

**GUIDELINES ON THE APPLICATION OF COUNCIL
DIRECTIVE 89/336/EEC OF 3 MAY 1989 ON THE APPROXIMATION OF THE
LAWS OF THE MEMBER STATES RELATING TO ELECTROMAGNETIC
COMPATIBILITY
(DIRECTIVE 89/336/EEC AMENDED BY DIRECTIVES
91/263/EEC, 92/31/EEC, 93/68/EEC, 93/97/EEC)**

NOTES

1. *These guidelines are intended to be a manual for all parties directly or indirectly affected by the EMC (electromagnetic compatibility) Directive. They should be read and used as a help for interpretation of the Directive, they do not substitute for it; they simply explain and clarify some of the most important aspects related to the application of this Directive. They are also intended to ensure the free movement of products in the EU Internal Market by agreement of these explanations and clarification's, reached by consensus among Member States' government experts and other parties concerned. The existence of these harmonised interpretations is expected to minimise the number of safeguard clause applications, at least those originating from divergent interpretations.*

2. *These guidelines have been prepared by the competent services of the General Directorate III Industry of the Commission in collaboration with the group of government experts of Member States, representatives of European industry, European standardisation bodies and Bodies entrusted with the technical tasks related to third party intervention in the conformity assessment procedures.*

3. *Guidelines are publicly available, but they are not binding in the sense of legal acts adopted by the Community. The legally binding provisions are those transposing the EMC Directive*

4. *Finally, the reader's attention is drawn to the fact that all references to the CE marking and EC Declaration of conformity relates only to the EMC Directive and that placing an apparatus on the market in the EEA territory is only guaranteed when applying all the relevant legislation.*

CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE EMC DIRECTIVE
3. DEFINITIONS
 - 3.1. Placing of an apparatus the market
 - 3.2. Taking an apparatus into service
 - 3.3. Manufacturer
 - 3.4. Authorised representative
 - 3.5. Importer
 - 3.6. Other Responsible persons
 - 3.7. Finished product
 - 3.8. Direct Function
4. KEY ARTICLES OF THE EMC DIRECTIVE WITH REGARD TO ITS SCOPE
 - 4.1. General
 - 4.2. EMC Analysis - Decision flow-chart
5. SCOPE OF THE DIRECTIVE
 - 5.1. General
 - 5.2. Apparatus explicitly listed within the scope of the EMC Directive
 - 5.3. Passive-EM equipment
 - 5.4. Additional practical criteria (accepted by consensus) to exclude equipment from the scope of the EMC Directive
 - 5.5. Apparatus partially or totally excluded from the EMC Directive
6. APPLICATION OF THE DIRECTIVE TO COMPONENTS, FINISHED PRODUCTS, SYSTEMS AND INSTALLATIONS
 - 6.1. General
 - 6.2. Application of the Directive to components
 - 6.3. Application of the Directive to finished products
 - 6.4. Application of the Directive to systems
 - 6.5. Application of the Directive to installations
7. APPLICATION OF THE DIRECTIVE TO USED, SECOND HAND, AND REPAIRED APPARATUS, AND TO SPARE PARTS.
 - 7.1. Definitions
 - 7.2. Application of the EMC Directive
 - 7.3. Modifications carried out by the end-user (under his responsibility)
 - 7.4. Repaired apparatus and spare parts
8. PROCEDURES FOR ASSESSMENT OF THE CONFORMITY
 - 8.1. Article 10.1 procedure
 - 8.2. Article 10.2 procedure
 - 8.3. Article 10.5 procedure

9. EC DECLARATION OF CONFORMITY
 10. INSTRUCTIONS FOR USE
 11. COMPETENT AUTHORITIES, COMPETENT BODIES, AND NOTIFIED BODIES
 - 11.1. Competent authorities
 - 11.2. Competent bodies
 - 11.3. Notified bodies
 12. APPARATUS MARKING
 13. SAFEGUARD CLAUSE
 14. PROGRESS ON STANDARDISATION
 - 14.1. Standards published in the Official Journal
 - 14.2. Standardisation programme
 15. APPLICATION OF THE DIRECTIVE TO SOME SPECIFIC CASES
 - 15.1 Application to Telecommunication and Radiocommunication equipment
 - 15.2 Application to Machines
 - 15.3 Application to Motor vehicles
 - 15.4 Application to Equipment to be fitted in aircraft
 - 15.5 Application to Medical devices
 - 15.6 Application to Active implantable medical devices
 - 15.7 Application to In Vitro Diagnostic Medical Devices
 - 15.8 Application to Marine equipment
 - 15.9 Additional Information
-

- Annex 1: Text of the Directives 89/336/EEC and 92/31/EEC, and extracts of the directives 91/263/EEC, 93/68/EEC, 93/97/EEC
- Annex 2: Consolidated text of the EMC Directive 89/336/EEC
- Annex 3: References of national transpositions of the EMC Directive
- Annex 4: Competent authorities
- Annex 5: List of competent bodies known to the Commission
- Annex 6: List of the notified bodies notified to the Commission
- Annex 7: Harmonised standards published in the Official Journal of the European Communities
- Annex 8: Standardisation programme for the development of harmonised standards
- Annex 9: Useful addresses

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| Note : The information provided in Annexes 3 to 9 was correct on 17 June 1997 |
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1. INTRODUCTION¹

The objective of this document is to clarify certain matters and procedures referred to in Directive 89/336/EEC,² amended by Directives 91/263/EEC³, 92/31/EEC⁴, 93/68/EEC⁵ and 93/97/EEC⁶ concerning electromagnetic compatibility, with a view to compiling a guide for use in conjunction with the Directive.

In view of the breadth of the scope of the Directive and the variety of products covered, it has become necessary to address this document not only to the Member States' competent authorities, but also to the main economic operators concerned, such as manufacturers, their trade associations, the bodies in charge of the preparation of standards and those entrusted with the conformity assessment procedures.

First and foremost, this document must ensure that, when correctly applied, the Directive leads to the removal of obstacles and difficulties related to the free circulation (free movement) of goods within the European Economic Area (EEA)⁷, which any of the groups concerned may encounter.

The EMC Directive is a new-approach directive laying down apparatus protection requirements and leaving it to standards, primarily European harmonised standards, to define technical requirements to achieve the level of protection required.

The EMC Directive is a total harmonisation Directive, i.e. its provisions replaced the national ones concerned when they came into force.

The EMC Directive had to be transposed into national law by 1 July 1991. Its provisions have applied since 1 January 1992.

However, the wide scope of the EMC Directive demonstrated the overriding need to provide for a transitional period, so as to ensure a smooth changeover from the application of legislation of a purely national character to a Community-wide system.

That is why, on 28 April 1992, the Council adopted Directive 92/31/EEC with a view to allowing a transitional period until 31 December 1995.

During this transitional period, a manufacturer *had* the choice of placing on the market and/or putting into service :

¹ *These guidelines are the first revised version of those published on 25/26 October 1993.*

² OJ No L 139, 23.5.1989.

³ OJ No L 128, 23.5.1991.

⁴ OJ No L 126, 12.5.1992.

⁵ OJ No L 220, 30.8.1993.

⁶ OJ No L 290, 24.11.1993

⁷ According to the agreement related to the European Economic Area (EEA) (Council and Commission Decision 94/1/EC of 13 December 1993 (OJEC n° L 1 of 3 January 1994, p. 1)) the territories of Liechtenstein, Iceland and Norway have to be considered, for the implementation of Directive 89/336/EEC, as part of the Community territory. The Community territory is therefore composed of 18 States for the purposes of this Directive. When this term, Community territory, is used in this guide, it is meant the EEA territory.

- apparatus manufactured in accordance with the EMC Directive, whereby the free movement of the apparatus was guaranteed pursuant to the Directive, or
- apparatus manufactured in accordance with national regulations, whereby free movement of apparatus was guaranteed pursuant to Article 30 of the EEC Treaty, albeit subject to the possible derogation provided for in Article 36 and the jurisprudence of the European Community Court of Justice.

During the transitional period the choice of system to be applied *was* left to the manufacturer, but conformity to the Directive greatly facilitated the free movement of apparatus in the EEA. In particular, free access of an apparatus conforming to the Directive was guaranteed, even if a pre-existing national regulation still in force during the transitional period was more onerous.

As of 1 January 1996, Member States have abolished national regulations concerning electromagnetic compatibility and applied the provisions of the Directive for all apparatus.

2. OBJECTIVE OF THE EMC DIRECTIVE

The main objective of the EMC directive is to ***guarantee the free movement*** of apparatus⁸ and to create an acceptable electromagnetic environment in the EEA territory. In order to achieve it, a ***harmonised and acceptable level of protection*** is requested in the Directive, based on Article 100a of the Union Treaty, leading to full harmonisation in the EEA.

The level of protection requested is further specified in the EMC Directive by protection aims in the field of electromagnetic compatibility. The main goals are:

- a) To ensure that the electromagnetic disturbances produced by electrical and electronic apparatus does not affect the correct functioning of other apparatus according to the definition of Article 1.1 of the EMC Directive (see note 8), as well as radio and telecommunications networks, related equipment and electricity distribution networks.
- b) To ensure that apparatus have an adequate level of intrinsic immunity to electromagnetic disturbances to enable them to operate as intended.

To achieve these objectives, the EMC Directive lays down protection requirements and procedures under which the manufacturer may himself assess his apparatus against these requirements or may have it assessed by third parties. Obviously, the goal of the protection requirement is not to guarantee absolute protection of the above apparatus (e.g. zero emission level or total immunity of the apparatus). These requirements accommodate both physical facts and practical reasons. To ensure that this process remains open to future technical developments, the EMC Directive only describes protection requirements along general lines.

⁸ As defined in Article 1.1 of the Directive: all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components.

When compliant with the provisions of the EMC Directive, electrical and electronic apparatus may be placed on the market in the EEA territory, freely moved and operated as designed and intended in the expected electromagnetic environment.

The requirements for compliance with the provisions of the EMC Directive will be further developed in the following chapters.

3. DEFINITIONS⁹

3.1. Placing of an apparatus on the market

This means the first making available, against payment or free of charge, of an apparatus covered by the Directive, in the EEA market, for the purpose of distribution and/or use in the EEA.

Comments :

The concept of placing on the market determines the moment when an apparatus passes for the first time from the manufacturing stage to the market of the EEA or the importing stage from a third country to that of distribution and/or use in the EEA. Since the concept of placing on the market refers only to the first time an apparatus is made available in the EEA for the purpose of distribution and/or use in the EEA, the EMC Directive covers only *new* apparatus manufactured within the EEA and *new or used* apparatus imported from a third country.

The Directive's provisions and obligations concerning placing on the market apply after 1st January 1996 to each apparatus individually and not to a type, group or family of apparatus and irrespective of the date and place of manufacturing. It is the manufacturer's responsibility to ensure that each and all of his apparatus comply, where this apparatus falls under the scope of the Directive. He can use any method he deems appropriate. If he uses a statistical approach, like sampling (lots), he should ensure that the method is designed and carried out to achieve this end.

"Making available" means the transfer of the apparatus, that is, either the transfer of ownership, or the physical hand-over of the apparatus by the manufacturer, his authorised representative in the EEA or the importer to the person responsible for distributing the apparatus on the EEA market or the passing of the apparatus to the final consumer or user in a commercial transaction, for payment or free of charge, regardless of the legal instrument upon which the transfer is based (sale, loan, hire, leasing, gift, or any other type of commercial legal instrument). The apparatus must comply with the Directive at the moment of transfer;

If a manufacturer, his authorised representative in the EEA or the importer offers an apparatus covered by the Directive in a catalogue, it is deemed not to have been placed on the market until it is actually made available for the first time. Therefore apparatus offered

⁹ For general definitions see also the "Guide to the implementation of Community harmonisation directives based on the New Approach and the Global Approach", sheet I/B. Further definitions specific to the particular EMC directive are covered in chapter 5 of this guide.

in a catalogue would not have to be in full conformity with the provisions of the EMC Directive, but this fact must be clearly advertised in the catalogue.

The placing of an apparatus on the market does not concern :

- the disposal of the apparatus from the manufacturer to his authorised representative established in the EEA who is responsible on behalf of the manufacturer for ensuring compliance with the Directive;
- imports into the EEA for the purpose of re-export, i.e., under the processing arrangements;
- the manufacture of an apparatus in the EEA for export to a third country;
- the display of the apparatus at trade fairs and exhibitions¹⁰. It may not be in full conformity with the provisions of the EMC directive, but this fact must be clearly advertised next to the apparatus being exhibited.

The person placing the apparatus in the EEA market, be it the manufacturer, his authorised representative in the EEA, importer or any other person, must retain at the disposal of the competent authority the EC declaration of conformity and, where applicable, the technical construction file¹¹. These documents shall be maintained by such person at the disposal of the competent authorities for ten years following the placing of the last apparatus on the market. This applies for apparatus manufactured in the EEA as well as those imported from a third country.

3.2. Taking an apparatus into service

This means the first use of an apparatus referred to in the Directive in the EEA territory, by its end user.

Comments :

An apparatus covered by the EMC Directive is put into service when it is first used.

However, apparatus which are ready for use as soon as they are placed on the market and which do not have to be assembled or installed, and where the distribution conditions (storage, transport, etc.) make no difference to the electromagnetic performance of the apparatus, are considered to have been put into service as soon as they are placed on the market, if it is impossible to determine when they were first used.

Where an apparatus is manufactured in the EEA or imported from a third country for the manufacturer's or end user's own use, placing on the market is combined with putting into service; the obligation to conform to the Directive begins with first use.

¹⁰ Although there is no reference in the EMC Directive to this specific situation, it is included as a recommendation.

¹¹ See chapters 11.1 and 11.2 of this guide.

Article 6 of the EMC Directive permits Member States to adopt certain measures to the putting into service and use of apparatus in some given circumstances. These measures do not directly concern the placing on the market and free movement of apparatus, they usually limit or impede their use in certain particular EMC environments. An example might be the prohibition of the installation and/or use of certain apparatus in sensitive areas such as hospitals, airports, etc.. This is, of course, within the rights of Member States' authorities, aimed at protecting those specific cases.

These special measures must be limited in scope and be communicated to the Commission and the other Member States. The Commission, for its part, will publish appropriate information in the Official Journal of the European Communities in respect of those special measures deemed to be justified.

3.3. Manufacturer

This is the person responsible for the design and construction of an apparatus covered by the Directive with a view to placing it on the EEA market on his own behalf.

Whoever modifies substantially an apparatus resulting in an "as-new" apparatus¹², with a view to placing it on the EEA market, also becomes the manufacturer¹³.

Comments :

The manufacturer bears responsibility for:

- design and construction of the apparatus in accordance with the protection requirements laid down in the Directive;
- following the procedures for the certification of the conformity of the apparatus with the protection requirements laid down in the Directive.

