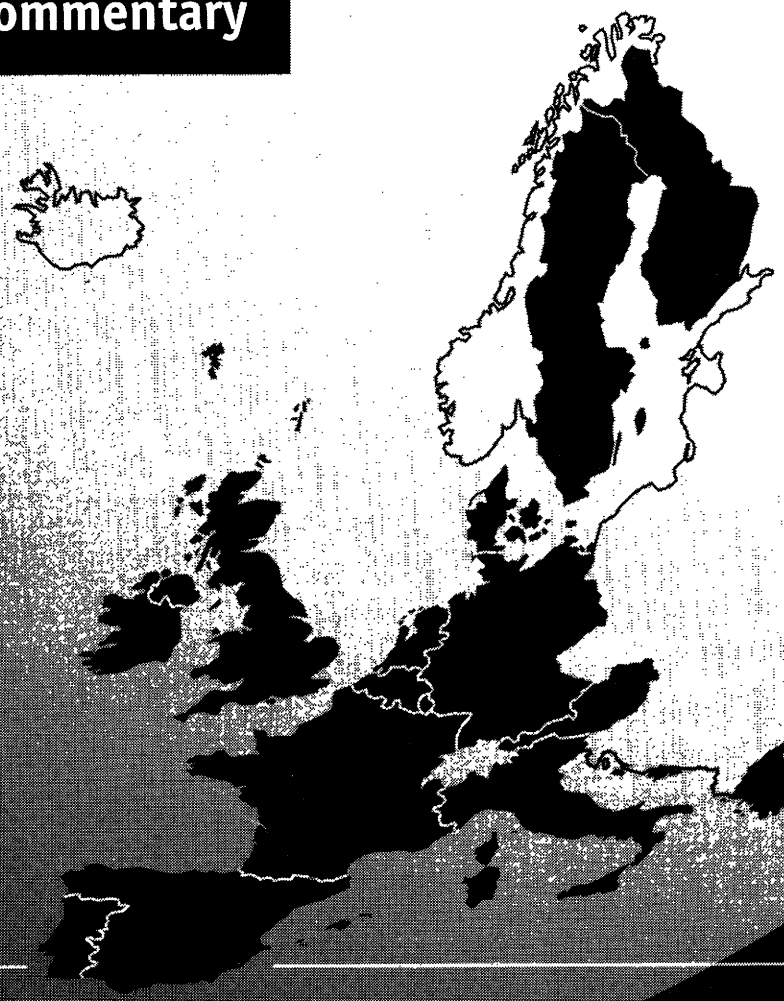
Maintaining the single market

Directive 83/189/EEC — A commentary

A guide to the procedure for the provision of information in the field of technical standards and regulations



PUBLISHER'S NOTE

Dear Reader,

Two important directives relating to the notification of national regulations have been adopted since this brochure was printed.

The first is a Parliament and Council Directive 98/34/EC[1] of 22 June 1998, which consolidates Directive 83/189/EEC and the directives amending this, and should now be invoked. The adoption of this consolidating text does not affect the substance of the provisions of the directive appearing in this brochure.

The second is a Parliament and Council Directive 98/48/EC[2] of 20 July 1998, which extended the scope of the procedure to cover rules on information-society services. This first amendment of Directive 98/34/EC entered into force on 5 August 1998. Among its provisions is the requirement that Member States must, as from 5 August 1999, notify their national rules on information society services. The latter are defined as "any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services".

We hope you will note the contents of this brochure and find it both interesting and useful.

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[1] OJ L 204, 21.7.1998, p.37.
[2] OJ L 217, 5.8.1998, p.18.

European Commission

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Directorate-General for Industry

A great deal of additional information on the European Union is available on the Internet.
It can be accessed through the Europa server (http://europa.eu.int).

Cataloguing data can be found at the end of this publication.

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Preface

One of the most difficult and important questions in the management of the internal market is how to prevent the adoption of national technical regulations and standards recreating the barriers which were removed under the 1985 White Paper programme up to 1992.

The solution has been found by obtaining the agreement of the Member States to inform and consult each other and the Commission before they adopt such measures and to modify their drafts in consequence. In doing so, they have agreed to try to ensure that problems will be avoided, rather than having to eliminate problems once they have arisen. The instrument which makes this possible is Directive 83/189/EEC.

Getting the Member States to accept a system of reciprocal transparency and monitoring in the field of standards and regulations was quite a challenge, but they were convinced by the advantages of the proposed system.

A pre-adoption screening procedure for all draft technical regulations and standards relating to products was therefore established and gradually expanded. The Commission, the Member States and industry thus have an open window upon technical activities, which enables them to eliminate at source any barriers to the free movement of goods.

Directive 83/189/EEC contributes to the application of the subsidiarity principle, both through enabling improvements to be made to national legislation and identifying areas where harmonisation is necessary.

Industry, as well as the Commission and the Member States, is involved in the notification procedure. Industrialists in the Member States have the opportunity of examining legislation proposed by countries to which they export or wish to export. As a consequence, they can plan to adapt their products to the new requirements; they can also identify protectionist elements in the drafts and take action to have them eliminated.

In order to use the system to full advantage, industry must therefore know how it works and how to access the notified texts.

This booklet is one of a number of Commission initiatives designed to bring Community law closer to those who use it. My hope is that its publication will help to enhance the exchange of information, dialogue and cooperation which has been initiated by Directive 83/189/EEC.

Jura vigilantibus non dormientibus prosunt (*).

S. Micossi

Stefano Micossi
Director-General
Directorate-General III, Industry

(*) The vigilant gain more than the idle.

Introduction

Directive 83/189/EEC — an instrument of transparency at the service of the internal market

At the beginning of the 1980s, the Commission stressed the need to give fresh impetus to the European internal market. Its objectives were twofold: to eliminate the differences between national regulations on products which gave rise to technical barriers, and to prevent the creation of new barriers. Directive 83/189/EEC, laying down a procedure for the provision of information in the field of technical standards and regulations, was amongst the legislation adopted at that time (1). This procedure concerned the second objective: to ensure that any technical standards and regulations introduced by the Member States did not restore the barriers that had been eliminated when the measures to complete the internal market were adopted.

The concept was revolutionary at the time and has remained so — to the extent that it is only now that the question has arisen as to whether it could be applied in its present form to other fields.

This innovative instrument requires Member States to inform the Commission — or its authorised representatives — of new technical standards and regulations which they are planning to draw up. The exchange of information is carried out in accordance with a two-pronged procedure which divides the directive into two distinct but complementary parts.

The first relates to the procedure for the provision of information on draft national standards between the national standardisation bodies, such as the AFNOR (Association française de normalisation), the DIN (Deutsches Institut für Normung), the BSI (the British Standards Institution) or the AENOR (Asociación Española de Normalización y Certificación), the European standardisation bodies, namely CEN (European Committee for Standardisation), Cenelec (the European Committee for Electrotechnical Standardisation) and ETSI (European Telecommunications Standards Institute), and the European Commission. The Commission has given the European standardisation bodies responsibility for implementing this procedure, by means of an annual contract.

The second part of the directive is addressed to the Member States who have in effect agreed to take part in a reciprocal transparency and monitoring system in the regulatory field. This initiative was original in several ways:

— the system is of a preventive nature: information is provided when technical regulations relating to products are still at the draft stage, and may be amended in order to conform with the principles of the internal market;

— it is not only the Commission which can examine and monitor the texts through the operation of standstill periods, but also all the Member States; they have all therefore acknowledged the advantages of a procedure which allows the others to influence the legislative processes of Member States. The Treaty itself merely made provision for retrospective monitoring by the Member States, through the use of an infringement procedure which is, incidentally, very rarely implemented;

— the cooperation established between the Member States and the Commission enables the Commission to propose the approximation of legislation, no longer retrospectively, but before the emergence of any new barriers to trade. As a result of the Directive 83/189/EEC procedure, the Commission can identify fields where harmonisation is necessary and delay the adoption of national legislation for a given period so that discussions can take place at Community level.

The system, which got off to a slow start, has gained momentum and has provided the Commission, the Member States and industry with a window on the activities of national authorities and standardisation bodies in the technical field (rules relating to product composition,

(1) Directive published in OJ L 109, 26.4.1983, p. 8.

labelling, name, testing, etc., as well as rules relating to product life cycle through to disposal). The scope of the directive has been progressively extended, so that it now covers all agricultural and industrially manufactured products and takes account of an ever growing number of provisions, in particular to prevent any measures which indirectly require compliance with technical specifications from slipping through the net ([1]).

The application of Directive 83/189/EEC has given rise to new practices. An entire philosophy of information exchange, dialogue and cooperation has evolved between the Member States.

The Commission has also modified its approach: Directive 83/189/EEC was the deciding factor which persuaded it to take the 'new approach' to technical harmonisation. This approach, which arose from the 'Cassis de Dijon' precedent ([2]) and the resulting concept of 'essential requirement' has enabled the work of approximation to be speeded up, this being the only way of taking full advantage of the standstill periods imposed on national legislators by Directive 83/189/EEC.

Thus, instead of the high degree of technical detail of traditional European directives, 'new approach' directives concentrate on the definition of essential requirements of general interest — safety, health, consumer protection, environmental protection — and refer to non-mandatory harmonised standards for detailed technical solutions.

Compliance with these standards, although voluntary, confers a presumption of product conformity with the essential requirements of the directive. The Member States are therefore required to grant free movement to products which comply with harmonised standards ([3]).

Moreover, in non-harmonised areas, where there is a proliferation of divergent technical regulations, the Commission is using Directive 83/189/EEC as an educational tool with a view to adjusting Member States' styles of legislation.

Through this instrument, the Commission not only succeeds in removing provisions which are contrary to Community law, but also contributes provisions to be written into national legislation to ensure that economic operators are fully informed of their rights and permit application in practice of the principle of 'mutual recognition' contained in Articles 30 et seq. of the Treaty.

According to this principle, each Member State must accept the sale in its territory of any product lawfully manufactured in another Member State, subject, where legitimate health and safety interests, etc. are at stake, to these products guaranteeing equivalent compliance. The corollary of this acceptance of products from the rest of the Community, extended by the Agreement on the European Economic Area to products from EFTA countries signatory to the agreement, is mutual recognition of the regulations relating to the design, manufacture and testing of products, and the conformity assessment procedures used, of which the Member States and the Commission are informed through the procedure for the provision of information established by Directive 83/189/EEC.

In order to enable the directive to be fully effective, all the players — national authorities, standardisation bodies and the economic operators of the European Union — need to have a thorough understanding of its provisions and so be precisely aware of their rights and obligations. This is all the more important in that the Court of

([1]) Directive 83/189/EEC was amended principally by Council Directive 88/182/EEC of 22 March 1988, published in OJ L 81, 26.3.1988, p. 75, and by European Parliament and Council Directive 94/10/EC of 23 March 1994, published in OJ L 100, 19.4.1994.

([2]) Judgment delivered on 20 February 1979 in Case 120/78, ECR p. 649 and subsequent related judgments.

([3]) This new approach to technical harmonisation was later supplemented by 'A global approach to certification and testing'. Adopted by a Council resolution of 21 December 1989 and subtitled 'Quality instruments for industrial products', this global approach (Document COM(89) 209 final, OJ C 267, 19.10.1989) consists in creating the necessary conditions for implementation of the principle of mutual recognition of proof of conformity in both regulatory and non-regulatory areas.

Justice, in April 1996, established the principle that failure to comply with the notification obligation results in the technical regulations concerned being inapplicable, so that they are unenforceable against individuals ([1]).

The aim of this booklet is to inform all the actors — and particularly Europe's manufacturers — of the objectives, content and scope of a key instrument of Community law for the removal at source of technical barriers to the free movement of goods in the market without frontiers.

([1]) 'CIA security' judgment of 30 April 1996 in Case C-194/94, ECR I, p. 2201.

Chapter I

The scope of the directive

Article 1 defines the meaning given by the directive to a number of key terms, used throughout its provisions. This terminological and semantic clarification is essential to an effective understanding of the text and simultaneously defines the scope of the directive.

Article 1

For the purposes of this directive, the following meanings shall apply:

1. 'product': any industrially manufactured product and any agricultural product, including fish products;

The scope of the initial version of Directive 83/189/EEC excluded cosmetic products within the terms of Directive 76/768/EEC, medicinal products within the terms of Directive 65/65/EEC, and products destined for human and animal consumption and agricultural products ([1]).

The scope of the directive has been extended, since the operation of the information procedure revealed that numerous national regulations and standards involving barriers to intra-Community trade had not been monitored by the Commission and the Member States because certain products were not covered.

In order to clarify the very broad definition which is now used, it is worth recalling that the Court of Justice included in the framework of the provisions relating to the free movement of goods under Article 30 of the Treaty 'products which can be valued in monetary terms and which may, as such, form the subject of commercial transactions' ([2]). In this context, the Court also ruled that waste, whether recyclable or not, is to be considered to be a product whose movement should not, in principle, be prevented ([3]). It is appropriate to take this into consideration in determining the scope of the directive.

It should be emphasised that services are still excluded from the scope of the directive, but that it may be amended in future to cover services related to the establishment of the information society.

2. 'technical specification': a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.

   The term 'technical specification' also covers production methods and processes used in respect of agricultural products as referred to in Article 38(1) of the Treaty, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Council Directive 65/65/EEC, as well as production methods and processes relating to other products, where these have an effect on their characteristics;

This provision defines the concept of technical specification, a generic term which covers standards as well as technical regulations.

It stipulates that the document containing the technical specification defines 'the characteristics required of a product'. The examples given are not exhaustive; the composition of the product, its shape, weight, packaging, presentation, performance, life span, energy consumption, etc., could have been added.

([1]) Within the meaning of Article 38(1) of the Treaty.
([2]) Judgment of 10 December 1968 in Case 7/68, ECR, p. 617.
([3]) Judgment of 9 July 1992 in Case 2/90, ECR I, p. 4431.

The specification can serve a multitude of goals: for example, protection of the consumer, the environment, public health or safety, standardisation of production, improvement of quality, fairness of commercial transactions, maintenance of public order.

The initial version of the directive limited the definition of technical specification to the characteristics required of the product. The broadening of the concept of technical specification to include production processes and methods was carried out in two stages: firstly in 1988 (by Directive 88/182/EEC) with regard to agricultural products, products for human and animal consumption and medicinal products, at the time of their inclusion in the scope of the directive; secondly in 1994 (by Directive 94/10/EC) with regard to other products, for the sake of consistency.

In the field of agriculture, products for human and animal consumption and medicinal products, production methods and processes generally affect the product itself (for example, the obligation to use certain equipment for reasons of hygiene). This is not always the case in the other product sectors, and here the directive makes impact on the product a condition of notification of the production methods and processes concerned, with the specific exclusion of regulations relating to the organisation of work, which does not affect products.

