EUROPEAN COMMISSION

Guide to the implementation of Community harmonization directives based on the new approach and the global approach

First version

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IMPORTANT NOTICE

This guide, which is intended as a practical manual for all those working with Community technical regulations based on the "new approach" and the "global approach", has a modular format consisting of a set of sheets as shown in the contents.

This format means that the guide can be added to and updated in a flexible and regular manner simply by amending a particular sheet or sheets where it has been agreed to include new information on the basis of the experience gained.

The first version of this guide has been prepared in all Community languages to ensure a wide circulation and to facilitate consultation. However, at this stage, it is still no more than an incomplete working document. The aim is to expand and finalize the guide during 1994.

Readers' should note that, where there are differences between the contents of a directive and what appears in this guide, only the text of the directive is authentic in law.

It should also be pointed out to readers that, in addition to the "new approach" directives, which deal with the conditions for the placing on the market and putting into service of the relevant products, these products may also be subject to other obligations under Community law which are not discussed in this guide.

PREFACE BY MARTIN BANGEMANN

Member of the Commission

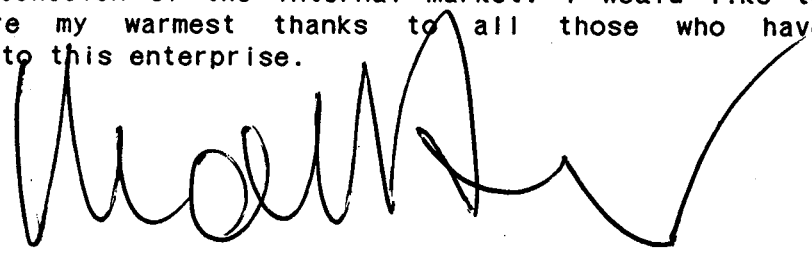
From 1 January 1993, the completion of the internal market has allowed free movement of goods throughout the territory of the Community.

A condition of such freedom of movement is the application of Community technical harmonization directives covering a wide range of industrial products such as machinery, construction products, personal protective equipment, medical equipment, telecommunications terminal equipment, toys, and so on. Furthermore, harmonization contributes to improvement in the quality of products, which enables the competitivity of enterprises to be improved in an increasingly global market place.

Recognizing that these provisions – drawn up by the Commission and adopted by the Council on the basis of the New Approach since 1985 – needed to receive wide publicity and that the method of implementing them required explanation, I asked my departments to prepare this guide.

The new principle is that of the use by the Community, in the drawing up of technical regulations of "quality instruments" such as European standardization and conformity assessment procedures (testing, product certification, certification of manufacturers' quality control procedures, accreditation, etc.) which call, as far as possible, for the participation of economic operators. These instruments enable manufacturers to affix the CE marking – a real "technical passport" – to their industrial products, and thus to indicate that they conform to Community requirements.

I am confident that this guide, drawn up with the participation of all the economic partners concerned in close cooperation with the Member States' representatives responsible for these matters will prove to be a useful and effective tool for all those responsible for implementing these directives with a view to greater cohesion of the internal market. I would like to express here my warmest thanks to all those who have contributed to this enterprise.



Foreword by Riccardo Perissich

Directorate General "Industry"

I believe that this guide, drawn up in close cooperation between services of the Commission of the European Communities and the national authorities responsible for the various topics covered, is important for the following reasons:

- it explains certain provisions of the Community's "New Approach" directives in everyday language, avoiding legal jargon;

- it should help these provisions to be better understood and more uniformly applied throughout the Community;

- it highlights the need for improved coordination at all levels to ensure that all manufacturers, especially small and medium-sized firms, apply these provisions as smoothly and as efficiently as possible.

Initial reactions from European organizations representing the various economic partners show that this is indeed a useful initiative.

To be fully operational this guide must of course be updated regularly to take account of experience acquired in the various sectors concerned, particularly as regards, for example, the future development of European standards, the administration of notified bodies and surveillance of the market.

The way in which these developments are covered should also highlight the complementary action to be taken in accordance with the principle of subsidiarity to strengthen the technical environment in which European industry operates in a harmonized way, an essential contribution to the Community's industrial competitiveness.

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(*) in preparation

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INTRODUCTION

1. Purpose of this guide

Since 1987 a dozen Community directives have been adopted on the basis of the provisions relating to the new approach and the global approach, and a further fifteen are at the draft stage at the Commission. The new approach implemented in 1985 has resulted in a new legislative procedure at Community level, based on the drafting of essential requirements and the use of harmonized European standards.

The resolution of 7 May 1985, which laid down the principles of the new approach, was supplemented in 1989 by a resolution on the global approach, which provided in particular for the establishment of procedures to assess the conformity of products with the requirements of the directives and the affixing of the CE marking to such products.

Many people are involved in the drafting, adoption, transposition, application and administration of these directives.

Now that the internal market has reached completion and at a time when some directives are already being applied, it is essential to take stock of experience to date and, in the light of these initial lessons, to propose a method to ensure the uniform application of these provisions throughout the Community.

It is therefore necessary to ensure that the "new approach" and the "global approach" are administered in a coherent fashion across all the Community directives based on them.

To that end, this guide takes the form of a manual to be used by practitioners of the new approach and the global approach, i.e. the negotiators, drafters and administrators of these provisions and those who are called on to ensure that they are applied in the best possible way:

- within the Commission, on the basis of closer coordination between Directorates-General;

- in the Member States, where a vast number of public authorities are concerned, depending on the products and risks covered, on account of the many and varied supervisory tasks carried out in respect of the bodies active in the fields of standardization, conformity assessment, market surveillance, etc.;

- in the notified bodies, who must cooperate with each other and coordinate their work so as to ensure the uniform application of the conformity assessment procedures laid down by each directive, especially where several directives apply to the same product;

- in the representative organizations, in industry itself, and among all economic partners who must be perfectly informed of the provisions in force and of the choices available to them throughout the Community.

In this way, a common "doctrine" should progressively fall into place which will facilitate intra-Community trade, while providing as many manufacturers as possible with modern means for designing and manufacturing their products in accordance with the essential safety requirements.

In view of these various aspects, this guide is divided into four more or less self-contained parts.

The list of contents gives an idea of what the guide contains. The layout emphasizes the "modular" nature of this approach: each information sheet can be included in the guide as soon as it is finalized, and regular updates can be inserted without affecting the rest of the guide.

II. Present status of community work

1. Reference text

Titles	Publications
White Paper on the completion of Internal Market (COM(85)310 final)	
Council Directive of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (83/189/EEC)	3. N°. L 109 of 26.04.83
Council Directive of 22 March 1988 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (88/182/CEE)	5. N°. L 81 of 26.03.88
Directive 94/10/EC of the European Parliament and the Council of 23 March 1994 materially amending for the second time Directive 83/189/CEE laying down a procedure for the provision of information in the field of technical standards and regulations	7. N°. L 100 of 19.4.94
Conclusions on standardisation approved by the Council on 16 July 1984 (85/C136/02)	J.O. N°. C 136 of 04.06.85
Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (85/C/136/01)	J.O. N°. C 136 of 04.06.85
Commission Communication to the Council submitted by the Commission on 15 June 1989 - A global approach to certification and testing - quality measures for industrial products (COM (89) 209 Final - SYN 208 (89/C 267/03)	J.O. N°. C 267 of 19.10.89
Council Resolution of 21 December 1989 on a global approach to conformity assessment (90/C 10)	J.O. N°. C 10 of 06.01.90
Council Decision of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives (90/683/CEE)	J.O. N°. L 380 of 31.12.90

Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (93/465/EEC)	J.O. N°. L 220 of 30.8.93
Commission Communication of the development of European Standardisation - Action for faster technological integration in Europe (90/C 20/01) (Green Paper on Standardisation)	J.O. N°. C 20 of 28.01.91
Commission Communication - Standardisation in the European Economy (Follow-up to the Commission Green Paper of October 1990) (92/C 96/02)	J.O. N°. C 96 of 15.04.92
Council Resolution of 18 June 1992 on the role of European standardisation in the European economy	J.O. N°. C 173 of 09.07.92
Council Directive of 29 June 1992 on general product safety(92/59/EEC)	J.O. N°. L 228 of 11.08.92
Council regulation of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries (339/93/EEC)	J.O. N°.L 40 of 17.02.93
Council Directive of 22.07.93 amending Directives:	O.J. N° L 220 of 30.08.93
87/404/EEC - simple pressure vessels, 88/378/EEC - safety of toys, 89/106/EEC - construction products, 89/336/EEC - electromagnetic compatibility, 83/392/EEC - machinery 889/686/EEC - personal protective equipment, 90/384/EEC - non-automatic weighing instruments, 90/385/EEC - active implantable medicinal devices, 90/396/EEC - appliances burning gaseous fuels, 91/263/EEC - telecommunications terminal equipment, 92/42/EEC - new hot-water boilers fired with liquid or gaseous fuels 73/23/EEC - electrical equipment designed for use within certain voltage limits (93/68/EEC)	

Adopted directives

At this moment, 14 New Approach Directives have been adopted according to the criteria of the New Approach

1. Council Directive of 25.06.87 on the harmonization of the laws of the Member States relating to simple pressure vessels (87/404/CEE)	O.J. N° L 220 of 08.08.87
Council Directive of 17.09.90 amending Directive 87/404/CEE on the harmonization of the laws of the Member States relating to simple pressure vessels (90/488/CEE)	O.J. N° L 270 of 02.10.90
2. Council Directive of 03.05.88 on the approximation of the laws of the Member States concerning the safety of toys (88/378/CEE)	O.J. N° L 187 of 16.07.88
3. Council Directive of 21.12.88 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (89/106/CEE)	O.J. N° L 40 of 11.02.89
4. Council Directive of 03.05.89 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/CEE)	O.J. N° L 139 of 23.05.89
Council Directive of 28.04.92 amending Directive 89/336/CEE on the approximation of the laws of the Member States relating to electromagnetic compatibility (92/31/CEE)	O.J. N° L 126 of 12.05.92
5. Council Directive of 14.06.89 on the approximation of the laws of the Member States relating to machinery (89/392/CEE)	O.J. N° L 183 of 29.06.89
Council Directive of 20.06.91 amending Directive 89/392/CEE on the approximation of the laws of the Member States relating to machinery (91/368/CEE)	O.J. N° L 198 of 22.07.91
Council directive of 14.06.93 amending Directive 83/392/EEC on the approximation of the laws of the Member States relating to machinery (93/44/EEC)	O.J. N° L 175 of 19.07.93
6. Council Directive of 21.12.89 on the approximation of the laws of the Member States relating to personal protective equipment (EPI) (89/686/CEE)	O.J. N° L 399 of 30.12.89

Council Directive of 29/10/93 1993 amending Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (PPE) (93/95/EEC)	O.J. N° L 276 of 09.11.93
7. Council Directive of 20.06.90 on the harmonization of the laws of the Member States relating to non-automatic weighing machines (90/384/EEC)	O.J. N° L 189 of 20.07.90
8. Council Directive of 20.06.90 on the approximation of the laws of the Member States relating to active implantable medical devices (90:385/EEC)	O.J. N° L 189 of 20.07.90
9. Council Directive of 29.06.90 on the approximation of the laws of Member States relating to appliance burning gaseous fuels (90/396/EEC)	O.J. N° L 196 of 26.07.90
10. Council Directive of 29.04.91 on the approximation of the laws of the Member States concerning Telecommunications equipment, including the mutual recognition of their conformity (91/263/EEC)	O.J. N° L 128 of 23.04.91
11. Council Directive of 21.05.92 on efficency requirements for new hot-water boilers fired with liquid or gaseous fuels (92/42/EEC)	O.J. N° L 167 of 22.06.92
12.Council Directive of 5.4.93 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses (93/15/EEC)	O.J. N° L 121 of 15.5.93
13. Council Directive of 14.06.93 concerning medical devices (93/42/EEC)	O.J. N° L 169 of 12.07.93
14. Council Directive of 23.03.94on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC)	O.J. N° L 100 of 19.4.94

1. DEFINITIONS AND COMMENTS

INTERPRETATION OF CERTAIN CONCEPTS CONTAINED IN THE "NEW APPROACH" DIRECTIVES

1. INTRODUCTION

The new approach directives contain certain basic concepts which are the key to consistent, effective application of the directives. The objective of this sheet, therefore, is to clarify interpretation of the concepts common to the new approach directives, by defining their content and scope where this has not already been done in the directives. In such cases, these definitions of the concepts, and the comments thereon, will provide a greater insight into the texts, as will some of the other sheets in this guide, which are referred to where necessary.

