ENTERPRISE AND INDUSTRY

Directive 98/34/EC:
An instrument of co-operation between institutions and enterprises to ensure the smooth functioning of the Internal Market

A guide to the procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services

European Commission

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Preface

In 2000 the European Union launched the Lisbon Strategy – an ambitious agenda for reform whose aim was to make the EU the most competitive and dynamic knowledge-based economy in the world by 2010. At its half-way mark, in 2005, the Commission proposed a renewed approach to this strategy focusing on growth and jobs. The Commission identified improving the quality of European and national regulation to ensure the smooth functioning of the internal market as a key challenge in this respect.

One of the most difficult and important tasks in the management of the internal market is preventing the adoption of national technical regulations and standards which create new barriers to trade. Twenty years after its entry into force the Notification Directive (Directive 83/189/EEC, codified by Directive 98/34/EC) has proved to be a fundamental internal market instrument.

The mechanism set up by the original Directive 83/189/EEC is based on the agreement of the Member States to inform and consult each other and the Commission *before* they adopt technical regulations and to modify their drafts if necessary. By means of transparency and the exchange of information at the legislative proposal stage, the Member States have agreed to prevent the emergence of new obstacles to the single market.

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, industry and individuals thus have an open window upon technical activities, which enables them to eliminate at source any barriers to the free movement of goods.

Throughout the past 20 years, the scope of the Directive has been gradually broadened to cover all industrial, agricultural and fishery products. Directive 98/48/EC extended the system to include Information Society services since a need was felt for a mechanism for supervising this new and rapidly evolving field, while leaving economic operators and the Member States alike as much freedom as possible to prevent obstacles to technological developments in this sector.

This procedure contributes to the application of the subsidiarity principle, both through enabling improvements to be made to national legislation and identifying areas where harmonisation is really necessary. Thus, the decision-making process can take place at the most appropriate level enabling decentralisation which safeguards the diversity of political, cultural and regional traditions. The Directive has provided an insight into national regulatory initiatives, has led to the creation of a genuine discussion forum, clearing the way for joint action to strengthen the internal market and has recently contributed to the establishment of the enlarged internal market of 25 Member States.

Furthermore, this mechanism is a tool of better regulation since it allows the different competent authorities, both at Community and national levels, to prevent problems *ex ante* thus avoiding costly and controversial infringement proceedings which can only be launched *ex post*. The exchange and gathering of information is also an effective way of ensuring that national best practices become known and are used as a model for other regulatory initiatives.

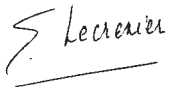
Following a 2002 Commission Report which analysed barriers to the freedom to provide services and the freedom of establishment in the Internal Market[1], the Commission's services are working on the possible extension of Directive 98/34 to cover services other than Information Society services.

[1] COM(2002) 441 final.

Industry, as well as the Commission and the Member States, is involved in the notification procedure. Besides being able to examine legislation in their own countries, enterprises in the Member States have the opportunity of examining legislation proposed by countries to which they export or wish to export or to which they provide or envisage to provide Information Society services. As a consequence, they can plan to adapt their products or services 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 may be done by means of a visit to our public database at the following address: http://europa.eu.int/comm/enterprise/tris.

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 constituted a new community culture.



Sabine Lecrenier
Head of Unit
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for Enterprise and Industry

Introduction

Directive 98/34/EC,
an instrument of transparency
at the service of the Internal Market

Introduction: Directive 98/34/EC, an instrument of transparency at the service of the Internal Market

At the beginning of the 1980s the Commission, basing itself on a Court of Justice ruling known as the 'Cassis de Dijon' judgment, launched a new policy designed to complete the internal market on the basis of three concepts:

– Acceptance in each Member State of products lawfully manufactured in the rest of the Community ('mutual recognition');

– Harmonisation limited to important economic sectors covering, in particular, health, safety and the environment;

– A prevention-based approach to monitoring national regulations.

Since 1984, Directive 83/189/EEC[2] which, following codification later became Directive 98/34/EC[3], has laid down a preventive mechanism, the scope of which has been progressively extended.

Today, the Member States of the European Union are obliged to notify to the Commission and to the other Member States any draft technical regulation concerning products and Information Society services before they are adopted in national law.

The concept was revolutionary at the time and has remained so - to the extent that the Commission is examining whether it could be extended to other areas.

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 part relates to the procedure for the provision of information on new national initiatives which should lead to the formulation of national standards between the national standardisation bodies, the European standardisation bodies, namely CEN (European Committee for Standardisation), CENELEC (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 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 or rules on Information Society services 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; the latter have acknowledged the advantages of a procedure which allows for reciprocal influence over their legislative processes. The Treaty itself merely made provision for retrospective monitoring by the Member States, through the use of the more cumbersome infringement procedures which are rarely applied between Member States.

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[2] Directive of 28 March 1983. OJ L 109, 26.4.1983, p. 8.

[3] Directive of 22 June 1998. OJ L 204, 21.7.1998, p. 37.