The manufacturer has sole and ultimate responsibility for the conformity of his apparatus to the applicable Directives. He must understand both the design and construction of the apparatus to be able to certify such conformity in respect of all applicable provisions and requirements of the relevant Directives.

¹² See chapter 7 - Application of the EMC Directive to used, to second hand, to repaired apparatus and to spare parts.

¹³ Even if the General Product Safety Directive (92/59/EEC) is not applicable for the provisions of the EMC Directive, it is interesting to consider the definition of producer as "any person presenting himself as the manufacturer by affixing his name, trade mark or other distinctive mark" given by this Directive due to the fact that is being discussed in the context of the revision of the "Guide to the implementation of Community harmonisation directives based on the New Approach and the Global Approach".

As the sole and ultimate responsible person, he will undertake an EMC analysis, as further explained in chapter 4, to conclude if his apparatus is subject to the EMC Directive and which requirements apply. He is ultimately responsible for such an analysis.

The manufacturer may subcontract certain operations, e.g., apparatus design or production, provided that he retains overall control and responsibility for the apparatus as a whole. By the same token, he may use ready-made items or components, CE marked or not, to produce the apparatus without losing his status as a manufacturer.

Articles 10.1, 10.2 and 10.5 of the EMC Directive define the obligations incumbent on the manufacturer with regard to conformity assessment, CE marking, the EC declaration of conformity and the arrangements for holding this EC declaration of conformity, together with the technical construction file (where applicable), at the disposal of the competent authorities for a period of ten years after the last apparatus was placed on the market.

3.4. Authorised representative

This is the person or persons expressly appointed by the manufacturer by a written mandate to act on his behalf in respect of certain manufacturer's obligations. The extent to which the authorised representative may enter into commitments binding on the manufacturer is determined in accordance with the mandate conferred on him/her by the latter.

As an example, he could be appointed to undertake the testing in the EEA territory, sign the declaration of conformity, affix the CE marking and hold the declaration of conformity and the technical construction file at the disposal of the competent authorities.

Comments :

If a manufacturer appoints an authorised representative, the latter must be established within the EEA.

Articles 10.1, 10.2 and 10.5 of the EMC Directive define the obligations incumbent on the authorised representative established within the EEA with regard to conformity assessment, CE markings, EC declaration of conformity and the arrangements for holding this EC declaration of conformity, together with the technical construction file (where applicable), at the disposal of the competent authorities for a period of ten years after the last apparatus was placed on the market.

3.5 Importer

This is a person who places on the EEA market an apparatus which is covered by a Directive and imported from a third country.

Under the terms of the Directive (Article 10.1, third paragraph, and Article 10.2, third paragraph), the importer must keep the manufacturer's declaration of conformity and the technical construction file at the disposal of the competent authorities for a period of ten years after the last apparatus was placed on the market, where neither the manufacturer nor his authorised representative is established within the EEA.

Should the importer want to accept more responsibilities than those above, he can of course become the authorised representative in agreement with the manufacturer (see chapter 3.4), or to become the manufacturer to, for example, modify a product to suit the local market, in which cases he must assume the obligations of such parties.

3.6 Other responsible persons

Where neither the manufacturer, nor the authorised representative, nor the importer is established within the EEA, any other person resident in the EEA who places the apparatus on the EEA market has obligations under the scope of the Directive. The obligation is to retain the necessary documentation at the disposal of the competent authorities for ten years after the last apparatus has been placed on the market of the EEA territory, in accordance with Article 10 of the Directive.

Should this person want to accept more responsibilities than those above, he can of course become the authorised representative in agreement with the manufacturer (see chapter 3.4), or to become the manufacturer to, for example, modify a product to suit the local market, in which cases he must assume the obligations of such parties.

3.7 Finished product

A finished product in these guidance notes is any device, or unit of equipment that has a direct function (See 3.8), its own enclosure and - if applicable - ports and connections intended for end users.

3.8 Direct Function

“Direct function” is defined as any function of a component or a finished product which fulfils the intended use specified by the manufacturer in the instructions for use for an end-user.

This function can be available without further adjustment or connections other than simple ones which can be performed by any person not fully aware of the EMC implications.

4. KEY ARTICLES OF THE EMC DIRECTIVE WITH REGARD TO ITS SCOPE

4.1 General

The objectives of the Directive have been already explained: free movement of apparatus and to create an acceptable EM environment in the EEA territory. It is important to understand fully the spirit and the logic of the EMC Directive. To achieve this, the key articles and expressions (**Bold italics**) should be considered:

4.1.1 Article 1.1: 'apparatus' means all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components.

NOTE 1 - The definition of apparatus given above is applicable throughout the text of these guidelines.

4.1.2 Article 1.2: 'electromagnetic disturbance' means any electromagnetic phenomenon which may **degrade the performance** of apparatus. An electromagnetic disturbance may be for example an electromagnetic **noise**, an **unwanted signal**¹⁴, etc..

Comments:

The protection objective of the EMC Directive is to ensure that the functioning of appliances, installations or systems is not degraded by an electromagnetic phenomenon. If an apparatus, when used as intended, does not degrade the performance of others in its electromagnetic environment, both present and foreseeable, it should be considered compliant with the emission essential requirement of the Directive.

The electromagnetic signals considered in the Directive do not include the signals wanted and required for the use of the apparatus . It must be allowed to produce them, otherwise it cannot work. For instance, the electromagnetic emission of radio transmitting equipment which is within the required bandwidth and admissible radiated power, does not come within the scope of the Directive. However, electromagnetic emissions of transmitting equipment outside the required bandwidth (spurious emissions, for example) are covered by, and are hence subject to, the EMC Directive, being "unwanted signals"¹⁵. The manufacturer should eliminate them at the design and construction stages.

4.1.3. Article 1.3: 'immunity' means the ability of apparatus to **perform satisfactorily against the performance criteria specified for the apparatus** in the presence of an electromagnetic disturbance.

Comments:

The aim of the protection requirement here, too, is the function of the electrical and electronic appliance, equipment and installation containing electrical and/or electronic components and not the quality of such apparatus.

For instance, an electronic greeting card playing melodies is not expected to be immune to electromagnetic disturbances outside the ones for which it has been designed when used as intended in its determined electromagnetic environment. Practice indicates that, normally, users would not buy more expensive greeting cards simply to ensure that they will never be affected by electromagnetic disturbances. The expected **level of protection must be proportional to the objectives pursued**.

4.1.4. Article 1.4: "electromagnetic compatibility" means the ability of an electrical and electronic appliance, equipment and installation containing electrical and/or electronic components to **function satisfactorily in its electromagnetic environment** without introducing **intolerable electromagnetic disturbances** to anything in that environment.

Comments:

¹⁴ See chapter 15.1.2.1 for emissions outside the required bandwidth.

¹⁵ See chapter 15.1.2.1 for emissions outside the required bandwidth.

The word “intolerable” should be highlighted. Once again, the manufacturer’s EMC analysis, **helped as appropriate by the relevant harmonised standards** and other technical knowledge, will determine the action to be taken. “Function satisfactorily” means here without degradation of quality of performance below an acceptable performance criteria level.

4.1.5. Article 2.1: this Directive applies to apparatus liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance.

4.1.6. Article 4: the apparatus referred to in Article 2 shall be so constructed that :

- a) the electromagnetic disturbance it generates does not exceed a level allowing radio and telecommunications equipment and other apparatus *to operate as intended*;
- b) the apparatus has an adequate level of *intrinsic* immunity to electromagnetic disturbance to enable it *to operate as intended*.

4.1.7 The principal protection requirements are set out in Annex III in a general manner which adds a non-exhaustive list of categories of products to which they apply. With regard to *immunity* apparatus, and especially the apparatus referred to in (a) to (l) of Annex III of the Directive, should be constructed in such a way that it has an **adequate level** of electromagnetic immunity **in the usual electromagnetic environment** where the apparatus is **intended to work** so as to allow its unhindered operation, taking into account the levels of disturbance generated by apparatus complying with the standards laid down in Article 7.

Comments on 4.1.5, 4.1.6, and 4.1.7:

“To operate as intended” means using the apparatus in accordance with the manufacturer’s instructions and using it in the electromagnetic environment determined by standards chosen by the manufacturer. Under Annex III of the Directive such information must be contained in instructions (operating and installation manual) accompanying the apparatus. It has to be noted that some harmonised standards apply to apparatus intended to operate in a given environment, such as the residential or the industrial environment.

4.2 EMC Analysis - Decision flow-chart

4.2.1 Introduction

The manufacturer, his authorised representative or the person who places a product on the EEA market or takes it into service has to find out whether or not this product is covered by the EMC Directive and to apply its provisions, if required. The manufacturer (in the broadest sense of the Directive) must therefore make an EMC analysis on the basis of the EMC Directive.

He is the first and ultimate person responsible for the conformity of his apparatus to the Directive. Furthermore, this person is responsible for evaluating the potential EMC problems that the apparatus may or will present when used as intended¹⁶, since *he has*

¹⁶ In the EMC directive this also includes the expected electromagnetic environment.

assumed responsibility for its design and construction. EMC problems can be caused both by the apparatus itself, and also by its environment, the way it is installed, etc..

This document provides practical criteria and tools to help the manufacturer to perform the EMC analysis, that nevertheless remains his full responsibility.

The decision flow-chart given in figure 1 is a practical tool which permits the simplification of the EMC analysis, defining which types of electrical or electronic equipment¹⁷ are within or outside the scope of the EMC Directive.

European Harmonised Standards play a key role, not just because they significantly simplify the conformity assessment procedures (Article 10.1 of the Directive) if used in full, but also because they provide by consent, a unique, harmonised, technical solution that has been based on an EMC analysis. This means that, even if those standards are not used (they are voluntary) in the design and manufacture of the apparatus, manufacturers should take them into account when performing their EMC analysis.

Although the EMC analysis is fully the manufacturer's responsibility, it is absolutely necessary that the Member States' enforcement authorities and all economic and social operators concerned with the EMC Directive (manufacturers in the first place, but also standardisers, competent and notified bodies, market surveillance authorities, the European Commission, etc.) reach the same level of understanding if the Internal Market is to function smoothly (Article 3 of the Directive obliges Member States to protect their territory).

Such a common interpretation should be reached by well-defined criteria to be transmitted to the interested parties in order to attain consensus. Relevant criteria are described in this and the following chapters.

4.2.2 Short description of the “Decision flow-chart”

The successive steps and criteria of the EMC analysis flow-chart will be described hereafter, with references to the relevant chapters where more precise criteria and provisions are developed:

1 to determine whether the equipment contains electrical and/or electronic parts or components.

2/3 to examine total/partial inclusions/exclusions quoted in the EMC Directive.

¹⁷ The word equipment is used in this chapter in its broader sense.

Detailed guidance is given in chapter 5.5 especially in relation to exclusions explicitly given in the EMC Directive, and specific Directives within the meaning of article 2.2 of the EMC Directive. In case of partial exclusions, the extent to which the protection requirements are harmonised by other regulations, especially specific Directives, is identified. The EMC Directive shall then be applied to apparatus or protection requirements where they are not covered by the specific directives or regulations.

4 to apply article 2.1 to determine whether the electrical equipment may be considered as passive from an EMC viewpoint (in this case it is excluded from the scope of the EMC Directive) or not. Chapter 5.3 gives the definition for passive-EM electrical equipment as well as illustrative examples.

5 to determine whether the equipment is mentioned explicitly in the list appended (Annex III) to the EMC Directive (chapter 5.2).

6 to check if any harmonised product standard or family product standard, published in the OJ under the umbrella of the EMC directive can be applied (see annex 7 of this guide).

7 to determine whether the equipment may be considered exempted from the EMC Directive with regard to the criteria described in chapter 5.4 which are commonly accepted by all parties involved in writing these guidelines.

8 to 10 the manufacturer has to determine the classification of his electrical apparatus as component, finished product, system or installation. This technical-commercial classification is based on the definitions given in this guide together with the detailed clarifications and different cases given in the relevant chapters for components, finished products, systems and installations.

Components with a direct function must always be accompanied by the instructions for use as required by the EMC Directive in its Annex III. Only when they have a direct function and they are placed on the market as single commercial units for distribution and/or a final user are they subject to the other provisions of the Directive. A definition, criteria and illustrative examples are given in chapter 6.2.

Finished products must be always accompanied by instructions for use as required by the EMC Directive in Annex III.

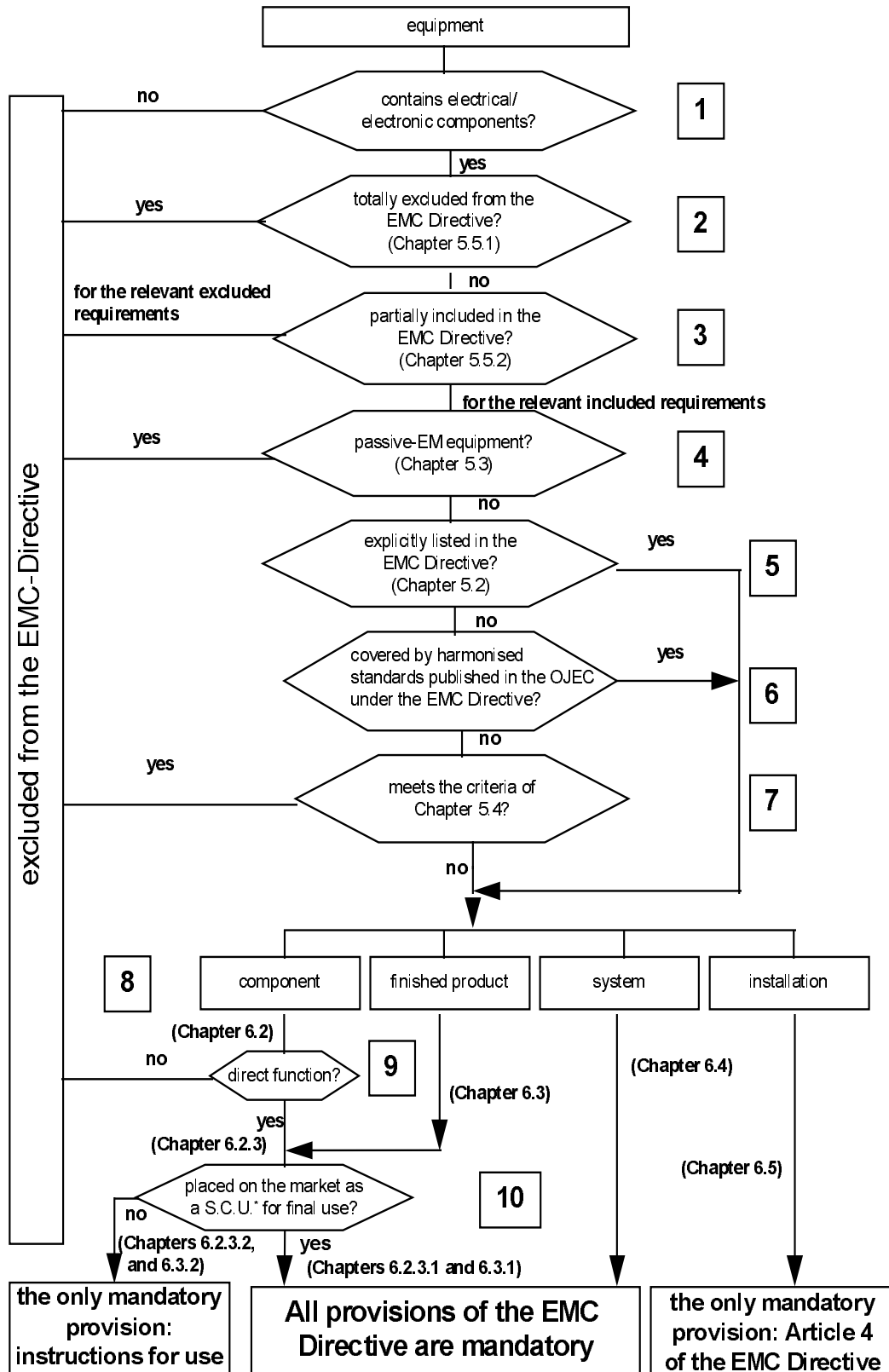
Only when they are placed on the market as single commercial units for distribution and/or a final user are they subject to the other provisions of the Directive. A definition, criteria and illustrative examples are given in chapter 6.3.