Against this background, bearing in mind that these directives provide for total harmonization, it must be stressed that the general clause on placing on the market and, where appropriate, putting into service plays a central role. These concepts must, therefore, be defined to provide the Member States and the economic circles concerned, throughout the Community, with clear, uniform information on their rights and obligations arising out of the directives.

In addition, the terms manufacturer, authorized representative, importer or person responsible for placing the product on the Community market need to be defined, given that they are the persons responsible for fulfilling the obligations imposed as regards the design, manufacture, placing on the market and/or putting into service of the products, irrespective of any responsibility which they may bear for the placing on the market of products which fail to comply with the directive or of defective products.

II. DEFINITIONS AND COMMENTS

1. PLACING ON THE MARKET

The initial action of making available on the Community market, for payment or free of charge, a product covered by the directive, with a view to distribution and/or use in the Community.

Comments

"Placing on the market" means the moment when the product first passes from the stage of manufacture within the Community to the stage of distribution and/or use on the Community market. Since placing on the market refers only to the first time that the product is made available on the Community market for distribution or use in the Community, the directives apply only to new(1) products manufactured in the Community and to new[1] or used products imported from a third country.

They can be placed on the Community market by the manufacturer himself, by his authorized representative in the Community or by the importer of the product (cf. paragraph 5 below).

"Making available" means:

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

- the offer of transfer, in cases where the manufacturer, his authorized representative in the Community or the importer, makes a product available in his own commercial distribution chain with a view to direct transfer to the final consumer or user. The product must comply with the directive from this point onwards.

The following are not considered placing on the market:

* transfer of the product from a manufacturer in a third country to his authorized representative in the Community whom the manufacturer has made responsible for completing the procedures required to ensure that the product conforms to the directive in order to place it on the Community market;

* import into the Community with a view to re-export, e.g. under processing arrangements;

* transfer of a product manufactured within the Community with a view to export to a third country;

* display of the product at fairs and exhibitions.

(1) or reconditioned

If a manufacturer, his authorized representative in the Community or the importer offers a product 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.

With effect from the date set by the directive for implementation in its entirety by the Member States, only products which comply with its provisions may be placed on the Community market. From then on, the Member States are also under an obligation not to create obstacles to, prohibit, restrict or hamper the placing on the market or putting into service of such products, and to take any measures necessary to ensure that they are placed on the market or put into service only if they meet the requirements of the directive.

However, the directive will not apply to products placed on the market before that date. If it contains provisions concerning putting into service, in which case it will not apply to products put into service before the date in question.

Directives may provide for a transitional period during which products complying with the national rules in force on the date when the directives took effect may still be manufactured, placed on the market and/or put into service (cf doc. Certif 92/5).

In the absence of express rules on stocks in the directive in question, the storage of a product by the manufacturer or the importer does not constitute placing on the market.

Placing on the market refers to each individual product which is covered by the directive in question and which exists physically and in finished form,(2) regardless of when and where it was manufactured, and whether it was produced individually or as part of a batch.

2. PUTTING INTO SERVICE

First use within the Community by the end user of a product covered by a directive.

Comments

"Putting into service" means the first use of a product.

This definition applies without prejudice to the Member States' right to lay down installation conditions, provided they entail no alterations to any product manufactured in accordance with the directive.

(2) The directives may contain express rules concerning components or products designed to be assembled or incorporated in products covered by the directives.

If a product is manufactured or imported from a third country for the manufacturer's or importer's own use, placing on the market is combined with putting into service; the obligation to conform to the directive begins with first use.

With effect from the date set by the directive for full implementation, the Member States are under an obligation:

- to put only products which conform to the provisions of the directive into service in the Community;

- not to create obstacles to, prohibit, restrict or hamper the putting into service of products satisfying the directive applicable;

- to take any measures necessary to ensure that the products are put into service only if they meet the requirements of the directive and are installed, maintained and used for the purpose for which they are intended.

However, products 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 safety of the product, 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.

3. MANUFACTURER

The person responsible for designing and manufacturing a product covered by the directive, with a view to placing it on the Community market on his own behalf.

Comments

The manufacturer may be based in the Community or elsewhere. In either case, the manufacturer may appoint an authorized representative, who must be established in the Community, to act on his behalf.

The manufacturer is responsible for[3]; designing and manufacturing the product in accordance with the essential requirements laid down by the directive and following the procedures for certification of conformity of the product with the requirements of the directive in question (declaration of conformity, application for type examination, affixing of the CE marking, preparation of file, forwarding of file to the competent authorities, etc.).

(3) This definition applies without prejudice to the manufacturer's responsibilities, as defined in Directive 85/374/EEC on liability for defective products.

The manufacturer may subcontract some of these operations, including the design - if he physically manufactures the product - or the manufacture - if he designs it - provided he retains overall control and responsibility.

In principle, the manufacturer may employ ready-made parts or components in the product, without affecting his status as manufacturer.

Any maker of a new finished product from existing finished products is regarded as the manufacturer of the new product.

Anyone who changes the intended use of a product is regarded as the manufacturer of that product and, as such, remains subject to the requirements which the directive in question places on manufacturers and assumes responsibility accordingly.

Anyone who imports a used product from a third country with a view to bringing it into line with the essential requirements of the directive in question must comply with the requirements imposed on manufacturers by that directive and assumes responsibility accordingly.

4. AUTHORIZED REPRESENTATIVE

A person appointed by the manufacturer to act on his behalf in carrying out certain tasks required by the directive, which have been delegated to him by the manufacturer.

Comments

All authorized representatives appointed by the manufacturer must be established in the Community in order to be able to act on the manufacturer's behalf under the terms of the directives. The manufacturer delegates these tasks in writing to the authorized representative, spelling out the manufacturer's obligations under the directives for which he is delegating responsibility to his authorized representative. Responsibility for actions by an authorized representative on behalf of the manufacturer without exceeding his powers lies with the manufacturer and not with the authorized representative.

5. IMPORTER OR PERSON RESPONSIBLE FOR PLACING ON THE MARKET

Any person who places on the Community market a product from a third country, which is covered by a directive.

Comments

Unlike the authorized representative, the importer has no preferential relationship with the manufacturer (in a third country).

Therefore, if neither the manufacturer nor his authorized representative is based in the Community, the directives may stipulate which tasks are to be carried out by the importer(4). In that case the importer is deemed responsible under the terms of the directives for placing the product he imports on the Community market. In this capacity he must keep the technical file (Sheet II/D) and the manufacturer's declaration of conformity available for examination by the supervisory authorities.

6. NOTIFIED BODY

A third party authorized to perform the conformity assessment tasks specified in the directive, which has been appointed by a Member State from the bodies falling within its jurisdiction, which has the necessary qualifications, meets the requirements laid down in the directive and has been notified to the Commission and to the other Member States.

Comments

(See doc. Certif 91/7 on the notified bodies, sheet II/B.)

7. DEFINITIONS RELATING TO LINKS BETWEEN THE REGULATION OF PRODUCTS AND MARKET PRACTICES IN CONFORMITY ASSESSMENT

These definitions are different from the preceeding ones in that they do not concern terminology used in the directives themselves. Rather their objective is to clarify the complementarity between regulatory and voluntary aspects.

Regulated Product

A product any aspect of which is governed by one or more technical regulations or directives.

Note

It is not usually helpful to refer to "regulated" or "non-regulated" sectors. Some element of directives or technical regulations affects almost all sectors, but at the same time almost all sectors have some aspects which remain unregulated.

Evaluation of conformity

Systematic examination of the extent to which a product(1) **process or service fulfils specified requirements. (ISO/IEC Guide 2 : 1991)**

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(4) Except for Article 8(6) of the Machinery Directive. The importer is in a different situation under the terms of Article 2 of Directive 92/59/EEC of 29 June 1992 on general product safety.

(1) a type or series production

Mandatory evaluation of conformity

Evaluation of conformity in respect of requirements contained in regulations or directives which must be undertaken before a product, process or service may be placed on the market.

Certification

Procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements. (ISO/IEC Guide 2 : 1991)

Mandatory certification

Certification which as a requirement of a regulation or directive has to be applied before a product, process or service can be placed on the market.

Comment

For a very large number of products some form of technical regulation applies if they are to be placed on the market. The most usual aspect of a product to be subject to technical regulation is that of safety. The fact that a product is subject to a regulation does not necessarily mean that mandatory certification or evaluation of conformity has to be applied. Whether either is a requirement depends on the regulation.

The New Approach Directives prescribe specific measures of mandatory evaluation of conformity, always including a declaration of conformity, for specific products ("the modules"). Some of these measures include mandatory certification. In these cases the design and/or production of the products has to be certified by one of those organisations responsible for carrying out the mandatory certification (Notified Bodies) in advance of the products being put on the market.

The CE marking has to be applied by manufacturers or their authorized representatives to products subject to New Approach Directives whether there is mandatory certification or not. Where there is a requirement for mandatory certification, a Notified Body must perform the statutory function specified in the relevant directive before the CE marking can be applied. Where the product, but not the certification, is regulated, the manufacturer applies the CE marking and declares conformity without the need for intervention by any third party.

Manufacturers are responsible for ensuring that the products they place on the market meet all relevant regulations. Where these regulations do not require mandatory certification, manufacturers often seek voluntary certification to assure themselves that their products do meet the requirements set by the law. Voluntary certification may also be used to confirm that requirements other than those contained in applicable

regulations, for example requirements relating to unregulated aspects of the product, have been met. Such voluntary certification cannot be an alternative to any mandatory certification. The voluntary must complement the mandatory without in any way interfering with or altering the processes required for compliance with the law.

In Europe, the European Organisation for Testing and Certification (EOTC)) is designed to coordinate voluntary certification. In doing this it should prevent the creation or operation of de facto barriers to trade arising from voluntary certification and provide the means for ensuring complementarity with any mandatory certification.

2. TRANSITIONAL PERIOD

Foreword

Most of the new approach directives contain a final clause introducing a transitional period. This sheet applies only to the directives containing such a clause.

A distinction must be drawn between this transitional period and any transitional period provided for by the harmonized standards and setting the date until when the previous standard, which has been revised, can still apply (see document Certif. 69/91).

I. Definition

The transitional period is the time which elapses between the date on which a directive enters into force and a subsequent date, set in each directive, until when the national measures implementing the Community directive exist alongside the previous national regulations.(1)

Generally, the clause introducing the transitional period is worded along the lines:

"Member States shall, for the period up to ..., permit the placing on the market and putting into service of products complying with the national rules in force in their territory on ..."

Throughout this period, manufacturers (or their authorized representative established in the Community) have a choice between placing on the market and/or putting into service in any Member State either a product conforming to the directive or a product conforming to the national rules.

(1) Each directive sets the date for freezing the national regulations in force. Generally, this is the date on which the directive enters into force. Sometimes, however, it is the date on which the directive is adopted, as, for example, with Directive 89/686/EEC of 21 December 1989 on personal protective equipment (OJ No L 399, 30.12.1989).

Directives 89/106/EEC of 21.12.88 on construction products and Directive 89/676/EEC mentioned above differ from the other directives on this point in that they involve not one but several transitional periods, which are dependent on European technical specifications (89/106) or harmonized standards (89/676).

At the end of the transitional period, the Community directive will apply to the exclusion of any national rules covering the same products and the same essential requirements.

2. Objectives

The aim of maintaining the pre-existing national rules is to allow a transition between application of the national rules and introduction of the exclusive Community rules.
Such a transition has proved indispensable, particularly where the Community rules introduce certification by a third party. In practice, manufacturers must be able to adjust gradually to the new certification procedure to avert the risk of blocking production. Similarly, the notified bodies must be able to issue certificates without interrupting the placing of the products on the market.

This period is also necessary to give manufacturers time to exercise any rights which they have acquired under the rules predating the directive.

For example, Directive 90/384/EEC of 20 June 1990 relating to non-automatic weighing instruments provides for a transitional period of ten years, the same as the term of validity of the approvals granted for model instruments under the previous directive (Directive 73/360/EEC, which was repealed by Directive 90/384/EEC)(2). The same rationale could apply to approvals granted to model instruments under national rules.