– The system also permits national draft legislation to be put on ice for a certain period to facilitate discussion at Community level on the matter in the light of harmonisation initiatives. Moreover, by means of this legislative observatory, the real needs for harmonisation can be identified more easily.

The system, which got off to a slow start, has gained momentum and has provided the Commission, the Member States and enterprises with a window on the activities of national authorities and standardisation bodies in the technical field (rules relating to product composition, 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. In 1998, the procedure was extended by Directive 98/48/EC to encompass rules on Information Society services[4].

The geographical scope of the Directive was also gradually extended. Directive 98/34/EC, which was already implemented in part in the EFTA countries since 1990,[5] has also been partly extended to Turkey under the Association Agreement with that country[6]. The Directive has also provided a model for a Convention of the Council of Europe[7].

The application of the notification procedure has given rise to new practices. An entire philosophy of information exchange, dialogue and cooperation has evolved between the Member States. This mechanism has also proved to be a formidable benchmarking tool which allows Member States to draw on the ideas of their partners in order to solve common problems regarding technical regulations, especially in newly regulated sectors such as GMOs, domain names and gene therapy.

Moreover, the Commission is using Directive 98/34/EC as an educational tool with a view to adjusting Member States' legislative style.

Through this instrument, the Commission not only succeeds in removing provisions which are contrary to Community law, but also contributes to the formulation of 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 the European Court of Justice (ECJ) interpretation of Articles 28 *et seq*. of the Treaty.

According to this principle, each Member State must accept the sale in its territory of any product lawfully manufactured or marketed in another Member State, subject, where legitimate interests, such as health and safety questions are at stake, to these products guaranteeing an equivalent level of protection. The corollary to this acceptance of products from the rest of

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4 Directive 83/189/EEC was amended principally by Council Directive 88/182/EEC of 22 March 1988 (OJ L 81, 26.3.1988, p. 75) and by European Parliament and Council Directive 94/10/EC of 23 March 1994 (OJ L 100, 19.4.1994, p. 30). Directive 98/34/EC of 22 June 1998 codified Directive 83/189/EEC and all its subsequent amendments while Directive 98/48/EC of 20 July 1998 amended Directive 98/34/EC.

5 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.

6 Agreement establishing an Association between the European Economic Community and Turkey (OJ C Vol. 16 No C 113, 24.12.1973) and Decision 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the customs union (OJ L 35, 13.2.1996, p. 1).

7 Convention No 180 of the Council of Europe on Information and Legal Co-operation concerning 'Information Society Services'.

the Community- extended by the Agreement on the European Economic Area to products from EFTA countries signatory to the Agreement[8] - is mutual recognition of the regulations relating to the design, manufacture and testing of products, and the conformity assessment procedures used; the Member States and the Commission are informed about these regulations through the procedure for the provision of information established by Directive 98/34/EC.

Furthermore, the provisions of Decision 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union[9], which provides for the elimination of quantitative restrictions or measures having equivalent effect between the EU and Turkey, are interpreted for the purposes of their implementation and application to products covered by the Customs Union, in conformity with the relevant decisions of the European Court of Justice concerning provisions of the EC Treaty, in particular Articles 28 to 30 thereof.

Directive 98/34/EC, by extending the scope of application of the information procedure to rules on Information Society services, ensured, since August 1999, the prevention of new barriers to the freedom of establishment and the free movement of Information Society services by providing a mechanism to analyse the compatibility of new national legislation in this field with Articles 43 and 49 of the EC Treaty.

According to the case-law of the European Court of Justice, Articles 43 and 49 of the Treaty require the elimination of restrictions, i.e. of all *'measures which prohibit, impede or render less attractive the exercise of such freedoms'* (freedom of establishment and freedom to provide services)[10].

To be admissible as an exception to the fundamental freedoms of the internal market in a non-harmonised area, a national restriction must, on the basis of this case law comply with the principles of non-discrimination, necessity and proportionality[11].

As regards freedom to provide services, in particular, this means that national regulations which make no allowance for requirements already met by an operator in his Member State of establishment, from which he offers his services[12] will prove to be a disproportionate restriction and therefore inadmissible under Community law where the service in question is provided, as in the case of Information Society services, without the provider having to enter the territory of the Member State in which the service is received.[13]

Therefore, when examining national draft rules in the field of Information Society services, the Commission's overriding objective has been, for example, basing itself on the case-law of the Court of Justice, to oppose any national regulatory approach aimed at applying blanket, extra-territorial legal arrangements which make no distinction between operators based in the notifying Member State and those wishing to provide services in such Member State without, however, being established there. The Commission has also made sure that planned national rules do not impose needless or exces-

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8 It must be pointed out that the relevant provisions of the Agreement on the European Economic Area apply only to 'products originating in the Contracting Parties' and not, consequently, to products simply marketed there.

9 OJ L 35, 13.2.1996, p. 1.

10 Case C-439/99 *Commission v Italy* - '*Trade Fairs*' [2002] ECR I-305.

11 Case C-76/90 '*Dennemeyer*' [1991] ECR I-4221; Case C-369/96 *'Arblade'* [1999] ECR I-8453 and Case C-55/94 *'Gebhard'* [1995] ECR I-4165.

