparatus with the relevant essential requirements set out in Annex I. The manufacturer may determine the subject and depth of the assessment to be carried out.

The technical documentation shall be held at the disposal of the competent authorities for a period of at least ten years after the date on which such apparatus was last manufactured.

3. The compliance of apparatus with all relevant essential requirements shall be attested by an EC declaration of conformity issued by the manufacturer or his authorised representative established within the Community.

The EC declaration of conformity shall be held at the disposal of the competent authorities for a period of at least ten years after the date on which such apparatus was last manufactured.

4. If neither the manufacturer nor his authorised representative is established within the Community, the obligation to hold the EC declaration of conformity and the technical documentation at the disposal of the competent authorities shall be the responsibility of the person who places the apparatus on the Community market.
5. The technical documentation and the EC declaration of conformity shall be drawn up in accordance with the provisions set out in Annex II.

Article 8 *CE marking*

1. Apparatus whose compliance with this Directive has been established by the procedure laid down in Article 7 shall bear the CE marking which attests to that fact. The affixing of the CE marking shall be the responsibility of the manufacturer or his authorised representative established within the Community.

The CE marking shall be affixed in accordance with the provisions set out in Annex III.

2. Member States shall take the necessary measures to prohibit the affixing to the apparatus, or to its packaging, or to the instructions for its use of marks which are likely to mislead third parties in relation to the meaning and/or graphic form of the CE marking.
3. Any other mark may be affixed to the apparatus, its packaging, or the instructions for its use, provided that neither the visibility nor the legibility of the CE marking is thereby impaired.
4. Without prejudice to Article 9, if a competent authority establishes that the CE marking has been unduly affixed, the manufacturer or his authorised representative established within the Community shall bring the apparatus into conformity with the provisions concerning the CE marking under conditions imposed by the Member State concerned.

Article 9
Safeguards

1. Where a Member State ascertains that an apparatus bearing the CE marking does not comply with the requirements of this Directive, it shall take all appropriate measures to withdraw the apparatus from the market, to prohibit its placing on the market or putting into service, or to restrict its free movement.
2. The Member State concerned shall immediately inform the Commission and the other Member States of any such measure, indicating the reasons and specifying, 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 harmonised standards referred to in Article 6;
 - (b) incorrect application of the harmonised standards referred to in Article 6;
 - (c) shortcomings in the harmonised standards referred to in Article 6.
3. The Commission shall consult the parties concerned as soon as possible, following which it shall inform the Member States whether or not it finds the measure to be justified.
4. Where the measure referred to in paragraph 1 is attributed to a shortcoming in harmonised standards, the Commission, after consulting the parties, shall, if the Member State concerned intends to uphold the measure, bring the matter before the Committee and initiate the procedure laid down in Article 6(3).
5. Where the non-compliant apparatus is accompanied by the report referred to in Article 7(2), the Member State concerned shall take appropriate action in respect of the author of that report, and shall inform the Commission and the other Member States accordingly.

Article 10

Decisions with respect to the withdrawal, prohibition or restriction of free movement of apparatus

1. Any decision taken pursuant to this Directive to withdraw an apparatus from the market, prohibit or restrict its placing on the market or its putting into service, 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, his authorised representative, or other interested party 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 with respect to public interest requirements.

Article 11
Notified bodies

1. Member States shall designate the bodies competent to draw up the reports referred to in Article 7(2) and shall notify them (notified bodies) to the Commission and to the other Member States.

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

2. Member States shall apply the criteria listed in Annex IV for the assessment of notified bodies.
3. Bodies which comply with the assessment criteria fixed by the relevant harmonised standards shall be presumed to comply with the criteria set out in Annex IV covered by such harmonised standards. The Commission shall publish in the *Official Journal of the European Communities* the references of these standards.
4. The Commission shall publish in the *Official Journal of the European Communities* a list of notified bodies. The Commission shall ensure that the list is kept up to date.
5. If a Member State finds that a notified body no longer meets the criteria listed in Annex IV, it shall inform the Commission and the other Member States accordingly. The Commission shall withdraw the reference to that body from the list referred to in paragraph 4.