Even if the manufacturers have acquired no rights, another aim of the transitional period is to give them time to sell their stocks of products manufactured in line with the national rules in force before the directive.

Finally, it was found that inclusion of a transitional period in new approach directives could help to create extra time for the adoption of harmonized standards, even though this is not, in principle, a precondition for application of new approach directives.

The need for a transition between the purely national arrangements and the exclusive Community system has prompted the Community legislators to include a transitional period in most of the new approach directives. In some cases, this insertion of a transitional period after a directive enters into force has created temporary difficulties at the implementation stage.

(2) Article 15(3) and (5) of Directive 90/384/EEC, OJ No L 189, 20.7.1990, p.1.

3. Legal system applicable during the transitional period

3.1 Continuation of the previous national rules

In line with the objectives of the transitional period, the Community legislation imposes an obligation on the Member States to keep in force their national rules(3). This is the difference between distinguishes the new approach directives and the earlier "optional" directives, which left the Member States free to apply the directive exclusively.

This obligation to maintain the pre-existing rules is interpreted as applying not only to all the mandatory provisions in force in each Member State but also to all the national specifications applied voluntarily by manufacturers.

Consequently, Member States with no regulations in the strict sense must maintain the existing "system" and, hence, refrain from legislation.
Although this interpretation is not obvious from the wording of the clauses on the transitional period in the directives adopted to date, it has proved the only way to ensure that the transitional period performs its role.

Any other interpretation would lead to the directives being applied solely in the Member States with no regulations, where, therefore, manufacturers would have no opportunity to adjust gradually to the new situation created by the directives.

Under this interpretation, the manufacturers and all the parties concerned are allowed access during the transitional period not only to national standards implementing harmonized standards but also to any previous national standard.

This forces the national standardization organizations to make available copies of previous national standards throughout the transitional period. This obligation lapses at the end of the transitional period.

Such national standards must be withdrawn at the end of the transitional period in every case.

3.2 Obligation to make no changes to the national systems in place on a given date

The effect of the clause introducing the transitional period is to "freeze" the national systems in place on the date set in the directive. Usually, this is the date on which the

(3) One special case, however, is Directive 90/396/EEC of 29 June 1990 relating to appliances burning gaseous fuels which imposes no obligation on the Member States but stipulates that they "may permit" the placing on their markets of products complying with the pre-existing rules (Article 14(2)).

directive enters into force but sometimes it is the date on which the directive was adopted. From then on, the Member States may make no further changes to the system in question.

Any other interpretation of the transitional clause would run counter to its objectives, particularly the aim of allowing manufacturers to exercise their acquired rights, sell off their stocks and adjust their manufacturing processes.

However, arrangements must be made to allow changes to the national system in cases of force majeure.

For example, should technical progress or exceptional circumstances reveal that the system in force fails to satisfy a legitimate requirement and that this shortcoming creates risks which the Member State was unable to prevent by amending the rules in force in good time, it must be possible to fill the gaps.

In any event, all amendments made for this purpose have to be notified at the draft stage, as required by Directive 83/189/EEC, so that they can be appraised to see whether they are justified on the abovementioned grounds.

3.3 Identification of the directives applied by manufacturers during the transitional period

Many products are covered by a number of directives each covering different risks.

This situation could create confusion during the transitional period both for the market surveillance authorities and for users.

If a product were covered by two directives (A and B) each covering different types of risk (1 and 2), the manufacturer could choose to conform to the national rules still in force rather than to directive A for risk 1 but to opt for the rules laid down in directive B for risk 2.

Under these circumstances the CE marking may be affixed only on the strength of directive B and not, under any circumstances, pursuant to directive A.

Consequently, during the transitional period the CE marking will not necessarily indicate that the product bearing it conforms to all the directives applicable thereto (and providing for affixing of the mark)[4].

(4) It is true that some Directives (for example, Directive 89/392/EEC on machinery and Directive 90/396/EEC on appliances burning gaseous fuels) contain an Article stating that the CE mark signifies conformity with the requirements of the other Directives providing for affixing such a mark. One of the principal aims of the proposal for a Regulation on the CE mark is to clarify the impact of this rule.

Details of the essential requirements satisfied by the product and of the directives applied are contained in the documents required for the conformity assessment procedures (in the declaration of conformity the manufacturer must declare that the products satisfy the relevant requirements of the directive). In addition, the inspection authorities have access to the technical file (see doc. Certif. 91/6).

However, users of the product and the inspection authorities have no way of knowing from the start whether or not the CE marking signifies conformity with directive A.

For this reason, the Commission considers that the work on the proposal for a Regulation concerning the CE marking should be taken as an opportunity to ensure that the documents accompanying the product (operating instructions) clearly indicate the directives applied by the manufacturer in cases where at least one of the directives applied contains transitional arrangements.

3.4 Free movement of products during the transitional period

Products conforming to a directive can move freely pursuant to the relevant provisions of that directive and can be identified by the CE marking.

Products manufactured in line with national regulations or with non-mandatory technical specifications can move freely on the basis of Article 30 of the EEC Treaty, subject to any exceptions made on the basis of Article 36.

Consequently, such products could be blocked by rules laid down by other Member States on the basis of one or more of the essential requirements mentioned in Article 36. They will qualify for mutual recognition, on the basis of Article 30, if they conform to regulations or specifications ensuring an equivalent level of protection. The same mutual recognition applies to any tests and inspections carried out in the past which need not be repeated.

Consequently, although over the transitional period the choice of system applied is left to the manufacturer, clearly conformity to the directive will make it much easier for the product to gain free access to the Community market.

4. System applicable at the end of the transitional period

4.1 Obligation to terminate the national systems at the end of the transitional period

At the end of the transitional period the Member States are under an obligation to terminate the national systems kept in force until then, i.e. to repeal the relevant regulations and to apply the directives to all the products concerned, whether or not they were previously subject to any specific rules.

At the end of the transitional period the national measures implementing the directive will be the only mandatory rules in force for the products and requirements concerned in every Member State, to the exclusion of all others(5).

As a result, products manufactured before or during the transitional period in line with the national system may no longer be placed on the market or put into service in the Community.

More specifically, at the end of the transitional period only products rightfully bearing the CE marking can be placed on the market and put into service.

4.2 Failure to adopt harmonized standards by the end of the transitional period

The length of the transitional period provided for in the directives depends on the products and sectors concerned. Generally, it is long enough to allow adoption of harmonized standards.

However, there could be cases where no harmonized standards have been adopted to cover one or more of the essential requirements to be met by a given product.

In this eventuality, the conformity assessment procedures allow manufacturers first to apply the harmonized standards and then, for any requirements not covered by those standards, to demonstrate that the specifications which they have used are adequate to meet those requirements.

The notified bodies whose task is directly to assess the conformity of the products to the essential requirements, without the aid of a harmonized standard, may use for that purpose any existing technical specification which, in their estimation, enables the essential requirements to be satisfied(6).

Such use of existing specifications and, particularly, of national standards by the notified bodies could help to facilitate the use of the procedure, provided for in most of the directives, of recognition of the national standards satisfying the essential requirements. The use of this procedure will help make up for any delay in the adoption of

(5) This obligation applies without prejudice to any non-mandatory specifications maintained, as allowed, for example, by Article 5(1) of Directive 89/392/EEC on machinery.

(6) Unlike harmonized standards, national specifications do not allow of a presumption of conformity to the relevant essential requirements.

harmonized standards, since conformity to national standards which are so recognized would confer a presumption of conformity to the essential requirements(7).

The solution chosen in Article 5(1), second subparagraph, of Directive 89/392/EEC of 14 June 1989 on machinery is different. In this case, the Member States, in the absence of harmonized standards, must notify to the interested parties the existing national standards and technical specifications which are considered to be important or useful for the correct application of the Directive's essential requirements.

Although these documents do not confer a presumption of conformity, they ensure transparency in the use of national technical specifications and help towards the mutual acceptance of the products when there are no harmonized standards.

(7) See Articles 5 and 6 of Directive 90/396/EEC, for example

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FICHE I/D

EXPLANATORY NOTE ON HARMONIZED STANDARDS

INTRODUCTION

1. The concept of harmonized standards plays an important role in the framework of New Approach Directives, in which it has a specific significance. It raises, however, a series of fundamental questions, relating to the definition of such standards, the role of Community mandates, the presumption of conformity with essential requirements, and the respective competences of the standards organizations and the public authorities at Community and at national level. Furthermore, the use of the terminology "harmonized standards" gives rise to some concern with standards organizations, as its definition does not coincide with the ISO definition.

2. In order to give an answer to the questions raised, this document indicates in a first part what is meant by harmonized standards, including the conditions under which they produce a presumption of conformity. In a second part it shortly indicates the use of the "standards safeguard clause". In a final part it describes, in general terms, the respective responsibilities of the standards organizations, the Commission and of the Member States with regard to harmonized standards.

THE CONCEPT OF HARMONIZED STANDARDS IN THE NEW APPROACH

3. Two elements should be clearly distinguished with regard to this concept, i.e. the existence of the harmonized standard, and the question of the presumption of conformity.

A. Definition of Harmonized Standards

4. The definition of harmonized standards in the recitals of New Approach Directives, or art. 4 of the Construction Products Directive, describes harmonized standards as technical specifications adopted by a European standards organization on the basis of the General Orientations signed between the European standards organizations and the Commission on 13 November 1984, following a mandate by the Commission issued pursuant to Directive 83/189/EEC.

This definition contains, in the reverse order, the following elements.

(i) **Mandates**

5. Mandates are the instrument by which the Commission, after consultation of the 83/189 Committee, and, if this is provided for, of the relevant sectoral Committee, formally invites the European standards organizations to present, when mandates are given under New Approach Directives, harmonized standards within the meaning of such Directives.

   Mandates are not restricted to New Approach Directives. Directive 83/189 foresees the possibility of the Community giving standardization mandates to the European standards organizations, on which Member States in the 83/189 Committee are consulted. The requirement of a mandate in New Approach Directives is therefore an application of the general principle of the 83/189 Directive.

   Examples of mandates given outside the area of New Approach Directives are the mandates relating to biotechnology, information technology, measurement methods for certain emissions in the environmental field, evaluation criteria for compliance with public procurement directives, etc. Since European standards elaborated on the basis of such mandates are not related to the New Approach Directives, they are not harmonized standards in the meaning of the New Approach.

6. Mandates should indicate as precisely as possible what is being asked of the standards organizations and the legal framework within which the standards have to be presented. This legal framework relates not only to the Directive for which the harmonized standards will be elaborated but also to other Directives or Community policy that the standardizers should be aware of in order to present the standards. The mandate may also specify that certain aspects are to be dealt with by Community legislation and are therefore not the subject of standardardization under the mandate.

7. As in practice mandates may cover activities to be carried out by more than one European standards organization, they will be addressed to the European standards organizations jointly or individually. In the case where a mandate is given to more than one organization, it may be expected that the mandate will be accepted jointly by the organizations concerned and that activities will be carried out in close concertation. The European standards organizations have put in place the mechanisms to assure a joint answer and a coordination of their activities.

8. Consultation of the 83/189 Committee is not a simple formality but essential for various reasons. The framework within which harmonized standards have to be developed must reflect consensus of national authorities. Consultation of the 83/189 Committee implies a wide consultation of sectoral authorities at the national level. Agreement of the terms of the mandate provides therefore a solid basis on which standards can be developed.

   In the case of the Construction Products Directive, consultation on the mandate of the Standing Committee set up under that Directive is also foreseen.

9. The term "mandate", although commonly used, is not the only term used in this context. In the English versions, for instance, terms used are "as instructed by the Commission"(1), "upon a remit from the Commission"(2) or "at the instigation of the Commission"(3). Rather than the terminology used, it is important to consider that standardization activities must be based on a formal invitation of the Commission, on which Member States were consulted.

10. The European standards organizations will formally take a position on a mandate given by the Commission in conformity with their own Internal Regulations. Acceptance of the mandate and the subsequent working programme by these organizations initiates the standstill as provided for in their Internal Regulations and in the 83/189 Directive.

(ii) General Orientations of 13 November 1984

11. These Orientations, which CEN/CENELEC have published as Memorandum 4, contain a series of principles and commitments agreed by the Commission and CEN/CENELEC relating to standardization and to the use of standards in technical harmonization.