12 See *'Arblade'* judgment cited above, footnote 11.

13 See *'Dennemeyer'* judgment cited above, footnote 11.

sive legal or administrative costs on operators and possibly on users.

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 since the Court of 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.[14]

The aim of this booklet is to inform all the actors - and particularly Europe's manufacturers and Information Society service providers - 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, to the freedom of establishment and the freedom to provide Information Society services in the internal market.

[14] Case C-194/94 *'CIA Security'* [1996] ECR I-2201.

Chapter I

The scope of the Directive

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.

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 the Directive (i.e. 83/189/EEC) excluded cosmetic products within the terms of Directive 76/768/EEC[15], medicinal products within the terms of Directive 65/65/EEC[16], products destined for human and animal consumption and agricultural products.[17]

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 28 of the Treaty, 'products which can be valued in monetary terms and which may, as such, form the subject of commercial transactions'.[18] 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.[19] It is appropriate to take this into consideration in determining the scope of the Directive.

2) 'service', any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services[20].

For the purposes of this definition:

- *'at a distance' means that the service is provided without the parties being simultaneously present,*

- *'by electronic means' means that the service is sent initially and received at its destination by means of electronic equipment for*

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15 OJ L 262, 27.9.1976, p. 169.

16 Repealed by Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use. OJ L 311, 28.11.2001, p. 67.

17 Within the meaning of former Article 38(1) of the Treaty (today Article 33(1) of the Treaty).

18 Case 7/68 *Commission of the European Communities v Italian Republic* [1968] ECR 617.

19 Case 2/90 *Commission of the European Communities v Kingdom of Belgium* [1992] ECR I-4431.

20 The notion of Information Society services was introduced by Directive 98/48/EC and then used in Directive 98/84/EC on the legal protection of services based on, or consisting of, conditional access (OJ L 320, 28.11.1998, p. 54) and Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (OJ L 178, 17.7.2000, p. 1). For more information concerning this legal notion and, more generally, on the aspects of Directive 98/34/EC specifically related to Information society services, as introduced by Directive 98/48/EC, one may consult *Vade-Mecum to Directive 98/48/EC which Introduces a Mechanism for the Transparency of Regulations on Information Society Services* (Doc. S-42/98 – EN (def.) – Directorate-General III – Industry and Directorate-General XV – Internal Market and Financial Services.

the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,

– *'at the individual request of a recipient of services' means that the service is provided through the transmission of data on individual request.*

An indicative list of services not covered by this definition is set out in Annex V.

This Directive shall not apply to:

– *radio broadcasting services,*

– *television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC.*

It should be emphasised that the inclusion of Information Society Services constitutes a very important extension of the scope of the Directive which has brought it in line with new developments in international commerce. To determine whether an activity comes within the definition of Information Society services, it is first necessary to verify whether the activity in question constitutes a 'service' in accordance with Community law.

According to the case-law of the Court of Justice, 'services' means a service provided normally for remuneration. The Court of Justice has stipulated that the 'essential characteristic of remuneration […] lies in the fact that it constitutes consideration for the service in question'.[21] Such a characteristic is lacking in the activities the State undertakes without consideration within the framework of its tasks, particularly in social, cultural, educational and legal areas.

Next, it is necessary to verify whether the service is, in the terms of the Directive, an 'Information Society service'. In accordance with Article 1(2) of the Directive, Information Society service means a service provided: 'at a distance', 'by electronic means' and 'at the individual request of a recipient of services'.

The concept of 'at a distance' concerns situations in which the service is provided using distance communication techniques, which are therefore characterised by the fact that the parties (i.e. the service provider and the recipient) are not physically and simultaneously present.

The expression 'by electronic means' means services whose constituent elements are transmitted, conveyed and received within an electronic network. The service must be conveyed from its point of departure to its point of arrival by means of electronic (processing and storage) equipment and by telecommunications means.

Finally, the service must be provided via the transmission of data at an individual request. This constitutes the element of interactivity which characterises Information Society services and sets them apart from other services that are sent without a request from the recipient being necessary. For this reason, Article 1 specifies that the Directive does not apply to radio broadcasting services or to television broadcasting services covered by Directive 89/552/EEC[22] (as amended by Directive 97/36/EC[23], the 'Television without Frontiers' Directive)[24].

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[21] Case C-109/92 *'Wirth'* [1993] ECR I-6447.

[22] Directive of 3 October 1989, OJ L 298, 17.10.1989, p. 23.

[23] Directive of 30 June 1997, OJ L 202, 30.7.1997, p. 60.

[24] In the *'Mediakabel'* judgment of 2 June 2005, Case C-89/04, not yet published, the Court of Justice has confirmed that near video on demand is not an Information Society service since it is not provided at the individual request of a recepient of services.

Examples of services covered by the Directive are general online information services (newspapers, databases etc.), distance monitoring activities, interactive teleshopping, electronic mail, online flight reservations, online professional services (access to databases, diagnostics etc.).

3) '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 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, presentation, performance, life span, energy consumption, etc., could have been added.