Chapter III
FIXED INSTALLATIONS

Article 12
Fixed installations

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

However, the provisions of Articles 5, 7 and 8 shall not be compulsory in the case of apparatus which is specifically designed for incorporation into a given fixed installation and is otherwise not commercially available. In such cases, the accompanying documentation shall name the site of the fixed installation and indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of the specified installation. It shall furthermore include the information referred to in Point 4(a) and (b) of Annex I.

2. Where there are indications of non-compliance of the fixed installation, in particular, where there are complaints about disturbances being generated by the installation, the competent authorities of the Member State concerned 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 into compliance with the protection requirements set out in Annex I.

3. Member States shall set out the necessary provisions for the identification of the person or persons responsible for the establishment of compliance of a fixed installation with the relevant essential requirements.

Chapter IV

FINAL PROVISIONS

Article 13 *Repeal*

Directive 89/336/EEC is hereby repealed as from [*date of application*¹¹].

References to Directive 89/336/EEC shall be construed as references to this Directive and be read in accordance with the correlation table set out in Annex VI.

Article 14 *Transitional provisions*

Member States shall not impede the placing on the market and/ or putting into service of equipment which is in compliance with the provisions of Directive 89/336/EEC and which was placed on the market before [*date of application* + 2 years].

Article 15 *Transposition*

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by [*date of application* – 6 months] at the latest. They shall forthwith inform the Commission thereof. They shall apply those provisions as from [*date of application*].
When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such a publication shall be laid down by Member States.
2. 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.

¹¹ Date of application is defined as the date of publication + 30 months

Article 16
Entry into force

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

Article 17
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I
Essential requirements

1. PROTECTION REQUIREMENTS

1. Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:
 - (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
 - (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

2. 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 Point 1.

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

In cases where the apparatus can take different configurations, the electromagnetic compatibility assessment shall confirm that the apparatus meets the protection requirements set out in Point 1 in all possible configurations identified by the manufacturer as representative of normal use in its intended application.

3. External devices:

All apparatus shall meet the protection requirements referred to in Point 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 and intended for installation by a person technically competent in the field of electromagnetic compatibility. In such cases 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;

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 Point 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 in terms of type, batch, serial number or any other information allowing for the identification of the apparatus;
- (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 or used, in order to ensure that, when put into service, the apparatus is in conformity with the protection requirements set out in Point 1;
- (d) Apparatus for which compliance with the protection requirements is not ensured in residential areas shall be accompanied by a clear indication of this restriction of use.

5. Ready-made connecting devices:

- (a) The requirements for apparatus set out in Points 2, 3, 4(c) and (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 Point 1 is ensured;
- (c) Ready-made connecting devices shall be accompanied by an indication of the technical characteristics of the apparatus to which they are intended to be connected, and 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 Point 1.

3. SPECIFIC REQUIREMENTS FOR FIXED INSTALLATIONS

6. Installation and intended use of components:

A fixed installation shall be installed 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 Point 1.

ANNEX II
Technical documentation, EC declaration of conformity

1. 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 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, a description and explanation of the steps taken 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.;
- on a voluntary basis, the manufacturer may include in the technical documentation a report from a notified body confirming the conformity of the apparatus with the relevant essential requirements set out in Annex I.