    The reference to these Orientations is significant because various elements mentioned in them, such as the participation of all interested parties, the role of public authorities, the quality of the standards, etc. assume particular importance in the field of New Approach Directives, which relate directly to the public interest.

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(1) Directive 90/384/EEC, non-automatic weighing instruments
(2) Directive 90/385/EEC, active implantable medical devices
(3) Directive 89/686/EEC, personal protective equipment

12. The fact that these Orientations foresee the participation of public authorities is important. Participation takes place on the basis of the fact that such authorities are interested parties for the implementation of New Approach Directives and that they represent the public interest. For these reasons, it is legitimate to expect that they effectively participate, although such participation is not obligatory. Public authorities do not, however, have any "hierarchical" position in the standardization process.

13. For standards organizations, participation by public authorities is important because participation and dialogue throughout the standardization process help to assure acceptance of standards once they have been adopted.

(iii) Technical Specification

14. The documents that European standards organizations are invited to present are European standards or Harmonization Documents. It should be noted that New Approach Directives in this definition do not refer to harmonized standards as if they were a specific category amongst European standards. The terminology used in the Directives is a legal qualification of documents existing in their own right in the framework of European standardization.

    From the point of view of the Commission, European standards should be given preference above harmonization documents.

15. In presenting harmonized standards, the standards organizations are not confined to presenting newly-developed standards. They may also identify existing standards which they judge, after examination, to meet the terms of the mandate or modify existing standards in order to meet those terms. In the same way, they may identify international or national standards and adopt them as European standards. The resulting European standard will then qualify as harmonized standard.

16. Consultation on the mandate of the 83/189 Committee (or the sectoral Committee if this is provided for) remains necessary even if no development of new standards is required and standardizers will present existing European standards or, for instance, international standards transposed into European standards.

17. In presenting the standards, the organizations should indicate the essential requirements to which the standards relate. Where a single European standard

contains provisions relating to essential requirements and other provisions, these parts should be clearly distinguished in the structure of the standard.

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18. Additional points to note in respect of harmonized standards concern Community financing and the publication of the reference of the harmonized standard in the Official Journal of the European Community.

(i) Financing

19. The Community may contribute to the financing of the development of European standards, whether or not elaborated on the basis of a mandate under New Approach Directives. The Community's financial contribution may be used to indicate priorities in standardization, to promote standards in areas traditionally not covered by private standards organizations, or to contribute to expenses in areas where there is no direct interest of industry or the market but where standards are needed in the general interest.

20. Community financing is however not a condition for European standards or harmonization documents to qualify under New Approach Directives as harmonized standards. Mandates for harmonized standards can be given without Community financing.

21. Community financing is realized through contracts with the European standards organizations, based upon a Framework Contract, and called "order vouchers" under the Framework Contract. Whereas mandates may be given to the European standards organisations individually or jointly, order vouchers will be concluded with the individual European standards organizations.

22. Order vouchers may thus be given for purposes other than mandates for harmonized standards, such as the development of European standards not intended for the implementation of New Approach Directives, preparation of standardization programmes, studies, the organization of conferences or workshops, etc.

23. The 83/189 Committee is not consulted on order vouchers. Where the order voucher relates to a mandate, the Committee will have been consulted on the mandate. Consultation of the 83/189 Committee is necessary for mandates, regardless of whether financing is involved or not.

(ii) Publication of the Reference of the Harmonized Standard

24. Publication of the reference is not considered to be a condition for the existence of harmonized standards. The qualification of European standards as harmonized standards within the meaning of New Approach Directives is not linked to publication in these Directives. Publication and definition are always dealt with in separate articles or recitals in such Directives.

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25. In conclusion, harmonized standards in the meaning of New Approach Directives are deemed to exist when the European standards organizations formally present to the Commission the European standards or harmonization documents elaborated or identified in conformity with conditions explained above. At that stage, however, such standards do not yet produce a presumption of conformity with the essential requirements of New Approach Directives.

B. Presumption of Conformity

26. According to New Approach Directives, conformity with national standards that have transposed harmonized standards, whose references have been published by the Commission in the Official Journal of the European Communities, confers a presumption of conformity with the essential requirements covered by harmonized standards (1).

The presumption of conformity depends on the following elements:

(i) Publication of the Reference

27. Without publication of the reference by the Commission in the Official Journal of the European Communities, use of the standard will not give rise to the presumption of the conformity. The main motives for publication by the Commission in the Official Journal are that, because of the legal implications, a clear date should be set as from which the presumption of conformity can take effect, and that all Community operators should be in an identical position to benefit therefrom.

(1) Or, in the case of the Construction Products Directive, a presumption of fitness for their intended use.

28. For reasons of transparency and legal certainty, Member States must publish references of the national standards which have transposed the harmonized standards. However, compliance with any national standards, that have transposed harmonized standards, but whose references have not (yet) been published by the Commission (for instance because titles of the European standards are not available in the Community languages), does not produce presumption of conformity.

(ii) Transposition

29. It follows from the New Approach Directives mentioned above that presumption of conformity is also dependent on the transposition of the European standard into a national standard. This means that no presumption exists unless the European standard has been transposed, even if the reference has been published in the OJEC. On the other hand, it is not necessary for transposition to take place in all Member States before benefit accrues from the presumption of conformity.

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30. It follows from the above that the concept of harmonized standards under New Approach Directives is different from the concept of harmonized standards used in the Low Voltage Directive, compliance with which means compliance with the safety objectives mentioned in the LVD. Harmonized standards under the LVD are defined as standards established by common agreement by bodies notified by each Member State to the other Member States and to the Commission, and published under national procedures. The list of harmonized standards and their references is published in the OJEC for purposes of information.

31. It is also different from the "harmonized standard" as defined in ISO/IEC, where harmonized standards are standards on the same subject approved by different standardizing bodies, that establish interchangeability of products, processes and services, or mutual understanding of test results or information provided according to these standards.

USE OF THE STANDARDS SAFEGUARD CLAUSE

32. New Approach Directives contain a procedure under which a harmonized standard can be challenged.

Where a Member State or the Commission considers that the harmonized standard does not fully meet the essential requirements, the Commission or the Member State concerned shall bring the matter before the 83/189 Committee, or, if this is provided for, the sectoral committee, giving its reasons for doing so. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw the references to those standards from the published information.

33. This clause is based on the distinction between the existence of harmonized standards and the presumption of conformity based on publication of the reference in the Official Journal. Use of the clause does not affect the existence of European standards qualified as harmonized standards, but may lead to the withdrawal of the information published by the Commission and by the Member States. This will imply that conformity with harmonized standards would no longer produce a presumption of conformity with the essential requirements. This in turn will have a bearing on the procedures under which the CE mark can be affixed.

RESPONSIBILITY OF THE EUROPEAN STANDARDS ORGANIZATIONS, THE COMMISSION AND MEMBER STATES

34. The New Approach is based on the premises that, on the one hand, the European standardization process is capable of producing standards that meet the needs of New Approach Directives and, on the other, that public authorities retain their responsibility for the protection in respect of the essential requirements. It implies shared responsibilities between the Community legislator, the Member States and the European standards organizations.

(i) Responsibility under the standardization process

35. The New Approach takes into consideration the fact that European standardization offers guarantees of democracy, transparency, independence and the possibility for interested parties to participate in the process, so as to ensure that a standard reflects the "state of the art" as agreed by all those interested. This is the sense of the reference to the General Guidelines referred to above.

36. On the basis of the above-mentioned General Orientations, the Commission and national authorities are entitled to participate in standardization activities covered by a mandate. In any case, they can formulate observations in the public enquiry phase.

37. For these reasons, New Approach Directives do not foresee a procedure under which the technical contents of harmonized standards adopted with the procedural guarantees of the standardization process have to be verified or approved at Community or at national level(1).

38. As the New Approach is conceived, it is therefore the responsibility of the European standards organizations to elaborate or to identify the standards and to present a list to the Commission. It is also their responsibility to make sure that the contents of the standards meet the essential requirements. In the way the New Approach is designed, the Commission cannot assume responsibility for the technical contents of a standard.

39. The Commission reserves the right, however, to verify that the terms of the mandate are fulfilled. When it finds that a standard does not meet the terms of the mandate, it will not publish the reference of the standard concerned(2). In such case, the conditions for a harmonized standard to produce a presumption of conformity are not met. Where a single European standard contains provisions relating to essential requirements and other provisions, based on market needs, such as product specifications not linked to essential requirements, conformity assessment procedures differing from those specified in the relevant directive, etc...., these parts should be clearly distinguished in the structure of the standard, so as to allow reference to be made only to the part related to the essential requirements.

40. The Commission's participation in the standardization process should, inter alia, help to ensure that the terms of the mandate are properly understood.

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(1) This contrasts with the situation foreseen under certain New Approach Directives whereby national standards may be verified for compliance with essential requirements by a procedure at Community level managed by the Commission, assisted by a Standing Committee composed of officials from national administrations.

(2) Or limit publication of the reference to parts of the standards.

(ii) Responsibility of Public Authorities

41. Under the New Approach, public authorities remain responsible for the protection of safety (or the fulfillment of other legal requirements). Levels of protection are, therefore, set in New Approach Directives themselves and indicated in the mandate to the standards organizations.

    For the same reason, New Approach Directives contain safeguard procedures giving the possibility of contesting the conformity of a product bearing the CE mark, the validity of a certificate or the quality of a standard.

42. The fact that under the New Approach the Commission and Member States can challenge a harmonized standard through a safeguard clause instead of through conducting an approval procedure indicates that there is not supposed to be a systematic verification of the technical contents of harmonized standards. Only in cases where a standard is found not to satisfy the essential requirements or to present shortcomings as mentioned above, do the public authorities have the possibility of taking appropriate action.

43. Similarly, the fact that publication of the reference of the harmonized standard is carried out does not imply systematic verification of the technical contents of a standard. Given the spirit of New Approach Directives and their wording, the Commission is bound to publish the reference of the standard or part of the standard, except in cases where it is found that the terms of the mandate are not fulfilled (see above). It has no discretionary powers in this respect. Neither do Member States exercise discretionary powers when they publish references of national standards transposing harmonized standards.

SAFEGUARD CLAUSE

INTRODUCTION

New approach directives include a reference to a general clause on placing on the market and a clause on free movement. The first stipulates that the products covered by such directives may be placed on the market only if they pose no danger to the health and/or safety of persons, animals or goods. Only products which meet the protection requirements of these directives may be placed on the market. In return, the free movement clause lays an obligation on the Member States not to obstruct the placing on the market and putting into service on their territory of products conforming to the relevant directives.

However, both the placing on the market and the free movement of goods may be restricted, or even forbidden, as one of the market surveillance measures taken by Member States, amongst which the safeguard clause constitutes the last resort.

This clause, included in every new approach directive, empowers Member States who find that a product bearing the CE marking and used for its intended purpose could endanger the health and/or safety of persons, animals and goods, to take all necessary measures to restrict or forbid its placing on the market or to have the product withdrawn from the market.

This is a way around the rule that the Member States must presume that products which, in principle, conform to the essential requirements set out in a directive comply.

Under these circumstances, the safeguard clause is a means of ensuring uniform market surveillance throughout the Community, since it engenders a Community approach to any Member State's decision that a given product does not conform by alerting the other Member States, via the Commission, that they too must take measures on their territory.

The safeguard clause provides for intervention by the public authorities, that is to say by the Member States and the Commission, who may submit the case to the other interested parties: the manufacturer, notified bodies, the bodies or authorities responsible for market surveillance, the organizations representing the economic circles (industrialists, workers, distributors, users, consumers,..)

This safeguard clause can be broken down into four successive stages:

1. Invocation.
2. Implementation.
3. Administration.
4. The consequences.

1. CONDITIONS FOR INVOKING THE SAFEGUARD CLAUSE

A. There are two preconditions for invoking the safeguard clause:

- every industrial product referred to in one or more of the new approach directives should normally bear the CE mark; these arrangements do not apply to products exempted from the CE marking by certain directives;[1]

- the product must be used or be suitable for use for its intended purpose, as provided for in the relevant directive.

These two preconditions imply that, in principle, the safeguard clause cannot be applied to any product which does not bear the CE mark, and is thus automatically forbidden for non-compliance with the regulations, or to any product not used for its intended purpose. In these cases the Member States intervene under the market surveillance provisions.