Testing and test methods, quoted as examples of technical specifications, cover the technical and scientific methods to be used to evaluate the characteristics of a given product. The conformity assessment procedures, which are also mentioned, are those used to ensure that the product conforms with specific requirements. They are the responsibility of specialist bodies, whether public or private, or of the manufacturer.

The inclusion of these parameters within the scope of the directive is of the utmost importance, because testing and conformity assessment procedures can, under certain conditions, have negative effects on trade. The multiplicity and disparity of the national systems of conformity certification can cause technical barriers to trade in the same way as the specifications applicable to the products, which are even more difficult to overcome as a result of their complexity.

3. 'other requirement': a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;

The concept of 'other requirement', as defined by this paragraph, does not exist in the initial version of Directive 83/189/EEC. It was introduced by Directive 94/10/EC, at the time of the second amendment of the text.

This term covers requirements which can be imposed on a product during its life cycle, from the period of use through to the phase of management or disposal of the waste generated by it.

The provision specifies that this type of requirement is principally imposed for the purpose of protecting consumers or the environment. These are two of the grounds of major needs which could, in exceptional circumstances, justify a Member State departing from the principle of the free movement of goods by imposing trading bans or restrictions.

The 'conditions of use, recycling, reuse or disposal of a product', quoted as examples of 'other requirements', refer to the most important specific cases. In order to qualify as 'other requirements', these conditions must be likely to have a significant effect on the composition, the nature or the marketing of the product. A decree relating to the management of medicinal waste or a national regulation seeking to impose a return or reuse system for packaging, or even the separate collection of certain products, such as discharged batteries, can therefore be expected to contain provisions which fall into the category of 'other requirements'.

4. 'standard': a technical specification approved by a recognised standardisation body for repeated or continuous application, compliance with which is not compulsory and which is one of the following:

   — international standard: a standard adopted by an international standardisation organisation and made available to the public,

   — European standard: a standard adopted by a European standardisation body and made available to the public,

   — national standard: a standard adopted by a national standardisation body and made available to the public;

This paragraph defines one of the two fundamental concepts of the directive.

It enables a distinction to be made between the concept of 'standard' and that of 'technical regulation', defined in paragraph 9.

In order to be given the status of a standard, a technical specification must, under the terms of the directive, meet four criteria:

1. It is 'approved by a recognised standardisation body'

The body in question, whether it be national (such as the AFNOR ([1]) in France, the DIN ([2]) in Germany and the BSI ([3]) in the United Kingdom), European (CEN ([4]), Cenelec ([5]) or ETSI ([6])), or international (ISO ([7]), or IEC ([8])), must be recognised as such, either by the public authorities by means of approval, a legislative or statutory text, or by the economic operators themselves, whether formally or informally.

The approval of a standard by such a body takes place by a voting procedure which brings the period of public enquiry to an end (also known as a preliminary enquiry) which enables comments to be obtained from the economic and social operators (industrialists, consumers' associations, environmental organisations, etc.).

2. It is destined for 'repeated or continuous application'

This criterion indicates that the standard is intended to be applied to products in general, in other words products normally encountered on the market, and not to products with specific technical characteristics compared with those of products routinely and lawfully marketed. This specific feature constitutes the fundamental difference between a standard and a procurement specification, whether public or private. A standard can be used as a reference in numerous contracts — this is in fact one of its functions — but the specific conditions which the purchaser may wish to have applied to the product (the procurement specifications) will appear, in the call for tender, as requirements in addition to the criteria laid down by the standard.

The concept of continuity in the application of the standard refers to the need to adapt this document to technical progress, which it generally reflects. The appearance of new products and new techniques, more or less continuously — particularly in the area of information

([1]) Association française de normalisation (French Standards Association).
([2]) Deutsches Institut für Normung (German Standards Institution).
([3]) British Standards Institution.
([4]) Comité européen de normalisation (European Committee for Standardisation).
([5]) Comité européen de normalisation électrotechnique (European Committee for Electrotechnical Standardisation).
([6]) Institut européen des normes de télécommunications (European Telecommunications Standards Institute).
([7]) Organisation internationale de normalisation (International Standards Organisation).
([8]) Commission électrotechnique internationale (International Electrotechnical Commission).

technology — creates an increasingly urgent demand for standards from economic operators, who require reference documents in order to organise the market as rationally as possible and ensure the economic success of these products and techniques.

The continuous application of the standard also assumes that the existing standards are constantly updated. A standard which has become obsolete will therefore be cancelled and replaced by a new one, which will take the latest technological advances into account.

3. Compliance with which is not compulsory

The voluntary nature of a standard distinguishes it from a technical regulation, application of which is mandatory. It stems from the principles and from the methods of preparation of a document which is the result of the initiative, voluntary participation and consensus between all the parties concerned: industrialists, scientists, consumer associations, environmental organisations, professional trade associations, etc.

4. It must be made available to the public

This last criterion appears obvious for a document whose application depends on the will of those who wish to use it. It is, nevertheless, important, because it implies that the public must be made aware of the existence of a standard and that its text should be readily accessible. Consequently, the standardisation bodies, whether national, European or international, publish their standards and sell them to the public. They are linked by distribution agreements which enable them to meet the request of anyone wishing to obtain a standard — whether national, European or international — from the body situated in their own country.

This definition of a standard differs slightly from that of the International Standards Organisation (ISO) ([1]) or the (United Nations) Economic Commission for Europe (UNECE), which place more emphasis on the economic role of the standard and the fact that it is the result of a consensus which serves the interests of the majority and is constantly adapted to scientific and technological progress ([2]).

The difference stems from the fact that Directive 83/189/EEC, following the 1979 GATT Code on technical barriers to trade, views standards solely from the viewpoint of combating technical barriers to trade.

The directive bases its definition on a geographical typology of standards, which categorises three types of standards according to the scale on which the issuing organisation works: international standards, European standards and national standards. There are links between these three levels: an international standard can be adopted as a European standard, and a European standard must be adopted as a national standard by the national standardisation bodies. An international standard, on the other hand, will not necessarily be substituted for a national standard on the same subject.

5. 'standards programme': a work programme of a recognised standardisation body listing the subjects on which standardisation work is being carried out;

This paragraph defines the general framework within which all the standardisation bodies, whether they be national, European or international, plan their work within their own structures, during the crucial phase between the definition of the need for a standard and the preparation of a draft for public enquiry.

([1]) ISO, Guide 2, first edition, No 1.2.2.

([2]) See in particular the work by F. Nicolas, *Des normes communes pour les entreprises* (common standards for enterprises), European Commission, Office for Official Publications of the European Communities, on the role of standardisation as a favoured method of organising economic relationships.

At a national level, these programmes are prepared in close collaboration with experts from the economic sectors which are most interested in the preparation of a standard. At the European and international levels, this cooperation takes place between representatives of the various members of these organisations.

The standards programmes of the national standardisation bodies are sent, on request, to the European Commission.

6. 'draft standard': document containing the text of the technical specifications concerning a given subject, which is being considered for adoption in accordance with the national standards procedure, as that document stands after the preparatory work and as circulated for public comment or scrutiny;

This paragraph defines the exact meaning of 'draft standard'; it is not merely an intention to begin the work of standardisation but a very specific stage in the process of preparing the standard, that of public enquiry, the last stage before final adoption of the document.

At this stage, the standard has still not been approved but it contains all the envisaged technical specifications, which makes it easier to identify potential barriers to trade.

7. 'European standardisation body': a body referred to in Annex I;

There are three European standardisation bodies, listed in Annex I to the directive: CEN (European Committee for Standardisation), Cenelec (European Committee for Electrotechnical Standardisation) and ETSI (European Telecommunications Standards Institute) ([1]).

These bodies prepare European standards in specific sectors of activity and the three of them together make up the European standardisation system. They function in an autonomous but coordinated manner.

Most standards are prepared at the request of industry. The Commission can also request these bodies to prepare standards in the context of the implementation of Community legislation. This is known as standardisation work 'mandated' by the Commission in support of the legislation. If these standards are prepared in the framework of the 'new approach' directives, they are known as 'harmonised standards'. The products manufactured in accordance with these standards benefit from a presumption of conformity with the essential requirements of a given directive. Such directives cover, among other things, electro-medical equipment, equipment used in an explosive atmosphere, machine safety, electromagnetic compatibility, etc.

CEN is the European standardisation body whose role is to cover all the sectors not covered by Cenelec or ETSI, such as mechanical engineering, construction and civil engineering, health, biotechnology, the environment, safety at work, gas, transport and packaging, consumer goods, sport and leisure, the food industry, materials, the chemical industry, aerospace, services, quality, testing and certification, etc.

CEN is an international association governed by Belgian law, whose headquarters have been in Brussels since 1975.

Until recently, it had 18 full members — the standardisation bodies of the 15 Member States of the Union ([2]) and of the Member States of EFTA, with the exception of Liechtenstein, which does not have a standardisation body ([3]).

CEN also has affiliate members, these being the standardisation bodies of Cyprus, Turkey, the countries of central and eastern

([1]) The details of these bodies are given in Annex 3 to this booklet.
([2]) Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, the United Kingdom.
([3]) Iceland, Norway, Switzerland.

Europe ([1]) and the Baltic States ([2]), countries which for the most part are already linked to the Union by an associate membership agreement with the prospect of accession, or which are in the process of becoming so. The standardisation body of the Czech Republic has recently been accepted as the 19th full member.

Since June 1992, CEN has enlarged its circle to include 'associate members', organisations representing economic and social interests on a European level, which may take part in preparatory discussions and in the decisions taken by the bodies responsible for administering standards programmes ([3]).

The organs of CEN comprise:

— the General Assembly, a policy body, composed of a representative of each national standardisation body, which directs CEN activities at the highest level; the Board of Directors which is responsible for the general administration of the system; the Central Secretariat, which is responsible for the day-to-day management of its activities; and the Technical Board, which is responsible for the coordination of technical activity and technical decision-making under the procedures for the adoption of standards;

— a system for administering technical activities, organised around the principal sectors of activity;

— the bodies responsible for preparing the standards, which are the technical committees and their working parties, composed of experts who are members of CEN from all the sectors concerned with standardisation (industry, public authorities, scientists, consumers, trades unions) wishing to make a contribution to technical work at a European level.

CEN's administrative costs are covered by the subscriptions of its members and resources allocated by the EC and EFTA, but the lion's share of the total cost of European standardisation, in other words the cost of the expertise required for preparing the standards, is covered by economic operators and particularly by industry.

Cenelec is the European standardisation body in the electrotechnical field. It was established on 13 December 1972, although European electrotechnical standardisation had started in the 1960s.

Like CEN, it is a non-profit-making international association governed by Belgian law whose headquarters are in Brussels. It has 18 full members — the national electrotechnical committees of the Member States of the Union and of EFTA — and several affiliated members.

Cenelec covers the field of safety of electrical and electronic appliances, electronic components and information and telecommunications technology (in cooperation with CEN and ETSI).

In order to provide the electrotechnical industry with the standards it requires, Cenelec has signed cooperation agreements with numerous trade federations and European industrial associations. The latter take part in the standardisation process, particularly at the pre-standardisation stage of the work.

On an international level, Cenelec works closely with the IEC (International Electrotechnical Commission), to which it is linked by an information exchange and cooperation agreement ([4]), comparable with the Vienna Agreement concluded between CEN and ISO.

The organs of Cenelec are, with some minor differences, similar to those of CEN: a General Assembly, a Board of Directors, a Technical

([1]) Albania, Bulgaria, Croatia, Hungary, Poland, Romania, Slovakia, Slovenia.
([2]) Estonia, Latvia, Lithuania.
([3]) European Association for Coordination of Consumer Representation in Standardisation, European Council of Chemical Manufacturers' Federations, European Computer Manufacturers' Association, European Construction Industry Federation, European Trade Union Confederation.
([4]) Lugano Agreement, signed by Cenelec and the IEC in October 1991, which became the Dresden Agreement.

Board, technical committees working in accordance with rules common to both CEN and Cenelec, and subcommittees.

ETSI is the European standardisation body which specialises in the field of telecommunications. It is a non-profit-making association governed by French law which was established in 1988 at the initiative of the European Conference of Postal and Telecommunications Administrations (CEPT). Its headquarters are in Sophia Antipolis (France).

ETSI was formed much more recently than CEN and Cenelec and does not appear in the initial version of Directive 83/189/EEC. It was added when Annex I was amended in 1992 ([1]), after having been officially recognised as a European standardisation body by the Community institutions ([2]).

ETSI arose from the realisation that a pan-European telecommunications infrastructure characterised by a high degree of interoperability was the only way to enable a European market for telecommunications equipment and services to be established. It was created in response to the Green Paper published in 1987 by the Commission of the European Communities on 'the development of a common market for telecommunications services and equipment' ([3]), with a view to accelerating the technical harmonisation which was essential to the growth of networks, industry and new technologies.

Centred on advanced technologies, ETSI is the product of its age; throughout the world telecommunications are constantly finding new applications (communications networks between companies, teleworking, access to scientific databases and games, the development of preventive health care and care at home for the elderly, etc.). However, in addition to these developments in the telecommunications sector, the convergence of information, communications and audiovisual technologies is causing a veritable industrial revolution which will culminate in the information society.

Europe is now participating in this revolution, and the socioeconomic stakes are high. If users are to benefit fully, interconnection and interoperability of operator networks are essential.

The standards published by ETSI contribute to this objective since they are aimed at ensuring the compatibility of new services offered to users as well as of the terminal equipment which is available on the market. These standards cover three main areas:

— multimedia services for industry and the residential market,

— terminal services for personal mobile communications,

— information superhighways, including infrastructure, services and applications.

The structures and operation of ETSI differ considerably from those of CEN and Cenelec. Whereas within CEN and Cenelec the work is organised largely around national delegations, ETSI is an open forum — the only one within the telecommunications field — which groups together all the market operators who wish to take part in its work and use its standards.

National governments, national standardisation bodies, network operators, equipment manufacturers, users, service suppliers, research bodies, consultancy companies, etc. can all be members of ETSI. Membership can be either on an individual basis or through national or European bodies.

([1]) Decision 92/400/EEC of 15 July 1992, OJ L 221, 6.8.1992, p. 55.

([2]) Before the standardisation of telecommunications became established on a European level, the telecommunications sector was almost exclusively covered by national regulations. Since there was no certainty that the Member States would adopt the recommendations of the CEPT, there was no effective harmonisation at the time.

([3]) COM(87) 290 final of 30 June 1987.

ETSI has three member categories: full members, associate members and observer members. All can attend the meetings of the General Assembly, but only full members can vote.