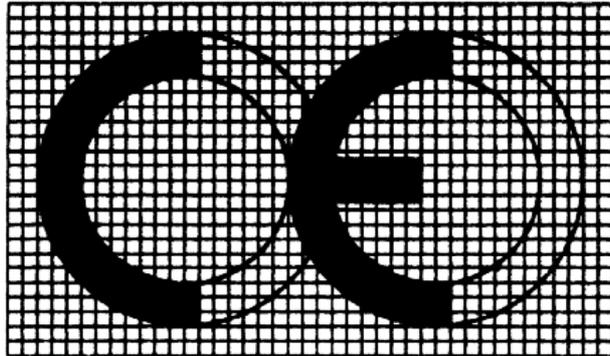
2. EC DECLARATION OF CONFORMITY

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 Point 4(a) of Annex I;
- 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 this Directive;
- date and place of issue of the declaration;
- identification and signature of the person empowered to bind the manufacturer or his authorised representative.

ANNEX III
CE marking

The CE marking shall consist in 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. Where this is not possible or not warranted on account of the nature of the apparatus, 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 marking, the latter shall indicate that the apparatus also conforms with those other Directives.

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

ANNEX IV

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 interested parties, groups or persons directly or indirectly concerned with the equipment 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 Point 1 shall be verified at intervals by the competent authorities of the Member States.

ANNEX V
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 Point 2 of 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.
3. Presumption of conformity via application of harmonised standard(s) is limited to the scope of the harmonised standard(s) applied and the relevant essential requirements covered by such harmonised standard(s).
4. Harmonised standards are to be selected and used in accordance with the provisions of the relevant standardisation documents. The reference to those documents shall be published in the *Official Journal of the European Communities*.

ANNEX VI
Correlation Table

Directive 89/336/EEC	This Directive
Article 1, point 1)	Article 2, points 1(a), 1(b), 1(c)
Article 1, point 2)	Article 2, point 1(e)
Article 1, point 3)	Article 2, point 1(f)
Article 1, point 4)	Article 2 point 1(d)
Article 1 points 5 and 6)	-
Article 2 point 1.	Article 1 point 1.
Article 2 point 2.	Article 1 point 4.
Article 2 point 3.	Article 1 point 2(c)
Article 3	Article 3.
Article 4	Article 5 and Annex I
Article 5	Article 4 point 1.
Article 6	Article 4 point 2.
Article 7 point 1.(a)	Article 6 points 1. and 2., Annex V
Article 7 point 1(b)	-
Article 7 point 2.	-
Article 7 point 3.	-
Article 8 point 1.	Article 6 points 3. and 4.
Article 8 point 2.	-
Article 9 point 1.	Article 9, points 1. and 2.
Article 9 point 2.	Article 9, points 3. and 4.
Article 9 point 3.	Article 9, point 5.
Article 9 point 4.	Article 9, point 3.
Article 10 point 1 1 st paragraph	Article 7
Article 10 point 1 2 nd paragraph	Article 8

Article 10 point 2	Article 7
Article 10 point 3	-
Article 10 point 4	-
Article 10 point 5	Article 7
Article 10 point 6	Article 11
Article 11	Article 13
Article 12	Article 15
Article 13	Article 17
Annex I, section 1	Annex II, section 2
Annex I, section 2	Annex III
Annex II	Annex IV
Annex III	-

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES (SMEs)

TITLE OF PROPOSAL

Proposal for a Directive of the European Parliament and of the Council on electromagnetic compatibility, amending Directive 89/336/EEC

DOCUMENT REFERENCE NUMBER

THE PROPOSAL

The aim of this proposal for a Directive is to ensure the free movement of the products referred to in it by guaranteeing a homogeneous electromagnetic environment and ensuring the proper functioning of the products concerned. The products concerned are essentially electrical and electronic apparatus, ready-made connecting devices intended for connection to an apparatus by an end user for the transmission of signals, and fixed installations created using such apparatus.

This proposal for a Directive is based on Article 95 of the Treaty establishing the European Community and revises Directive 89/336/EEC, which is currently in force. It meets the request for simplification expressed by all economic operators by establishing a better definition of certain concepts and clarifying the wording of texts which caused difficulties in applying the current Directive. Moreover, the scope has been redefined to make it clearer and to include certain products.