Systems and installations are covered by the EMC Directive, but the specific provisions are detailed respectively in chapter 6.4 for systems and 6.5 for installations.

Note 1: If the manufacturer uses the flow chart described above and if he concludes that his equipment is excluded from the EMC Directive, then he is not obliged to provide an EC declaration of conformity not to CE mark the equipment. However, the manufacturer (or his authorised representative, the importer or any person who places the equipment on the market) is strongly advised to keep documentation available at the disposal of the competent authority for inspection purposes under the same conditions as the EC declaration of conformity, in which the reasons for his decision are clearly stated. This is particularly important in the case of the seventh step if he concludes that his equipment meets the criteria of chapter 5.4.

Note 2: For the purpose of simplification the flow-chart is limited to **new** equipment. Used, second-hand and repaired apparatus together with spare parts are covered by chapter 7.

Decision Flow Chart



* S.C.U.: single commercial unit

Specific provisions are detailed and have to be carefully considered in the chapters indicated in the decision flow chart.

5 SCOPE OF THE DIRECTIVE

5.1 General

Within the limits explained in chapter 4 above, the Directive applies to a vast range of apparatus encompassing as broadly as possible all electrical appliances, systems and installations whether or not they are connected to the mains. Moreover, recitals 3, 4 and 12 of the Directive clearly indicate that to protect electricity distribution networks¹⁸ and public telecommunication networks¹⁹, equipment capable of being connected to them must comply with the Directive so as not to affect the electromagnetic characteristics or cause electromagnetic interference to these networks when connected to them, or to any other equipment operating in the environment where they will be functioning.

The Directive does not impose any lower or upper limits on the apparatus as regards power output or selection of transmission frequencies.

The Directive, therefore directly covers several sectors of electrical and electronic engineering, in particular household appliances, consumer electronics, industrial manufacturing, information technology, radio communication and telecommunications apparatus.

5.2. Apparatus explicitly listed within the scope of the EMC Directive (emission and immunity); non restrictive list:

- 5.2.1 • Electrical household appliances, portable tools and similar equipment (last recital of the EMC Directive and Annex III(g));
- 5.2.2 • Fluorescent lighting luminaires fitted with starters (last recital of the EMC Directive);
- 5.2.3 • Fluorescent lamps (partially Annex III(l));
- 5.2.4 • Industrial manufacturing equipment (Annex III(b) of the EMC Directive);
- 5.2.5 • Information technology equipment (Annex III (f));
- 5.2.6 • Domestic radio and television receivers;
- 5.2.7 • Radio and television broadcast transmitters (Annex III (k));
- 5.2.8 • Aeronautical and marine radio apparatus ²⁰(Annex III(h)); (See Chapter 15.4. and 15.8.)

¹⁸ See definition given by the International Electrotechnical Vocabulary in the IEV 50-601

¹⁹ See definition given by the International Electrotechnical Vocabulary in the IEV 50-701

²⁰ Marine equipment is covered by the Directive 96/98/EC (OJ No L 46, 20.12.1996) that constitute a specific Directive within the meaning of Article 2.2 of the EMC Directive for equipment included in its scope.

Equipment intended for use in aircraft in flight are covered by the Council Regulation (EEC) No 3922/91 and it is also considered a specific Regulation.

5.2.9 • Educational electronic equipment (Annex III(i));

Apparatus in training, research and educational establishments intended for studying electromagnetic phenomena, may exceed the limits of emitted disturbance contained in the relevant standards published in accordance with Article 7.1 of the EMC Directive.

However, the EC declaration of conformity must in such a case, indicate which EM phenomena the apparatus is used to study, and must also indicate that the instructions for the apparatus specify that such apparatus may only be operated under the supervision of qualified personnel, and that where electromagnetic disturbances cause a problem, the person working in such institutions must take the necessary measures to eliminate such disturbances. The training, research or educational establishment shall take all necessary measures to ensure that apparatus installed outside the electromagnetic environment can function properly.

5.2.10 •Radio equipment intended for use in amateur radio bands if commercially available (Article 2.3). This is subject to the conformity assessment procedures laid down in Articles 10.1 or 10.2 of the EMC Directive (see also 5.2.12)

5.2.11 •Telecommunications apparatus: (See also chapter 15.1)

Telecommunication terminal equipment (covered by Directive 91/263/EEC²¹) and earth stations for communications by satellite equipment (covered by Directive 93/97/EEC²²): For apparatus covered by these Directives, the provisions related to electromagnetic compatibility phenomena laid down by the three Directives 89/336/EEC, 91/263/EEC, 93/97/EEC have to be observed on a complementary basis.

The electromagnetic compatibility essential requirements to be observed for apparatus covered by Directive 91/263/EEC or 93/97/EEC, insofar as they are not specific²³ to such apparatus, are those laid down in the Directive 89/336/EEC.

5.2.12 •Radio communication transmitters not covered by Directive 91/263/EEC nor by Directive 93/97/EEC are subject to the conformity assessment procedure laid down in Article 10.5 of Directive 89/336/EEC. These apparatus includes transmitters such as Citizens' Band (CB), walkie-talkies, etc. The Directive does not apply to the normal operating frequency band, as already mentioned in chapter 4 of this guide. This band is outside the scope of the Directive. Frequencies outside the required bandwidth, called spurious emissions are, of course, subject to the Directive.

5.2.13 •Radio communication receivers are subject to the conformity assessment procedures laid down in Articles 10.1 or 10.2 of Directive 89/336/EE

5.3 Passive-EM equipment

²¹ OJ No L 128, 23.5.1991, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

²² OJ No L 290, 24.11.1993.

²³ CENELEC/ETSI Annex II of their report R0BT-001/ETR 238 of Oct. 1995 discusses the specific and non-specific EMC phenomena.

The Directive applies to apparatus liable to cause electromagnetic disturbances or whose normal operation may be affected by such disturbances (see chapter 3).

In this context, electromagnetically passive (passive-EM) equipment, defined below, is **excluded** from the scope of the EMC Directive, since it is considered not liable to cause or be susceptible to disturbances.

To facilitate the practical interpretation of this clause, the general definition of passive-EM equipment is given hereafter, together with practical criteria and illustrative examples.

5.3.1 Definition and examples

Equipment is considered a passive-EM equipment if, when used as intended (without internal protection measures such as filtering or shielding) and **without any user intervention**, it does not create or produce any switching or oscillation of current or voltage and is not affected by electromagnetic disturbances.

The immediate application of the definition enables the exclusion, for example of the following equipment from the application of the EMC Directive, on the clear understanding that they include no active electronic part:

- cables and cabling systems²⁴, cables accessories.
- equipment containing only resistive loads without any automatic switching device; e.g. simple domestic heaters with no controls, thermostat, or fan.
- batteries and accumulators.

5.4 Additional practical criteria (accepted by consensus) to exclude equipment from the scope of the EMC Directive.

5.4.1 Practical criteria and illustrative examples

Although it should in principle be considered as within the scope of the Directive, the following apparatus can be considered as exempted, based upon both of the following criteria, which have also been taken in account into the development of EMC standards:

1. The emission level is by the inherent nature of the physical characteristics and mode of operation (without internal protection measures such as filtering or shielding) far below the most stringent limits of the relevant EMC standards.

2. With regard to immunity, experience shows that such apparatus does function satisfactorily by the inherent nature of its physical characteristics without

²⁴ Manufacturers should be aware that the characteristics and installation of such equipment can have a very significant impact upon the EMC performance of the systems into which they are installed.

additional measures when used as instructed by the manufacturer in the intended electromagnetic environment.

- Protection equipment which only produce transitory disturbances of very short duration (e.g. $\ll 1$ s) during the clearing of a short-circuit fault or an abnormal situation in a circuit and which do not include electronic components which are EM active.

Illustrative examples:

- fuses.
- circuit breakers without electronic parts or components which are EM active

- Manual switches: appliances switches, home and building switches, etc. which do not contain any components which are EM active.
- High voltage equipment in which possible sources of disturbances are due only to localised insulation defects which may be the result of the ageing process and are anyway under the control of other technical measures included in non-EMC product standards (e.g. partial discharge tests), and which do not include electronic components which are EM active.

Illustrative examples:

- High voltage inductors.
- High voltage transformers.

NOTE 3 - Some of the equipment mentioned above may also be exempted from some provisions of the EMC Directive, as components not intended for final use and without a direct function (see 6.2.3.2)

Other equipment fulfilling the criteria above:

Illustrative examples:

- Capacitors (e.g. power factor correction capacitors).
- Induction motors.

NOTE 4 - High levels of harmonics in the applied voltage may have a significant effect in causing overheating and therefore a reduction in life duration of capacitors and motors which directly interface with the applied voltage.

- Quartz wrist watches without additional functions (e.g. radio receivers).
- Filament lamps (bulbs).

5.4.2. Technical justification

- Only three types of **emitted** disturbances have to be considered at present:

- * conducted (continuous and intermittent) radio-frequency disturbance;
- * radiated radio frequency disturbance;

- * harmonics, flicker and voltage fluctuations on the mains power supply.

- Regarding **immunity**, the list of phenomena to be considered is given in the relevant standards.

- A careful examination of the circuit, mode of operation and physical characteristics of an apparatus which does not contain electronic components which are EM active, may indicate whether it is liable to cause electromagnetic disturbances of one of the three types identified above. If this is not the case, such non-electronic equipment should be considered exempted from the EMC Directive.

This analysis should be performed with great care as sources of important disturbances may not always be obvious.

As a guideline, sources of disturbance in the above mentioned apparatus are for example:

- * for radio-frequency disturbance, all operations inside apparatus which lead to any form of switching or oscillation of current, or voltage, or arcing;
- * for voltage fluctuations on the mains power supply, the presence of high in-rush or starting currents.

5.5 Apparatus partially or totally excluded from the EMC Directive

These exclusions are based on either Article 2.2, specific exclusions laid down in the EMC Directive, or in accordance with common interpretation reached by Member States government experts during various EMC Directive application meetings.

Article 2.2 of the EMC Directive states that *"Insofar as protection requirements specified in this Directive are harmonised, in the case of certain apparatus, by specific Directives, this Directive shall not apply or shall cease to apply with regard to such apparatus or protection requirements upon the entry into force of those specific Directives"*.

However, if the EMC requirements for a given apparatus or category of apparatus are dealt with in a specific Directive, the latter should clearly and in a more complete way specify the EMC requirements with which to comply.

5.5.1 Apparatus totally excluded (emission and immunity) from the EMC Directive (non restrictive list):

- 5.5.1.1 • Radio equipment used by radio amateurs unless the apparatus is available commercially (Article 2.3 of the EMC Directive).
This exclusion has been stipulated because of the specific nature of the activities of radio amateurs, which do not constitute any kind of commercial transaction. Radio amateurs are persons carrying out experimental activities within the field of radio communications, according to definition No 53 of

the ITU (International Telecommunication Union) Radio Communications Regulation.

Amateur radio equipment which is commercially available comes within the scope of the Directive (see 5.2.10)

- 5.5.1.2 • Motor vehicles : covered by specific Directive 72/245/EEC²⁵ (see chapter 15.3);
- 5.5.1.3 • Active implantable medical devices: covered by specific Directive 90/385/EEC²⁶(see chapter 15.6);
- 5.5.1.4 • Medical devices : covered by specific Directive 93/42/EEC²⁷, after the end of the transitional period scheduled for 14 June 1998; during the transitional period the manufacturer can choose whether to apply the EMC Directive or the Medical Devices Directive (see chapter 15.5);
- 5.5.1.5 • In vitro Diagnostic Medical Devices: to be covered by the proposal for a Directive COM(95) 130 final, as soon as this proposal is adopted and implemented in full (see chapter 15.7);
- 5.5.1.6 • Equipment intended for use in aircraft in flight covered by the Council Regulation (EEC) No 3922/91 of 16 December 1991²⁸;
- 5.5.1.7 • Marine equipment : if covered by the specific Directive 96/98/EC²⁹, after the end of the transitional period scheduled for 31 December 1998. During the transitional period the manufacturer can choose whether to apply the EMC Directive or the Marine Equipment Directive (see chapter 15.8).

5.5.2. Apparatus partially excluded

a) *Emission requirements covered only by the EMC Directive:*

- Non-automatic weighing instruments: the EMC Directive covers the emission requirements. The immunity requirements are laid down in Annex I-8(2), of Directive 90/384/EEC³⁰.

b) *Immunity requirements covered only by the EMC Directive:*

²⁵ OJ No L 152, 6.7.1972, amended by Directives 89/491/EEC, OJ No L 238, 15.8.1989 and 95/54/EC, OJ No L 266, 8.11.1995. See separate chapter on this.

²⁶ OJ No L 189, 20.7.1990 amended by Directives 93/42/EEC, OJ No L 169, 12.7.1993 and 93/68/EEC, OJ No L 220, 30.08.1993. See separate chapter on this.

²⁷ OJ No L 169, 12.7.1993, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993. See separate chapter on this

²⁸ OJ No L 373, 31.12.1991, currently under modification (COM (96) 186 final). See separate chapter on this

²⁹ OJ No L 46, 20.12.96

³⁰ OJ No L 189, 20.7.1990, amended by Directive 93/68/EEC, OJ No L 220, 30.8.1993.