The specification can serve a multitude of goals: for example, protection of the consumer, of 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 vaccinate cows before selling them). This is not always the case in the other product sectors, and here the Directive makes impact on the product a condition for 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.

4) '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, did 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'.

5) 'rule on services', requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point 2, in particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point.

Examples of measures likely to constitute a rule on Information Society services include measures concerning the conditions for taking up an activity (e.g. obligation to obtain a licence); measures relating to the conditions for pursuing an on-line activity (e.g. general ban on commercial promotion or certain forms of advertising); measures concerning the provider of on-line services (e.g. requirements relating to professional experience required to be an on-line tax consultant); measures concerning the supply of on-line services (e.g. laws laying down the maximum fees which may be charged) and measures related to the recipient of such services (e.g. participation limited to certain age group, measures applying to specific categories of recipients, such as minors).

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC[25].

Directive 90/387/EEC defines telecommunications services as 'services whose provision consists wholly or partly in the transmission and routing of signals on a telecommunications network by means of telecommunications processes, with the exception of radio broadcasting and television'.

The reason for this specific exemption is that in the field of telecommunications services (as in financial services, see following section) a large number of matters are already harmonised

[25] Council Directive 90/387/EEC of 28 June 1990 on the establishment of the internal market for telecommunications services through the implementation of open network provision (OJ L 192, 24.7.1990, p. 1). This Directive has been repealed by Framework Directive 2002/21/EC of 7 March 2002 on a common framework for electronic communications networks and services (OJ L 108, 24.4.2002, p. 33). However, the definition of 'telecommunications services' found in Directive 90/387/EEC should be retained for the purposes of Directive 98/34/EC.

and are part of an already existing and sufficiently defined Community regulatory framework.

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Annex VI to this Directive.

The reason for such an exemption from the scope of the Directive is identical and is due to the fact that such rules are part of an already sufficiently established Community legal framework.

Purely as a guide, a non-exhaustive list of financial services is supplied in Annex VI to Directive 98/48/EC.

With the exception of Article 8(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 93/22/EEC or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

Directive 93/22/EEC of 10 May 1993 regulates investment services in the securities field.[26]

As a result of this exemption, the *rules drawn up by* or *concerning* regulated markets or other markets or bodies carrying out clearing or settlement operations for such markets are not subject to the obligation of prior notification. The only obligation to which such rules, in the interests of minimal transparency, are subject is that of 'ex-post' notification, i.e. they should be communicated to the Commission after adoption at national level pursuant to Article 8(3), which - as indicated by the fourth subparagraph of Article 1, point 5 - is the only provision in the Directive which applies to these rules.

For the purposes of this definition:

- *a rule shall be considered to be specifically aimed at Information Society services where, having regard to its statement of reasons and its operative part, the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner,*

- *a rule shall not be considered to be specifically aimed at Information Society services if it affects such services only in an implicit or incidental manner.*

It is extremely important to emphasise that the obligation to notify in advance does not apply to all draft national regulations which - directly or indirectly, explicitly or implicitly - may concern Information Society services. Only a limited number and a well-defined category of draft national regulations will, for the purposes of the Directive, have to be notified in advance, namely the regulations specifically aimed at Information Society services. All other regulations affecting services are not notifiable.

In view of the above, one should point out that the Directive requires the notification of regulatory drafts whose justification, content or purpose indicate that they are directly and openly devoted, in whole or in part, to controlling Information Society services. The provision(s) in a national regulatory instrument must be expressly drafted or in any event specifically designed to reflect the fact that the activity/service is supplied 'at a distance, by electronic means and at the individual request of a recipient of services'.

Another point which should be emphasized is that it is not solely regulatory instruments which *as a whole* are devoted to Information Society services (e.g. a law on electronic signatures) that must be notified. Regulations *of which only a part*

[26] This Directive was recently repealed by Directive 2004/39/EC of 21 April 2004 on markets in financial instruments. OJ L 145, 30.4.2004, p. 1.

(possibly an article or even a paragraph) specifically concerns an Information Society service (e.g. within a law on pornography, a specific provision on the liability of an Internet access supplier) must also be notified.

On the other hand, the following draft regulations need not be notified: those which relate only *indirectly*, implicitly or incidentally to Information Society services, i.e. which concern an economic activity in general without taking into consideration the typical technical procedures for supplying the Information Society services (e.g. a provision which prohibits the distribution of paedophile material by any means of transmission, including the Internet or electronic mail, among the various possible means of dissemination).

6) 'standard', a technical specification approved by a recognised standardisation body for repeated or continuous application, with which compliance 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 (11).