Consequently, only products allowed to move freely, bearing the CE marking and leaving no doubt as to their intended purpose may be subjected to the safeguard clause.

Similarly, the safeguard clause may be applied to products placed on the market if it is found that the CE marking should not have been affixed to them and that this marking prejudices the essential protection requirements.

In practice, the rules laid down in most of the new approach directives and in the proposal concerning the affixing and use of the CE marking leave it to the Member States to take appropriate measures against every case of incorrect use of the CE marking. The severity of the action depends on the extent

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1 Directive 87/404/EEC relating to simple pressure vessels, Article 3(2).
Directive 90/384/EEC relating to non-automatic weighing instruments, Articles 1(2b) and 3(2).
Directive 90/385/EEC relating to active implantable medical devices, Articles 4(2) and 1(2d).
Directive 90/396/EEC relating to appliances burning gaseous fuels, Articles 1(2) and 8(4).
Directive 89/106/EEC relating to construction products, Article 4(5)

of the non-conformity of the product and the situation that has arisen. The safeguard clause is only invoked where there is doubt as to the product's conformity to the essential requirements.

B. Moreover, this clause may be invoked only under strictly defined conditions:

(a) First, the Member States must establish an infringement;

* This finding can be established either by the market surveillance authorities themselves on their own initiative or after referral of the matter to the competent national authorities by a third party (expert, consumer, etc.).

* This finding must describe a state of affairs; it must, therefore, be objective and based on verifiable evidence (tests, examinations, ...) constituting sufficient means of proof.

* In principle this finding should concern not an isolated case but one or more repeated errors. These can be in the design or the manufacture of the product.

* "Isolated case" means a single incident or a limited number of products which, in principle, satisfy the conditions for invoking the safeguard clause but where the Member State decides not to invoke the clause in view of the limited consequences of the finding.

* The Member State must indicate the conformity assessment procedure which the manufacturer has followed.

  In its finding, it must assess the consequences of the non-conformities for users of the product.

(b) Second, the product must be likely to endanger the health and/or safety of persons, animals or goods or any other requirement contained in the directive concerned.

Assessment of this risk to persons, animals or goods remains the full responsibility of the Member States. They bear responsibility for evaluating whether there is a foreseeable potential danger likely to have serious consequences.

This is the most delicate problem with invoking the safeguard clause, as the Member States must avoid two pitfalls: the danger of being too lax and failing to avert the risk to the detriment of users and consumers, and an overzealous attitude which would disturb the market without any real reason, notably by damaging the interests of manufacturers.

2. IMPLEMENTATION OF THE SAFEGUARD CLAUSE

As soon as a danger to the health and/or safety of persons, animals or goods under the foreseeable conditions for proper use of the product has been established, the Member State which invoked the safeguard clause takes administrative measures to restrict or forbid marketing of the product or to have it withdrawn from the market.

A Member State therefore has an automatic right to take any measure necessary to withdraw the product from the market or to forbid or restrict its placing on the market. No prior authorization is required to exercise this right, which responds to the requisite urgency.

These measures are taken by the market surveillance authorities of the Member State mentioned above.

They take the form of immediate administrative or regulatory safeguards on the territory of the Member State in question with the aim of preventing continuation, aggravation or occurrence of the danger.

However, the major objective of the safeguard clause lies in the fact that its effects must extend to the whole of the Community.

The aim of the safeguard clause is to ensure that the products conform to the essential requirements and are able to move freely throughout the Community once again, by making the level of protection the same for the whole of the Community.

That is why the Member State which invoked the safeguard clause must inform the Commission of the measures it has taken, indicating the reasons and motives for the decision. It is very important for the Member State to give the precise reasons for its decision to invoke the safeguard clause. To this end, the information sent to the Commission must be contained in a solidly argued document to reduce the time taken to process the file by the Commission.

This information must be sent to the Commission as soon as possible, that is to say as soon as the Member State has established and assessed the danger and at the same time as it takes the national preventive measures.

It should be officially submitted to the Commission's Secretariat-General, with a copy to the department responsible for managing the directive in question.

The reasons for invoking the safeguard clause must be based in particular on:

- non-compliance with the essential requirements if the product falls short of the standards set in the relevant directive;

- incorrect application of the standards;

- a shortcoming in the standards.

In other words, Member States may contest the conformity of a product, the validity of a conformity assessment procedure or the quality of a standard, in which case a product could conform to one or more standards but still not be safe according to the relevant regulations.

Obviously, other motives can be added or specified in order to strengthen the case for invoking the safeguard clause provided they are directly linked with the abovementioned reasons.

Once the Member State has put the safeguard clause into operation and informed the Commission, the procedure must be administered at both national and Community level.

3. ADMINISTERING THE SAFEGUARD CLAUSE

The Member States must administer the safeguard clause on their own territory.

It is up to the Commission to manage the safeguard clause at Community level and ensure that it applies to the whole of the Community as soon as possible.

To this end, the Commission consults the interested parties. As soon as the Commission departments responsible for managing the directive have been informed they will contact:

- first, the Member State and the market surveillance authorities which invoked the procedure;

- the other Member States most directly concerned by the case in question;

- possibly, the manufacturer(s) concerned and the notified bodies (or other third parties) involved in the conformity assessment procedure.

If it considers these preliminary consultations inadequate or if doubts persist about the decision to invoke the safeguard clause, the Commission may, by way of exception, seek the opinion of other adequately qualified, impartial bodies or experts capable of providing further information directly relevant to the subject (other surveillance authorities, other notified bodies, standardization organizations, conformity assessment bodies, organizations representing industry, distributors, consumers, etc.).

Although these consultations can be relatively wide, the urgency of the problem must be taken into account and the procedure must be kept as short as possible.

At the end of these consultations the Commission must establish whether or not the measures taken by the Member State which invoked the safeguard clause are justified:

- Should the Commission consider that the measures are justified, it informs the Member State concerned and the other Member States as soon as possible so that they can adopt, on their territory, appropriate measures ensuring a similar level of protection throughout the Community, thereby fulfilling their market surveillance obligation.

  The Commission's position must be circulated rapidly (by telex or fax) and further explanations can be given within the 83/189 Committee if the problem relates to standards and within the Commission working groups set up for the purpose of implementing the directives.

  The Member State which invoked the safeguard clause will react to the Commission's position by confirming, reinforcing or, possibly, modifying of its own accord the immediate measures that it took.

- Conversely, should the Commission see no justification for the measures adopted by the Member State which invoked the safeguard clause, it will ask that Member State to withdraw its measures and immediately to take the appropriate action to re-establish the free movement of the products in question on its territory.

  If a Member State refuses to follow the Commission's position, the Commission should initiate the procedure provided for by Article 169 of the Treaty.

In either case, the Commission must keep the Member States informed of the progress and the results of the procedure.

If the safeguard clause is invoked because of a shortcoming in the standards referred to in the directive, the Commission, after consulting the interested parties, will submit the case to the Committee set up by Directive 83/189/EEC.

At this stage of the procedure, when it becomes evident that there were good reasons for invoking the safeguard clause and that measures must be taken to restrict, forbid or withdraw the products from the Community market, all the parties must be kept informed so that they can take measures to provide protection against the dangers detected.

As regards products intended for consumers which represent a serious and immediate danger, and in respect of which a Member State has taken or is to take restrictive measures, the Community procedure for the rapid exchange of information, for which Decision 89/45/EEC provides the legal basis, will also apply.

4. CONSEQUENCES OF APPLYING THE SAFEGUARD CLAUSE

If a product bearing the CE marking is found not to conform with the essential requirements laid down by the directive or if the standards were not correctly applied, action must be taken against the manufacturer, representative, importer or person responsible for placing the product on the market, based on the national legislation.

However, the Commission and the Member States must, in administering the safeguard clause, take account of the need to uphold rights of the manufacturers if certain public authorities are proved guilty of abusing their powers to implement the safeguard clause.

If the product fails to conform because of shortcomings in the standard, the Commission, after receiving the opinion of the Committee set up by Directive 83/189/EEC, informs the Member States whether or not the standard concerned should be withdrawn from the list published in the directive. In practice, straightforward withdrawal may create problems since the standard could apply to a far wider range of points than the non-conformity in question here. The Commission informs the relevant European standardization body and issues, where appropriate, a new standardization mandate.

This signifies that use of the safeguard clause was justified and that the Member States must take the appropriate measures.

FICHE II/B

NOTIFIED BODIES

New Approach legislation has moved away from the traditional method of drawing up Community technical harmonization directives providing for the recognition of attestations and certificates of conformity issued under the sole responsibility of the national competent authorities and in their name. The traditional system often led Member States to delegate the technical work to entities unknown to the other Member States or the Commission, designated on the basis of unspecified criteria. Such practice rendered more difficult the operation of legislation which was based on the trust (very often political) which national authorities were prepared to place in each other.

The New Approach - reinforced in this by the Global Approach - reoriented Community legislative policy on such matters as technical competence, objectivity and transparency as the foundations for the necessary degree of trust in the system, on the basis of documented technical criteria enshrined in the legislation itself and in the appropriate European Standards.

Hence Member States are invited under all New Approach legislation to notify to the Commission those bodies which they consider competent to undertake the responsibilities of "notified bodies".

I. General principles

(a) The national authorities which notify the bodies must have not only the necessary authority to notify but also to withdraw notification as soon as the conditions of notification are no longer met.

(b) The bodies concerned should come under the jurisdiction of the national authorities in question. The notified bodies are, almost by definition, taking on the responsibilities of their national notifying authorities and therefore should remain answerable to them. This entails legal jurisdiction and therefore means that Member States can only notify bodies established on their territory.

(c) The legal status of the bodies to be notified, i.e. whether they are privately-owned or State-owned, is irrelevant, but they should be able to demonstrate to the competent authorities that they meet the legally binding criteria set out in the annexes to the directives.

(d) It has been recognised by the Council either in its Minutes or in the texts of the directives themselves that, conformity to the relevant standard of the EN 45000 series of standards on the part of the notified bodies constitutes an element of presumption of conformity to the requirements of the said annexes but is not always in itself sufficient. Demonstration of technical capability within the scope of the directives is necessary. Recourse to appropriate accreditation mechanisms can contribute to such demonstration. (See below chapter VI, paragraphs 2-5)

(e) Member States remain free to notify any number of bodies they consider necessary, as long as the conditions are respected. Should a Member State feel that there are no bodies on its territory capable of meeting the conditions, it should not notify any body.

(f) A clear distinction should be made at the national level between the notified bodies who intervene in the pre-market conformity assessment procedures and the national public authorities (national, regional or local) responsible for the market surveillance imposed by the directives for products on the market.

(g) The bodies which are notified are free to offer their conformity assessment services for which they are notified, to any economic operator established either inside the Community or in third countries. They may carry out these activities on the territory of other Member States or of third countries, either with their home base means or with the personnel of their foreign offices. Certificates are, however, always issued by and in the name of the body notified and not by or in the name of any subsidiary. A subsidiary established in another Member State can only issue certificates if notified by that Member State.

II. Notified bodies and conformity assessment procedures.

Notified bodies are designated to carry out the conformity assessment requirements as set out in the Directives.

According to the modular approach set out in the Council Decision of 13 December 1990, these procedures have been split up into a set of separate, coherent and self-standing modules, which cannot be further subdivided without putting into question the coherence of the system and, more importantly, the responsibilities which should lie with the notified bodies. It is recognised that the 13 December 1990 Decision addresses itself to future directives and not directly to those already adopted before that date. However, these were drawn up on the basis of the major political options set out in the Decision and are therefore not incompatible with it. The Decision may therefore be used as the reference document for the purposes of this document.

This means that notified bodies, notified under one or several directives must be capable of taking the responsibility for a complete module or for several complete modules. They cannot be notified for part of a module.

However, since the scope of most "new approach" directives can be relatively wide and heterogeneous, laboratories or certification bodies may not be qualified to cover all the products falling within its scope. In such cases, bodies may be notified for only part of the scope of the directive in terms of products.

When the directives provide for module H with the supplementary process relating to the design record, no special body should be notified to deal with only the supplement as it is an integral part of the module.

It follows that a body notified to carry out modules D, E or H which involve the control of the manufacturer's quality system, must be capable of taking the responsibility not only for the aspects of the quality systems involved but also for product-related requirements. In either case, the principles relating to sub-contracting (see below) are applicable where the situation so requires.