- Agricultural and forestry tractors: the EMC Directive covers the immunity requirements. The emission requirements are covered by Directive 75/322/EEC³¹.

5.5.3 Additional Information

- A proposal for a Directive covering measurement instruments subject to legal control is under preparation. The immunity requirements for those measurement instruments will be only covered by this proposal for a Directive; the emission requirements are still under discussion between Government experts and the Commission (see chapter 15.9).

6. APPLICATION OF THE DIRECTIVE TO COMPONENTS, FINISHED PRODUCTS, SYSTEMS AND INSTALLATIONS.

6.1. General.

In order to make the EMC Directive easier to understand, particularly its scope and the conformity assessment procedures laid down in it, it is necessary to explain or clarify some terms used in the Directive by taking account of practice in this sector, particularly for:

- components;
- finished products
- systems;
- installations.

NOTE 5 - The contents of these guidelines define the "status" for different types of apparatus as regards as the application of the EMC Directive. These guidelines do not prejudice the application of EMC requirements for those apparatus excluded from the Directive according to this document, when established through a contractual framework between suppliers, subcontractors, etc.

6.2. Application of the Directive to components

6.2.1. Grounds

The EMC Directive contains no explicit provisions on components, sub-assemblies, devices or other units intended for incorporation in electrical or electronic apparatus, equipment or installations.

However, common industrial, technical and commercial practice has revealed that it is sometimes difficult to decide to which category (i.e. electrical or electronic appliances, equipment or installation) a given apparatus belongs, where electromagnetic compatibility is concerned. In other words, it is sometimes difficult to say whether it must be regarded as "apparatus", as defined in Article 1.1, or if it is just a component.

³¹ OJ No L 147, 9.6.1975, amended by Directive 82/890/EEC, OJ No L 378, 31.12.1982.

Many components can be placed on the market for distribution and/or use as a single commercial unit. For example, electronic circuit boards, sometimes complex, are commonly available to the general public, to be incorporated into apparatus.

Components of this type have to comply with the provisions of the Directive if they are considered equivalent to "apparatus", as defined in Article 1.1 of the Directive and in the criteria **included in chapter 4** of this guide.

Accordingly, manufacturers must bear in mind the following criteria:

- Does the component deliver a "direct function"?

If so,

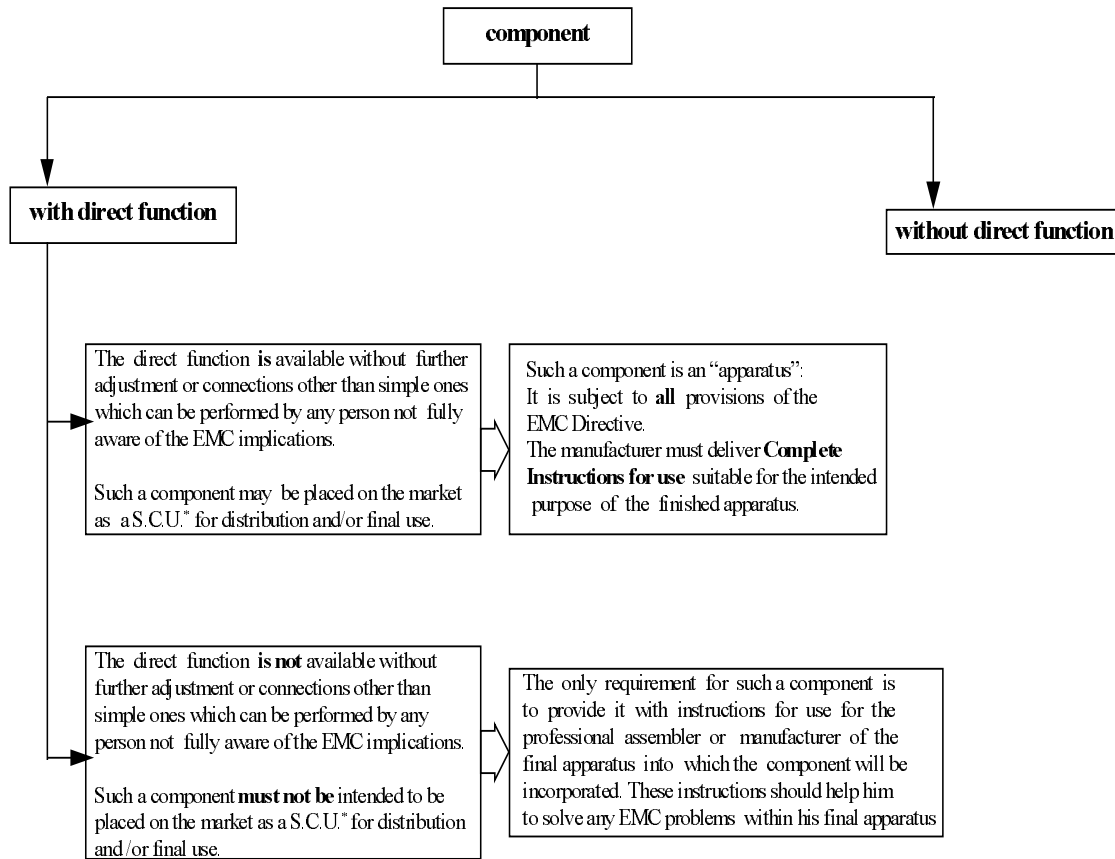
- the "end use" of the component and the particular electromagnetic environment:
 1. Is the component intended exclusively for an industrial assembly operation for incorporation in "apparatus", as defined in Article 1.1 of the EMC Directive?, or
 2. Is it also intended to be marketed individually for distribution and/or use as a single commercial unit?

The manufacturer of the end apparatus will, under his responsibility, comply with the Directive; in both design and construction. He will use the right components, taking account of their technical characteristics and limitations, with due consideration given to their intended use and expected electromagnetic environment .

The concept of direct function is also important to help to define what is subject to compliance with the EMC Directive.

Within this context ***“direct function” is defined as any function of the component itself which fulfils the intended use specified by the manufacturer in the instruction for use for an end-user. The instructions for use*** of components delivering a direct function must be clear in these respects, so that the user can follow them without causing EMC problems.

If the component is intended to be placed on the market as a single commercial unit for distribution and/or final use this function has to be ***available without further adjustment or connections other than simple ones which can be performed by any person not fully aware of the EMC implications.***



*S.C.U. = Single Commercial Unit

6.2.2. Components performing no direct function

Although components always fulfil a function within the apparatus in which they are incorporated, they do not always in themselves perform a direct function. For example, a transistor, mounted on a printed circuit board with the function of amplification fulfils a function but it is only the complete card which fulfils the expectations of the end-user, as specified by the manufacturer, e. g. the amplification of a given signal.

Another example is a cathode-ray tube which performs a function within the visual display unit in which it is installed, but only the complete monitor supplies the user with the direct function sought, i.e. that of the visual display screen. The transistor and the cathode-ray tube perform no direct function and cannot, therefore, be regarded as "apparatus" but are components, whereas the printed circuit board, and the monitor are apparatus.

Similar examples of components **without** a direct function are:

- ◆ electrical or electronic components forming part of electrical or electronic circuits;
 - resistors, capacitors, coils;
 - diodes, transistors, thyristors, triacs, etc.;
 - integrated circuits;

- ◆ Cables and cabling accessories;
- ◆ All or nothing relays
- ◆ Plugs, sockets, terminal blocks, etc.;
- ◆ LEDs, liquid-crystal displays, etc.
- ◆ Simple mechanical thermostats

These types of components *with no direct function* are not considered as apparatus within the meaning of the EMC Directive. The EMC Directive does not apply to them. They need incorporation into an apparatus that will deliver the expected intended direct function.

6.2.3. Components performing a direct function

These are components that can be placed on the market in retail outlets for distribution and/or putting into service, fulfilling the criteria defined in 6.2.1, therefore delivering a direct function.

Plug-in cards, such as smart cards or input/output modules, designed for incorporation into computers are apparatus commonly found in retail outlets, and available to the general public. Once cards of this type are inserted in a PC they perform a direct function for the user. They must therefore be considered as apparatus and are, consequently, *subject to the provisions of the EMC Directive*.

This does not mean that they must necessarily be intrinsically compliant from the EMC point of view in all cases, if this is either impossible or impracticable³². However, in such cases, they must be designed in such a way that they become fully EMC compliant (emissions and immunity) when they are installed as intended in the apparatus, in any of its possible variants and configurations, without exceptions, and used in the electromagnetic environment determined by the manufacturer. **The instructions accompanying the component must clearly indicate these requirements**, the pertinent limitations of use and how to comply without resorting to an EMC specialist (such components are available to non-EMC specialists, for a wide range of applications). The manufacturer has the ultimate responsibility for this decision.

Similar examples of components **with** a direct function are:

- plug-in cards for computer systems, micro-processor cards, central processing unit cards/mother boards, electronic mail cards, telecommunication cards, etc.;
- programmable logic controllers;
- lift controls;
- electric motors (except for induction motors, see chapter 5.4);

³² Sometimes EMC compliance can only be achieved once the component is installed, using the EMC protection circuits or characteristics of the apparatus in which it is to be operated.

- computer disk drives;
- power supply units (PSU), where they take the form of autonomous equipment;
- electronic temperature controls;

6.2.3.1 Components performing a direct function intended to be placed on the market for distribution and final use.

This category covers components which, in accordance with the end use criterion, are placed on the market for distribution and/or use. The direct function is available without further adjustment or connections other than simple ones which can be performed by any person not fully aware of the EMC implications. Such components need to comply with the provisions of the Directive as they are considered equivalent to "apparatus", as defined in the Directive and chapter 4. They *are fully subject to the provisions of the EMC Directive and must be CE marked.*

6.2.3.2 Components performing a direct function not intended to be placed on the market for distribution and final use.

This is the case with components designed, manufactured and intended for incorporation in "apparatus" by professional manufacturers. These components are not placed on the market for distribution and/or direct use. **The manufacturer must provide with such components *the relevant instructions to enable their operation within the apparatus in which they will be incorporated in accordance with the intended purpose.*** The instructions for use of such components must indicate EMC aspects to be considered by the manufacturer of the final apparatus to help him to solve foreseeable EMC problems within the final apparatus. The manufacturer of a component knows more than any other party the characteristics of his component; he knows the oscillation frequencies, internal clock rates, etc. and very often he already has experience related to EMC problems. If so, he should give appropriate warnings and advice in the instructions for use. **None of the other provisions of the EMC Directive, such as CE marking, the EC declaration of conformity or the involvement of a notified or a competent body, are mandatory.**

6.3 Application of the Directive to finished products

According to the definition giving in 3.7 a finished product is any device or unit of equipment that always has a **direct function**, an enclosure of its own and - if applicable - ports and connections intended for end users.

Accordingly manufacturers must bear in mind the following criteria when applying the EMC Directive to finished products:

1. Is the finished product intended exclusively for an industrial assembly operation for incorporation in "apparatus", as defined in Article 1.1 of the EMC Directive?, or
2. Is it (also) intended to be marketed individually for distribution and/or use as a single commercial unit?

The manufacturer of the end apparatus will, under his responsibility, comply with the Directive; in both design and construction. He will use the right finished product and components, taking account of their technical characteristics and limitations, with due consideration given to their intended use and expected electromagnetic environment.

6.3.1 Finished products intended to be placed on the market for distribution and final use.

This category covers finished products which, in accordance with the end use criterion, are placed on the market for distribution and/or use. They are "apparatus", as defined in the Directive and chapter 4.1.1 of these guidelines, and therefore they *are fully subject to the provisions of the EMC Directive and must be CE marked.*

6.3.2 Finished products not intended to be placed on the market for distribution and/or final use.

This is the case with finished products designed, manufactured and intended for incorporation in "apparatus" by professional manufacturers. These finished products are not placed on the market for distribution and/or direct use. **The manufacturer must provide with such finished product the relevant instructions to enable their operation within the apparatus in which they will be incorporated, in accordance with the intended purpose.** The instructions for use of such finished products must indicate EMC aspects to be considered by the manufacturer of the final apparatus to help him to solve foreseeable EMC problems within the final apparatus. The manufacturer of a finished product knows more than any other party about the characteristics of his product; he knows the oscillation frequencies, internal clock rates, etc. and very often he already has experience related to EMC problems. If so, he should give appropriate warnings and advice in the instructions for use. **None of the other provisions of the EMC Directive such as CE marking, the EC declaration of conformity or the involvement of a notified or a competent body, are mandatory.**

6.4 Application of the Directive to systems

6.4.1 A common understanding of "Systems"

In normal usage, the word "system" is sometimes used for an optional combination of several apparatus to perform a specific task where the end-user is the person who decides which apparatus are used to construct this so-called "system", and where the apparatus were not intended to be placed together on the market as a single functional unit.

A computer "system" consisting of a CPU, keyboard, printer, monitor, etc. is a good example. Each one of those parts is an apparatus placed on the market independently from the others and complying in full with the EMC Directive. *They are all CE marked.* They can be interconnected by a person not technically proficient in EMC matters. In accordance to chapter 10 they are supplied with clear instructions for interconnection, integration, use and maintenance (when applicable), as well as limitations for connection and use.

Following those instructions, in particular those related to cabling, in the manner intended by the manufacturer(s) of the constituent parts incorporated into the system justifies the assumption that the system is electromagnetically compatible.

The manufacturer of each constituent piece of apparatus in the system has already fully applied the Directive, and particularly taken into account the expected electromagnetic environment and the intended use.

Clearly, for such a so-called "system", the EMC Directive has already produced its effect. As the parts are **not placed on the market as one functional unit**, further measures that might be needed are outside the application of the EMC Directive. This kind of "system" neither needs an additional CE marking nor an additional EC declaration of conformity for the "system" as a whole.

If the EMC environment in which the "system" is used is different from that intended by the manufacturer(s) of the apparatus incorporated into the "system", the "system" may be subject to EMC problems. The user, the assembler or the installer must therefore overcome these specific unforeseen EMC problems, or else, purchase other apparatus suitable for that environment. But here such initiatives fall outside the scope of the Directive.

6.4.2 "Systems" within the EMC Directive

For the purposes of the EMC Directive, a system is defined as a combination of several equipment, finished products, and/or components (hereinafter called "parts") combined, designed and/or put together by the *same person (system manufacturer) intended to be placed on the market* for distribution as *a single functional unit for an end user and intended to be installed and operated together to perform a specific task*.

The system as a whole is a final apparatus; within the meaning of the EMC Directive it is an apparatus; it can enjoy free movement within the EEA. It must therefore be designed and put together so as to comply with the essential requirements of the EMC Directive. This compliance should include any reasonably foreseeable situation, in any intended electromagnetic environment and in any of its configurations.