This proposal for a Directive originates from phase III of the SLIM programme, in particular from the recommendation from the SLIM team, endorsed by the Commission (COM(1999)88).

The proposal has, to a very large extent, been favourably received by the parties concerned and is seen as being suited to the market requirements. It complies with the principles of subsidiarity and proportionality required by Community texts.

THE IMPACT ON BUSINESS

This proposal for a Directive covers all electrical and electronic sectors, including domestic appliances, information technology and telecommunications.

As further developed in the explanatory memorandum, the impact on business is based on both an independent impact analysis study ("Cost benefit analysis on the draft amendment of the EC Directive on electromagnetic compatibility", RPA Ltd, January 2002) and an internal market business test panel initiated by the Commission. The impact analysis study based its finding on an enquiry process during which contact was made with more than 410 European and International organisations, representing manufacturers of apparatus, installers and users of installations, certifying laboratories, professional and end-user of equipment and

consumers of appliances, users and operators of radio, telecommunications and electricity networks, together with public authorities.

Both studies showed that small and medium-sized enterprises made up around 60% of the enterprises covered, representing an annual total of 800 million products, and the total annual turnover of the sector amounted to around €400 billion. These enterprises are spread throughout the territory of the Community, with Germany, France, Italy and the United Kingdom accounting for 75% of the equipment produced.

The majority of the enterprises manufacturing the products referred to in this proposal for a Directive are already required to apply Directive 89/336/EEC. Consequently, they will not have to take any particular measures in order to comply with the new text. The sector which has now been included in its scope comprises chiefly manufacturers of ready-made connecting devices intended for connection to an apparatus by an end user for the transmission of signals and these are, in the main, small and medium-sized enterprises. The proposal will therefore not have a major effect on the economy as a whole. It is thus not expected that the proposal will have effects neither on employment nor on investment or creation of new businesses, with the possible exception of an increase in the business of competent bodies. In figures, the impact analysis concluded that there would be a net utility loss for all EU manufacturers of EMC products of €2.1 billion, which amounts to 0.1% of the sector's turnover, discounted over a period of 8 years.

This proposal does not contain any specific measure applicable to small and medium-sized enterprises. This is because, in the proposal for a Directive, the conformity assessment procedures have already been reduced to a simple declaration of conformity made by the manufacturer without the compulsory intervention of a third party.

CONSULTATION

From the beginning of the work on this proposal, the Commission has, via the "EMC SLIM" working group, associated all the professional bodies concerned in the work, including manufacturers, utility operators, certification bodies, etc... During the elaboration of this proposal for a Directive, eight drafts have been elaborated and discussed by this SLIM working group, and made available on the Internet site of the Commission, in order to reach the widest possible audience of interested parties. The federations and organisations consulted include the following:

(1) **Manufacturers**

- ORGALIME Liaison Group of the European Mechanical, Electrical, Electronic and Metalworking Industries
- EURELECTRIC Union of Electricity Industry
- EICTA European Information, Communications and Consumer Electronics Technology Industry Association
- EACM European Association of Consumer Electronics Manufacturers

- EUROPACABLE European Confederation of National Associations of Manufactures of Insulated Wire and Cable

(2) Users

- ANEC European Association for the co-ordination of consumer representation in standardisation

(3) Others

- CEN European Committee for Standardization
- CENELEC European Committee for Electrotechnical Standardization
- ETSI European Telecommunications Standards Institute
- ECACB European EMC Competent Bodies group

CONCLUSIONS

The impact analysis study has recommended the revision of the directive. Additionally, in Commission's opinion, net social utility loss identified should thus be viewed against the benefits brought by the proposal. These benefits will include improved operation of the internal market, greater flexibility for the actors of the market, and for given products, an improved level of protection. The proposal will also include an improvement of the tools made available to the competent authorities to perform market surveillance, which will ensure a fairer competition between the actors of the market.