Where a notified body has already granted a certificate for a given product category based on the existence of a quality system, that or any other notified body granting a certificate for another product category of the same manufacturer should take account of this quality system approval. It may require appropriate supplementary audits specifically relating to the new product category, but it should not duplicate the basic system approval.

Bodies are to be notified for the tasks which they have to carry out. Should a directive only provide for testing to be carried out (e.g. under module AA), the notified bodies may be testing laboratories and do not have to be certification/inspection bodies. In such a case the applicable standards are EN 45001 and EN 45002.

However, should the modules provide for certification processes (i.e. all modules except A, AA, C and CA), then the notified bodies shall be certification bodies. In this instance it is important to underline that the name of the body is irrelevant. Many bodies call themselves laboratories and are nevertheless certification or inspection bodies. As long as these "laboratories" can demonstrate conformity to such standards as EN 45011, 45012, 45013, etc. or to equivalent criteria, they may be notified for the certification module.

In the case of certain new approach directives adopted before the Council Decision of 13 December 1990, the description of the procedure or modules for conformity assessment is not always absolutely clear. Insofar as is possible these directives should be interpreted in the light of that Decision.

III. Notified bodies and market surveillance

A clear distinction should be made between the pre-market conformity assessment functions set out in the directives and the verifications imposed on the Member States for ensuring the appropriate mechanism for the surveillance of the market. The conformity assessment processes are designed to ensure proper placing on the market and putting into service and are the responsibility of the manufacturers and notified bodies (whether they are private or public bodies).

The mechanisms for surveillance of the market intervene at the distribution and marketing stage or once the products are on the market and aim at ensuring that all the requirements of the directives have been effectively respected by all the operators, including manufacturers, importers and the bodies involved in the conformity assessment. This clearly means that there can be no question of the notified bodies carrying out the market surveillance. In those Member States where the notified bodies and the market surveillance authorities come under the same superior authority, the lines of responsibility will be organised in such a manner as to ensure the separation and independence one from the other of the two activities, conformity assessment and market surveillance.

Market surveillance of goods on the Community market must remain the clear responsibility of the public authorities (national, regional, or local) and should include the customs services which have the primary role of checking the conformity of products coming into the Community from third countries.

In order to verify whether the product on the market is in conformity or not, when they have a doubt, these surveillance authorities may have recourse either to their own testing or inspection facilities, or to those of notified bodies, preferably not those involved in the original evaluation of the product in question. However it is clear that the judgement belongs to the surveillance authorities and not to the notified bodies, who cannot be both judge and interested party.

IV. The status of notified bodies

Notified bodies are and must remain third parties. As third parties, they should remain independent of their clients and other interested parties.

The principal reasoning behind such a position lies in the fact that if the Community introduces legislation at all, not only setting out the essential safety etc. requirements, but also requiring specific conformity assessment processes it is

because the public authorities have felt the need to impose such mechanisms on a market which, in the presence of specific risks, has not given them the necessary guarantees of protection in terms of public safety, health, consumer protection etc... In such conditions, if Member States are to accept certificates from bodies on their territory or on that of other Member States, the bodies must demonstrate the transparency of their procedures as well as their competence and independence vis-a-vis the interested economic partners.

When the Community legislator decides that third party intervention is unwarranted, the onus of the controls is placed firmly in the hands of the manufacturer, i.e. in the hands of the first party. The degree of confidence that the legislator has in the market place will determine the degree of severity of the obligations imposed on the said first party.

To date, under the global approach to testing and certification the Community has only worked on the basis either of first party (modules A, and C) or third parties (modules B, D to H, AA and CA).

Facilities such as laboratories or inspectorates owned by economic operators (first or second parties) cannot be notified separately, but this do not prevent them from becoming involved in other ways to be defined, case by case, in each specific directive.

The question of ownership of a facility is irrelevant as long as its independence and neutrality is ensured and that it is separately identifiable. This is in line with the provision in the last paragraph of clause 4 of EN 45001.

It is recognised that the process of determining independence is not a simple matter and in many instances may have to be done on a case by case basis. The guiding principle should be that the lines of responsibility shall be organised in such a manner that the persons responsible for the conformity assessment activities shall be free from commercial influence in their decision-making process.
In short, Community legislation only recognizes third party status for notified bodies. Where notified body status is not required, the legislation will have recourse to the manufacturer's declaration or will place specific requirements or conditions upon the second party. Thus in certain industrial sectors where the public authorities and the market are used to recognising the value of user inspectorates, they could continue to do so in a directive, by placing certain conditions on such inspectorates in the directive, but without giving them notified body status.

V. Role of Notified Bodies

The primary role of the notified bodies is to provide the facilities for conformity assessment on the conditions set out

in the directives, as a service to the economic operators (manufacturers, importers, users), in a competent, transparent, neutral, independent, and non-discriminatory manner.

Their role is particularly important at the outset, when the directives are adopted and during transitional periods. With the Commission and the Member States they must put into place the mechanisms for the proper operation of the procedures and find generally agreed practical solutions for transforming existing national attestations and certificates into Community certificates, without obliging the manufacturers to go through unnecessary duplication of procedures.

They keep their notifying authorities informed of their activities in this field but it is the notified bodies that will thus ensure consistent technical application of the modules. They may call coordination meetings as between themselves on their own initiative or at the request of the Commission. Notified bodies should consider it a duty to take part in such activities (cf. §10 of EN 45002 for example).

Where essential requirements or other provisions of the directives are not sufficiently specific, the notified bodies, with the Commission and the Member States and those with appropriate technical expertise in conformity assessment, will have to develop appropriate technical guidance to enable them to be implemented in practice. Such clarifications, which are the responsibility of the public authorities, will have to be discussed between the Member States and the Commission in order to ensure consensus.

In all these respects, the information the notified bodies can give the Commission is fundamental to the proper operation of the directive, including for the proper application of existing European standards and the issuing of new standardisation mandates, or even proposals to modify the directives themselves should this prove necessary.

Notified bodies do not operate the market surveillance mechanisms of the directives as this is the responsibility of the public authorities (national, regional and local)(See II above). However the latter may wish to use the technical capacities of the notified bodies in certain specific conditions (preferably not of those involved in the original evaluation of the product in question), as long as the public authorities retain the power of decision. In this sense the notified bodies can constitute a technical back-up for the Member States in their surveillance duties and can be an important source of information for the proper operation of the safeguard clause.

VI. Notifying authorities

Notification is both a technical and a political decision. It is technical in that it is part of the assurance process

relative to the competence of the bodies in question. It is fundamentally political in that the modification made by the competent national authorities commits the Member State to taking the final responsibility vis-a-vis the other Member States and the Community institutions (including the Court of Justice).

Notification will normally be carried out by the national ministries responsible for the implementation and management of the directive(s) in question via their Permanent Representatives. The technical part of the notification can be performed on the basis of the work of private or semi-private organisations such as accreditation bodies (these need not necessarily be centralised at the national level).

In its Resolution of 21 December 1989 on a global approach to conformity assessment, the Council underlines the desirability of a generalized recourse to accreditation techniques amongst others, both at Community and national levels. It confirmed this attitude in its Decision of 13 December 1990 concerning the modules to be used in technical harmonization directives (general guideline (m)).

Accreditation of notified bodies is not a requirement under directives but remains an important instrument for evaluating their competence. Accreditation certificates contribute considerably to the presumption of conformity with the provisions of the directives through the EN 45000 series of standards.

Notifying authorities should therefore, wherever possible, have recourse to accreditation. Such accreditation should be to the requirements of the relevant part of the EN 45000 series of standards, but to provide the basis for notification it should make specific reference to the provisions of the directives in question, or be seen clearly to cover them. In the absence of evidence of such specific coverage, the notifying authorities would have to take into account supplementary evidence considered to be equivalent.

The decision to notify, i.e. to choose amongst those who have shown their technical competence remains with the national public authorities. The national authorities are not obliged, under Community law, to notify all the bodies which can demonstrate technical competence. To be notified is not a right, under Community law, for a technically competent body, but the public authorities must restrict their choice to those who can demonstrate that they are technically competent.

Whatever be the technical means the public authorities use to evaluate and continuously control the technical competence of notified bodies, (accreditation or other mechanisms), they must be capable of withdrawing notification immediately and of so informing the Commission and the other Member States.

Where a Member State withdraws its notification of a body, it shall take appropriate steps to ensure that dossiers of the body concerned are processed by another notified body in order to ensure continuity.

The number of notifications should be linked to the needs of the market. Member States should keep this in mind when preparing their notifications. The Commission may bring Member States together on this issue to review the situation whenever appropriate.

VII. The notification process

Member States are free to notify at any time after the adoption of a directive by the Council of Ministers. Notification and/or withdrawal of such is not a one-off operation but rather a continual process. However, Member States should envisage the possibility of being able to notify as soon as possible after the adoption of the directive and to treat notification as separable from the legal transposition.

In order that the transition periods provided for in the directives can be put to effective use (i.e. to prepare and put into place the conformity assessment processes before the final operational deadlines set in the directives), so that certificates may effectively be granted as from the date of application, it is indispensable that Member States notify as soon as possible after adoption. Such notified bodies are not, however, entitled to issue certificates before the deadlines for entry into force of the Directive, just as manufacturers may not affix the CE marking before the deadlines, even if the conformity assessment is restricted to the manufacturer's declaration of conformity.

Member States should consider the possibility of ensuring that their public authorities have the necessary authority to notify bodies before formal transposition. At least they should inform the Commission of those bodies that they would "expect" to notify, so that the coordination work can start as soon as possible.

Notification should be made officially, through the Permanent Representatives, to the Commission itself (Secretariat-General) and to the other Member States. The notification will comprise the names and addresses of the establishments (operational units) concerned, with details of the product range covered by the individual notifications as well as a clear indication of the modules for which the bodies are notified. Should notification be limited in time by the notifying authorities, the duration of the notification will also be indicated.

Prior to this "official" notification the Commission will have attributed an identification number to each notified body and informed the requesting Member State thereof via its Permanent Representative.

The Commission will also have all information concerning the notification, including the identification number, published in the Official Journal of the European Communities. The Member States will also have published at the national level the information concerning all the notified bodies i.e. concerning those they notify as well as those notified by the other Member States.

As soon as it has been established by a Member State (and/or the Commission) that a notified body ceases to conform to the required criteria, the Commission will have its name withdrawn from the list in the Official Journal and shall ensure that this information is correspondingly publicized at the national level. Should a notified body cease to fulfil the criteria for a part of its scope of notification or should a Member State wish to reduce the scope of notification for other reasons, the reduction of the scope will be reflected in the publications.

VIII. Responsibilities

A. Member States

Member States, i.e. the national notifying authorities are responsible to the other Member States and to the Commission for the bodies they notify. It is their responsibility to ensure that notified bodies implement fully and at all times the conditions under which they are notified.
Should a Member State find that a body it has notified has ceased to fulfil these conditions, the notifying authorities shall so inform immediately the body in question, the Commission and the other Member States and withdraw notification and have this information publicized. They should indicate to the body in question any possibility of appeals against such decision. Such withdrawal does not affect attestations issued by the notified body until such time as demonstration can be made that the attestations should be withdrawn.

Member States may dispute that a notified body fulfils its obligations properly. In such a case they so inform the Commission. They may have recourse to the procedures laid down in Article 170 of the Treaty, as the conditions for notification are set out in Community law, or they may present a complaint to the Commission which may either examine the question with the notifying authority of the body in question, or bring it to the attention of the other Member States for discussion, or have recourse to Article 169.

B. The Commission

The Commission is responsible for coordinating the procedures for the notification of bodies, including the allocation of an identification number. It also has to ensure that the

information relative to the names, identification numbers and tasks of the notified bodies, is circulated to the other Member States (via the Permanent Representations) and published in the Official Journal of the European Communities. The Commission shall ensure that a consolidated list of notified bodies is regularly kept up to date. It shall also ensure, through proper coordination of the Member States, whenever appropriate, a review of market needs for notified bodies.