A combination of "parts" may only be considered as a system if the manufacturer lists all "parts" in the instructions for use and declares for the attention of the installer and/or end user that **this combination forms a system**. The system manufacturer assumes responsibility for the compliance of the system as a whole with the Directive, and must therefore, in accordance with chapter 10, provide clear instructions for assembly, interconnection, integration, installation, use and maintenance (where applicable), as well as limitations for connection and use. Given that the assembler, installer and/or end-user have only to follow these instructions, they may assume that they install and operate the system in conformity with the relevant provisions.

An apparatus, that could also be called a system, composed of other apparatus and/or components (whether or not they are CE marked) **and** which is a single commercial unit, **must comply** fully with the EMC Directive. An illustrative example is a computer CPU, composed of a power supply, CD ROM, mother board and disk drive supplied in **an**

enclosure. This “system” is regarded as an apparatus and therefore subject to the EMC Directive.

Several cases of systems in the sense of the Directive ought to be considered:

6.4.2.1 Systems assembled from only CE marked apparatus³³.

As a good example we can take again the computer system consisting of a CPU, keyboard, printer, monitor, etc., as described in chapter 6.4.1. The difference between that chapter, and the case described here, is that in this instance, the above mentioned parts are *put together by the same person* (the system manufacturer) and placed on the market as a single functional unit, and that *this person assumes responsibility for the compliance of the system as a whole with the Directive*. Since the manufacturer(s) of each part of the system has/have already fully applied the Directive, and particularly taken into account the expected electromagnetic environment and the intended use, there are additional requirements for the system manufacturer to apply to comply with the EMC Directive:

The EC declaration of conformity, as well as the instructions for use must refer to the system as a whole. It must be clear (e.g. by enclosing a list of all parts) which is/are the combination(s) that form(s) the system placed on the market for distribution and/or use. The manufacturer assumes responsibility for compliance with the Directive, in particular with the protection requirements in all expected electromagnetic environments, and must therefore, in accordance with chapter 10, provide clear instructions for assembly/installation/operation/maintenance in the instructions for use. The system as a whole does not need to bear the CE marking (all this applies even if it is offered on the market as a single functional unit, as long as each part bears the CE marking).

If the electromagnetic environment in which the system is used is different from that intended by the manufacturer(s) of the apparatus intended to be incorporated into the system, the system may be subject to unforeseen EMC problems. The user, the assembler or the installer must therefore overcome these specific unforeseen EMC problems e.g. by following the procedure within 6.4.3, or else, purchase another system suitable for that environment.

Additional comment: Manufacturers of systems described above should be aware that combining two or more CE marked subassemblies may not automatically produce a system which meets the requirements of the relevant standard. E.g.: a combination of CE marked PLC's (Programmable Logic Controllers) and motor drives within a machine tool put together to be placed on the market as a system may fail the requirements, whereas a HI-FI system composed of a separately CE marked amplifier, tuner, CD player and cassette deck, wired up correctly is quite likely to maintain its compliance

6.4.2.2 Systems assembled from apparatus³⁴ including some not CE marked.

³³ Insofar not excluded according to 5.3 and 5.4.

³⁴ Insofar not excluded according to 5.3 and 5.4

Constituent parts considered in this section are:

- CE marked apparatus, finished products and components with a direct function, which fully comply with the Directive.
- Non-CE marked apparatus, finished products or components intended exclusively for an industrial assembly operation for incorporation in other “apparatus”.

Systems discussed in this section are composed of non-CE marked apparatus, finished products or components and may also include CE marked apparatus. They must only be combined into a system (intended to be placed on the market in view of its free movement as a single functional unit) by a professional person.

As a professional person, he is supposed to understand the EMC related technical implications of the parts when combined into a system and make the right judgements so as to fulfil the objectives of the Directive. ***He becomes manufacturer*** -in the full sense-. **The system is therefore an apparatus** in the sense of the EMC Directive and **must comply with all its provisions**.

The EC declaration of conformity, as well as the instructions for use must refer to the system as a whole. It must be clear (e.g. by enclosing a list of all parts) which is/are the combination(s) that form(s) the system placed on the market for distribution and/or use. The system manufacturer assumes responsibility for compliance with the Directive, in particular with the protection requirements in all expected electromagnetic environments, and must therefore in accordance with chapter 10, provide clear instructions for assembly/installation/operation/maintenance in the instruction for use. One CE marking is sufficient, affixed just once on the main part of the system, if all parts are supplied as one unit.

Those parts of the system which are themselves compliant apparatus may, of course, be distributed and/or used outside the system.

If the electromagnetic environment in which the system is used is different from that intended by the system manufacturer, the system may be subject to EMC problems. The user, the assembler or the installer must therefore overcome these specific unforeseen EMC problems, (e.g. by following the procedure within 6.4.3) or else, purchase another system suitable for that environment.

6.4.3. System or apparatus with various configurations

Most often systems or apparatus are offered in different configurations, to perform different tasks. These configurations are variants of a complete or complex configuration. The system manufacturer (assembler or integrator) can follow the approach below, suggested as a way to simplify his tasks while fully complying with the EMC Directive:

The responsible person should attempt to define, from an EMC perspective, the configuration most likely to cause the maximum disturbance, or to be the most susceptible

to possible disturbances. This configuration, often called the “worst case”³⁵ should be defined, so that the other possible configurations are included in it in EMC terms.³⁶ Such a configuration is then brought into full compliance with the Directive, in accordance with article 10. The manufacturer then declares conformity and affixes the CE marking.

Once the *worst case configuration defined above* is in conformity, the manufacturer (assembler or integrator) can place on the market any of the possible variants or configurations *without further verification*, since they are included in it in EMC terms. They have better electromagnetic performance, i.e. they do not introduce new electromagnetic disturbances not covered in the worst case configuration(s) or do not deteriorate the immunity compared with the (fully EMC compliant) worst case configuration(s). He then draws up and signs the EC declaration of conformity and affixes the CE marking to each variant.

The responsible person might want to add some new components that were not included in the original (fully EMC compliant) worst case configuration(s), from the EMC perspective, that were fully EMC verified. He may use either electromagnetically “relevant” or electromagnetically “irrelevant” components:

In the context of various configurations the following definitions apply:

An *electromagnetically relevant component* is defined as one that, due to its electromagnetic characteristics, is liable to cause or have its performance degraded by, electromagnetic disturbances such that it influences the EMC characteristics or the intended operation of typical assemblies into which it may be incorporated³⁷.

A *electromagnetically irrelevant component* is then defined as one that, due to its electromagnetic characteristics, neither is liable to cause nor have its performance degraded by, electromagnetic disturbances such that it will not influence the EMC characteristics or the intended operation of typical assemblies into which it may be incorporated.

It must be noted, that some passive-EM equipment may not be electromagnetically irrelevant in particular applications. Therefore, the classification of components as electromagnetically relevant or irrelevant is strictly related to the application and may change from application to application. (Some examples include: inductors, motors, cables). The effect of this phenomenon must be taken into account by the assembler of the system or apparatus.

If the manufacturer (assembler or integrator) later wants to add some new *electromagnetically irrelevant- components* to his configuration(s), that were not included in the original EMC “worst case” that was fully EMC compliant, he *is not*

³⁵ This “worst case” may be identified by a simple consideration of the various combinations, limited testing, or both. The “worst case” may often be the most complex variant.

³⁶ He can use the services and advice of an EMC expert if he is in doubt.

³⁷ This can be considered as widely understood within the industry and, in particular, by the professional manufacturer (assembler or integrator). Experience, good engineering practices and the state of the art, in addition to the intrinsic EMC characteristics of the component, help the manufacturer to make such a judgement.

requested to carry out further verifications from the EMC point of view. He then signs the EC declaration of conformity and affixes the CE marking to the configuration(s).

However, if the manufacturer (assembler or integrator) later wants to add some new *electromagnetically relevant components* to his configuration(s), that were not included in the worst case(s) that were fully EMC compliant, he must then ensure that the new EMC *worst case configuration(s)* are in full compliance with the Directive.

6.5 Application of the Directive to installations

6.5.1 A common understanding of “Installations”

In normal usage the word "installation" is sometimes used to refer to an optional combination of several apparatus, to perform a specific task where the end-user is the person who decides which apparatus are used to construct this so-called "installation" and where the apparatus were not intended to be placed on the market as a single functional unit. **Such installations must be considered like those combinations described in chapter 6.4.1 which are commonly referred to as "systems" and treated as such.** They are not treated further in this chapter.

A good example of such an "installation" is a HI-FI installation composed of an amplifier, tuner, CD player and cassette deck, each of them separately CE marked and separately placed on the market.

6.5.2 Fixed “Installation” within the EMC Directive

6.5.2.1 General

Under Articles 1.1 and 2.1 the Directive applies to installations containing electrical and /or electronic components.

The application of the EMC Directive to installations is, from the experience obtained over the last four years, a very controversial issue. It is therefore important to present in this chapter an analysis on the applicability of the Directive, based on its spirit:

"Fixed Installation", in the broadest sense, is defined as "a combination of several equipment, systems, finished products and/or components (hereinafter called "parts") assembled and/or erected by an assembler/installer at a given place to operate together in an expected environment to perform a specific task, but not intended to be placed on the market as a single functional or commercial unit".

The Directive does not distinguish between different kinds of installations, but in order to avoid unnecessary burdens for manufacturers of parts and assemblers/installers, it is convenient to investigate which provisions of the Directive can be declared non-applicable without compromising the objectives of the Directive.

6.5.2.2 Application of the EMC Directive to fixed installations

In the installations defined in chapter 6.5.2.1, parts not intended to be placed on the market as a single commercial or functional unit may well be used, and it makes no difference whether they were placed on the market by the same or different manufacturers because none of these manufacturers will know the final electromagnetic effect the combination of parts in the installation will have; they can only assume responsibility for each individual part when placing it on the market.

EMC problems in apparatus when used in installations are solved on a case by case basis, by co-operation between manufacturers of parts incorporated into the installation, the user and on some occasions, an installation contracting company. The combined expertise of these parties results in the correct operation of the total installation, and also enables its integration into a network.

The installation must comply with the essential requirements of the Directive as defined in Article 4.

The person(s) responsible for the design, engineering, and construction (assembly and erection) becomes the "manufacturer" in the sense of the Directive, and assumes responsibility for the installation's compliance with all applicable provisions of the Directive, when taken into service. The EMC assembly instructions given by the manufacturer(s) of parts, and the whole method of installation has to be in accordance with good engineering practice within the context of installations, as well as installation rules (national, regional or local) that will ensure the compliance of the whole installation with the essential requirements of the EMC Directive. Such rules must, of course, be fully compatible with the Union Treaty and, in particular, cannot influence the design and manufacture of apparatus that are already in conformity with the EMC Directive.

Such an installation cannot "enjoy" free (physical) movement within the EEA market, and in respect of the EMC Directive there is no need for CE marking or an EC declaration of conformity or to involve a competent body. The manufacturer of the installation must provide clear instructions for operation and maintenance in the instructions for use in accordance with chapter 10.

6.5.3 Application of the Directive to movable installations.

Installations which are intended to be moved to and operated in a range of locations (e.g. the outside broadcast vehicle of a TV or radio station) may experience or cause changes in the electromagnetic environment. Such a movable installation has free (physical) movement within the EEA market, or within the EEA territory. Therefore such movable installations have to comply with the Directive like a system as described in chapter 6.4.

If such installations are, however, intended to substitute for, or to extend a fixed installation (e. g. for electricity generation or transmission in the high-voltage network) they have to be treated in the same way as a fixed installation in chapter 6.5.2. The temporary connections to the networks of such installations must be carefully planned, and installed by experts.

7. APPLICATION OF THE DIRECTIVE TO USED, SECOND HAND, AND REPAIRED APPARATUS, AND TO SPARE PARTS.

Within this context, two points should be made:

- In all that follows, we will refer only to apparatus for which the EMC Directive is potentially applicable under the criteria developed in chapters 4, 5 and 6 of this guide. Apparatus not subject to the EMC Directive are, therefore, excluded from these discussions.

- The application of the EMC Directive to a “as-new apparatus” is without any prejudice to intellectual property legislation³⁸.

7.1. Definitions

- **Used apparatus:** an apparatus which has *previously* been placed on the EEA market *and put into service on the EEA territory*. This apparatus was in compliance with the then applicable legislation: national or EU, depending on the date³⁹. It must have complied with the provisions of the EMC Directive, if applicable to it at that date.

Used apparatus that were in the market and used in the EEA before the date of entry into force of the *EMC Directive are not covered by it*; they had been marketed and used in accordance with the then existing regulations; they were "legal" then; they continue to be so today, unless such apparatus are modified such that they become “as new apparatus”. They circulate in the EEA based on Articles 30/36 of the Union Treaty.

Used apparatus imported from a third country made available for the first time in the EEA for the purpose of distribution and/or use in the EEA, are not considered as used apparatus as regards the application of the EMC Directive, but as *new* apparatus.

- **Second-hand apparatus:** these are used apparatus, which are supplied to a user and which may or may not have been modified by refurbishment, reconditioning or reconfiguration.

Reconditioned (or refurbished⁴⁰) apparatus: this is a used apparatus whose performance has changed over time (due to ageing, obsolescence, etc.), and which has been modified so as to be *restored*. The case of an apparatus whose external appearance has been modified and improved by a cosmetic or aesthetic operation after it has been placed on the market and put into service is a particular form of refurbishment aimed at restoring the external appearance of the apparatus⁴¹.

Reconfigured apparatus: a reconfigured apparatus is a used apparatus whose configuration has been modified, by the addition (upgrading) or the removal

³⁸ See Directive 89/104/EEC relating to the marks and the decision of the European Court of 11th July 1996, C427/93, 429/93, 436/93 Bristol Meyer Squibb.

³⁹ See chapter 1 of this guide for transitional periods.

⁴⁰ Both terms, reconditioned / refurbished, as well as reconditioning / refurbishment are used interchangeably in this chapter.

⁴¹ This can involve a modification of electromagnetic characteristics. The use of different materials or different external dimensions of the apparatus might change EMC performance. For example, a metallic enclosure may provide much better electromagnetic shielding than a plastic enclosure.

(downgrading) of one or more parts (components, sub-assemblies such as plug-in cards or modules, etc.)⁴².

“As-new apparatus”: *This is an apparatus already taken into service which is subject to an industrial operation that implies a substantial modification in order to obtain identical (or similar) performance as, and adapted to the technical progress to the new apparatus placed on the market at the same time.*

7.2 Application of the EMC Directive

The general principle is that the EMC directive re-applies **only** if the modifier claims that the modified apparatus is to be considered "as-new apparatus" in accordance with the definition given in 7.1, and if it is intended to be placed again on the EEA market for distribution and /or use as a single commercial unit.