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 AFNOR[27] in France, DIN[28] in Germany and BSI[29] in the United Kingdom), European (CEN,[30] CENELEC[31] or ETSI[32]), or international (ISO,[33] or IEC[34]), 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 which enables comments to be obtained from the economic and social operators (industry, 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, as opposed to products which have

[27] Association française de normalisation [French Standards Association].
[28] Deutsches Institut für Normung [German Standards Institution].
[29] British Standards Institution.
[30] Comité européen de Normalisation [European Committee for Standardisation].
[31] Comité européen de Normalisation électrotechnique [European Committee for Electrotechnical Standardisation].
[32] European Telecommunications Standards Institute.
[33] International Standards Organisation.
[34] International Electrotechnical Commission.

specific technical characteristics when compared to 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 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)[35] or the United Nations Economic Commission for Europe (UN/ECE), 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.[36]

The difference stems from the fact that Directive 98/34/EC, following the 1995 WTO Agreement 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 standard 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

[35] ISO, Guide 2, Sixth Edition, 1991 (EN 45020:1993).

[36] See in particular the work by F. Nicolas '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, ISBN 92-826-8111-4.

the other hand, will not necessarily be substituted for a national standard on the same subject.

7) '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.

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 co-operation 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.

8) '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.

9) '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).[37]

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 or in the context of an European policy. Such requests are known as mandates from the Commission. If these standards are prepared in the framework of the 'New Approach' directives, they are known as 'harmonised standards' and products manufactured in accordance with these standards benefit from a presumption of conformity with the essential requirements of a given directive. Such directives were adopted for several sectors such as electromedical equipment, equipment used in explosive atmospheres, machine safety, electromagnetic compatibility. This 'New Approach' to technical harmonisation meant that the work leading to the approximation of national laws was speeded up considerably compared to traditional European directives which were characterized by a high degree of technical detail.[38]

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[37] The details of these bodies are given in Annex 2 to this booklet.

[38] This New Approach to technical harmonisation was later supplemented by the Council resolution of 21 December 1989 on a Global Approach to certification and testing which lays down the guiding principles for Community policy on conformity assessment (OJ C 10, 16.1.1990, p. 1). The Global Approach was completed by Council Decision 93/465/EC (OJ L 220, 30.8.1993, p. 23) which lays down general guidelines and detailed procedures for conformity assessment that are to be used in New Approach Directives.

CEN (European Committee for Standardization) is a multi-sectorial standardisation body covering all sectors except electrotechnical (CENELEC) and telecommunications (ETSI). CEN's business domains are mechanical engineering, construction and civil engineering, health, biotechnology, the environment, safety at work, gas, transport, packaging, consumer goods, sport and leisure, the food industry, materials, the chemical industry, aerospace, services, quality, testing and certification, nanotechnology and many more.

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

Since January 2004, CEN has had 28 full members – the national standardisation bodies of the 25 Member States of the Union and of the Member States of EFTA, with the exception of Liechtenstein, which does not have a standardisation body.[39]

CEN also has affiliates, these being the standardisation bodies of Turkey and countries of South-Eastern Europe[40], 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.

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.[41]

Through a cooperation agreement with the International Organization for Standardization (ISO), the so-called Vienna Agreement, European and international standards can be developed in common to avoid duplication of work. Indeed, more than 30% of the European standards adopted by CEN are identical to international standards and many more are closely related.

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 Administrative Board,* which is responsible for the general administration of the system, *the CEN Management Centre*, which is responsible for the day-to-day management of its activities and the *Technical Board,* which is responsible for the co-ordination of technical activity and technical decision-making under the procedures for the adoption of standards. Two consultative committees support the Administrative Board in its decision making process: the Consultative Committee for External Policy (CACC EP) and the Consultative Committee for Finance (CACC Finance);

– 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,

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[39] Iceland, Norway, Switzerland.

[40] Albania, Bulgaria, Croatia, Romania and the Former Yugoslav Republic of Macedonia (FYROM).

[41] European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC)
European Chemical Industry Council (CEFIC)
European Environmental Citizens Organisation for Standardisation (ECOS)
European Committee for Co-operation of the Machine Tool Industries (CECIMO)
European Medical Technology Industry Association (EUCOMED)
European Office of Craft/Trades and Small and Medium-sized Enterprises for Standardisation (NORMAPME)
European Trade Union Technical Bureau for Health and Safety (TUTB)
European Construction Industry Federation – FIEC

composed of experts 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.[42]

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 nineteen-sixties.

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

CENELEC covers the field of safety of electrical and electronic appliances, electronic components and information and telecommunications technology (in co-operation with CEN and ETSI).

In order to provide the electrotechnical industry with the standards it requires, CENELEC has signed co-operation 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 co-operation agreement,[43] 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 Administration, a Technical Board, Technical Committees working in accordance with rules common to both CEN and CENELEC, and sub-committees.

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 after 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,[44] after having been officially recognised as a European standardisation body by the Community institutions.[45]

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

[42] More information about CEN can be obtained from www.cenorm.be or by writing to infodesk@cenorm.be

[43] Lugano Agreement, signed by CENELEC and the IEC in October 1991, which became the Dresden Agreement in 1996.

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

[45] 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.

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',[46] with a view to accelerating the technical harmonisation which was essential to the growth of networks, industry and new technologies. In spite of the history of its creation, ETSI is an independent organisation, governed by its members.