The Commission is responsible with the Member States for the proper implementation of the directives in question and should, as soon as possible after the adoption of directives, bring the notified bodies together so that they work together and implement coherently the relevant Community provisions. Such meetings should take place both within the field of application of individual directives as well as across the scopes of several directives when they overlap, to debate the more important issues such as the difficulties of implementing the directives in practice. Should the number of notified bodies per directive become excessive, the Commission could ask the Member States to put in place a proper mechanism for their representation.
The notified bodies may meet at their own initiative whenever they feel the need to deal with the more technical issues relating to the everyday operation of the conformity assessment procedures so as to be sure that they are being applied consistently. They should feel free to invite representatives of appropriate interested parties. Such meetings should be financed by the bodies themselves. However, the Commission and the Member States should be kept informed of these discussions in order to be able to take all relevant decisions relating to the proper implementation of the directive in question, should the need arise.

But in any event, irrespective of the joint discussions at Community level, the notified bodies shall remain individually responsible to their respective notifying authorities.

When the Member States or the Commission consider that a notified body no longer fulfils the conditions for notification or is refusing to cooperate with the others, it shall invite the national notifying authorities to take the appropriate measures, which could in the final instance lead to withdrawal of notification.

It is not the role of the Commission to accredit notified bodies nor to check their technical competence on notification. However, Member States having notified bodies unable to prove their conformity with the harmonized standards (EN 45000 series) may be requested to provide the Commission with the appropriate supporting documents on the basis of which notification was carried out.

Moreover, it is the Commission's responsibility to act when doubt arises as to the competence of a notified body. Should it consider, at its own initiative or after complaint, that a

notified body is not fulfilling its responsibilities, it will so inform the national notifying authorities and shall ask for appropriate documented evidence of the basis for the notification.

Should a Member State not provide such information, the Commission may initiate the procedures under Article 169 of the Treaty, against the notifying Member State.

C. Notified Bodies

Notified bodies are responsible for carrying out correctly the conformity assessment processes and shall be appropriately insured to cover this professional activity, and are liable for any errors they make in carrying out this task. Under Council Directive n° 85/374/EEC of 25 July 1985, the manufacturer or the importer remain responsible for product liability.
Notification implies for the bodies, not only that they meet the competence criteria and that they can carry out conformity assessment activities under the directives, but also their willingness to take part in any coordination activities organised by the Commission. Such coordination may, moreover, imply their active participation in comparative testing, Round Robins or standardization activities, for example. Notified bodies should consider participation in these coordination activities as a duty which they owe to their clients and to their notifying authorities for having been notified.

Notified bodies are responsible to the national authorities who notified them, and to them alone. They should keep these authorities regularly informed of their activities and should be prepared to provide all information concerning their proper implementation of the conditions under which they were notified, (including their sub-contractors, see below) either at the request of those authorities or of the Commission.

Notified bodies are answerable only to the national authorities who notified them, meaning that only those national authorities can withdraw notification. The Commission can only withdraw a notified body from the list published in the Official Journal of the European Communities when the notifying authority of a Member State itself withdraws its notification or when, at the end of an infringement procedure under Article 169 of the Treaty, the Court declares a Member State to be in infringement of a given directive and consequently declares a notification to be invalid.

IX. Notified bodies and subcontracting

1) Purpose, form and Scope

It is the responsibility of notified bodies to fulfil at all times the conditions under which they are notified and in

particular to ensure that they answer the competence criteria and are capable of "carrying out the work for which they are notified. This, however, does not prevent them from subcontracting part of their activities.

Subcontracting by notified bodies must in no event undermine the public authorities' confidence in compliance with the conformity assessment procedures to ensure that the products marketed meet the requirements set out in the provisions of the directives.

A notified body which subcontracts remains in all cases responsible for all the activities covered by the notificatior Subcontracting does not entail the delegation of powers or of responsibilities.

The notified body cannot under any circumstances subcontract all of its activities, as that would make the notification meaningless. It cannot subcontract assessment and appraisal activities, which are the essential tasks for which it was notified.

The purpose of subcontracting therefore closely depends on the nature of the notified body, since a testing laboratory, a certifying body or an audit body may be involved in fairly wide-ranging areas of conformity assessment. Conformity assessment procedures may be subcontracted on the basis of two essential criteria:

- firstly, the procedures are subdivided into technical operations and assessment operations;

- secondly, the methodology used to carry out these operations must be sufficiently precise.

A subcontractor must nevertheless carry out substantial and coherent parts of these technical operations, e.g. the whole of the procedure defined for carrying out tests.

Furthermore, with regard to tests, certification bodies may subcontract activities relating to the technical operations while continuing to assess these operations, and in particular validate the test report. Similarly, subcontracting is possible in the field of certification of quality management systems, in particular auditing of the quality systems, provided that the notified body carries out the audit assessment.

The purpose of subcontracting also depends on the content of the notification:

Only strictly limited technical tasks described in detail can be subcontracted, e.g. tests, examinations, comparisons, quality system audits that can be carried out as necessary with the participation of the notified body on the occasion of the initial audit and/or the follow-up audits. At all events, the notified body reviews and assesses the quality management

system so that it can give assurance that the overall effectiveness of the system is in conformity with the specified requirements.
The work in question must be carried out on the basis of pre-established technical specifications setting out, in all cases, a detailed procedure based on objective criteria so as to guarantee total transparency.

Where the subcontractor is involved in the assessment of conformity to standards, it must use them if they lay down the procedures.

If the subcontractor is involved in the assessment of conformity to essential requirements, it must use the procedure followed by the notified body itself or a procedure deemed by the notified body to be equivalent to that used in the context of conformity to standards.

For all these reasons, subcontracting can only be carried out under contracts which make it possible to ensure transparency and confidence in all the conformity assessment processes.

Serial subcontracting is prohibited in order to avoid undermining the coherence of the system and the confidence placed in it. The notified body must in all cases have a direct contractual link with its subcontractor(s).

2) Conditions of subcontracting

The bodies acting as subcontractors for the notified bodies need not be notified as such by the Member States.

Nevertheless, they must be easily identifiable. The notified body must inform the Member State concerned of its intention to subcontract certain work.

The notified body must keep a register of all its subcontracting which must be systematically updated. This information must be available for communication without delay to the Commission and the other Member States on request.

The subcontractor must be technically competent and display independence and objectivity on the basis of the same criteria and under the same conditions as the notified bodies.

To this end, it must be able to provide proof of compliance with certain requirements such as those laid down in the "new approach" directives and in this paper. Compliance with the harmonized standards in the EN 45000 series entails a presumption of conformity with those requirements. This will make it possible to uphold the credibility of the subcontracted activities.

The notified body must register and keep detailed information concerning the competence and conformity of its subcontractors.

The notified body must satisfy itself that the competence of its subcontractors is being maintained, e.g. by carrying out regular evaluations of the latter and keeping itself regularly informed of the details regarding the performance of their tasks.

The notified body, which in any case remains entirely responsible for the work carried out for it by the subcontractor, can have its notification withdrawn by the Member State for any reason connected with improper performance of the subcontract, in particular having regard to these guiding principles.

3) Consequences of subcontracting

Subcontracting is thus an operation whereby a notified body can have part of its work carried out by another body within clearly specified limits and on the basis of established and regularly monitored competence.

The subcontracting conditions set out above will therefore apply *mutatis mutandis* to any subcontractor whether or not it is on Community territory.

Subcontracting is therefore based on private-law contractual negotiations.

For this reason, subcontracting must be distinguished from mutual recognition agreements which it complements in relations with third countries.

Efforts to achieve a balance between the Community on the one hand and third countries on the other form part of the negotiating mandates provided for in the Council Resolution of 21 December 1989 which seeks to promote international trade in products subject to regulation through the conclusion of mutual recognition agreements based on Article 113 of the Treaty.

These agreements should ensure a balance in the resulting benefits for the parties. (See fiche II/G)

TECHNICAL FILE

N.B.

This sheet refers only to procedures laid down in the directives which do not provide for intervention by notified bodies.

1. Introduction

Most of the new approach directives impose an obligation for the manufacturer to draw up and to provide technical documentation (or a technical file) containing certain information to demonstrate the conformity of the product to the requirements of the directive.

Although each directive specifies the content of the file, further details concerning the extent, content and form of the information supplied must be given to ensure better exploitation of the technical file by the national inspection authorities and to facilitate the manufacturer's task at the drafting stage.

2. Objectives of the Technical File

(a) In some directives[1] the technical file is the principal means of assessment of the conformity of a product within the framework of the market surveillance by the Member States (cf. Doc. Cert. 92/2). In these cases, the assessment of conformity is based almost exclusively on the manufacturer's declaration of conformity, without the intervention of a third party or a notified body (module A in Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives[2].

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(1) Directives:

87/378/EEC (safety of toys)
89/336/EEC (electromagnetic compatibility)
89/392/EEC (machinery)
89/686/EEC (personal protective equipment)
90/385/EEC (active implantable medical devices, Annex VI).

(2) OJ No L 380, 31.12.1990, p. 13.

In these cases, the file compiled by the manufacturer is intended essentially for the national inspection authorities. Indeed, the Council Resolution of 7 May 1985 underlines that "with regard to the manufacturer's declaration of conformity, the national authorities have the right to ask the manufacturers or the importer to communicate the data relating to the tests carried out concerning safety, etc., when they have good grounds for believing that a product does not offer the degree of safety required in all respects. Refusal on the part of the manufacturer or the importer to communicate these data constitutes sufficient reason to doubt the presumption of conformity".

It must, therefore, be possible to place this technical file at the disposal of the competent national authorities should they so request when the product is placed on the Community market.

(b) In other directives, the documentation or technical file is just one of the means of completing a specific conformity assessment procedure with the intervention of a third party (notified body).

This is the case with the directives which provide only for the EC type examination (module B in Decision 90/683). This certificate is in turn included in the technical file.

This sheet concerns the technical file referred to in paragraph (a), that is to say, as the principal means of market surveillance without intervention by a notified body.

3. Format and contents of the Technical File

In Decision 90/683/EEC of 13 December 1990 the Council established that "the essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers".

This guideline from the Council is, therefore, the essential criterion to be taken into account when considering the content and extent of the information to be supplied in the technical file provided for in the directives, i.e. the content and extent of the obligation to provide information.

Consequently, the details included in the technical file always depend on the nature of the product and on what is necessary, from the technical point of view, to demonstrate the conformity of the product either to the harmonized standards, if the manufacturer has followed them, or to the essential

requirements of the relevant directive if the manufacturer has followed none or only some of the harmonized standards. This must, therefore, be determined case by case depending on the product.

To allow effective exploitation of this file for market surveillance purposes, excessive paperwork should be avoided. To achieve this and to facilitate the manufacturers' task, it is proposed that the inspection authorities should accept subdivision of the file into two parts.

1. The first part (A) would consist of a summary of the essential technical data relevant to the conformity assessment procedures, including in particular:

   - the name and the address of the manufacturer and the identification of the product;
   - the list of harmonized standards followed by the manufacturer and/or the solutions adopted to satisfy the essential requirements;
   - a description of the product;
   - the operating instructions, if any;
   - the overall plan of the product, if any.

2. The second part (B) would consist of a full file containing all the test reports, information concerning the quality manual, plans, descriptions of the products and processes, standards applied, etc.

If the manufacturer fails to follow this two-part breakdown of the technical file, the inspection authorities could demand the full technical file or part thereof according to the requirements for inspection purposes, unless the details given in the declaration of conformity or in the certificate of conformity appear sufficient for the purposes of conducting a preliminary inspection.

4. Availability of the Technical File

The technical file must be kept at the disposal of the national authorities for inspection and control purposes. With certain exceptions,(*) this obligation to keep at least one technical file inside the territory of the Community starts at the time of the placing of the product on the Community market whatever the geographical origin of the product.

This obligation is incumbent upon the manufacturer or his representative established in the Community.

If the manufacturer is not established in the Community and has no representative in the Community, the person who places the product on the Community market must take on this obligation.

(*) cf. Annex V - Directive 89/392/EEC on machinery.

Any person responsible for placing a product on the Community market but not in possession of the technical file must be capable of:

- stating where the technical file is situated inside the Community;

- presenting the technical file as soon as possible on request from the national authorities.

However, the name and address of the person in possession of the file need not be expressly mentioned on the product or on its packaging, unless otherwise specified.

The file cannot be requested systematically. In general, it can be requested only during checks made for market surveillance purposes by the Member States.