Nevertheless, the following criteria can be applied, in addition to those covered in chapters 4, 5 and 6 of this guide:

7.2.1 The "original" apparatus was ***not CE marked***, not in compliance with the EMC Directive (because it did not then apply).

7.2.1.1 If after the modifications of the apparatus it does **not** become in a **“as-new apparatus”**. **The EMC Directive is not mandatory**. The "original" one had been acceptable and, it would not be logical to force compliance in this case⁴³. It will circulate in the EEA based on Articles 30/36 of the Union Treaty. The person responsible for placing it on the EEA market should be able, however, to justify his decision in case of challenge by the competent authorities. He should also ensure that the name of any “new” manufacturer (modifier) is included in the operating instructions supplied with the apparatus.

7.2.1.2 If, however, the modified apparatus results in a **as-new apparatus**, it makes sense to request ***compliance with the EMC Directive***, to insist on the necessary protective actions and protect other equipment in its environment. The party responsible for the "as-new" apparatus is here considered as the manufacturer and all the applicable criteria (and simplifications) given in this guide should be addressed.

7.2.2 The "original" apparatus was ***CE marked***, it complied with the EMC Directive:

7.2.2.1 The modified apparatus does **not** result in an **“as-new apparatus”**, the re-application of the EMC Directive is not mandatory. The modifier must, in any case, document what he has done, his EMC analysis, tests carried out if any, and his final conclusions. Such documentation will be required in case

⁴² An example of reconfiguration commonly encountered in the ITE sector is the case of a PC with different options, whose memory capacity (8 to 16 Mbytes) and the number of ports (1 to 8, for instance) may be changed from one option to another.

⁴³ The responsible party can, of course, choose to bring the apparatus in full compliance with the directive, with all its applicable provisions, assess conformity, certify it, declare it and affix the CE marking.

of a challenge. The resulting apparatus should bear sufficient information that permits enforcement authorities and the end user to know that this is a modified apparatus and to permit the identification of the modifier; the "original" manufacturer could otherwise be considered responsible for things that he has not done.

7.2.2.2 If, however, the modified apparatus results in an "as-new apparatus" it makes sense to *re-apply the EMC Directive*, to insist on the necessary protective actions and protect other equipment in its environment. The party responsible for the modification is here considered as the manufacturer and all applicable criteria (and simplifications) given in this guide should be addressed.

In all cases, if the modified configuration had been envisaged and documented by the "original" manufacturer and made part of his assessment of conformity, as EMC conformant variants or configurations of his apparatus before it was placed on the market (as in chapter 6.3 of this guide) and if the modifier follows strictly the "original" manufacturer's instructions and limitations, *the Directive does not need to be re-applied*. In these conditions, the modifier has not altered the manufacturer's conformity assessment, he has not done anything not intended by the "original" manufacturer⁴⁴. He does not need to carry out additional tests, etc.. The "original" manufacturer remains responsible for the EMC conformity and the "original" assessment is valid.

- Whoever produces an "as-new" apparatus from an "original" apparatus through an industrial operation that implies a substantial modification in order to obtain identical (or similar) performance as the new apparatus placed on the market at the same time, must, therefore, be able to certify its conformity before placing it on the market again. He can do so by *assuming, in full, the responsibility of manufacturer* and completing the full EMC analysis, conformity assessment, EC declaration of conformity and CE marking.

7.3 Modifications carried out by the end-user (under his responsibility)

Such modifications should be considered excluded from the application of the EMC Directive. They are made under the sole responsibility of the end user, subject to product liability and other pertinent legislation, but not under the EMC Directive. This apparatus is not being traded. The "client" receiving the modified apparatus is here the end user (and modifier) himself; he cannot claim that anybody else is responsible for what he has done. Action to correct possible EMC problems generated by the modification affecting other apparatus in its environment will have to be taken by the end user if challenged. In any case, he *should not trade such modified apparatus* unless it is brought into conformity with the applicable provisions of the Directive.

⁴⁴ In the instructions for use or in any other documentation issued by the "original" manufacturer under his responsibility.

In any case, he ought to document what he has done, EMC analyses, tests carried out if any, and his final conclusions. Such documentation will be required in case of challenge by the competent authorities. The resulting apparatus must have on it or in its documentation the name of the modifier and details of the modifications, in so much as they affect EMC performance, which must be made available to the competent authorities in case of challenge.; the "original" manufacturer could otherwise be considered responsible for things that he has not done.

7.4 Repaired apparatus and spare parts.

Repaired apparatus: This is an apparatus whose functionality has been restored following a defect without adding new features or any other modification.

This operation does not affect the EMC characteristics of the original apparatus. From the EMC point of view, the repaired apparatus is not different from the original product. *The EMC Directive does not apply.*

A spare part: This is any item intended to replace a defective or worn out item of apparatus, equipment or system previously placed and put into service on the EEA market. A typical repair operation would be replacement by a spare part .

If the manufacturer of the original spare part offers a new, different one in its place (due to technical progress, discontinued production of the old part, etc.), and it is used for the repair, the repaired apparatus does not need to be brought into conformity again with the EMC Directive, if such parts do not produce an apparatus with worse EMC performance apparatus as compared with the "original". Whenever possible manufacturers of such parts should indicate their general intended use and warn of potential EMC behaviour, to allow corrective EMC action if required.

The spare parts for which the EMC Directive applies are those intended to be placed on the EEA market as single commercial units to be distributed and/or used, according to the criteria for the application of the Directive listed in chapters 4, 5 and 6 of this guide. All this applies whether the spare part is manufactured in or outside the EEA.

Those spare parts that, although complying with the criteria mentioned regarding the application of the Directive, are *exclusively* intended for replacement of an *identical* part of apparatus not CE marked, placed in the EEA market before the date of full entry into force of the EMC Directive should also be considered. It does not make sense to insist on compliance for these parts if the equipment for which they are *solely* destined does not comply with the Directive, because it did not need to do so when it was "legally" placed on the EEA market. Since they are identical to the parts to be replaced, they do not alter the EMC characteristics of the apparatus.

8 PROCEDURES FOR ASSESSMENT OF THE CONFORMITY OF APPARATUS INTENDED TO BE PLACED ON THE MARKET

Article 10 of the Directive specifies three procedures for assessment of the conformity of

apparatus :

- Article 10.1 describes the procedure in the case of apparatus for which the manufacturer has applied harmonised standards;
- Article 10.2 describes the procedure where the manufacturer has not applied the standards, or has applied them only in part, or in the absence of relevant standards;
- Article 10.5 describes the specific procedure for apparatus designed for the transmission of radio communications.

Although the EMC Directive pre-dates and therefore does not refer specifically to the modules set out in Council Decision 93/465/EEC⁴⁵, the following information, based on these modules, is nevertheless included for guidance:

8.1 Procedure for the assessment of conformity in accordance with Article 10.1

This article describes the procedure whereby the manufacturer or his authorised representative established within the EEA ensures and declares that the products concerned *conform to the applicable harmonised standards*. The manufacturer (or his authorised representative established within the EEA) affixes the CE marking and draws up a written EC declaration of conformity. The manufacturer (or his authorised representative established within the EEA) keeps this EC declaration of conformity at the disposal of the competent authorities for inspection purposes for a period of ten years after the last apparatus was placed on the market.

Where neither the manufacturer nor his authorised representative is established within the EEA, the obligation to keep the EC declaration of conformity available is the responsibility of the person who places the product on the EEA market.

The general content of the declaration of conformity is set out in Annex I of the Directive (see also Chapter 9 of this guide).

The manufacturer takes all necessary measures in order to ascertain that the manufacturing process ensures compliance of the manufacturer's products with the applicable protection requirements of the Directive as described in the declaration of conformity.

The administrative simplicity of this procedure and the fact that the only documentation required is the EC declaration of conformity should be noted. There is no requirement for a technical file to demonstrate the steps taken to show compliance with the Directive. The manufacturer is fully responsible. After the EMC analysis referred to in chapter 4 of this guide, he has decided to use the applicable harmonised standards, has applied them, prepared an EC declaration of conformity, and affixed the CE marking to the apparatus. (However, it is recommended that manufacturers retain all relevant technical documentation in support of their conformity assessment)

8.2 Procedure for the assessment of conformity in accordance with Article 10.2

⁴⁵ OJ No L 220, 30 8.1993.

This article describes the procedure whereby the manufacturer or his authorised representative established within the EEA ensures and declares that the apparatus concerned satisfies the protection requirements of the Directive that apply to them where the manufacturer has not applied the harmonised standards, or has applied them only in part, or in the absence of relevant standards. The manufacturer or his authorised representative established in the EEA affixes the CE marking and draws up a written EC declaration of conformity.

From the time the apparatus is placed on the market, the manufacturer keeps a technical construction file⁴⁶ at the disposal of the competent authorities. This technical construction file must contain all the technical data needed in order to assess the apparatus' EMC performance and must include a certificate or technical report obtained from a 'competent body'.

This is a delicate Article in the Directive that requires careful analysis. Article 10.2 reads: *"in the case of apparatus for which the manufacturer has not applied, or has applied only in part, the standards referred to in Article 7(1) or failing such standards, the manufacturer or his authorised representative established within the EEA shall hold at the disposal of the relevant competent authorities, as soon as the apparatus is placed on the market, a technical construction file. This file shall describe the apparatus, set out the procedures used to ensure conformity of the apparatus with the protection requirements referred to in Article 4 and include a technical report or certificate, one or other obtained from a competent body."*

There are important comments here:

- The Directive does not require the intervention of a notified body for this procedure (Article 10.2). It creates a 'competent body', whose tasks and responsibilities are not to be confused with those of a 'notified body' in the sense of Article 10.5. The reason for this legislative choice is to simplify the procedures to be followed by the manufacturer and the recognition that a full and complex third party intervention of the type of a notified body is probably not justified in EMC matters, other than for Article 10.5 issues. It is an explicit, clear choice taken by the Council when the Directive was adopted.
- The tasks of such 'competent bodies' are not defined in the Directive: the only requirement is that the technical construction file prepared by the manufacturer under his sole responsibility must contain "a technical report or a certificate obtained from a competent body", but it does not say of what, or in which form, or with what contents, or even for what purpose, although the purpose can be inferred: to help complete the conformity assessment.
- However, we have clearly established that the manufacturer is the only person responsible for the conformity of the apparatus to the applicable provisions. He is the person ultimately responsible for the EMC analysis and the decision regarding which protection requirements apply and how to assess and certify conformity to them. The

⁴⁶ For further details, see the "Guide to the implementation of the Community harmonisation directives based on the New Approach and the Global Approach", sheet II/D.

Directive recognises his abilities since Article 10.1 clearly shows that enforcement authorities must not, a priori, contest his simple declaration of conformity; so he is therefore recognised as capable of assessing his apparatus.

- The electrical engineering industry has a large number of SME's (small and medium size enterprises), capable of assessing their products, as they have until now, but most lacking a full understanding of some of the "new" EMC requirements. In the case of Article 10.1, for instance, where the manufacturer applies the relevant provisions of the harmonised standards, he may ask a test house to carry out some tests for him/her (see chapter 3.3). Of course he is and remains fully responsible for his apparatus.
- The manufacturer is, therefore, fully responsible for defining what parts of the conformity assessment he is able to undertake "in-house" and which ones require outside help. It can then be concluded that he chooses what assessment he requires from the 'competent body' that he has chosen, in order to complete his technical construction file. Otherwise the Directive would have introduced 'notified' instead of 'competent' bodies.
- The intention of the Directive is to document in the technical construction file those steps taken to certify the conformity of the apparatus for those aspects for which the manufacturer has not used harmonised standards or parts thereof and that require EMC assessment. The Directive then requires that the technical construction file be evaluated and endorsed by a 'competent body' through a report or certificate, that will be included in the technical construction file prepared by the manufacturer under his sole responsibility.

In these conditions, the "technical report or certificate" requested by the Directive should be *limited to a report or certificate that the procedures carried out for the conformity assessment of those parts not covered by applied harmonised standards has been correctly performed, regardless of whether they were done by the manufacturer or by the competent body.*

The manufacturer defines the procedures to be carried out "in-house", carries them out, documents them and submits such proof to the 'competent body', who evaluates them. Of course, the 'competent body' may, in order to carry out his task, request additional data from the manufacturer if required for the evaluation. The manufacturer defines also what other procedures he wishes to be carried out by the 'competent body', who can, of course, also carry out the full conformity assessment if so requested by the manufacturer.

The 'competent body' may, of course, suggest other actions to the manufacturer, that he considers necessary based on his experience and own EMC analysis, that might differ from that of the manufacturer. The manufacturer decides, his responsibility remains intact: if the report or certificate included in the technical construction file is considered incomplete by a particular enforcement authority, the manufacturer may face restrictions on the free movement of the apparatus, but based on the application of the safeguard clause (Article 9 of the Directive).

The 'competent body' issues his report or certificate requested of him by the manufacturer. In contrast with the 'notified body' approach, he is not responsible for a full module of conformity assessment; he is only responsible for the assessment that he performs.

It should be noted that the report or certificate is not required for those parts and/or procedures covered by the part of the harmonised standards that the manufacturer has used. The spirit of Article 10.1 should be maintained: those parts do not require any reporting or documentation, other than what is requested in the technical construction file.

The certificate or report may cover several variants or configurations of the apparatus insofar as the differences between the variants do not affect the level of requirements in terms of electromagnetic compatibility (see the approach for systems in chapter 6.3.3 of this guide).

The manufacturer must, therefore, ask a competent body of his choice to draw up such technical report or certificate before the apparatus is placed on the market. As the technical reports and certificates are equivalent, it is sufficient to obtain either of them for the apparatus to be placed on the market throughout the EEA.

Contents of the technical construction file:

The technical data must include the following information, limited to what is essential to assess the conformity of the apparatus with the Directive :

- a general description of the product;
- design and manufacturing drawings together with layout diagrams covering components, sub-assemblies, circuits, etc.;
- descriptions and explanations needed in order to understand the above mentioned drawings and diagrams as well as the operational aspects of the product;
- list of standards applied in whole or in part and a description of the solutions adopted in order to comply with the protection requirements of the Directive in cases where the standards have not been applied;
- design calculation results arising from the EMC tests;
- the technical report or the certificate issued by the competent body, as discussed above;
- a copy of the EC declaration of conformity (this is not a requirement of the EMC Directive but as both it and the technical construction file have to be kept at the disposal of the competent authorities it seems sensible to do so);
- a copy of the instructions for use (see Annex III of the Directive and chapter 10 of this guide).

The manufacturer or his authorised representative established within the EEA keeps this documentation at the disposal of the competent authorities in case of challenge for a period of ten years after the last apparatus was placed on the market.

Where neither the manufacturer nor his authorised representative is established within the EEA, the obligation to keep the technical documentation available is the responsibility of the person who places the apparatus on the EEA market.