Full members and observer members must be established in a CEPT Member State (Member States of the EU, Member States of EFTA, the countries of central and eastern Europe, Turkey, Cyprus and Malta).

'Associate members' are representatives of non-European countries (for example, Australia and Israel). They can take part in the technical work and attend the General Assembly.

'Observer members' are European organisations which are authorised solely to attend the General Assembly, such as CEN, Cenelec, the CEPT, the ECITC (European Committee for Information Technology Testing and Certification) and the ECMA (European Computer Manufacturers' Association), to name but a few.

In addition, representatives of the European Commission and the EFTA Secretariat play a specific role as 'advisers' to ETSI, as a result of which they can attend meetings of the General Assembly and the technical committees and are invited to meetings of the Board of Directors.

The organs of ETSI comprise:

— the General Assembly, the supreme authority, composed of all the members, which determines general policy and supervises the administration of the institution and its activities;

— the Board of Directors, composed entirely of representatives of full members;

— the Technical Committee, which prepares standards;

— the Secretariat (managed by a chief executive, assisted by a deputy chief executive), which plays an important role in running ETSI and assists in routine administration;

— special committees set up by the General Assembly for specific tasks and for a defined period.

In accordance with the principle of openness governing its organisation, ETSI is a party to various international agreements, notably with the ISO/IEC, the CEPT and the ITU (International Telecommunication Union).

The work of ETSI is financed in part by the EC and EFTA in the context of mandated work for the preparation of standards in support of Community policies. Other resources come from the subscriptions of members of ETSI, contributions from the national telecommunications authorities, and a small amount from the sale of standards.

Although they are precisely defined, the functions of CEN, Cenelec and ETSI inevitably overlap in a number of fields, such as the machinery sector or the sector of information and communications technology (ICT), which is situated at the crossroads between information technology, electronic components and telecommunications networks. Coordination of the work of these three bodies is therefore essential.

This is mainly done through the ICT Standards Board, which is open to economic operators. It was set up in 1995 to coordinate the work and identify market requirements. In order to do this, it examines the requirements contained in standardisation requests which come in particular from the industry high-level strategy group and the European Commission, before organising them into coherent standards programmes. The division of the work between the three bodies takes place within the ICT Standards Board.

The close cooperation between CEN, Cenelec and ETSI is formalised at the highest level by a policy structure common to the three bodies: the joint presidents' group (JPG), which is responsible for ensuring the most efficient administration possible of the areas of overlapping competence. The JPG, which is composed of a delegation of the administrators and secretaries-general of each of the European

standardisation bodies, prepares for this purpose agreements relating to common problems.

It was in this context that an agreement was concluded on the division of tasks for standardisation of electrical vehicles: Cenelec was given responsibility for preparing standards for vehicles connected to the electricity network, whilst CEN is responsible for standards for vehicles independent of the network. The cooperation between Cenelec and ETSI is based on a set of guidelines designed to resolve the difficulties inherent in the overlapping of responsibilities and avoid duplication of effort. The adoption of the Cenelec/ETSI standards programme for the development of harmonised standards guaranteeing electromagnetic compatibility in the field of telecommunications is another example of the kind of cooperation which must be extended, since the standards programmes will increasingly call for the participation of two or even three European standardisation bodies.

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8. 'national standardisation body': a body referred to in Annex II;

The national standardisation bodies referred to in Annex II to the directive are the institutions in the various Member States which are responsible for preparing and publishing standards, in accordance with a procedure which allows all economic and social operators concerned to take part in the work on a voluntary basis ([1]). Their tasks are therefore of general interest.

These bodies, which were for the most part established during the period between the two world wars, are, with one or two exceptions, very similar in terms of their constitution, their organs and their operating methods.

They are, in most cases, centralised bodies ([2]) in the form of associations supported by the public authorities, which use the national standards as reference documents in specifications for the award of public contracts or for the preparation of national technical regulations.

These institutes have the support of bodies which are normally decentralised and ensure the necessary consensus between the economic and social partners, namely sectoral technical committees composed of unpaid experts provided mainly by industry to prepare standards on subjects in the work programme; bodies providing logistical support and bringing about a consensus through a system of public enquiry; and bodies which publish and sell the standards adopted.

The national standardisation bodies are all members of the European standardisation bodies, whether CEN or Cenelec, and generally also of ISO or the IEC.

This simplified description of the national standardisation bodies does not cover differences relating to factors such as:

— the degree of dependence of the standardisation body on the public authorities. The legal form of the relationship between the body and the State, formalised contractually (as in Germany or the United Kingdom) or by regulations (as in France, Italy or Spain), is an indicator of this degree of dependence;

— the respective share of the various sources from which the work is financed: voluntary contributions from industry, the sale of standards and additional services (for example, certification), State subsidies;

— the degree of centralisation of the organs responsible for preparing draft standards, which varies according to whether these or-

([1]) The details of these bodies are given in Annex 3 to this booklet.

([2]) In the United States and Canada, on the other hand, the publication of standards is the responsibility of several hundred specialist organisations, each in a specific sector.

gans are linked to trade associations (as in France or in Germany), or form part of the national institution (as in the United Kingdom);

— the degree of involvement of the national standardisation body in the organisation of the technical work of CEN or Cenelec;

— the size of the body.

. . . . . .

9. 'technical regulation': technical specifications and other requirements, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 10, prohibiting the manufacture, importation, marketing or use of a product;

. . . . . .

In defining the concept of 'technical regulation', Paragraph 9 provides information regarding the type of texts which must be notified under the procedure for the provision of information established by the directive in this field.

On the one hand there are the technical specifications or other requirements (see the above definitions), which are laid down by the Member States and which are applicable to industrial and agricultural products, and on the other there are the laws, regulations and administrative provisions of the Member States which prohibit certain specified activities.

In order to qualify as a technical regulation, a technical specification or 'other requirement' must fulfil the following conditions:

— it must be 'compulsory'. This characteristic, which is inherent in the documents prepared by the public authorities, to which this directive applies, constitutes the major difference between a technical regulation and a standard, which is prepared by private bodies and is in essence voluntary ([1]);

— it must influence the marketing or use of industrial and agricultural products in a Member State or a significant part of that State.

The administrative provisions applicable to a specification or 'other requirement' are also technical regulations within the meaning of the directive. These measures, as with all technical regulations, must be notified under the directive when they emanate from the central governments of the Member States or from one of their bodies as specified in the list drawn up by the Commission in the framework of the Standing Committee of the directive (see Annex 1 to this booklet).

On the other hand, certain technical specifications or other requirements which meet the definition of technical regulations are excluded from the scope of the directive, particularly if they comply with binding Community acts or are limited to implementing a judgment of the European Court of Justice, as specified in Article 10 of the directive.

The binding nature of a technical specification or other requirement may be conferred upon them in two ways:

1. *de jure,* when compliance with the technical specification or other requirement is made compulsory by a measure emanating directly from the relevant public authorities or attributable to the latter.

   By way of example, the conditions regarding the small-scale production of jam and preserved fruit, laid down by decree, will be

([1]) We shall see later, under Article 7(2) of the directive that, in certain cases, compliance with the standard may become mandatory, so that it then acquires the status of a 'technical regulation'.

considered to be a technical regulation which is mandatory *de jure*. The same will apply to a ban on using plastic bottles for the marketing of mineral water, as laid down by ordinance, etc.

2. *de facto,* where the technical specification is not laid down by a formal and binding act of the State concerned, but where the State encourages its observance; as a result of the similar effects which they may have upon trade, these measures are considered equivalent to binding regulations.

   Paragraph 9 gives three examples of the most important and the most frequent *de facto* technical regulations, in order to clarify a concept which was not defined in the initial version of the directive and gave rise to different interpretations that were prejudicial to the correct implementation of the information procedure (1).

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De facto technical regulations include:

— laws, regulations or administrative provisions of a Member State which refer either to technical specifications or other requirements or to professional codes or codes of practice which in turn refer to technical specifications or other requirements and compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions;

  The laws, regulations or administrative provisions referred to are measures adopted by the national authorities which refer to technical specifications or other requirements (2) usually laid down by bodies other than the State (by a national standardisation body, for example), which are not compulsory as such (standards, professional codes or codes of practice), but observance of which is encouraged since it confers on the product a presumption of conformity to the provisions of the aforementioned measures.

  Such is the case, in particular, if a law relating to insurance releases the users of products complying with certain non-mandatory standards from the responsibility of proving conformity to mandatory requirements, since these products benefit from a presumption of conformity to the requirements.

— voluntary agreements to which a public authority is a contracting party and which provide, in the public interest, for compliance with technical specifications or other requirements, excluding public procurement tender specifications.

  Agreements entered into between economic operators which establish technical specifications or other requirements for certain products are not binding as such owing to their origin in the private sector. They are nevertheless considered to be *de facto* technical regulations when the State is a signatory to one of these agreements.

  This circumstance is becomingly increasingly frequent, since such agreements have become instruments of national regulatory policy. They are often used by Member States in the north of the Community in sectors such as the automobile industry, chemical industry and oil industry, in most cases for environmental reasons: to reduce pollutant vehicle emissions or the discharge of harmful substances into water, promote the use of certain types of packaging, etc.

(1) With regard to the possible interpretations of the concept, see the article by S. Lecrenier 'Articles 30 et seq. of the EC Treaty and the monitoring procedures provided under Directive 83/189/EEC' — *Common market review* No 283, January 1985.

(2) In the meaning of Article 1(2) and (3) of the directive, as explained above.

These agreements allow greater flexibility in implementing the measures necessary to attain the objectives of the legislation, and the voluntary participation of the industry involved ensures that they will be achieved.

The State has to be involved in these agreements if they are to fall within the scope of Directive 83/189/EEC. For the public authority to be able to fulfil the information obligation incumbent on it and take account of comments by the Commission or a Member State in the framework of the information procedure laid down by the directive, the State must actually be a contracting party.

— technical specifications or other requirements which are linked to fiscal or financial measures affecting the consumption of products by encouraging compliance with such technical specifications or other requirements; technical specifications or other requirements linked to national social security systems are not included.

The fiscal or financial measures referred to in this paragraph are laid down by the national public authorities for a purpose other than that traditionally pursued by the fiscal legislation of the Member States.

They are considered to be efficient instruments for implementing policies decided at a national level, particularly with a view to protecting the environment and consumers, since they are basically aimed at influencing the behaviour of the latter with regard to a specific product.

This provision of the directive came about because of certain cases of tax incentives granted to 'clean vehicles' which meet certain emission limits or are equipped with catalytic converters. Experience has shown that Member States often linked incentives to conditions, with the result that the system introduced was contrary to Community law, so that it became clear that there was a need to examine such drafts.

The category of measures in question includes, in particular, those which seek to encourage the purchase of products complying with certain specifications, by granting financing facilities (for example, subsidies for the purchase of certain heating appliances or the use of alternative sources of energy such as wind power) or, alternatively, to discourage their purchase (for example the exclusion of grants in the building industry when certain materials are used). It also includes fiscal or financial measures which may affect consumption by encouraging compliance with 'other requirements' within the meaning of the directive (for example, exemption from ecotax for the packaging of given products when a deposit system is set up, or exemption from ecotax for certain products when a collection and recycling system is established).

Directive 83/189/EEC does not cover the whole of the fiscal or financial legislation of the Member States; it only refers to technical specifications or 'other requirements' linked to fiscal or financial measures which have the objective of changing consumer behaviour. The fiscal or financial measure does not, as such, form the subject of examination by the Commission or the Member States; but only that aspect of the technical specifications or other requirements which may form barriers to trade.

It should be emphasised that this provision of the directive does not cover the fiscal or financial measures carried out in support of certain enterprises or products, pursuant to Articles 92 and 94 of the Treaty, relating to State aid, which form the subject of the specific procedure stipulated by the latter.

Measures connected with the national social security systems are also excluded (for example the regulation which makes the refund of a medicine conditional on a certain type of packaging).

National laws, regulations and administrative provisions intended to prohibit the manufacture, importation, marketing and use of a product are considered to be technical regulations, in addition to the technical specifications and other compulsory requirements *de jure* or *de facto*.

Such prohibitions constitute, as it were, the ultimate form of technical specification. Unless they are justified in Article 36 of the Treaty or by essential requirements within the terms of the 'Cassis de Dijon' precedent, they constitute barriers *par excellence* to the free movement of goods within the Community.

This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list to be drawn up by the Commission before 1 July 1995, in the framework of the Committee referred to in Article 5.

The same procedure shall be used for amending this list;

The list of authorities referred to in this paragraph appears in Annex 1 to this booklet.

10. 'draft technical regulation': the text of a technical specification or other requirement, including administrative provisions formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made';

This paragraph defines the concept of 'draft technical regulation': in order to be considered a draft, the technical regulation must be at a stage of preparation which will enable 'substantial amendments' to be made to the text.

The procedure for the provision of information laid down by the directive in the field of technical regulations provides that, on completion of the examination of drafts which it has been sent, the Commission in particular can request the Member States to amend any text which is considered to be contrary to the rules of the internal market.

It is a matter for each Member State to decide, in accordance with the nature of its legislative process, the stage at which its draft technical regulations should be sent to the Commission, as long as it is still possible to make amendments.

This directive shall not apply to those measures Member States consider necessary under the Treaty for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

This provision reinforces a concept already expressed in paragraphs 2 and 3 of the article, to the effect that technical specifications which affect the characteristics of the product are covered.

Chapter II

The procedure for the provision of information with regard to standards

Article 2

1. The Commission and the standardisation bodies referred to in Annexes I and II shall be informed of the new subjects for which the national bodies referred to in Annex II have decided, by including them in their standards programme, to prepare or amend a standard, unless it is an identical or equivalent transposition of an international or European standard.

Article 2 stipulates that the procedure for the provision of information in the field of standards is limited to new work which the national standardisation bodies are planning to initiate, at the time of its inclusion in the standards programme, in other words at a sufficiently early stage to enable interested sectors in the various Member States to take part and their comments to be taken into account.

These new initiatives must be communicated under Directive 83/189/EEC, whether their objective is to establish a new standard or amend an existing standard — but only if the envisaged standard does not arise from the 'identical or equivalent' transposition of an international or European standard.

The reason for this is simple: it is only 'purely' national standards that are likely to act as barriers to the proper functioning of the internal market. An international or European standard should not, in principle, jeopardise the free movement of goods within the European Community, since its technical specifications have been the subject of consensus on a much larger scale than the limits of national boundaries.

Identical transposition means that the national standard includes *in extenso* the text of the international or European standard.

The inclusion *in extenso* of the European standard in sets of national standards is usually the rule. The harmonisation of national standards is achieved when products manufactured in accordance with national standards of one Member State may be considered to comply, without modification, with the national standards of the other Member States.