Centred on advanced technologies within the ICT domain, ETSI is the product of its age, and is increasingly having to respond to the challenges and needs of converging sectors: telecommunications, information technology, broadcasting and entertainment. Throughout the world this convergence is constantly being reflected in new applications (business-to-business communications, teleworking, access to entertainment, scientific databases and games, the development of preventive health care and care at home for the elderly, 'intelligent' transportation, etc.). Even within traditional telecommunications, convergence of the technologies associated with fixed networks, mobile networks, other wireless communications, satellite, banking and so on is turning the old order on its head. ETSI is at the forefront of managing this change.

The promised Information Society is truly arriving: Europe is participating in this revolution, and the socio-economic stakes are high. If users are to benefit fully, interconnection and interoperability of operator networks is 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 for home use,

– terminal services for personal mobile communications,

– next-generation networks that will have universal application both geographically and in terms of their ability to deliver information in whatever form it may exist.

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 which groups together all the market interests 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, regulators etc. can all be members of ETSI. Membership can be either on an individual company basis or through national or European bodies.

ETSI has three member categories: Full Members, Associate Members and Observers. All can attend the meetings of the General Assembly, but only Full and Associate Members can vote. As of 2004, ETSI has nearly 700 members.

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;

[46] COM(87) 290 final, 30.6.1987.

– *the Technical Organisation*, made up of *Technical Committees, Projects and Working Groups,* which prepare standards and reports;

– *the Secretariat* (managed by a Director-General (Chief Executive), assisted by a Deputy Director-General), which plays an important role in running ETSI and assists in routine administration;

– *Specialist Task Forces* 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. ETSI's primary focus for its standards is Europe, naturally, but with a truly international membership (even most of its European members are global players), the Institute seeks to develop standards for world-wide application.

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. Co-ordination 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 co-operation 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. Furthermore, the co-operation 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 co-operation which must be extended, since the standards programmes will increasingly call for the participation of two or even three European standardisation bodies.

10) '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.[47] Their tasks are therefore of general interest.

These bodies 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[48] 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 organs 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.

11) 'technical regulation', technical specifications and other requirements, or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator 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 or prohibiting the provision or use of a service, or establishment as a service provider.

In defining the concept of 'technical regulation', Paragraph 11 provides information regarding the type of texts which must

[47] A list of national standardisation contacts is given in annex 2 to this booklet. However, the formal list of national standardisation bodies is to be found in annex II of the directive.

[48] 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.

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 or rules on services (see the above definitions), which are laid down by the Member States and which are applicable to industrial and agricultural products and to Information Society services, 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, an 'other requirement' or a rule on services must fulfil the following conditions:

– it must be 'compulsory' (i.e. '*de jure*' or '*de facto*' binding, see hereinafter). 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;[49]

– it must influence the marketing or use of industrial and agricultural products, the provision of a service or the establishment of a service operator, in a Member State or a significant part of that State.

The administrative provisions applicable to a specification, to an 'other requirement' or to a rule on services can also constitute 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 authorities as specified in the list drawn up by the Commission in the framework of the Standing Committee of the Directive.

Certain technical specifications, 'other requirements' or rules on services 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 'compulsory' nature of a technical specification, an 'other requirement' or a rule on services may be conferred upon them in two ways:

1. *de jure*, when compliance with them 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 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 11 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.

[49] 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'.

De facto technical regulations include:

– laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or other requirements or to rules on services, 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'[50] or to rules on services 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 or the service a presumption of conformity with 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 with mandatory requirements, since these products benefit from a presumption of conformity with the requirements.

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

Agreements entered into between economic operators which establish technical specifications or other requirements for certain products or rules on services 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 party to one of these agreements.

This circumstance is becoming increasingly frequent, since such agreements have become instruments of national regulatory policy. They are often used by some Member States in sectors such as the automobile industry, chemical industry and oil industry, in most cases for environmental reasons. For example to reduce pollutant vehicle emissions, the discharge of harmful substances into water, or the use of certain types of packaging, etc. In the field of Information Society services, a notified text -a draft Code of Practice on voluntary retention of communication data- provides a good example of such voluntary agreement.

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 must be involved in these agreements if they are to fall within the scope of Directive 98/34/EC. 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 be a contracting party.

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

[50] In the meaning of Article 1(3) and (4) of the Directive, as explained above.

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 the recipients of services (notably the consumers), since they are basically aimed at influencing the behaviour of the latter with regard to a specific product or service.

This provision of the Directive came about because of certain cases of tax incentives granted to 'clean vehicles' which met certain emission limits or were 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. 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 complying with defined technical requirements) or, alternatively, to discourage their purchase (for example the exclusion of grants in the building industry when materials possessing certain characteristics 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). Similarly this category of measures concern those aiming at encouraging or discouraging the purchase of services having certain features (e.g. services received via specific devices or originating from operators established in certain areas).

Directive 98/34/EC does not cover the whole of the fiscal or financial legislation of the Member States; it only refers to technical specifications or 'other requirements' or rules on services linked to fiscal or financial measures which have the objective of changing the behaviour of consumers or service recipients. The fiscal or financial measure does not, as such, form the subject of examination by the Commission or the Member States. Only that aspect of the technical specifications, of 'other requirements' or of rules on services which may form barriers to trade is examined.