The manufacturer takes all measures necessary to ascertain that the manufacturing process ensures compliance of the manufactured apparatus with the applicable protection requirements as described in the technical construction file.

8.3 Procedure for the assessment of conformity in accordance with Article 10.5

This procedure is only applicable to apparatus designed for the transmission of radio communications, as defined in the International Telecommunication Union Convention.

This paragraph describes that part of the procedure by which a notified body ascertains and attests that a type (specimen), representative of the production envisaged, meets the applicable provisions of the Directive.

The application for EC type-examination is lodged by the manufacturer or his authorised representative established within the EEA with a notified body of his choice.

The application includes :

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation described below.

The applicant places at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called the "type". The notified body may request further specimens if needed for carrying out the test programme.

The notified body may, on its own responsibility, commission an independent laboratory to carry out the appropriate examinations and tests.

The technical documentation must enable the conformity of the apparatus with the protection requirements of the Directive to be assessed. It must, for the purposes of such assessment, cover the design, manufacture and operation of the apparatus.

The notified body :

- examines the technical documentation, verifies that **the type** has been manufactured in conformity with it and identifies the components which have been designed in accordance with the relevant provisions of standards referred to in Article 7 and those which have been designed without applying the relevant provisions of the standards;

- agrees with the applicant the location where the examinations and necessary tests are to be carried out.
- performs or has performed the appropriate examinations and necessary tests to check whether, where the standards have not been applied, the solutions adopted by the manufacturer meet the essential protection requirements of the Directive;
- performs or has performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;

Where **the type** meets the provisions of the Directive, the notified body issues an EC type-examination certificate to the applicant. The certificate contains the name and address of the manufacturer, conclusions of the examination, conditions for the validity of the certificate and the necessary data for the identification of the approved type.

A list of the relevant parts of the technical documentation is annexed to the certificate and a copy kept by the notified body.

If the manufacturer is denied a type certification, the notified body provides detailed reasons for such denial.

Provision must be made for an appeals procedure.

The applicant informs the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the EC type certified apparatus. The modified apparatus must receive additional EC-type-examination certificates where such changes may affect the conformity with the protection requirements or the prescribed conditions for use of the apparatus. This further certificate is given in the form of an addition to the original EC type-examination certificate.

Each notified body communicates to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.

The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The annexes to the certificates are kept at the disposal of the other notified bodies.

The manufacturer or his authorised representative keeps with the technical documentation copies of EC type-examination certificates and their additions for a period of ten years after the last apparatus has been placed on the market.

On the basis of the EC type-examination certificate, the manufacturer declares that the series-manufactured products are in conformity with the type described in the certificate and satisfy the protection requirements of the Directive. The manufacturer or his authorised representative established in the EEA affixes the CE marking and draws up a written declaration of conformity.

The manufacturer takes all necessary measures in order that the manufacturing process ensures compliance of manufactured apparatus with the type as described in the EC type-examination certificate and with the protection requirements of the Directive.

The manufacturer or his authorised representative established within the EEA keeps a copy of the declaration of conformity for a period of ten years after the last apparatus has been placed on the market.

Where neither the manufacturer nor his authorised representative is established within the EEA, the obligation to keep the copy of the EC declaration of conformity available is the responsibility of the person who places the apparatus on the EEA market.

9 EC DECLARATION OF CONFORMITY

The EC declaration of conformity provided for in Article 10 of the Directive is important both for assessment of the conformity of the apparatus and for the procedure for monitoring the market.

The EC declaration of conformity is drawn up by the manufacturer or by the manufacturer's authorised representative established within the EEA.

Where neither the manufacturer nor his authorised representative is established within the EEA the obligation to keep the EC declaration of conformity available is the responsibility of the person who places the apparatus on the EEA market.

A copy of the declaration of conformity is kept at the disposal of the competent authority for inspection purposes under the same conditions as the technical construction file.

It is not a requirement of this Directive to supply a declaration of conformity with the apparatus.

Paragraph 1 of Annex I of the Directive describes the content of the EC declaration of conformity, which must include the following:

- description of the apparatus to which it refers,
- reference to the specifications⁴⁷ under which conformity is declared and, where appropriate, to the internal measures implemented to ensure the conformity of the apparatus with the provisions of the Directive,
- identification of the signatory empowered to bind the manufacturer or his authorised representative, established within the EEA
- where appropriate, reference to the EC type-examination certificate issued by a notified body.

The declaration of conformity must be written in one of the official languages of the EEA.

⁴⁷ Pursuant to Article 7 of the directive.

10 INSTRUCTIONS FOR USE

Annex III of the Directive stipulates that all "apparatus" must be accompanied by instructions containing all the information required in order to use the apparatus in accordance with the intended purpose and in the defined electromagnetic environment. Other than to facilitate the operation of the apparatus, their purpose is to ensure that no EMC problem is encountered in use.

These instructions must give the following information:

- intended conditions of use;
- instructions on:
 - installation;
 - assembly;
 - adjustment;
 - taking into service;
 - use;
 - maintenance;
- where necessary, warnings about limitations of use.

A copy of the instructions for use should be included in the technical construction file, when Article 10.2 has been used.

11 COMPETENT AUTHORITIES, COMPETENT BODIES AND NOTIFIED BODIES

11.1 Competent authorities

The competent authorities are represented by the administrations of the Member States of the EEA responsible for fulfilling the obligations of market control (Article 3 of the Directive) incumbent on them. Each Member State must notify the competent authorities to the Commission and to the other Member States of the EEA.

As a guide, a list of the names and addresses of the competent authorities known to the Commission is reproduced in Annex 4.

11.2 Competent bodies

Under the EMC Directive, a body is considered to be competent if it fulfils the criteria set out in Annex II of the Directive. Bodies which are able to provide proof of their conformity with Annex II by presenting a certificate of accreditation or other means of

documentary proof, as defined below, to their Competent Authorities and the Commission are considered competent and in this respect they conform to the requirements of the Directive. The appropriate (voluntary) harmonised standards of the EN 45000 series provide presumption of conformity to Annex II.

A manufacturer's laboratory can be recognised as a competent body provided that it satisfies the criteria set out above and, in particular, provided that it can give assurances regarding its independence and impartiality from the design and production processes.

A competent body must ensure that it is ready to accept any request, wherever this request comes from, taking into account its capabilities and work load.

The competent body is responsible for issuing the technical reports or certificates referred to in Article 10.2 of the Directive, largely explained in chapter 8.2 of this guide. They carry out an extremely important task to *help the manufacturer* to assess and declare conformity to the Directive. Such tasks must, nevertheless, be proportional and limited to the objective being pursued and to the intended use of the apparatus.⁴⁸

A body can be recognised as competent :

- either by an accreditation body recognised as such by the competent authority of a Member State of the EEA;
- or by a body representing the supervisory authority of a Member State of the EEA.

Although not explicitly indicated in the Directive, the appointment of Competent Bodies ought to be communicated by EEA Member States' authorities. Article 1.5 reads: "*competent body*' means any body that meets the criteria listed in Annex II and is *recognised as such*" and Annex II reads: "...The bodies *designated* by Member States must.....".

Such knowledge is necessary for the proper management of the Directive, both for the Member States of the EEA and for the Commission. A compilation of the details of Bodies accepted as competent, including their name, address, telephone, fax, proof and **scope of their competence** must be regularly sent by the Competent Authorities. The Commission will publish it for information purposes.

As a guide, a provisional list of the competent bodies as well as their area of competence sent to the Commission as information is reproduced in Annex 5.

11.3 Notified bodies⁴⁹

⁴⁸ Competent Bodies could limit the testing required by the manufacturer to what is essential for the purposes of the assessment of conformity, using their know-how related to the apparatus or systems. Often apparatus or systems are similar or very similar, from the EMC stand point, to others already fully tested and certified. They can build up on such experiences and offer a cost-effective service, whilst maintaining full compliance with the directive

⁴⁹ See the "Guide to implementation of the Community harmonisation directives based on the New Approach and the Global Approach", sheet II/B.

Annex II of the EMC Directive defines the criteria that these bodies must fulfil. Bodies which are able to provide proof of their conformity with Annex II by presenting a certificate of accreditation or other means of documentary proof, as defined below, to their Competent Authorities are considered notifiable and in this respect they conform to Annex II of the Directive. The appropriate harmonised standards (voluntary) of the EN 45000 series provide presumption of conformity to Annex II. This does not rule out the possibility that bodies not conforming to the harmonised standards may be notified, on the grounds that compliance is obligatory only with respect to the criteria set out in Annex II to the Directive.

A notified body is responsible for issuing the EC type-examination certificates referred to in Article 10.5 of the Directive.

Member States of the EEA must notify, on their own responsibility, the bodies under their jurisdiction responsible for issuing the EC type-examination certificates referred to in Article 10.5 of the Directive to the Commission and the other Member States of the EEA. They have been chosen from among those considered to be technically competent. For the Member States of the EEA, this responsibility of notification involves the obligation to ensure that the notified bodies permanently maintain the technical competence required by the EMC Directive and that they keep their notifying authorities informed about the performance of their tasks.

Therefore, a Member State of the EEA which does not have a technically competent body under its jurisdiction to notify is not required to make such a notification. This means that a Member State of the EEA which does not have such a body is not required to create one if it does not feel the need to do so. A manufacturer always has the choice of contacting any body which has been notified by a Member State within the EEA.

As a guide, Annex 6 includes a list of bodies notified to date and published in the Official Journal of the European Communities.

12 APPARATUS MARKING

All apparatus covered by the Directive in accordance with the protection requirements and accompanied by one of the means of certification provided for in Article 10 must bear the CE marking.

The CE marking is affixed by the manufacturer or his authorised representative established within the EEA to the apparatus or, if this is not possible, to the packaging, instructions for use or guarantee certificate, in that order of priority⁵⁰.

Where the apparatus is covered by other Directives providing for the CE marking, application of the CE marking also indicates that the apparatus conforms to the provisions of the other Directives applicable to it.

⁵⁰ This order of priority was the original intention of the Commission when the Directive was drafted. The Commission is aware that, perhaps due to language translation problems, there are differing national interpretations. The Commission's intent has not changed.

The CE marking is to be affixed visibly, legibly and indelibly.

It is prohibited to affix any marks or inscriptions that are likely to mislead third parties as to the verbal or pictorial significance of the CE conformity marking.

It would be sensible, but it is not mandatory, to more readily facilitate free movement to affix the CE marking to more than one place, for example, marking the outer packaging, as well as the apparatus inside can be ascertained without opening the package. There is nothing in the Directive to prevent this.

13 SAFEGUARD CLAUSE⁵¹

The safeguard clause referred to in Article 9 is the EEA procedure whereby any measure taken by a Member State, on the grounds of non-compliance with the protection requirements and for the purpose of withdrawing from the market, prohibiting the placing on the market or restricting the free movement of apparatus accompanied by one of the means of attestation provided for in the Directive and therefore bearing the CE marking, must be immediately notified to the Commission by the Member State which has taken it.

A notified measure which fulfils the criteria of invoking the safeguard clause is followed by a process of consultation between the Commission and the "parties concerned" The "parties concerned" primarily means the Member State of the EEA which was taken the restrictive measure, the manufacturer or his authorised representative established within the EEA or, failing them, the person who placed the apparatus on the EEA market.

The consultation procedure enables the Commission, on the basis of the above reasons, to assess whether the restrictive measure is justified. This means that the measures notified to the Commission must be accompanied by detailed information specifying in particular the reasons why the protection requirements laid down in the Directive have not been complied with by the apparatus concerned.

Where the Commission finds, following such consultation, that the measures are justified, it immediately informs the Member State which took the initiative and the other Member States. In the Commission's view, the objective of informing the other Member States is to prompt these Member States to take appropriate measures in accordance with Article 3 of the Directive.

Where the Commission finds that the measures are not justified, it reserves the right to proceed under Article 169 of the Treaty. Before doing this, it will immediately inform the Member State which took the initiative and the manufacturer or, failing this, any other person who placed the apparatus on the EEA market.

In order to ensure transparency and the proper uniform application of the safeguard clause, Article 9.4 states that "the Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure".

⁵¹ For a detailed analysis of the "Safeguard clause", see the "Guide to implementation of the Community harmonisation directives based on the New Approach and the Global Approach", sheet I/E, Chapters 2, 3, 4.

14 PROGRESS ON STANDARDISATION

14.1 Standards published in the Official Journal

By way of information, Annex 7 contains a reference list of harmonised European standards that have been published in the EC's Official Journal. The application of the appropriate harmonised standards to an apparatus confers on that apparatus a presumption of conformity with the protection requirements of the Directive. In other words, in the case of a challenge, the responsible national authorities will have to prove that the product is not in conformity with the protection requirements of the Directive.

The presumption of conformity is conferred, in regulatory terms, only by the use of the national standards transposing a harmonised standard. Where the relevant standardisation committee has not transposed the standard, use of the original harmonised standard or of a transposed standard in another Member of the EEA confers the same presumption of conformity. However, such transposition must have taken place into the national standards collection of at least one of the Member States of the European Community.

European standards are available from:

- CENELEC, rue de Stassart, 35, 1050 Brussels,
- ETSI , 650 Route des Lucioles F-06921 Sophia Antipolis CEDEX- France, and
- CEN, rue de Stassart, 36, 1050 Bruxelles.

National transpositions of harmonised standards are available from the national standardisation Bodies. (See Annex 9).

The list of harmonised standards published in the Official Journal is also available at the following Internet address:

<http://www2.echo.lu/nasd/>

14.2 Standardisation programme

By way of information, Annex 8 provides the two standardisation programmes addressed to the European standardisation bodies. Each one is the subject of a standardisation mandate drawn up by the Commission.

The first mandate was addressed to CENELEC (BC/CLC-02/92) and was adopted by the Committee established under Directive 83/189 on 7 October 1992.

The second was addressed to CEN, CENELEC and ETSI, (M/237) and was adopted by the Committee established under Directive 83/189 on 13 December 1995. Within these mandates, the standardisation bodies concerned have to prepare standards covering the electromagnetic emissions and immunity. These standards will define the limits and the test methods that are necessary and sufficient to provide a presumption of conformity with the Directive for the apparatus that are built in conformity with relevant harmonised standards.

15 APPLICATION OF THE DIRECTIVE TO SOME SPECIFIC CASES

15.1 Application of the EMC Directive to Telecommunication and Radiocommunication equipment.

15.1.1 Telecommunication terminal equipment

Telecommunication terminal equipment (covered by Directive 91/263/EEC) and satellite earth stations equipment (covered by Directive 93/97/EEC):

For apparatus covered by these Directives, the provisions related to electromagnetic compatibility phenomena laid down by the three Directives 89/336/EEC, 91/263/EEC, 93/97/EEC have to be observed on a complementary basis.