Equivalent transposition means that the text of the national standard contains certain differences, of a technical nature, compared with the European reference standard, which will not in principle create barriers to the free movement of goods, and which the national standardisation body can be authorised to retain during a specified transition period.

The harmonisation document, which is prepared along the same lines as European standards, is less restrictive for the national standardisation bodies with regard to its inclusion as a standard in national collections. While it must be brought into force at a national level by a public announcement of its title and its index number and by the withdrawal of any contradictory national standard, an institution is free to retain or publish a national standard relating to a subject covered by the harmonisation document, as long as its content is technically equivalent.

In practice, the procedure for the provision of information in the field of standards began on 1 January 1985.

With regard to new draft standards in the areas of responsibility of CEN and Cenelec, the two European standardisation bodies are responsible for the technical operation of the procedure by means of annual contracts concluded with the Commission and the EFTA Secretariat.

Since 1992, the Commission has included two clauses in these contracts regarding the quality of the information, according to which CEN and Cenelec undertake, firstly, to define clearly the internal rules necessary to ensure the accuracy, clarity and reliability of the notifications and, secondly, to equip their respective central secretariats with the resources necessary for monitoring the quality of the information received.

The information is communicated by the national standardisation bodies on a daily basis to the central secretariats of the two European bodies, where it is checked, processed and stored in a database.

The results are then recorded, sector by sector, in a monthly register which is distributed to the members of CEN and Cenelec, in addition to the relevant departments of the Commission (Directorate-General for Industry — DG III/B.2) for examination and comments.

The publication of this register, and its distribution on a national level, is a guarantee of the transparency of the information communicated under the 83/189/EEC procedure.

It is essential that industry and all interested parties know of this instrument and have access to the information in order to be able to exercise the following options open to them:

— to comment on draft standards relating to their sector of activity;

— to apply to take part in the work of the relevant technical committee of a standardisation body in another Member State (for example, a French company could apply to participate in the German committee);

— to suggest that the standard be prepared on a European rather than a national level.

This assumes that the national bodies are consulting industry by distributing the register as widely as possible, particularly through relays allowing easy access to the information.

It is important to emphasise that interested parties, particularly industry, in practice have only a relatively short period of time in which to react. In the case of subsequent litigation, the fact that an objection was not raised will risk negative consequences for those who have not examined the register.

As far as new standardisation subjects in the field of telecommunications is concerned, ETSI has been involved in the information procedure since it was included in Annex I to Directive 83/189/EEC. In practice, this participation was limited, until 1996, to the receipt and evaluation of data provided by the members of CEN and Cenelec and forwarded by the central secretariats of these two bodies, the reason being that national standardisation activity in the field of telecommunications was, until recently, extremely limited.

2. The information referred to in paragraph 1 shall indicate, in particular, whether the standard concerned:

— will transpose an international standard without being the equivalent,

— will be a new national standard, or

— will amend a national standard.

The obligation on the national standardisation bodies to provide details of the nature of the new draft standard has the objective of ensuring transparency and facilitating the examination of notifications. It arises directly from the preceding paragraph. The three categories of standards listed are in fact those which do not correspond to the 'identical or equivalent transposition of an international standard' and must consequently be notified under Directive 83/189/EEC.

— A new draft national standard could contain technical specifications which may constitute a barrier to the free movement of goods if the standard is used restrictively. This can only be ascertained by examining these specifications individually.

— A national standard transposing an international standard (ISO or IEC) may not be equivalent to the original document, since this transposition is not, as such, compulsory and since the national standardisation bodies can decide, on their own account, to make amendments if they consider that the technical specifications are not relevant to their own market. In this case, it is advisable to evaluate the technical specification of the transposed standard with regard to the part which differs from the international standard.

— A national standard can be amended in order to adapt it to the requirements of technical progress. The notification of the draft then makes it possible to examine whether the amendment (addition, modification or removal of certain technical specifications) could introduce new risks of technical barriers to trade within the Community.

In addition, in the course of this examination, the national standardisation bodies, the European standardisation bodies and the Commission can, if they consider that the envisaged amendment would merit setting up a new subject for research on a European level, suggest the preparation of a European standard.

In the field of standardisation, the aim of Directive 83/189/EEC is to ensure the transparency of national initiatives, but it also has a role to play in encouraging the development of European standardisation.

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After consulting the Committee referred to in Article 5, the Commission may draw up rules for the consolidated presentation of this information and a plan and criteria governing the presentation of this information in order to facilitate its evaluation.

Although the operation of the procedure for the provision of information in the field of standards has been delegated by contract to CEN and Cenelec, the Commission itself supervises its proper functioning, in particular by retaining the option of suggesting that the two European standardisation bodies adopt a methodology for the presentation of the collected information, in order to ensure easier processing.

However, the regulations laid down cannot be unilaterally determined by the Commission. It must first seek the opinion of the Standing Committee of Directive 83/189/EEC, the composition, role and operation of which are described in Article 5.

3. The Commission may ask for all or part of the standards programmes to be communicated to it.

   It shall make this information available to the Member States in a form which allows the different programmes to be assessed and compared.

This paragraph supplements paragraph 1. It stipulates that the Commission must not only be informed of new national initiatives but that it must also have access to all the standards programmes drawn up by the national and European standardisation bodies.

In order to fulfil this requirement, the latter are no longer under the obligation, as initially provided under Directive 83/189/EEC, of notifying their standards programmes on an annual basis (through the central secretariats of CEN and Cenelec), but they must communicate all or part of these programmes if the Commission so requests.

The Commission acts as a clearing house for forwarding this information to the Member States.

4. Where appropriate, the Commission shall amend Annex II on the basis of communications from the Member States.

This paragraph stipulates that the Commission has the authority to update the list of national standardisation bodies which appears in Annex II to the directive. This updating is carried out by the Member States, which must provide the Commission with the necessary information.

5. The Council shall decide, on the basis of a proposal from the Commission, on any amendment to Annex I.

This paragraph stipulates that, unlike Annex II, the updating of Annex I, containing the list of officially recognised European standardisation bodies, does not come under the exclusive jurisdiction of the

Commission but requires a decision by the Council of Ministers on the basis of a proposal from the Commission.

Annex I to the directive was, for example, amended in 1992 in order to add ETSI to the list of European standardisation bodies ([1]).

Article 3

The standardisation bodies referred to in Annexes I and II, and the Commission, shall be sent all draft standards on request; they shall be kept informed by the body concerned of the action taken on any comments they have made relating to drafts.

Directive 83/189/EEC stipulates that once they are informed of the preparation of new draft standards in the various Member States, the national standardisation bodies, European standardisation bodies and the Commission shall have the right to require the standardisation body of a Member State to send the text of any draft standard which it has notified. The latter must comply with this request.

It is also required to inform all those who have commented on one of these drafts of the action taken: whether amendment to the draft, the withdrawal of the draft or the justification for retaining it.

Article 4

Article 4 (like Article 7) sets out Member States' obligations with regard to the organisation of the procedure for the provision of information in the field of standards. It is an obligation as to the result, not the means, because whilst a directive must be transposed into internal law by the Member States to which it is addressed, the choice of transposition method is left to the Member States, as long as the objective pursued is attained.

([1]) Decision 92/400/EEC, already cited.

Furthermore, the fact that most of the national standardisation bodies have the status of a private institution reduces the national authorities' scope to give them orders. Hence the very flexible wording of the directive in this context.

1. Member States shall take all necessary steps to ensure that their standardisation bodies:

   — communicate information in accordance with Articles 2 and 3,

This subparagraph stipulates that each Member State must ensure, by whatever means it considers necessary, that its standardisation body does in fact notify all new subjects for standards at the time they are entered in the annual work programme, supplies any draft standard which is requested by the standardisation body of another Member State, a European standardisation body or the Commission, and keeps them informed of the action taken on any comments made on the draft standard.

— publish the draft standards in such a way that comments may also be obtained from parties established in other Member States,

According to this subparagraph, each Member State must ensure that its standardisation body provides parties throughout the Union with the opportunity of commenting on national draft standards. This amounts to extending to the other Member States the public enquiry which, on a national level, is an essential stage at the end of the process of drafting the standard before validation and publication of the definitive text. This formal consultation of all socioeconomic operators enables the national standardisation bodies to be sure that there is total consensus on the text.

Basically, each national body sends, on request, a copy of any draft standard to all the standardisation bodies of the other Member States. This copy is obviously written in the working language of the issuing body. The recipients are responsible for having it translated into their own language and organising a consultation on their own territory, in accordance with the procedures in force in the country (the draft standard is, for example, sent by the national body to the standards engineer responsible for the sector concerned, who in turn passes it on to the relevant standardisation committee which is composed of all the interested parties).

A questionnaire, usually attached to the draft standard by the body which prepared it, calls for comments regarding the objectives of Directive 83/189/EEC (for example, 'Do you think that such a draft may result in barriers to trade?', 'Do you think that it should be used as a basis for European work?', 'Would you like to be involved in the work of preparation on the standardisation committee?', etc.)

The draft is then returned to the issuing body, with comments from all the economic and social operators of the various Member States of the Community.

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— grant the other bodies referred to in Annex II the right to be involved passively or actively (by sending an observer) in the planned activities,

The directive requires all the Member States to ensure that their respective bodies grant another national institute (AFNOR, DIN, BSI, etc.) the right to be involved in the work of preparing a standard, on the relevant technical committee. This right of involvement may be exercised passively or actively.

Active involvement assumes that an observer will be sent (a manufacturer, an economic operator or a standards engineer). If the manufacturer or economic operator is not available, and the decision is taken to send a standards engineer, the latter will need to know the position of industry in his country in order to have sufficient knowledge of the market and to be able to say whether or not the draft standard risks prejudicing the free movement of goods on the market concerned.

Passive involvement is synonymous with involvement at a distance: for example, an expert will give an opinion on a draft standard being prepared in another Member State, without attending the working meetings in the Member State concerned.

The possibility of intervention is evaluated by the national standardisation body, which chooses one or other type of involvement.

The directive cannot formally require national bodies to accept the comments of other national bodies, but acceptance should, in principle, be guaranteed since all standardisation procedures stipulate that a standardisation body should endeavour to take these comments into account.

— do not object to a subject for standardisation in their work programme being discussed at European level in accordance with the rules laid down by the European standardisation bodies and undertake no action which may prejudice a decision in this regard.

In this subparagraph, the directive calls on the Member States to make every effort to ensure that their respective standardisation bodies do not attempt to impede the work of technical harmonisation being carried out by the European standardisation bodies, by preventing a draft standard which they intend to prepare on a national level from ultimately being prepared at the European level.

Directive 83/189/EEC contains such a provision because the national standardisation bodies are all members of CEN and Cenelec and could therefore use their votes, in accordance with purely national interests, to oppose a draft standard being considered at a European

level ([1]). The directive encourages them — through the Member States — to show the solidarity which is indispensable to the common aim of the single market.

2. Member States shall refrain in particular from any act of recognition, approval or use by reference to a national standard adopted in breach of Articles 2 and 3 and of paragraph 1 of this article.

Paragraph 2 stipulates that the Member States cannot abdicate their responsibilities by taking refuge behind those of their respective standardisation bodies, where the latter have adopted a standard in breach of a provision of Directive 83/189/EEC. If they have been unable to prevent the adoption of a document of private origin and voluntary application that contravenes Community law, the Member States must prevent such a standard being used as a reference document, by refusing to recognise it or adopt it formally. In other words, if the national bodies act unreasonably, the national governments should not exploit the situation.

Article 7

1. Member States shall take all appropriate measures to ensure that, during the preparation of a European standard referred to in the first indent of Article 6(3) or after its approval, their standardisation bodies do not take any action which could prejudice the harmonisation intended and, in particular, that they do not publish in the field in question a new or revised national standard which is not completely in line with an existing European standard.

This article stipulates that the Member States must ensure that their respective standardisation bodies observe a standstill period when the work in progress at European level relates to the preparation of a European standard mandated by the Commission. This eventuality is mentioned in the first indent of Article 6(3) of the directive (see below), which provides that the Commission can request the European bodies to prepare a European standard.

In this case, therefore, the Member States must do everything possible to ensure that their standardisation bodies do not carry out any work on the mandated subject: whether with regard to the preparation of a new standard or the amendment of an existing one which is not a European standard *in extenso*.

This standstill period is an expression of the solidarity which must be exercised with a minimum of discipline once the decision has been made to work together on a European level. It is an integral part of the rules of procedure of the European standardisation bodies and is reinforced by Directive 83/189/EEC.

The standstill obligation remains after the adoption of the European standard. As a result, when an industry requires standards in the fields covered by the mandated standard, the work must be exclusively carried out on a European level. By this article, therefore, the directive provides the Community with the means of strengthening the activity of European standardisation.

2. Paragraph 1 shall not apply to the work of standards institutions undertaken at the request of the public authorities to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products.

([1]) A proposal to prepare a European standard, made by a national standardisation body to CEN or Cenelec, has to receive the support of a minimum of countries for the Central Secretariat of CEN or Cenelec to propose its acceptance to the Technical Board.

Member States shall communicate all requests of the kind referred to in the preceding subparagraph to the Commission as draft technical regulations, in accordance with Article 8(1), and shall state the grounds for their enactment.

Paragraph 2 of this article concerns specific cases in which the standards are to be made compulsory. It refers to the State's ability, in certain circumstances, to enforce compliance with the technical specifications for products contained in these standards.

In order to enforce the observance of standards which are essentially voluntary, the State may use two procedures:

— it may request its country's standardisation body to prepare standards in view of establishing technical regulations;

— the State can also make existing standards compulsory, and in doing so, transform them into technical regulations.

In such cases, the procedure applicable to technical regulations, described in the following chapter, is used.

Chapter III

The procedure applicable to technical regulations

Article 8

1. Subject to Article 10, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these have not already been made clear in the draft.

   Where appropriate, and unless it has already been sent with a prior communication, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.

   Member States shall communicate the draft again under the above conditions if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

   Where, in particular, the draft seeks to limit the marketing or use of a chemical substance, preparation or product on grounds of public health or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Council Regulation (EEC) No 793/93 in the case of an existing substance or to Article 3(2) of Directive 67/548/EEC, as amended by Directive 92/32/EEC, in the case of a new substance.

   The Commission shall immediately notify the other Member States of the draft and all documents which have been forwarded to it; it may also refer this draft, for an opinion, to the Committee referred to in Article 5 and, where appropriate, to the committee responsible for the field in question.

   With respect to the technical specifications or other requirements referred to in the second subparagraph of Article 1(9), third indent, the comments or detailed opinions of the Commission or the Member States may concern only the aspect which may hinder trade and not the fiscal or financial aspect of the measure.

2. The Commission and the Member States may make comments to the Member State which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. Member States shall communicate the definitive text of a technical regulation to the Commission without delay.