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 87 and 88 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).

The last type of technical regulation contemplated by the directive which should be notified (in addition to technical specifications, 'other requirements' and rules on services which impose *de jure* and *de facto* compulsory requirements) consist of national laws, regulations and administrative provisions intended to prohibit the manufacture, importation, marketing and use of a product or prohibiting the provision or use of a service or the establishment as a service provider.

To fall within this fourth category of technical regulation concerning a prohibition *inter alia* on use, the measures must have a scope which goes well beyond a limitation to certain possible uses of the product or the service in question and must not be confined to a mere restriction of their use. That category of technical regulation is particularly intended to cover national measures which leave no room for any use

which can reasonably be made of the product concerned other than a purely marginal one.[51]

Such prohibitions constitute, as it were, the ultimate form of technical regulation. Unless they can be justified under Article 30 or Article 46 of the Treaty or proportionate in relation to essential requirements within the terms of the case law of the Court of Justice, they constitute barriers *par excellence* to the free movement of goods and services and to the freedom of establishment 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 5 August 1999, 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 is published on the Internet Site of the Commission.[52]

12) 'draft technical regulation', the text of a technical specification or other requirement or of a rule on services, 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 and the Member States can request the regulatory authority 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 substantial amendments.

In that regard, it must be observed that a national measure which reproduces or replaces, without adding new or additional specifications, existing technical regulations which, if adopted after the entry into force of Directive 83/189/EEC, have been duly notified to the Commission, cannot be regarded as a 'draft' technical regulation within the meaning of Article 1(12) of Directive 98/34/EC and consequently, as subject to the obligation to notify.

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 (3) and (4) of the Article, to the effect that technical specifications which affect the characteristics of the product are covered.

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[51] Case C-267/03 *'Lars Erik Staffan Lindberg'*, judgment of 21 April 2005, not yet published.

[52] http://europa.eu.int/comm/enterprise/tris/

Chapter II

The procedure for the provision of information with regard to standards

Chapter II: The procedure for the provision of information with regard to standards

The provision of information to the Commission and the standardisation bodies on new subjects in the national standards programmes

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 98/34/EC, 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 or refers *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.

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

With regard to new standardisation initiatives 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

periodical register (monthly for CEN and quarterly for CENELEC) which is distributed to the members of CEN and CENELEC, in addition to the relevant departments of the Commission (Directorate-General for Enterprise and Industry) 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 98/34/EC 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 new standards initiatives 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 inevitably be used against 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 98/34/EC. In practice, this participation is limited 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 is 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 98/34/EC.

– 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 98/34/EC is to ensure the transparency of national initiatives, but it also has a role to play in encouraging the development of European standardisation.

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.

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.[53]

[53] Decision 92/400/EEC, already cited.

Communication of draft standards to the European and national standardisation bodies and the Commission

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 98/34/EC stipulates that once they are informed of the preparation of new standards initiatives 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.

Measures for which the Member States are competent

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.

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 socio-economic 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 98/34/EC (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.

– 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 98/34/EC 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.[54] The Directive encourages them - through the Member States - to show the solidarity which is indispensable to the common aim of the Single Market.

[54] 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.

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 98/34/EC. 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.

The Member States' obligation to ensure that European technical harmonisation is not impeded

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 requested 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 98/34/EC.

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 requested standard, the work may not be carried out on national 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.

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

Chapter III: The procedure applicable to technical regulations

The communication and distribution of information on draft technical regulations and the possible reactions open to the Commission and the Member States

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 in Article 3 (2) of Directive 67/548/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 or rules on services referred to in the third indent of the second subparagraph of point 11 of Article 1, the comments or detailed opinions of the Commission or the Member States may concern only aspects which may hinder trade, or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators, 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.[55]

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.[56] 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 to the national ministries (a list of these central units and their addresses is given in Annex 1 to this booklet). Notification to the Commission takes the form of a message to the relevant Commission unit.

This 'notification message' is coded in seventeen points, each of which corresponds to a specific item of information. In point 9, for example, the Member State notifying the draft must explain, in a maximum of ten lines, the *raison d'être* of the draft legislation.

At the end of the national process of adopting regulatory provisions, the Member States must send the Commission the de-

[55] 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.

[56] An examination of the grounds presented shows that they most often relate to the protection of persons or animals, the environment, public safety, or to consumer information.

finitive text of the technical regulation (see Article 8(3)). The Commission will thus be in a position to consider whether the Member State has adapted its text to Community law 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 226 of the Treaty.[57] Where the Commission sends a detailed opinion to the notifying Member State which the latter then fails to take into account, the detailed opinion in question can serve as a basis for drafting a letter of formal notice. The Member States themselves can bring the matter before the Commission, under Article 227 of the Treaty, in order to institute an enforcement action before the Court of Justice of the European Communities against a Member State which they consider to have failed to fulfil its obligations.[58]

2. Specific cases

2.1. ***Single notification valid for multiple acts.*** Under Directive 98/34/EC, 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 98/34/EC. 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 98/34/EC '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,[59] with a view to reducing Member States' administrative costs.