Electromagnetic compatibility protection requirements to be observed for apparatus covered by Directives 91/263/EEC or 93/97/EEC, insofar as they are not specific⁵² to such equipment, are those laid down by the Directive 89/336/EEC.

That implies that for all non specific electromagnetic phenomena the conformity assessment procedures of Articles 10.1 or 10.2 of Directive 89/336/EEC apply to equipment covered by Directives 91/263/EEC and 93/97/EEC; this includes radio telecommunication terminal equipment.

Mobile telecommunication apparatus which, even if capable of being used in a vehicle, is by definition not intended for fitment (installation) therein, must comply with Directive 89/336/EEC and the TTE Directive, and they are not covered by the motor vehicle Directive, 95/54/EC.

15.1.2 Radiocommunication equipment

- Radio communication transmitters not covered by Directive 91/263/EEC nor by Directive 93/97/EEC are subject to the conformity assessment procedure laid down by Article 10.5 of Directive 89/336/EEC.
- Radio communication receivers are subject to the conformity assessment procedures laid down in Articles 10.1 or 10.2 of Directive 89/336/EEC.

For the two types of equipment mentioned above, the directive does not apply to the normal operating frequency bands, as already mentioned in chapter 4 of this guide. They are outside the scope of the Directive..

15.1.2.1 Emissions outside the required bandwidth

⁵² CENELEC/ETSI Annex II of their report R0BT-001/ETR 238 of Oct. 1995 describes the specific and non-specific EMC phenomena. The ITU has defined out-of-band emissions as unwanted emissions (basic definitions of RR1-17).

In every type of radio transmission (emission) there is a band of frequencies occupied that constitute the fundamental transmission (emission) and which is due to the modulation process used. The content of the emission and the bandwidth occupied is dependent on the technique and form of modulation process used, which may be analogue or digital in content.

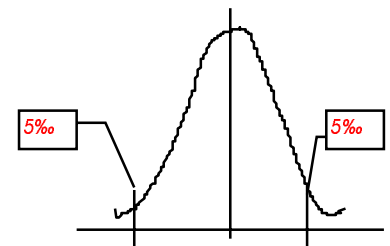
This occupied band of frequencies is basically made up of two parts, which form what is known as the transmitter mask. The two parts which make up this mask are defined by the ITU as follows:

'Necessary Bandwidth': *for a given class of emission, the width of the frequency band which is just sufficient to ensure the transmission of information at a the rate and with the quality required under specified conditions* (Article 1, No 146 of the Radio Regulations); and

'Out-of-band Emissions': *Emission on a frequency or frequencies immediately outside the necessary bandwidth which results from the modulation process, but excluding spurious emissions* (Article 1 No 138 of the Radio regulations).

The transmitter mask defined above is an element used in the planning and allocation of frequency bands for all radio services. it is important to note that although "out of band" emissions contain the **unwanted** emissions due to the modulation process it is part of the transmitter mask and is taken into account in the planning of the frequency band.

In consequence, "out of band" emissions **if used when planning and allocating frequency band for radio services and needed in the management of the radio spectrum** are not subject to the directive.



In every modulation process additional undesired signals exist. They are summarised under the expression "spurious emissions", as defined in Article 1 No 139 of the Radio regulations:

'Spurious Emission': Emission on a frequency or frequencies which are outside the necessary bandwidth and the level of which may be reduced without affecting the corresponding transmission of information. Spurious emissions include harmonic emissions, parasitic emissions, intermodulation products and frequency conversion products, but exclude out-of-band emissions.

Spurious emissions are subject to the directive.

15.2 Application of the EMC Directive to machines

15.2.1 Parallel application of the EMC and Machinery Directives

In order to avoid confusion in the interpretation of the texts of the EMC and the machinery Directives⁵³, it is important to point out that the essential requirements stipulated by these two Directives are of *very different nature*:

- The EMC requirements laid down by the machinery Directive (see 89/392/EEC, Annex I, paragraph 1.5.10 and 1.5.11) concern only the *emission of radiation*⁵⁴, aimed at the *user's protection, safety and immunity to external radiation*⁵⁵, aimed at ensuring its proper functioning.
- On the other hand, the EMC requirements stipulated by the electromagnetic compatibility Directive (Articles 4a and 4b) are aimed at functional protection of the *apparatus itself and other apparatus in its environment*, for emissions and immunity. It is definitely *not user oriented* as such, and *not limited to radiation*, which is only one EMC aspect to be considered.

Their requirements and objectives being clearly different, neither of these two Directives can be regarded as being specific one to the other. *Both Directives have to be applied in a parallel and complementary way* by following the approach described as follows.

15.2.2 Criteria of applicability of the EMC Directive

The machinery sector is characterised by a very vast range of products of different types, sizes and nature, from small machines produced in series to large and even very large machines sometimes manufactured as “one-off’s” according to the technical requirements and needs laid down by the customer. Some are apparatus, others have to be considered as systems, others as installations.

The sector is also characterised by a majority of SMEs (small and medium sized enterprises), experienced professionals in mechanical engineering, but often with limited knowledge of EMC and other related matters, and little or no EMC test equipment.

As explained in sections 4, 5 and 6 the manufacturer of the equipment (in this case, machinery), should perform an EMC analysis to define what essential safety and/or protection requirements apply to his apparatus, from which applicable Directive and how to conform to them, using the choices of procedures given in each Directive that applies, which, in turns, may also depend on the extent of use of voluntary harmonised standards.

In all cases, where the machine's manufacturer only uses *CE marked apparatus* (complying with the EMC Directive) and follows strictly the instructions and limitations of use of the manufacturer of these products who intended them to be used in machinery, the finished machine could be considered in compliance with the EMC Directive and no further verification would then be needed. The EC declaration of conformity as well as the instructions for use must refer to the finished machine as a whole. The manufacturer assumes responsibility for compliance with the Directive in all expected electromagnetic

⁵³ 89/392/EEC, 91/368/EEC, 93/44/EEC and 93/68/EEC.

⁵⁴ Annex I, 1.5.10 reads: "*Machinery must be so designed and constructed that any emission of radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions*".

⁵⁵ Annex I, 1.5.11 reads: "*Machinery must be so designed and constructed that external radiation does not interfere with its operation*".

environments and must therefore in accordance with chapter 10, provides clear instructions for assembly/installation/operation/maintenance in the instructions for use. The finished machine as a whole does not need to bear the CE marking (all this applies even if it is offered on the market as a single functional unit, as long as each part bears the CE marking). This is consistent with the criteria and procedures developed in chapters 6.4.2.1 and 6.5. The addition of electromagnetically irrelevant components (See definition in 6.4.3) should also have the same effect since the EMC characteristics are mainly due to the electrical and electronic devices incorporated in the machine, and not the mechanical components, that are "electromagnetically irrelevant" in this context.

This simplification does not alter the full responsibility of the machine's manufacturer. If the resulting machine needs additional EMC protective measures to fulfil the EMC protection requirements, they must be undertaken by him, but not subject to the procedures of the EMC Directive.

In all other cases where the machine's manufacturer does not restrict himself to only using CE marked apparatus, the criteria and procedures of chapter 6.4.2.2 and 6.5 can be applied accordingly. Within this context, the EMC analysis and the nature of the machine, will enable the manufacturer to know if his machine is an apparatus, (finished product, system or installation) and apply the respective criteria of this guide (and, of course, its simplifications) to comply with the EMC Directive.

15.2.3 Harmonised standards that may be used for machines

The so-called harmonised generic standards for the residential, commercial, and light industrial environment, and industrial environment can be used by machine manufacturers to bring machines into compliance with the EMC Directive until specific product family standards (already under preparation) are available as harmonised standards.

15.3 Application of the EMC Directive to motor vehicles (95/54/EC)

The EMC protection and safety requirements applicable to motor vehicles are laid down by the Directive 95/54/EC, that amends the Directive 72/245/EEC concerning electromagnetic interference produced by spark ignition engines intended to be fitted into motor vehicles.

In recognition of *the need for more stringent safety standards for the electromagnetic compatibility of vehicles and related components*, the Member States and Industry agreed the establishment of specific EMC provisions, under the terms of Article 2.2 of the EMC Directive. Directive 95/54/EC, the so-called "Automotive EMC Directive" was therefore adopted, entering into force on 1 January 1996, as specific Directive with respect to 89/336/EEC.

Scope and application of the Automotive EMC Directive (95/54/EC)

- For *new types* of vehicles placed on the EEA market after 1/01/1996, *new types* of components and *new types* of separate technical units intended to be fitted into motor vehicles and placed on the EEA market after 1/01/1996, the specific Directive

95/54/EC *is mandatory*. These products must bear the 'e' marking that confers free movement throughout the EEA area.

- For *new* components and *new* separate technical units type-approved before 1/01/1996 within Directive 72/245/EEC, which continue of being placed on the EEA market and/or put into service after 1/01/1996, compliance with Directive 95/54/EC is optional until **1st October 2002**.

For those products, Directive 95/54/EC will become mandatory only on **1st October 2002**. In other words, Directive 95/54/EC has a certain degree of optionality for such items until 1 October 2002. The circumstances under which the EMC Directive *may* continue to apply to products in the vehicle sector, for which Directive 95/54/EC is optional, are described in more detail later on.

Specific case of in-car entertainment products

Entertainment products (e.g. radios, cassette and compact disc players), intended for fitment in vehicles, fall within the scope of Directive 95/54/EC and are governed by the substantive provisions therein.

With the aim of clarifying the applicability of both EMC Directive 89/336/EEC and the Automotive EMC Directive (95/54/EC amending 72/245/EEC), to in-car entertainment products intended to be incorporated into a motor vehicle, such as car radios, CD players, etc., during the period 1/1/96 to 1/10/2002, the Commission issued a communication setting out its interpretation of the application of Directive 95/54/EC. This interpretation is explained as follows:

1. *Directive 95/54/EC establishes more stringent and appropriate safety requirements for the electromagnetic compatibility for vehicles and their components than are found in the general Directive 89/336/EEC. Therefore Directive 95/54/EC, which entered into force on 1 January 1996, constitutes a specific Directive for the purposes of Article 2.2 of Directive 89/336/EEC.*
2. *Entertainment products (e.g. radios, cassette and compact disc players), intended for fitment in vehicles, fall within the scope of Directive 95/54/EC and are governed by the substantive provisions therein. For such products, for the purposes of European type approval, these provisions apply on an optional basis until 1 October 2002, as stated in Article 2.5 of the Directive. From that date the provisions of Directive 95/54/EC become mandatory.*
3. *During this optional phase of the Directive Member States may deny free circulation to such products, intended for fitment in vehicles and which comply with Directive 89/336/EEC, on duly motivated safety grounds, having respect to Article 30 and 36 of the EC Treaty.*
4. *Therefore, due to its more stringent provisions, only compliance with Directive 95/54/EC provides a guarantee of free circulation within the EEA with respect to the electromagnetic compatibility of products intended for fitment in vehicles.*

5. *Products which are intended for fitment in both vehicles and other applications (such as boats or caravans) may be CE-marked in respect of that other application but such marking does not confer free circulation for products intended for fitment in vehicles.*

15.4 Application of the EMC Directive to equipment to be fitted into aircraft

This chapter can not yet be completed; discussions continue. The general approach is that apparatus **covered** by Council Regulation 3922/91 are excluded from the application of the EMC Directive, this regulation being specific with respect to the EMC Directive (89/336/EEC), in accordance with Article 2.2.

As soon as it can be completed, this chapter will be added to the document..

15.5 Application of the EMC Directive to Medical devices.

- 1) The requirements of the "Medical devices" Directive (93/42/EEC) are fully applicable from 1.01.1995 (Article 22.1 of this Directive)
- 2) Member States will accept, until 14.06.1998, the placing on the EEA market and/or the putting into service, medical devices complying with legislation in force in their territory at 21.12.1994 (Article 22.4 of this Directive)

As a consequence, the manufacturer has the following choices to comply with the EMC requirements:

◆ **-from 1.01.1995 to 14.06.1998:**

- -either the requirements of Directive 93/42/EEC, or
- -those of the EMC Directive (89/336/EEC), using the criteria developed in this guide.

◆ **-from 15.06.1998, the end of the transitional period, the requirements of 93/42/EEC are mandatory. The EMC Directive (89/336/EEC) will no longer apply.**

Harmonised Standards: The reference of standard EN 60601-1-2 has been published in the Official Journal of the European Communities; any national transposition of this European standard can be used to provide a presumption of conformity to the EMC requirements.

15.6 Application of the EMC Directive to Active implantable medical devices.

The requirements of the "Active implantable medical devices" Directive (90/385/EEC) are fully applicable from 1.01.1993. Member States have accepted, until 31.12.1994 the placing on the EEA market and/or the putting into service, Active implantable medical devices complying with legislation in force in their territory at 31.12.1992 (Article 16.1 of this Directive).

As a consequence, the EMC (89/336/EEC) Directive has not applied since 31/12/94, the "Active implantable medical devices" Directive (90/385/EEC) being a fully specific Directive.

15.7 Application of the EMC Directive to In Vitro Diagnostic Medical Devices

This chapter cannot yet be completed. The general approach is that apparatus covered by the proposal for a Directive COM(95) 130⁵⁶ final will be excluded from the application of the EMC Directive, this Directive being specific with respect to the EMC Directive (89/336/EEC), in accordance with Article 2.2, upon the date of entry into force of this specific Directive.

15.8 Application of the EMC Directive to Marine equipment.

1) The requirements of the "Marine Equipment" Directive (96/98/EC)⁵⁷ will be fully applicable from 30.06.1998 (Article 20 of this Directive)

2) Member States will accept, until 31.12.1998, the placing on the EEA market and/or the putting into service, Marine equipment covered by this Directive complying with legislation in force in their territory at 29.06.1998. (Article 20 of this Directive)

As a consequence, the manufacturer has the following choices to comply with the EMC requirements:

◆ **-from 30.06.1998 to 31.12.1998:**

- -either the requirements of Directive 96/98/EC, or
- -those of the EMC Directive (89/336/EC), using the criteria developed in this guide.

◆ **-from 1.01.1999, the end of the transitional period, the requirements of 96/98/EC are mandatory. The EMC Directive (89/336/EEC) will no longer apply.**

For all Marine equipment *not* covered by the Marine equipment Directive (96/98/EC), the EMC Directive is mandatory from 1.1.1996.

15.9 Additional information

- A proposal for a Directive covering certain measurement instruments subject to legal control is under preparation. The immunity requirements for those measurement instruments will be only covered by this proposal for a Directive; the emission requirements are still under discussion between Government experts and the Commission.

⁵⁶ OJ No C 172, 7.7.95

⁵⁷ OJ No L 46, 20.12.96

These Guidelines are free of charge and can be found in the following addresses:

- Competent Authorities (See Annex 4)
- CENELEC (See Annex 9)
- ORGALIME (See Annex 9)