4. Information supplied under this article shall not be confidential except at the express request of the notifying Member State. Any such request shall be supported by reasons.

   In cases of this kind, if necessary precautions are taken, the Committee referred to in Article 5 and the national authorities may seek expert advice from physical or legal persons in the private sector.

5. When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Community act, Member States may make a communication within the meaning of paragraph 1 under that other act, provided that they formally indicate that the said communication also constitutes a communication for the purposes of this directive.

   The absence of a reaction from the Commission under this directive to a draft technical regulation shall not prejudice any decision which might be taken under other Community acts.

Article 8 lists the obligations of the Member States and the Commission respectively under the procedure for the provision of information in the field of technical regulations, and the possible reactions open to them, apart from reactions relating to standstill periods to be respected before the adoption of the notified drafts, which are referred to in Article 9 of the directive.

First stage: the obligation to inform

(a) The Member States' obligations

1. General rules

In order to guarantee the transparency of national initiatives, Article 8 requires the Member States to communicate immediately to the Commission any draft technical regulation which they plan to adopt.

The full text of the draft regulation must usually be sent; however, when the draft involves the incorporation in full of an international or European standard into internal law, the Member State may make reference to the standard rather than communicate the full text ([1]).

The Member State must also send the Commission the text of the basic legislative and regulatory provisions, informing it of the legal context of the notified draft and enabling it to assess the implications (for example, the text to be amended by the draft). If these basic legislative and regulatory provisions are not sent, the Commission can request them on receipt of the draft.

This obligation is coupled with an obligation to notify the grounds justifying the enactment of the proposed measures ([2]). The nature of the grounds given obviously does not prejudge the action which will be taken with regard to the notification of the draft technical regulation.

In practice, each Member State nominates a central unit which is to be responsible for sending information to the Commission and the national ministries (a list of these central units and their addresses is given in Annex 2 to this booklet). Notification to the Commission takes the form of a message to the relevant department ([3]).

This 'notification message' is coded in 14 points, each of which corresponds to a specific item of information. Point 9, for example, must provide clear grounds. The Member State notifying the draft must explain, in a maximum of 10 lines, the grounds for its preparation.

At the end of the national process of adopting regulatory provisions, the Member States must send the Commission the definitive text of the technical regulation (see Article 8(3)). The Commission will thus be in a position to consider whether the Member State has respected all its obligations under the procedure and, if appropriate, to take any measures necessary.

If, therefore, the Member State has adopted a text without taking account of the detailed opinions issued by the Commission or the other Member States on the draft regulation, the Commission can initiate the infringement procedure provided for in Article 169 of the Treaty ([4]). Where the Commission sends a detailed opinion to the

([1]) This reference enables the Commission, and the Member States which wish to do so, to obtain without difficulty the text of the standard which has been made compulsory.

([2]) An examination of the grounds presented shows that they most often relate to the application of international, Community or national law; the protection of persons, animals, the environment, public safety, consumer information; technical reasons (for example, adaptation to technical progress); certification requirements; the introduction or amendment of methods of analysis or inspection; the removal of barriers to trade.

([3]) Directorate-General III, Industry, Unit B.1, Coordination of regulatory activities. See Annex 2 to this booklet.

([4]) Article 169 provides that 'If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations. If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.'

notifying Member State which the latter then fails to take into account, the detailed opinion in question can be regarded as a letter of formal notice, which has the advantage of accelerating the infringement procedure.

The Member States themselves can bring the matter before the Commission, under Article 170 of the Treaty, in order to institute infringement proceedings before the Court of Justice of the European Communities against a Member State which they consider to have failed to fulfil its obligations ([1]).

2. Specific cases

2.1.
Under Directive 83/189/EEC, Member States are not obliged to communicate again a draft technical regulation which has already been communicated under another Community act. In this case, they must indicate that the communication in question also applies for the purposes of Directive 83/189/EEC.

This provision of the directive (see Article 8(5)) reflects the Commission's desire to reduce bureaucracy in the event of overlapping notification procedures, where several Community directives require Member States to inform the Commission of their intention to legislate in a specific area, i.e. to notify the same text at the draft stage. Member States are not, however, released from the requirement to comply with the obligations specified in each Community act. Following the official communication that it is valid for several Community procedures, the national draft is thus examined on its own merits on the basis of each Community act to which it refers, and is the subject of a Commission opinion under each procedure.

This is why the absence of a Commission reaction to such a text under Directive 83/189/EEC 'shall not prejudge any decision which might be taken under other Community acts' (see the second subparagraph of Article 8(5)).

The Member States are responsible for indicating all the procedures under which the national draft is notified, on the basis of the information provided in the text of the Community legislation governing the field covered by the draft.

In practice, a 'one-stop shop' has been established for the food sector ([2]), with a view to reducing Member States' administrative costs.

In accordance with this system, the latter always notify their drafts under Directive 83/189/EEC, independently of the notification procedure(s) which may be legally applicable. Member States shall clearly indicate, at the time of communication, the procedures in accordance with which they intend to submit their drafts.

When the subject of the draft is exclusively covered by a specific procedure, the 83/189/EEC procedure is set aside; if this is not the case, the part which is not covered by the specific procedure will be examined by the Commission under Directive 83/189/EEC and, for the remainder, the specific procedure will take its course ([3]).

([1]) Article 170 provides that 'A Member State which considers that another Member State has failed to fulfil an obligation under this Treaty may bring the matter before the Court of Justice. Before a Member State brings an action against another Member State for an alleged infringement of an obligation under this Treaty, it shall bring the matter before the Commission. The Commission shall deliver a reasoned opinion after each of the States concerned has been given the opportunity to submit its own case and its observations on the other party's case both orally and in writing. If the Commission has not delivered an opinion within three months of the date on which the matter was brought before it, the absence of such opinion shall not prevent the matter from being brought before the Court of Justice'.

([2]) A sector with overlapping notification procedures (see in this connection Directive 79/112/EEC of 18 December 1978 regarding the labelling and presentation of foodstuffs, OJ L 33, 8.2.1979, page 1, Council Regulation No 315/93 of 8 February 1993 relating to the establishment of Community procedures regarding contaminating substances in foodstuffs, OJ L 37, 13.2.1993, page 1, and Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs , OJ L 175, 19.7.1993, p. 1).

([3]) Thus, for example, when a draft national technical regulation lays down specifications for the labelling of foodstuffs which exceed the requirements of Directive 79/112/EEC, the procedure referred to in Article 16 of that directive shall apply.

Furthermore, with regard to protection of the environment, Directive 94/62/EC relating to packaging and packaging waste ([1]) expressly stipulates that the procedure under Directive 83/189/EEC applies to all draft measures which Member States plan to adopt in this area.

2.2.
With the same concern for efficiency, Member States are exempt from the obligation to send the Commission the text of the basic legislative and regulatory provisions concerning a draft technical regulation, if this text has already been sent with a prior communication. This is the case, for example, when a draft technical regulation which has already been notified must be notified again because it has been significantly amended (see the third subparagraph of Article 8(1)).

2.3.
Conversely, Directive 83/189/EEC introduces a new obligation for Member States with regard to draft technical regulations designed to limit the marketing or use of a substance, a preparation or a chemical product for reasons of public health, the protection of consumers or the environment (see the fourth paragraph of Article 8(1)).

In addition to the obligation to communicate the text of the draft and notify the grounds for its enactment, Member States must also supply additional documentation to the Commission.

In order to fulfil this obligation, they must send a summary of or references to all the relevant facts available on the substance, the preparation or the chemical product concerned and any known substitute, the foreseeable effects of the measure, and the results of the risk analysis.

In this respect, the directive specifies that the analysis must be carried out in accordance with the general principles laid down in two Community acts: Council Regulation 793/93/EEC of 23 March 1993 ([2]), in the case of existing substances and Council Directive 67/548/EEC, as amended by Directive 92/32/EEC of 30 April 1992 ([3]), in the case of new substances.

2.4.
Member States must notify again a draft which has already been examined under the provisions of Directive 83/189/EEC, if they have made significant amendments to the text in the meantime.

The third subparagraph of Article 8(1) specifies that amendments made to the text are considered to be significant if they have the effect of altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

If a Member State nevertheless has doubts whether the amendments made to its technical regulation since the initial notification are significant, it can consult the Commission on the need for a fresh notification ([4]).

It should be emphasised that notification is not necessary in the case of a simple restatement of provisions which are already applicable (for example, in the event of consolidation) and do not have new legal effect.

([1]) Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ L 365, 31.12.1994, p. 10.
([2]) Regulation on the evaluation and control of the risks of existing substances, OJ L 84, 5.4.1993, p. 1.
([3]) Directive amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 154, 5.6.1992, p. 1.
([4]) At the time of adoption of Directive 94/10/EC, which amended Directive 83/189/EEC for the second time, the Council and the Commission made a declaration in the minutes inviting the Member States to consult the Commission prior to amendments, in circumstances where there were doubts relating to their impact.

(b) The obligations of the Commission

When the Commission has been notified of a new draft national technical regulation, it must send all the information communicated by the notifying Member State to all the other Member States (the draft will simultaneously be sent to all the Commission departments which may be concerned by the notified regulation as a result of their specific or horizontal responsibilities).

This communication of information enables all the Member States to be fully involved in the monitoring procedure laid down by the directive, and offers all the economic operators in the internal market the opportunity to express their views on draft national legislation (except where the notifying Member State expressly requests, with justification, that the information communicated to the Commission should exceptionally be treated as confidential with regard to economic operators).

The directive makes provision for the Commission to submit the draft to the Standing Committee (see Chapter IV) or 'to the committee responsible for the field in question' for an opinion. These are committees which cover sectoral directives, like the ACTE Committee, established by Directive 91/263/EEC ([1]) for the telecommunications sector or the 'Recreational Craft Committee', established by Directive 94/25/EC ([2]) for the recreational craft sector.

In practice, the Commission is responsible for administering the procedure for the provision of information in the field of technical regulations. The whole procedure, including the reactions to the notified projects, is based on a system of electronic data exchange, transmitted in accordance with a nomenclature set up by the Commission.

The Directorate-General for Industry (DG III) ([3]) acts as the central point for the receipt of all messages, texts and notifications communicated by the Member States, regardless of the field of the draft technical regulation (telecommunications, mechanical engineering, food and agricultural products, transport, construction, etc.).

The information which is circulated under the procedure is re-communicated by the Commission, firstly in the language of the notifying Member State and then in the form of translations into all or some of the official languages of the Union.

Second stage: possible reactions open to the Commission and the Member States (comments, detailed opinions, 'blockage')

During the three months following the notification of a draft (this period corresponds to the standstill period referred to in Article 9(1)), the Commission and the Member States examine the notified text in order to ascertain its compatibility with Community law, particularly with Articles 30 and 36 of the Treaty and to reach a decision, where necessary, on its consistency with Community policies in the sector concerned.

The results of this evaluation can give rise to two types of reaction by the Commission and the Member States (the Commission has, in addition, a specific option: 'blockage' of the draft as a result of harmonisation work, which will be examined below in the comments on Article 9 of the directive). The various reactions, whose impact is proportional to the seriousness of the findings, are as follows:

([1]) Council Directive of 29 April 1991 relating to the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, OJ L 128, 23.5.1991, p.1

([2]) European Parliament and Council Directive of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, OJ L 164, 30.6.1994, p.15.

([3]) See Annex 2 to this booklet.

1.
The Commission and/or the Member States can decide that the draft technical regulation is not of a nature to form barriers to the free movement of goods and calls for no specific comment.

In this case, neither the Commission nor the Member States react during the three-month period (1). At the end of this period, the notifying Member State can adopt its draft regulation, without further obligation.

This right does not, however, exclude subsequent intervention by the Commission, outside the procedure under Directive 83/189/EEC, if the regulation as finally adopted should prove to be contrary to the Treaty or to secondary legislation.

2.
The Commission and the Member States can send comments or a detailed opinion to the Member State which notified the draft technical regulation.

Comments are sent when the notified text, although in accordance with Community law, raises issues of interpretation or calls for details of the arrangements for its implementation. They can also give an overall assessment of the measure, having regard to the general principles of Community law and policies implemented in this context, or inform the Member State of its future obligations with regard to acts to be adopted on a Community level.

Directive 83/189/EEC provides, in Article 8(1) (last subparagraph), that the comments and detailed opinions issued with regard to technical specifications or other requirements linked to fiscal or financial measures can only relate to aspects which may create barriers to the free movement of goods and not to the fiscal or financial side of the measure. The Member States' fiscal powers are thus preserved. The drafts concerned also benefit from special treatment with regard to the standstill periods (see Article 10(4): no period is laid down for the adoption of these texts by Member States).

Under the directive, the notifying Member State has no formal obligation to reply to the comments received. In practice, however, the Member State frequently does so on a voluntary basis, which is much appreciated.

The directive stipulates that the Member States must take comments into account 'as far as possible' (Article 8(2)). The restrictive nature of this phrase indicates that the fact of not having amended the notified text on the basis of the comments received does not, in principle, result in initiation of the infringement procedure referred to in Article 169 of the Treaty. Member States do, however, generally take account of the comments they receive.

Detailed opinions (mentioned later, together with their consequences, in Article 9 of the directive) are sent by the Commission or the Member States when factors concerning the operation of the internal market oppose their acceptance of the draft as it stands. These detailed opinions seek to obtain an amendment to the proposed measure, in order to remove at source any resulting barriers to the free movement of goods.

These difficulties relate to the illegality of the draft in terms of Community law, either through a breach of Article 30 of the Treaty (the most frequent breaches of this provision are the absence in the text of a clause of mutual recognition of equivalent technical specifications established by another Member State, or the fact that some of the provisions of the draft are disproportionate to the pursued objective), or through a breach of a Community harmonisation directive, a regulation or a decision.

(1) Although it is not sent to the notifying Member State, the decision not to follow up the notification is a formal decision by the Commission.

A detailed opinion may not, under any circumstances, be issued against draft regulations which seek manufacturing prohibitions but which do not constitute a potential barrier to the free movement of goods.

Member States must reply to a detailed opinion addressed to them by the Commission or another Member State. Although the directive does not specify the time allowed for reply, it is nevertheless desirable that a response be made as soon as possible in the interests of efficiency.

If a Member State considers that the response to its detailed opinion is unsatisfactory, it has the right, in the event of adoption of the notified draft, to institute the infringement proceedings provided for by Article 170 of the Treaty. If the Commission considers that the reply to its detailed opinion is unsatisfactory, it can use the procedure referred to in Article 169 of the Treaty.

3.

The Commission can announce a Community initiative on the subject of the proposed national measure. This is known as 'blockage'. The consequences of this reaction, which is for the exclusive use of the Commission, are described in Article 9(3), (4) and (5) of the directive.