In any event the request for the technical file must remain in proportion to the requirements of the inspection carried out. Therefore in general the manufacturer or person responsible for placing a product on the Community market should initially provide the inspection authorities with only a summary of the essential technical data (part A of the technical file). One or more specific points of the second part can nevertheless be requested in cases of serious doubt about the conformity of the product to the Community regulations.

The full technical file can only reasonably be requested where necessary and certainly not when only an individual point is to be checked, in which case only the relevant part of the file should be required.

If the competent authorities in the Member State request the technical file, the first part of the technical file (part A) should be made available immediately, allowing a reasonable time for transmission. Extra time should be granted for submission of the second part (part B) of the file, taking into account its volume and form (written, computerized ...).

Community-wide organization of the market surveillance procedures and coordination of the inspections should avoid repeated submission of the same technical file by the same manufacturer to different inspection authorities (cf. Sheet II/E).

The technical file must be kept for at least ten years from the last date of manufacture of the product, unless the directive expressly provides for any other duration (Cf. Council Decision of 13 December 1990).

5. Language of the Technical File

If the Community directives contain no specific provisions concerning the language of the file, the requirements of the

Member States must be assessed on the basis of Article 30 of the EEC Treaty on a case by case basis, taking into consideration the proportionality of their demands. A Member State may request presentation of the first part of the technical file (part A) in its official language but should not do so if the national authorities can understand the file or its contents in the other language. Where a translation is required the person in possession of the file will be allowed extra time to submit the first part of the file to the inspection authorities.

Moreover, no further conditions may be imposed concerning this translation, such as a requirement of a translator accredited or recognized by the public authorities, or of official translators or other similar requirements.

6. Confidentiality

Decision 90/683/EEC (Annex I.i) stresses the need to ensure the legal protection of confidential information.

No exceptions can be made to this very important principle which the Member States must observe strictly.

To this end, Member States must ensure that everyone involved in the assessments, inspections and surveillance and who has knowledge of the contents of the technical file is bound to professional secrecy.

Precise rules will, where necessary, have to be laid down by the Member States to guarantee this confidentiality.

This applies in particular to the bodies notified by the Member States, which must ensure that these bodies maintain this confidentiality.

Confidentiality is also mentioned in the EN 45000 series of standards which serve as the reference standards for the notification of bodies by the Member States.

NEGOTIATIONS WITH THIRD COUNTRIES CONCERNING THE MUTUAL RECOGNITION OF CONFORMITY ASSESSMENT

1. INTRODUCTION

1.1 Pursuant to the Council Resolution of 21 December 1989 on a Global approach to conformity assessment, negotiations should be opened with third countries on the mutual recognition of conformity assessment under Article 113 of the Treaty in accordance with Community law and the Community's international obligations.

1.2 The Council meeting of 21 September 1992 took the decision to authorize the Commission to negotiate agreements between the European Communities and certain third countries on the mutual recognition of conformity assessment.

1.3 As emphasized by the GATT TBT (Technical Barriers to Trade) Code, Article 113 of the EEC Treaty, the Council Resolution of 21 December 1989 and the Council Decision on 21 September 1992, agreements on the mutual recognition of conformity assessment are intended to facilitate international trade. Accordingly, the Community will, on a case-by-case and country-by-country basis, weigh up the economic and political advantages of granting such a facility.

1.4 The Council Resolution of 21 December 1989 provides for the conclusion of mutual recognition agreements on condition that:

- the competence of the third country bodies is and remains on a par with that required of their Community counterparts;
- the arrangements are confined to reports, certificates and marks drawn up and issued directly by the bodies designated in the agreements;
- in cases where the Community wishes to have its own bodies recognized, the agreements establish a balanced situation with regard to the advantages derived by the Parties in all matters relating to conformity assessment for the products concerned.

With regard to this last condition, the agreement must ensure that the Parties have an equivalent guarantee of access to the market for the sector(s) covered by the agreement in terms of the requirements of the laws of the two Parties and the means of proof of conformity with these requirements.

To this end, the respective practices of each of the Parties will be examined prior to agreement, in particular the nature of the technical rules of the third country concerned, i.e. the type of technical requirements involved, the conformity assessment procedures, the geographical restrictions (part or all of the territory) and the other administrative conditions for market access.

1.5 In the context of Community legislation, the characteristics of products and their components are linked to technical requirements, which means that all products placed on the Community market have a safety level equal to or greater than that laid down by these essential requirements.

In the context of mutual recognition agreements on conformity assessment, products placed on the market of either contracting Party will have to comply with safety levels at least equivalent to those laid down in the laws of the Party in question.

1.6 The purpose of mutual recognition agreements is to secure mutual acceptance by the Parties of certificates, marks of conformity and test reports issued by the bodies designated in the agreement with regard to the conformity assessment required in the area or areas covered by the agreement.

Community bodies will be able to certify compliance by Community products with the requirements of the third country concerned. Conversely, third countries will be able to have the conformity of their products with Community requirements evaluated by laboratories and certification bodies established on their territory.

It follows that signature of such agreements, which are intended to facilitate trade between the Parties, does not at this stage signify acceptance by each Party of the standards or technical regulations of the other Party or that the two are considered equivalent. However, such agreements can constitute a first step towards a harmonized system of standardization and certification for the Parties to the agreement.

1.7 Mutual recognition agreements must not be confused with subcontracting agreements.

Mutual recognition agreements (mutual acceptance of conformity assessment work carried out by the other Party) are signed by the Parties to the agreement and concern all of the authorities responsible for making notifications and the notified bodies listed in an Annex (for the Community, the Commission will draw up the lists of bodies on receipt of information from the Member States).

Subcontracting agreements (concerning specific work relating to the verification of the degree of conformity, in particular laboratory testing and quality checks carried out, with reference to EN 29000 and EN 45000 standards or other standards shown to be equivalent, on the basis of private-law agreements) are signed by two bodies and do not in any way diminish the responsibilities of the subcontracting body (see the appended document on subcontracting).

2. SCOPE

2.1 The agreements will have to specify their scope, i.e. the sectors covered by the mutual recognition of conformity assessment by the third party with respect to Community directives or non-harmonized national regulations, on the one hand, and/or the laws or regulations of the third country, on the other.

2.2 The aim of the negotiations is to conclude, between the European Economic Community and third countries, agreements on the mutual recognition of test reports, certificates and the conditions for affixing the marks of conformity used in the "regulated" field.

The "regulated" field concerns the products or sectors for which the public authority has decided to take action to defend the public interest on grounds of safety, health protection, environmental protection, consumer protection, etc. , by requiring evaluation of conformity by third parties. This results in the existence of Community directives or national rules of the Member States which have not yet been harmonized and may involve both "old approach" and the "new approach" directives and national regulations.

2.3 The agreements on the mutual recognition of product conformity assessment are based on the existence of conformity assessment infrastructures set up by each Party.

2.4 The agreements will have to ensure that the technical competence and responsibility of the bodies instructed to carry out the conformity assessment in the third countries are and remain on a par with that required of their Community counterparts.

2.5 The agreements may be drawn up on a case-by-case basis with the various countries either for one directive or for several. This will not prevent new agreements from being concluded or agreements already in force from being amended at some time in the future.

2.6 A mutual recognition agreement concluded by the Council of Ministers will cover the entire Community territory. It will not be affected by the number or location of the conformity assessment bodies within the Community.

3. PROCEDURES

3.1 Negotiating procedures

3.1.1 "Harmonized" field

3.1.1.1 For the sectors in which there are Community directives, the Commission will conduct the negotiations for the conclusion of the agreements, in coordination and close consultation with the Member States throughout the negotiations.

3.1.1.2 The Commission will ask the Member States for a list of national experts in the fields covered by the agreement, to be selected in accordance with specific needs, capable of providing the technical assistance required by the Commission during the negotiations.

3.1.2 "Non-harmonized" field

3.1.2.1 When a Member State which has a non-harmonized national regulation wishes to regulate its relations with a third country in this field, it so informs the Commission.

After consulting the other Member States, the Commission either asks the Council to authorize the Member State concerned to negotiate a bilateral agreement or it requests negotiating directives when it is in the general interest to deal with the matter at Community level. The Council decision authorizing bilateral negotiations to be carried out by the Member States will set out the procedure to be followed for the approval of the agreement in question.

3.1.2.2 An agreement between a Member State and a third country will have the effect that third country products which conform to the provisions of the agreement are treated as products of the Member State concerned, as far as conformity assessment is concerned.

3.1.2.3 Such an agreement will apply, where appropriate, to all Community products certified as being in conformity with the third country legislation by the certification body or bodies of the Member State in question. Third country products which have undergone conformity assessment in accordance with the agreement will be given access to the markets of the other Member States under the same conditions as the products of the Member State in question, provided that they enter the Community through that Member State.

3.1.3 Common procedures

3.1.3.1 The agreements will list the notified bodies and the field for which they have been notified and the authorities competent to make and/or to withdraw the notification. Any addition of new notified bodies must be approved by a joint committee on the management of agreements.

3.1.3.2 The contracting Parties will hold regular consultations to ensure the smooth operation of the procedure laid down in the agreement. Furthermore, they may, by common agreement, hold ad hoc meetings to deal with specific matters that are of particular interest to one of them.

3.1.3.3 The Parties will agree to exchange all information on regulations relating to the agreement and also any relevant information on the implementation of regulations in the sectors covered by the agreement.

3.1.3.4 The management of the agreements will be the responsibility of a joint committee consisting of representatives of each Party to the agreement.

3.1.3.5 Agreements concluded by a Party with a third country will not under any circumstances create obligations for the other partner.

3.1.3.6 Where the Community directives cover only part of a sector, the negotiations may be extended to include non-harmonized national regulations.

3.2 Technical procedures

3.2.1 The agreement must indicate the procedures followed by the Parties to ensure the technical competence and conformity with the criteria of the bodies which have asked to be included in the agreement.

3.2.2 The following conditions must be fulfilled to ensure that the bodies concerned are technically competent:

(a) the bodies must meet the standard criteria set out in the directives (compliance with organizational

and operating criteria defined in the EN 29000 and the EN 45000 series of standards, or in specifications judged equivalent, will be deemed to indicate compliance with the technical competence criteria);

(b) each Party must have an authority which has the powers, the responsibilities and the authority required to notify the competent bodies.

Notification consists of two acts: the act of designating the competent body and the act of recognizing its competence to ensure objectivity, transparency and conformity with the criteria;

(c) the notifying authority must have the power required to withdraw the notification as soon as the bodies cease to conform to the abovementioned criteria.

3.2.3 The notified bodies of the third countries must take part in coordination meetings with the Commission and their Community counterparts.

3.2.4 The agreement must lay down procedures for intercomparison of the methods for verifying the technical competence and conformity with the criteria of the notified bodies, either by providing for joint verifications or by other methods deemed equivalent. The accreditation systems for conformity assessment bodies can be used within the framework of the intercomparison procedures.

3.2.5 The agreement must provide for the possibility for each of the Parties to verify the notified bodies' technical competence and their conformity with the criteria, in cases of dispute.

3.2.6 The authority responsible for making the notification must periodically check the validity of the list of notified bodies.

4. CRITERIA FOR THE ESTABLISHMENT OF NEGOTIATING PRIORITIES

4.1 The negotiation of mutual recognition agreements assumes that, in the field(s) concerned, the partners have reached an equivalent technical and industrial level.

4.2 The agreements on the mutual recognition of conformity assessment will be concluded with partners selected on the basis of the following priority criteria:

(a) a mutual interest in the regulated areas listed above, where they provide for conformity assessment by a third party,

(i) the "new approach" directives as and when they enter into force;

(ii) the fields covered by the other Community directives relating to technical harmonization;

(iii) the fields covered by non-harmonized national legislation in the Member States, according to applications put forward by those Member States;

(b) the interest expressed by economic operators in the Community;

(c) subscription to the GATT "Technical Barriers to Trade" (TBT) Code;

(d) the volume of trade between the two Parties.

5. THE EUROPEAN ECONOMIC AREA

5.1 For the EFTA countries, the system of marks and certificates will be covered by the agreement on the European Economic Area and is therefore not covered by this mandate.

5.2 The benefit of the agreements concluded by the Community under this mandate may be extended to cover all of the EFTA countries in accordance with the terms of the agreement on the European Economic Area. That is to say, the Community undertakes to hold negotiations on mutual recognition with third countries in close collaboration with the EFTA countries with a view to the conclusion of parallel agreements.

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