Article 9

1. Member States shall postpone the adoption of a draft technical regulation for three months from the date of receipt by the Commission of the communication referred to in Article 8(1).

2. Member States shall postpone:

— for four months the adoption of a draft technical regulation in the form of a voluntary agreement within the meaning of Article 1(9), second indent,

— without prejudice to paragraphs 3, 4 and 5, for six months the adoption of any other draft technical regulation,

from the date of receipt by the Commission of the communication referred to in Article 8(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of goods within the internal market.

The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.

Article 9 relates to the timing involved in notification. The date of receipt by the Commission of the draft national technical regulation communicated by a Member State and of all the requested documents is the signal for the beginning of a period during which the Member State concerned is strictly obliged not to adopt the draft in question.

This period is commonly known as the standstill period.

The three-month period referred to in Article 9(1) is the initial standstill period. It represents the period which is considered to be necessary in order to allow the Commission and the other Member States to examine the notified draft text and to react to it if necessary ([1]).

In addition to this period, the notifying Member State is subject to an additional standstill period, varying in length according to the nature of the text and the type of reaction it receives. Although comments sent to the Member State do not result in an extension of the initial three-month standstill period, the same does not apply to detailed opinions sent by the Commission or the other Member States.

([1]) With the exception of: (a) urgent cases, (b) laws, regulations or administrative provisions by Member States prohibiting manufacture, as long as these do not form barriers to the free movement of goods (see Article 10(2)), (c) technical specifications or other requirements connected with financial or fiscal measures (see Article 10(4)).

In the event of a detailed opinion relating to a voluntary agreement, the directive stipulates that the Member States must respect a standstill period of four months (Article 9(2)). It adds only one month to the initial standstill period so that the Member States do not lose time in gaining the benefit of measures, the effectiveness of which is a satisfactory alternative to legislation.

The standstill period is extended to six months for all other drafts which are the subject of a detailed opinion. A Member State to which such an opinion is addressed must inform the Commission of the actions it intends to take (revocation of the disputed text, justification for retaining it, or the amendment of certain provisions in order to render them compatible with the rules of the internal market), irrespective of whether another Member State or the Commission was the author. The Commission will comment, in turn, on the actions envisaged by the Member State in response to the detailed opinion, in order to let the Member State know whether these measures are suited to eliminate the barriers to the free movement of goods which may have resulted from the adoption of the text, or whether the justification given for retaining the text is acceptable.

3. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 8(1) if, within the three months following that date, the Commission announces its intention to propose or adopt a directive, regulation or decision in accordance with Article 189 of the Treaty.

4. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 8(1) if, within the three months following that date, the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the Council in accordance with Article 189 of the Treaty.

5. If the Council adopts a common position during the standstill period referred to in paragraphs 3 and 4, that period shall, subject to Article 9(6), be extended to 18 months,

Paragraphs 3, 4 and 5 of Article 9 stipulate much longer standstill periods as a result of the blockage imposed by the Commission — and by the Commission alone — following examination of the draft.

This reaction, the most serious consequence for the Member States in terms of time, is intended to prevent the notified draft from adversely affecting a legislative harmonisation process which has commenced at Community level.

The blockage of a draft national regulation can be imposed by the Commission in three specific cases:

1.
Paragraph 3 covers the first case: the Commission announces its intention to propose or adopt a directive, regulation or decision (in other words any of the binding Community acts under Article 189 of the Treaty) on the same subject as the text of the draft technical regulation.

This paragraph does not specify what is meant by 'the intention' to propose, but it concerns an intention that has been explicitly expressed, for example through inclusion in the Commission's annual legislative programme.

Member States must then respect a standstill period of 12 months.

2.
In the second case (paragraph 4), the Commission finds that the notified draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the Council.

In this case, as in the preceding case, the notifying Member State must respect a standstill period of 12 months.

3.
Paragraph 5 envisages the third specific case, when the Council adopts a common position during the twelve-month blockage imposed in the two previous situations.

The directive then stipulates that the standstill period imposed on the Member States is extended to 18 months.

It should be emphasised that the 'common position' referred to represents a stage of the Community legislative process under the procedures of cooperation ([1]) and co-decision ([2]), the first involving the European Parliament in the Council's decision-making power and the second giving it the power to adopt, jointly with the Council, certain regulations, decisions and directives.

These two procedures provide for a second reading of the text by the Parliament, which explains the need to extend the standstill period.

6. The obligations referred to in paragraphs (3), (4) and (5) shall lapse:

   — when the Commission informs the Member States that it no longer intends to propose or adopt a binding Community act,

   — when the Commission informs the Member States of the withdrawal of its draft or proposal,

   — when the Commission or the Council has adopted a binding Community act.

Paragraph 6 concerns the expiry of the standstill periods imposed on the Member States in the case of the Commission blocking a draft technical regulation.

Since blockage allows the adoption of national legislation to be postponed without precise knowledge of the length of the process which will lead to the final approval of Community legislation, the Commission uses this instrument with caution.

It is logical that, where Community action which is envisaged or in progress does not produce a result, the standstill obligations imposed by paragraphs (3), (4) and (5) should lapse in order to allow the Member States to complete the postponed legislative work at a national level and to adopt the technical regulation.

These standstill obligations also lapse when the Council or the Commission adopts a binding Community act, as Member States are bound by these acts and may no longer introduce a different technical regulation on the same subject.

7. Paragraphs 1 to 5 shall not apply in those cases where, for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible. The Member State shall give, in the communication referred to in Article 8, the reasons which warrant the urgency of the measures taken. The Commission shall give its views on the communication as soon as possible. It shall take appropriate action in cases where improper use is made of this procedure. The European Parliament shall be kept informed by the Commission.

([1]) Procedure established by the Single European Act in 1986 and then introduced as Article 189c of the EC Treaty by the Maastricht Treaty.
([2]) Article 189b, introduced into the EC Treaty by the Maastricht Treaty.

This paragraph provides that the standstill periods are not applicable when a Member State, in order to respond to an urgent and unforeseeable situation such as, for example, a natural disaster (the need to protect people, the atmosphere, soil or water), an epidemic, an animal epidemic, etc., is obliged to prepare technical regulations for immediate introduction, without having time to consult the Commission and the other Member States beforehand.

These exceptional circumstances do not exempt the Member State from the obligation to inform the Commission of the planned measures and clearly justify its request for urgency at the time when the text is communicated. The Commission has to assess whether the use of the urgency procedure is justified and to give its views on the communication as quickly as possible.

In practice, the Commission carries out a very thorough analysis of the reasons given, on the basis of the two criteria contained in this paragraph: the seriousness of the situation and its unforeseeable nature.

If the Commission considers that these criteria are not met, it disputes the justification of urgency; conversely, the Commission may accept application of this procedure. This does not prejudice the Commission's assessment on the merits, namely its analysis of whether the measure adopted may form a barrier in any way.

In the event of the adoption of measures whose urgency has been disputed, without observance of the standstill period, the Commission can institute the infringement procedure referred to in Article 169 of the Treaty against the Member State concerned.

Article 10

This article supplements Articles 8 and 9 of the directive, by stating the statutory exceptions to the obligation to notify a draft national technical regulation. It also provides for certain exceptions to the obligation to comply with the standstill periods stipulated in Article 9.

1. Articles 8 and 9 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements by means of which Member States:

   — comply with binding Community acts which result in the adoption of technical specifications;

   — fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications in the Community;

The limits to this exception can best be illustrated with reference to the fundamental objective of the directive, which is the elimination of unjustified trade barriers.

If the Member States adopt the same set of rules as required by a Community directive, trade barriers and differences between national laws are removed at the same time, and the procedure laid down by Directive 83/189/EEC is no longer needed.

This reasoning is the same with regard to international agreements: when such an agreement contains precise provisions and there is no scope for divergence, the adoption by the 15 Member States of a uniform set of rules is not, in principle, likely to result in trade barriers.

The situation is different when the Community act or the international agreement is implemented through measures which may differ from one Member State to another, or when uniform provisions, which have to be transposed, are supplemented by rules which are of purely national origin.

— make use of safeguard clauses provided for in binding Community acts;

The Member States do not have to notify the Commission of the draft provisional measures which they are authorised to take under the safeguard clause contained in Community directives, in accordance

with Article 100a of the Treaty. This article lays down in paragraph 5 that 'The harmonisation measures (...) shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Community control procedure'.

These non-economic reasons can relate to public morality, public order or public security, the protection of the health and life of humans, animals or plants, the protection of national treasures possessing artistic or archaeological value or the protection of industrial and commercial property.

— apply Article 8(1) of Council Directive 92/59/EEC ([1]);

The Member States do not have to notify draft national technical regulations relating to the application of Article 8(1) of the directive on general product safety.

This article provides that 'where a Member State adopts or decides to adopt emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use within its own territory, of a product or product batch, by reason of a serious and immediate risk presented by the said product or product batch to the health and safety of consumers, it shall forthwith inform the Commission thereof, unless provision is made for this obligation in procedures of a similar nature in the context of other Community instruments (...)'.

— restrict themselves to implementing a judgment of the Court of Justice of the European Communities;

The Member States do not have to notify national measures which have the sole objective of implementing a judgment of the Court of Justice relating to an aspect other than the notification of a technical regulation. Judgments by this Court, which is responsible for ensuring compliance with Community law, must be enforced immediately.

— restrict themselves to amending a technical regulation within the meaning of Article 1(9) of this directive, in accordance with a Commission request, with a view to removing an obstacle to trade.

The Member States are not required to notify national measures aimed solely at amending a technical regulation in order to remove obstacles in response to a request from the Commission (for example, a request for the inclusion of a mutual recognition clause, based on Article 30 of the Treaty), since these measures are precisely in accordance with the objective of Directive 83/189/EEC.

2. Article 9 shall not apply to the laws, regulations and administrative provisions of the Member States prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9(3) to (6) shall not apply to the voluntary agreements referred to in Article 1(9), second indent.

4. Article 9 shall not apply to the technical specifications or other requirements referred to in Article 1(9), third indent.

([1]) Directive of 29 June 1992 on general product safety, OJ L 228, 11.8.1992, p. 24.

Under the terms of paragraphs 2 and 4, a standstill period does not apply to measures seeking to prohibit manufacturing, to the extent that these do not obstruct the free movement of goods within the Community, or to technical specifications or other requirements linked to fiscal or financial measures.

In the first case, it is obvious that postponement of the adoption of measures only makes sense if the manufacturing prohibitions present a potential risk of constituting a technical barrier to trade in the internal market. In the second case, it was considered inopportune to require postponement of adoption of the category of measures concerned.

As far as draft regulations linked to fiscal or financial measures are concerned, the absence of the standstill obligation for the notifying Member State does not exclude the Commission or another Member State from reacting to these drafts by means of comments or detailed opinions (see Article 8(1)).

Under the terms of paragraph 3, standstill obligations applicable to draft national regulations concerning a subject covered by current or imminent Community work do not apply to voluntary agreements.

It may be concluded from the reading of Articles 8, 9 and 10 of Directive 83/189/EEC that the information procedure applicable to technical regulations is highly complex. The handbook produced by the Commission departments explains in detail how the procedure operates in practice ([1]).

Furthermore, the directive's provisions on technical regulations impose very strict obligations on the Member States (much more restrictive than those applicable to standards), which are balanced by the right to react to draft national regulations being prepared by other Member States.

Where the Member States fail to meet their obligation to communicate their draft technical regulations to the Commission, or do not observe the standstill periods laid down in the directive, the Commission can institute infringement proceedings, under Article 169 of the Treaty, as already mentioned ([2]).

When the Member State concerned does not comply, the procedure leads to a judgment of failure to fulfil obligations by the Court of Justice ([3]).

Private individuals can, for their part, rely on the fact that technical regulations with which they are required to comply, but which have not been notified, cannot be enforced against them ([4]).

([1]) Standing Committee Document 94/94 — final of 8 June 1995.
([2]) National publications containing technical regulations are monitored to identify texts adopted in breach of the directive.
([3]) Reference is made to these judgments in Point III of the bibliography.
([4]) See the 'CIA security' judgment of 30 April 1996, which will be discussed in Chapter VI.

Chapter IV

The Standing Committee

Article 5

A Standing Committee shall be set up consisting of representatives appointed by the Member States who may call on the assistance of experts or advisers; its chairman shall be a representative of the Commission.

The Committee shall draw up its own rules of procedure.

Article 6

1. The Committee shall meet at least twice a year with the representatives of the standards institutions referred to in Annexes I and II.

2. The Commission shall submit to the Committee a report on the implementation and application of the procedures set out in this directive, and shall present proposals aimed at eliminating existing or foreseeable barriers to trade.

3. The Committee shall express its opinion on the communications and proposals referred to in paragraph 2 and may in this connection propose, in particular, that the Commission:

   — request the European standards institutions to draw up a European standard within a given time limit,

   — ensure where necessary, in order to avoid the risk of barriers to trade, that initially the Member States concerned decide amongst themselves on appropriate measures,

   — take all appropriate measures,

   — identify the areas where harmonisation appears necessary, and, should the case arise, undertake appropriate harmonisation in a given sector.

4. The Committee must be consulted by the Commission:

   (a) before any amendment is made to the lists in Annexes I and II (Article 2(1));

   (b) when drawing up the rules for the codified presentation of information and the plan and criteria for the presentation of standards programmes (Article 2(2));

   (c) when deciding on the actual system whereby the exchange of information provided for in this directive is to be effected and on any change to it;

   (d) when reviewing the operation of the system set up by this directive;

   (e) on the requests to the standards institutions referred to in the first indent of paragraph 3.

5. The Committee may be consulted by the Commission on any preliminary draft technical regulation received by the latter.

6. Any question regarding the implementation of this directive may be submitted to the Committee at the request of its chairman or of a Member State.

7. The proceedings of the Committee and the information to be submitted to it shall be confidential.

However, the Committee and the national authorities may, provided that the necessary precautions are taken, consult, for an expert opinion, natural or legal persons, including persons in the private sector.

Articles 5 and 6 describe the composition and role of the Standing Committee, which is referred to repeatedly in the provisions of Directive 83/189/EEC.

The Committee is composed of representatives of the Member States' national authorities and chaired by a representative of the Commission, and is also the consultative body for Directive 83/189/EEC, with competence for standards and technical regulations ([1]), and a focal point for discussion of all the problems connected with the implementation of the directive. It therefore plays a very important role in supervising the operation of the procedure and in the examination of policy issues raised by the notifications.

([1]) Hence its current title: 'Standards and Technical Regulations Committee' or '83/189/EEC Committee'.

The operating rules of this body have been agreed by the Member States and the Commission, since Directive 83/189/EEC stipulates that the Committee shall draw up its own rules of procedure. The only rules imposed by the directive on the Standing Committee are the obligation to meet representatives of the European and national standards institutions at least twice a year, and to guarantee the confidential nature both of the information submitted to it and of its proceedings.

This duty of discretion does not, however, prevent the Committee and the national authorities from using the expertise of natural persons or legal entities in the private sector, who are capable of examining and forming an opinion on the notified drafts. This advice can in fact be indispensable, since the national authorities of the Member States do not always have the necessary knowledge and resources to carry out this task. The directive makes this possible unless, in accordance with Article 8(4), the Member States expressly request that notifications which they have carried out be treated confidentially as an exception. In this case, the Committee must take the necessary precautions in order to safeguard the legitimate and duly justified interests of the Member States.

In practice, the Standing Committee meets approximately five times per year. These meetings are convened by the Commission.

Because of its varied responsibilities, the Standing Committee has general powers, common to the two aspects of Directive 83/189/EEC, and specific powers limited to each of them.

1. General powers

In its capacity as a consultative body, any question relating to the implementation of the directive can be brought before the Standing Committee at the request of its Chairman or of a Member State.

In addition, it must be consulted by the Commission on certain points, including the choice of the system to be used in practice for the exchange of information laid down by the directive ([1]).

The Committee expresses an opinion on proposals presented by the Commission in order to limit existing or potential trade barriers: it can, for example, ask the Commission to encourage dialogue between the Member States, so that they can find — in application of the subsidiarity principle — solutions between themselves. The encouragement of such dialogue is in accordance with the spirit of Directive 83/189/EEC, which seeks to remove barriers at source, by prevention rather than coercion.

Every two years, the Commission presents to the Committee the report which it will send to the European Parliament and the Economic and Social Committee of the European Communities on the results of the application of the directive (see Article 11).

2. Specific powers under the procedure applicable to technical regulations

The meetings of the Standing Committee enable the Commission departments and the Member States to exchange views on all aspects of the application of the 'technical regulations' part of the directive.

The Standing Committee can specifically request the Commission to identify those areas in which harmonisation of national legislation is necessary and to begin work at a European level (the preparation of a proposal for a directive or a regulation).

It must give its opinion on the rules regarding the codified presentation of information, both when these rules are drafted and when they are adapted to each amendment of Directive 83/189/EEC ([2]). It

([1]) System described in the handbook already mentioned — Doc. 94/94 final.

([2]) The nomenclature established for transmitting messages between the Commission and the Member States underwent, for example, numerous changes when the directive was amended for the second time, in order to take account of *de facto* technical regulations, the 'other requirements' concerning the life cycle of the product when it has been placed on the market, and the new standstill periods.

draws up a list of national authorities, other than central governments, whose technical regulations fall within the scope of the directive (see Annex 1 to this booklet) and examines any draft amendment to Directive 83/189/EEC. The Committee is also the forum for discussion of numerous issues, from technical problems encountered in the exchange of information by electronic mail, to the difficulties arising from the overlapping of the 83/189/EEC procedure and the notification procedures provided for by other Community acts, or certain notified draft technical regulations which are placed on the agenda with a view to finding solutions to specific problems raised.

Apart from the 83/189/EEC Committee, meetings organised within the Member States, known as 'package' meetings, extend where necessary direct contacts between the representatives of the national authorities responsible for drafts and the Commission departments.

These meetings also provide an opportunity for contacts with the representatives of the central units of the Member States responsible for the application of Directive 83/189/EEC, with a view to settling practical problems encountered in the application of the information procedure and finding solutions which will enable infringement proceedings instituted by the Commission for non-notification of draft national regulations to be closed.

3. Specific powers under the standards procedure

The Standing Committee must be consulted by the Commission on any amendment to the lists of European or national standardisation bodies shown in the annexes to the directive, and on the presentation format of national and European standards programmes.

It must also be consulted on any draft mandate which the Commission plans to give to CEN, Cenelec or ETSI, for the preparation of harmonised European standards. This relates, among other things, to standards in the fields governed by the 'new approach' directives (machinery, construction products, toys, personal protection equipment, simple pressurised appliances, gas appliances, medical devices, telecommunications terminals, etc.), standards supporting Community legislation in the field of public contracts (water supply, gas transportation and distribution, the production, transmission and distribution of electricity, railways, telecommunications, etc.) and standards in other fields with a view to encouraging European economic integration (energy, the environment, consumer protection, new technologies, etc.).

Before giving a mandate to the standardisation bodies, the Commission always ensures that it has the political support of the Member States by consulting them through the Committee on the relevance and timeliness of undertaking standardisation work on a European level. Under the 'new approach' directives, draft mandates are submitted to the relevant sectoral management committee before being discussed in the Standing Committee ([1]).

A positive response from the Standing Committee leads the Commission to invite the European standardisation bodies to prepare one or more standards within a given period. During this period, the Member States will take all necessary measures to ensure that their respective standardisation bodies neither prepare nor introduce standards in the same field (see Article 7).

The fact that the national authorities participate in the award of mandates has the result of involving them in the results of European standardisation work. They therefore have an incentive to facilitate the work of the standardisation bodies and endeavour to remove any possible obstacles to the application in full of European standards.

The Standing Committee also reviews progress with mandated work and discusses all problems relating to standardisation in the framework of Directive 83/189/EEC, for example, an omission in a mandated European standard.

([1]) In principle, the 'new approach' directives each have a sectoral management committee, but in some cases, such as the 'toys' directive, the 83/189/EEC Committee takes on this role.

Chapter V

The application of the directive

Article 11

The Commission shall report every two years to the European Parliament, the Council and the Economic and Social Committee on the results of the application of this directive. Lists of standardisation work entrusted to the European standardisation organisations pursuant to this directive, as well as statistics on the notifications received, shall be published on an annual basis in the *Official Journal of the European Communities*.

This article sets out the Commission's obligations in respect of guaranteeing the transparency of information on the application of Directive 83/189/EEC, both as regards the Community institutions and bodies representing the political and economic interests of the citizens of the Union, and the citizens themselves.

The report which the Commission must submit every two years to the European Parliament, the Council of Ministers and the Economic and Social Committee of the European Communities describes the operation of the directive during the reference period ([1]).

These three institutions are interested in the results of the Member States' application of the directive: the first as the political institution representing the peoples of the Union, which is responsible for monitoring the activity of the Council and the Commission; the second as the institution representing the governments of the Member States and having decision-making power; the third in its capacity as a body with an advisory role in the Community legislative process representing the economic and social actors in the Member States.

The list of tasks entrusted by the Commission to CEN, Cenelec or ETSI ('mandates'), and the statistics prepared by the Commission on the basis of communications received under Directive 83/189/EEC, are also directly accessible, since they are published every year in the *Official Journal of the European Communities* (OJ) ([2]).

Article 12

When Member States adopt a technical regulation, it shall contain a reference to this directive or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States.

This article requires Member States to make reference to Directive 83/189/EEC either in the text of the new technical regulations they adopt or as an accompaniment to this text at the time of its publication. The wording of this reference is left to the discretion of the Member States.

Although this reference is not an absolute guarantee of compliance by the Member State with the provisions of the directive, it does at least allow the presumption that the technical regulation has been duly notified.

This obligation is of fundamental importance for the information of private individuals, who are authorised to assert their rights in the case of the adoption of a technical regulation without prior notification (see the 'CIA security' judgment, referred to in the following chapter). Consequently, the Commission regularly reminds Member States of this obligation in the comments sent to them.

([1]) The last report, published under the reference COM(96) 286 final, 26 June 1996 covers the period 1992-94.

([2]) This publication obligation was laid down by Directive 94/10/EC, in force since 1 July 1995. Statistics relating to technical regulations notified in 1996 under Directive 83/189/EEC were published in OJ C 311, 11.10.1997, p. 2.

The fact that the obligation to make reference to the directive solely relates to newly adopted national technical regulations shows once again that the procedure for the provision of information in the field of standards is much less restrictive.

Timetable and application methods

Directive 83/189/EEC was adopted on 28 March 1983 and entered into force on 31 March 1984. It was first amended by Directive 88/182/EEC, which entered into force on 1 January 1989. The second amendment came into force on 1 July 1995.

The manner in which Directive 83/189/EEC and its successive amendments were transposed was left, as for any other directive, to the discretion of the Member States; in accordance with Article 189 of the Treaty, 'A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods' (1).

Directive 83/189/EEC is characterised by the fact that it contains a large number of procedural rules, which the Member States had to implement by establishing appropriate bodies and administrative mechanisms.

Work has begun on codification of Directive 83/189/EEC, by consolidating the initial text and the successive amendments whilst maintaining the integrity of their substance.

At the time this booklet went to press, the codification text was in the process of adoption by the European Parliament and the Council.

Once adopted, the codified directive will have a new reference number, but it is likely that the procedure will still be referred to as 'the 83/189/EEC procedure'; at all events, there will be no change to the text of the provisions quoted in this booklet.

(1) As opposed to a regulation which 'shall be binding in its entirety' and 'directly applicable in all Member States'.

Chapter VI

Access by private individuals to information and their reaction options

Although the implementation of Directive 83/189/EEC is above all a matter for the parties involved in the procedure for the provision of information in the field of technical standards and regulations — the Commission, Member States, the European and national standardisation bodies — information on draft national standards and technical regulations is of considerable interest to all the citizens of the Union.

The Commission urges all economic operators to inform themselves of all the initiatives planned by the national standardisation bodies and all the draft legislation and regulations being prepared by the Member States at a sufficiently early stage, in order to be able, should they so wish:

— to take part in the work of preparing standards relating to their field of activity in the standardisation committee of the national body which has initiated this work;

— to anticipate the adoption of future national standards or technical regulations in neighbouring countries, by adapting their production in order to comply with the precise content of these texts. In this way, manufacturers can, when the time comes, immediately export products which comply fully with the requirements of these standards or regulations;

— to express their views on necessary amendments to planned technical regulations which may form barriers to trade. Economic operators can submit their comments on difficulties which may arise from the application of the texts, once adopted, in their field.

This is invaluable information for the Commission departments, since they do not have equivalent practical experience of the relevant fields.

These comments may be sent directly to the relevant Commission departments or to the national authorities responsible for administering Directive 83/189/EEC in the field of technical regulations. The Commission and Member States may then, on this basis, send comments or detailed opinions to the notifying Member State with a view to the removal of protectionist elements identified in the draft.

If the options open to the citizens of the European Union under Directive 83/189/EEC are to be exercised in full, private individuals must consult the sources of information made available by the Commission. A list of these information sources is given below:

1. Information published in the *Official Journal of the European Communities,* Series C

— Each year the Commission publishes a list in the *Official Journal of the European Communities* of the new standardisation work which it has mandated CEN, Cenelec or ETSI to carry out (in accordance with Article 11 of the directive).

— Each year, the Commission publishes statistics in the OJ on the notifications received, the reactions to these notifications, and infringement proceedings instituted during the year for failure to fulfil the obligations under the directive (in accordance with Article 11 of the directive) ([1]).

— Each week, the Commission publishes in the OJ the titles of draft national technical regulations notified under the 83/189/EEC procedure and in each case the expiry date of the initial three-month standstill period provided for by the directive (when the Commission accepts a request for urgency by a notifying Member State, this information is also published in the OJ).

([1]) See the statistics on technical regulations notified in 1996 under Directive 83/189/EEC, OJ C 311, 11.10.1997, p. 2.

The publication of this list enables private individuals to be informed of the notifications and to ensure that technical regulations with which they are obliged to comply have indeed been notified. If this is not so, they can assert their rights through reference to the case-law of the Court of Justice.

The 'CIA security' judgment, delivered under the preliminary ruling procedure by the Court of Justice, is a key element in the protection of private individuals against failure on the part of Member States to fulfil their obligations under Directive 83/189/EEC ([1]).

This judgment specifies the consequences of the adoption of a technical regulation in breach of the obligations laid down by Directive 83/189/EEC: private individuals can invoke Articles 8 and 9 of the directive before the national court, which must refuse to apply a national technical regulation that has not been notified in accordance with the directive.

Private individuals have the possibility to ensure that any technical regulation adopted by a Member State is monitored before its adoption by the Commission and the other Member States (with the exceptions mentioned in the directive). If this is not the case, a company, for example, can cite the inapplicability of the regulation in question, should it be accused of non-compliance by an authority. In the event of any court proceedings resulting from the matter, the court must then set aside the application of the regulation and cannot, as a result, regard it as having been breached.

This sanctioning of the principle of the non-applicability to third parties of national technical regulations which have not been notified, supports the position already adopted by the Commission in 1986 ([2]) and enhances the protection of the interests of private individuals in this respect.

2. Other sources of information

— Private individuals may be able to obtain the text of draft technical regulations from the central units of the Member States (listed in Annex 2 to this booklet) which are responsible for notifying the Commission of national draft technical regulations.

— They can ask to consult the monthly register at the Central Secretariat of CEN/Cenelec, which is distributed to all the national standardisation bodies (listed in Annex 3 to this booklet), in order to find information communicated on new work entered in the national standards programmes.

— They can contact the national standardisation bodies, members of CEN or Cenelec, in order to obtain the texts of drafts entered in the national standards programmes.

— They can consult the reports on the operation of the directive, both as regards the 'standards' and the 'technical regulations' aspect, which are regularly published by the Commission ([3]).

— The Commission issues press releases to inform private individuals of infringement proceedings against texts of technical regulations adopted in breach of the directive. This information can be used by a private individual before a national authority, in support of the principle of non-applicability of a technical regulation adopted in breach of Directive 83/189/EEC.

— In order to facilitate industry's access to national technical regulations, the Commission is studying the possibility of creating a database containing the texts which have been notified, in several or all of the Union's languages.

([1]) Judgment of 30 April 1996 'Interpretation of Article 30 of the EC Treaty and of Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations — National legislation on the marketing of alarm systems and networks — Prior administrative approval, delivered in Case C 194/94. ECR 1996 I, p. 2201.

([2]) Communication from the Commission concerning the non-respect of certain provisions of Directive 83/189/EEC, No 86/C 245/05, published in OJ C 245, 1.10.1986, p. 4.

([3]) The reference numbers of these reports are given in the bibliography for this booklet.

Conclusion

It is clear from a review of more than 10 years' experience with the implementation of Directive 83/189/EEC that significant progress has been made in preventing the emergence of new barriers to trade.

Although the completion of the internal market in 1993 does not appear to have diminished Member States' need to enact detailed legislation on products, they have become gradually familiar with the rules of the internal market, the principle of mutual recognition arising from the 'Cassis de Dijon' precedent and the principles of transparency and cooperation, which now govern their activities in the field of technical standards and regulations.

This is evident, among other things, from the inclusion of the mutual recognition clause in certain draft national legislative texts at the notification stage; the goodwill shown by the Member States in correcting errors discovered by the Commission or by the other Member States in notified drafts; the compliance in the vast majority of cases with the obligation to notify planned new standardisation activities and draft technical regulations; and from the rapid development of European standardisation.

This progress in European integration, which facilitates the maintenance and growth of trade, is the fruit of the joint efforts of the Commission and the Member States. By acting together to prevent the emergence of new technical barriers to trade, they reduce the need for legislation on a Community level, and at the same time enhance the quality of the technical standards and regulations adopted at national level. Directive 83/189/EEC is the key instrument of Community policy to combat barriers to trade which has made this possible.

The application, since 1 January 1997, of a new procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community ([1]) has proved to be a useful addition to the system. This new procedure requires Member States to notify the Commission of any measure — other than a judicial decision — which acts as a barrier to the free movement of certain models or types of products lawfully manufactured or marketed in another Member State for reasons relating in particular to safety, health or protection of the environment. Whereas Directive 83/189/EEC concerns the period preceding the adoption of technical regulations, this procedure operates after adoption and permits monitoring of the way in which they are applied.

Despite its success, the procedure laid down by Directive 83/189/EEC could still be improved, which requires clear identification of the points in need of improvement.

As far as standards are concerned, late notifications and sometimes rather vague descriptions of new work are the shortcomings most frequently mentioned by the European standardisation bodies when examining the notifications. In addition, the number of comments submitted by the national standardisation bodies remains very low in comparison with the number of notifications received. This is a sign that economic operators in the Union are still not making full use of their opportunities to express objections to texts which constitute a potential threat to the satisfactory operation of the internal market.

The reason seems to be that the European standardisation bodies can still not fully rely on the assistance of their national counterparts in organising, on a national level, the widest possible distribution of the information which they have on draft standards in preparation in other Member States, with a view to encouraging comments or participation by manufacturers in their sector of activity. By being on the alert and requesting the necessary information from the proper quarters, industry itself can contribute to a more effective circulation of information, since the voicing of its needs could encourage the establishment, where necessary, of appropriate information relays.

([1]) European Parliament and Council Decision 3052/95/EC of 13 December 1995, OJ L 321, 30.12.1995, p. 1.

With regard to the procedure for the provision of information applicable to technical regulations, experience has shown that in some cases Member States are failing to notify their drafts, in breach of the provisions of the directive, or applying some of these provisions erroneously as a result of insufficient knowledge of the procedure on the part of the bodies responsible for preparing the texts of these regulations. The Commission intends to pursue its information activities in this area, in particular through enhanced dialogue with the national authorities.

The Commission regrets that industry's participation in the examination of drafts is still at a very low level. Whereas some European federations exercise a high degree of 'legislative vigilance' and are very active in defence of their legitimate interests by informing the Commission or the national authorities of technical barriers which they have found in certain drafts, individual enterprises and particularly small and medium-sized businesses are often more reserved. They should not hesitate to seek information and speak up when they consider that the technical product specifications being prepared in countries to which they export could harm their interests, if adopted as they stand.

The Commission intends to take action to facilitate the participation of industry. It will also ensure that the procedures are administered as flexibly as possible, in order to avoid unduly restricting the activities of the Member States.

The additional effort required is all the more important as Directive 83/189/EEC is at a turning point: the accession of three new Member States to the Union on 1 January 1995 and the entry into force, in July of the same year, of Directive 94/10/EC of 23 March 1994, amending the text for the second time, have radically changed the application of the legislation, the geographical scope of which will continue to expand.

Directive 83/189/EEC, which has already been implemented in part in the EFTA countries since 1990 (1), will eventually have to be extended to Turkey and to the countries of central and eastern Europe, which are candidates for Union membership.

In the case of Turkey, work is in progress in the framework of the decision on the final phase of customs union, which provides that Turkey will incorporate in its internal legal system Community acts relating to the removal of technical barriers to trade.

The application of the directive to Turkey should be limited to the 'technical regulations' area, and the procedure considerably simplified and streamlined.

In the case of the countries of central and eastern Europe, the application of Directive 83/189/EEC should take place in the framework of the European agreements, which provide for the creation of a free trade area between these countries and the Union. As far as the approximation of legislation is concerned, these agreements stipulate that the countries of central and eastern Europe must ensure, as far as possible, that their future legislation is compatible with Community law. In the sphere of industrial cooperation, they are designed, among other things, to reduce the differences in standards and technical regulations. Directive 83/189/EEC has been included in the White Paper (2) as an instrument for the prevention of technical barriers to trade. A simplified procedure for the provision of information will have to be introduced, in the same way as for Turkey, when these countries have brought their legislation into line with established Community law (i.e. all the Community provisions in force) on the internal market.

(1) The agreement between the Member States of EFTA and the EEC laying down a procedure for the provision of information in the field of technical regulations entered into force in November 1990. The agreement on the European Economic Area, applicable since 1 January 1994, subsequently incorporated Directive 83/189/EEC with the necessary adaptations. Switzerland, though not a signatory to this agreement, continues to apply the procedure for the exchange of information.

(2) White Paper on the preparation of the associated countries of central and eastern Europe for integration into the internal market of the Union. COM(95) 163 final, 10 May 1995.

What is more, Directive 83/189/EEC, which has already been amended twice, is likely to undergo further changes, since a third amendment to the directive is envisaged in order to cover information society services. The Commission has proposed that regulatory transparency should be extended to these new services, in order to prevent the fragmentation of the single market in future as a result of the adoption of isolated and uncoordinated national regulations in this field ([1]).

([1]) Proposal for a European Parliament and Council directive amending for the third time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations, 24 July 1996, COM(96) 392 final, OJ C 307, 16.10.1996, p. 11; amended proposal presented by the Commission on 17 November 1997, OJ C 65, 28.2.1998, p. 12; common position adopted by the Council on 26 January 1998, OJ C 62, 26.2.1998, p. 48.

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IV. Articles

Revue du marché commun (*Common market review*)

'Articles 30 et seq. of the EC Treaty and the monitoring procedures laid down by Directive 83/189/EEC', by Sabine Lecrenier, No 283, January 1985, Editions techniques et économiques *(Technical and economic publications),* Paris.

'Towards completion of the internal market: the development of the monitoring procedures laid down by Directive 83/189/EEC over four years', by Sabine Lecrenier, No 315, March 1988, Editions techniques et économiques, Paris.

Revue du marché unique européen (*European single market review*)

'Certification, mutual recognition and the single market', by Jacques McMillan, No 2-1991, Editions Clément Juglar (Published by Clément Juglar), Paris.

'The monitoring procedure for technical regulations provided for by the new Directive 83/189/EEC, a tool for the prevention of trade barriers and for a coherent industrial policy', by Joachim Fronia and Guiseppe Casella, No 2-1995, Editions Clément Juglar, Paris.

Journal des tribunaux — droit européen — (*Court journal — European law*)

'Monitoring Member States' technical regulations and protecting the rights of private individuals', by Sabine Lecrenier, No 35, January 1997, Editions Larcier, Brussels (Published by Larcier, Brussels).

V. Book

Florence Nicolas, with the collaboration of Jacques Repussard, *Common standards for enterprises*. European Commission, Office for Official Publications of the European Communities, Luxembourg.

ANNEXES

Annex 1

List of authorities required to notify draft technical regulations (in addition to the central governments of the Member States)

Belgium
Régions (3) et communautés (3)

Denmark
Amtskommuner (16)

Germany
Länder (16)

Greece
Perifereia (13)

Spain
Communidades autónomas (17)

France
Régions (including overseas departments) (26)

Ireland
/

Italy
Regioni (20)

Luxembourg
/

Netherlands
Bedrijfslichamen ingevolge de Wet op de bedrijfsorganisatie

Austria
Bundesländer (9)

Portugal
Regiões autónomas (2)

Finland
Ahvenanmaan maakunta (1)

Sweden
/

United Kingdom
Nations (4)

Annex 2

Contact points at the Commission and in the Member States for the 'technical regulations' aspect of the directive

1. COMMISSION

Directorate-General for Industry
DG III/B.1
Sc. 15 1/98
rue de la Loi 200
B-1049 Brussels
Fax (32-2) 296 08 51 or (32-2) 299 57 25
Internet: 83189@dg3.cec.be

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BELGIUM

Institut belge de normalisation
29 avenue de la Brabançonne
B-1040 Brussels

Mme Vergauwen
Tel. (32-2) 738 01 10
Fax (32-2) 733 42 64

DENMARK

Danish Agency for Trade and Industry
Tagensvej 137
DK-2200 Copenhagen N

Hr. K. Dybkjaer
Tel. (45) 35 86 86 86 or 82 62
Fax (45) 35 86 85 75
X400:C = DK;A = DK400;P = EFS;S = DYBKJAER;G = KELD
Internet: keld.dybkjaer@efs.dk

GERMANY

Bundesministerium für Wirtschaft
Referat E B 3
Villenomblerstrasse 76
D-53123 Bonn

Frau Defosse
Tel. (49-228) 615 41 63
Fax (49-228) 615 44 30
X 400: C = DE;A = BUND400;P = BMW;0 = BONN1;S = DEFOSSE

GREECE

Ministry of Development
General Secretariat of Industry
Michalacopoulou 80
GR-11528 Athens
Tel. (30-1) 778 17 31
Fax (30-1) 779 88 90

ELOT
Acharnon 313
GR-11145 Athens
Mr E. Melagrakis
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Fax (30-1) 228 62 19
Internet: 83189@elot.gr

SPAIN

Ministerio de Asuntos Exteriores
Secretaria de Estado de politica exterior y para la Unión Europea
Dirección General de Asuntos tecnicos de la Unión Europea
Subdirección general de asuntos industriales, energéticos, transportes, comunicaciones y medio ambiente
c/Padilla, 46, Planta 2a, Despacho 6276
E-28006 Madrid

D. Luis Antonio Rico Urios
Tel. (34-1) 379 83 32
Sra María Ángeles Martinez Álvarez
Tel. (34-1) 379 84 64
Fax (34-1) 575 56 29, 575 86 01, 431 55 51
X400: C = ES;A = MENSATEX;P-MAE;O = SECE;S = D83-189

FRANCE

Délégation interministérielle aux normes
Squalpi
22 rue Monge
F-75005 Paris

Mme Piau
Tel. (33) 143 19 51 43
Fax (33) 143 19 50 44
M. Crignou
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NSAI
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Fax (353-1) 807 38 38
X400:C = IE;A = EIRMAIL400;P-NRN;O = NSAI;S = BYRNEO
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ITALY

Ministero dell'Industria, del commercio e dell artigianato
via Molise 2
I-00100 Roma

Signor P. Cavanna
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X400:C = IT;A = MASTER400;P = GDS;OU1 = M.I.C.A-ISPIND;
DDA:CLASSE = IPM;DDA:ID-NODO = BF9RM001;S = PAOLO CAVANNA

Signor E. Castiglioni
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Fax (39-6) 47 88 77 48

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Fax (43-1) 715 96 51
X400:C = AT;A = GV;P = BMWA;0 = BMWA;OU = TBT;S = POST

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Instituto Portugês da Qualidade
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Fax (351-1) 294 82 23
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Fax (44-171) 215 15 29
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Annex 3

Contact points for the 'standards' aspect of the directive

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Directorate-General for Industry
DG III/B.2 — Standardisation
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B-1049 Brussels
Fax (32-2) 296 70 19

2. European standardisation bodies

CEN Central Secretariat
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Fax (32-2) 550 08 19
Infodesk Tel. (32-2) 550 09 99; fax (32-2) 550 08 19
Internet: vaningelgem@cenclcbel.be
homepage: www.cenorm.be

Cenelec Central Secretariat
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B-1050 Brussels
Tel. (32-2) 519 68 71
Fax (32-2) 519 69 19
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before 1.7.1998: cenelec@cenebel.be
after 1.7.1998: general@cenelec.be

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650 Route des Lucioles
F-06921 Sophia Antipolis Cedex
Tel. (33) 492 94 42 00
Fax (33) 493 65 47 16
Infocentre: Tel. (33) 492 94 42 22; fax (33) 492 94 43 33
Internet: secretariat@etsi.fr
homepage: www.etsi.fr

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Belgium

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Belgisch Institut voor Normalisatie (BIN)
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Fax (32-2) 733 42 64

Comité Electrotechnique Belge (CEB)
Belgisch Elektrotechnisch Comité (BEC)
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Fax (45) 39 96 61 02
Internet: dansk.standard@ds.dk

Telestyrelsen (NTA)
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DK-2100 Copenhagen Ø
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Fax (45) 35 43 14 34
Internet: tst@tst.dk

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Deutsches Institut für Normung (DIN)
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D-10787 Berlin
Tel. (49-30) 26 01 27 38
Fax (49-30) 26 01 12 65

Deutsche Elektrotechnische Kommission im DIN und VDE (DKE)
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D-60596 Frankfurt am Main
Tel. (49-69) 630 80
Fax (49-69) 96 31 52 18
Internet: dke.zbt@t-online.de

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GR-11145 Athens
Tel. (30-1) 228 00 01
Fax (30-1) 228 62 19

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Fax (353-1) 807 38 38

Electro-Technical Council of Ireland (ETCI)
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Fax (353-1) 454 58 21

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Fax (31-15) 269 01 90

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Fax (31-15) 269 01 90

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Fax (43-1) 586 74 08

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Fax (351-1) 294 82 22

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Fax (358-9) 146 49 25
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homepage: www.sesko.fi

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Tel. (358-9) 696 61
Fax (358-9) 696 64 10
Internet: info@thk.fi
homepage: www.thk.fi

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St Eriksgatan 115
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S-11382 Stockholm
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Fax (46-8) 30 77 57
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Svenska Elektriska Kommissionen (SEK)
Kistagången 19
Box 1284
S-16429 Kista Stockholm
Tel. (46-8) 444 14 00
Fax (46-8) 444 14 30
Internet: sek@sekom.se

Informationstekniska standardiseringen (ITS)
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British Standards Institution (BSI)
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London W4 4AL
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Fax (44-181) 996 74 00

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Fax (44-181) 996 77 99

European Commission

Maintaining the single market — Directive 83/189/EEC — A commentary
A guide to the procedure for the provision of information in the field of technical standards and regulations

Luxembourg: Office for Official Publications of the European Communities

1998 — 77 pp. — 21 x 29.7 cm

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Fax (421-7) 531 83 64
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Each of the directive's provisions is quoted in full and accompanied by a detailed commentary explaining its meaning and its implications for all interested parties: Member States, national and European standardisation bodies and, last but not least, present or potential economic operators within the European Union.

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