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[57] Article 226 (former 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.'

[58] Article 227 (former 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'.

[59] A sector with overlapping notification procedures (see in this connection Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29; Council Regulation (EC) 315/93 of 8 February 1993 relating to the establishment of Community procedures regarding contaminating substances in foodstuffs, OJ L 37, 13.2.1993, p. 1, and Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs, OJ L 175, 19.7.1993, p. 1). The latter directive will be repealed, as from 31 december 2005, by Regulation (EC) 852/2004 of the European Parliament and of the Council of 29 april 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1.

In accordance with this system, Member States always notify their drafts under Directive 98/34/EC, 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 98/34/EC 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 98/34/EC and, for the remainder, the specific procedure will take its course.[60]

Furthermore, with regard to protection of the environment, Directive 94/62/EC relating to packaging and packaging waste[61] expressly stipulates that the procedure under Directive 98/34/EC applies to all draft measures which Member States plan to adopt in this area.

2.2. ***Basic legislation already sent.*** 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. ***Additional documentation.*** Conversely, Directive 98/34/EC 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 (c.f. the fourth subparagraph 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 data 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,[62] in the case of existing substances and Council Directive 67/548/EEC[63] (as amended by subsequent directives), in the case of new substances.

2.4. ***New notification.*** Member States must notify again a draft which has already been examined under the provisions of Directive 98/34/EC, 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

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[60] Thus, for example, when a draft national technical regulation lays down specifications for the labelling of foodstuffs which exceed the requirements of Directive 2000/13/EC, the procedure referred to in Article 19 of that Directive shall apply.

[61] Directive 94/62/EC of the European Parliament and Council of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10) as amended by Directive 2004/12/EC of 11 February 2004 (OJ L 47, 18.2.2004, p. 26).

[62] Regulation on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1) as amended by Regulation No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[63] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 10.

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's services on the need for a fresh notification.

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 which are without added legal effect or of course in the cases provided for by Article 10 (e.g. integration in the text of remarks made by the Commission in a detailed opinion, see hereinafter).

b) The obligations of the Commission

When the Commission has been notified of a new draft national technical regulation, it must transmit 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.

The Commission also places the notified drafts and their translations on its Website, which 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 allowing 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 TCAM Committee, established by Directive 1999/5/EC[64] for the telecommunications sector or the 'Recreational Craft Committee', established by Directive 94/25/EC[65] 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 Enterprise and Industry (DG ENTR)[66] 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 regulation (telecommunications, mechanical engineering, food and agricultural products, transport, construction, Information Society services, etc.).

The information which is circulated under the procedure is recommunicated by the Commission to all the Member States, firstly in the language of the notifying Member State and then

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[64] Directive 1999/5/EC of the European Parliament and Council of 9 March 1999 relating to radio and telecommunications terminal equipment, including the mutual recognition of their conformity, OJ L 91, 7.4.1999, p.1.

[65] Directive 94/25/EC of the European Parliament and Council 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 (amended by Directive 2003/44/EC of 16 June 2003, OJ L 214, 26.8.2003, p. 18).

[66] See Annex 1 to this booklet.

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

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 28 and 30, 43 and 49 of the Treaty, but also with the sectoral Directives involved, and to reach a decision, where necessary, on its consistency with the concerned provisions.

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. 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 services and to the freedom of establishment.

In this case, neither the Commission nor the Member States react during the three-month period.[67] 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 98/34/EC, 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 98/34/EC provides, in Article 8 (1) (last subparagraph), that the comments and detailed opinions issued with regard to technical specifications, 'other requirements' or rules on services linked to fiscal or financial measures, can only relate to aspects which may create barriers to the free movement of goods or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators, and not to the fiscal or financial side of the measure. The Member States' fiscal powers are thus not under scrutiny in this respect. 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 and this increases the dialogue.

The Directive stipulates that the Member States must take comments into account 'as far as possible' (Article 8(2)). Member

[67] 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.

States do, however, generally take account of the comments they receive.

Detailed opinions (mentioned later, together with their consequences, in the analysis of Article 9 of the Directive) are sent by the Commission or the Member States when they consider that the draft measure envisaged would, if adopted, create obstacles to the free movement of goods, the freedom to provide services or the freedom of establishment of service operators within the internal market. These detailed opinions seek to obtain an amendment to the proposed measure, in order to remove at source any resulting barriers to such freedoms.

These issues relate to the illegality of the draft in terms of Community law, through a breach of Article 28, 43 or 49 of the Treaty. The most frequent breaches of these provisions are the absence in the text of a clause of mutual recognition of equivalent technical specifications or of rules on services established by another Member State, or the fact that some of the provisions of the draft are disproportionate to the pursued objective. Furthermore, the detailed opinion may relate to a breach of a Community harmonisation directive, a regulation or a decision.

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, preferably during the standstill periods of six or four months, respectively for goods and Information society services.

If the Commission considers that the reply to its detailed opinion is unsatisfactory, it can use, if the draft is actually adopted, the procedure referred to in Article 226 of the Treaty. In the same case, a Member State has the right, in the event of adoption of the notified draft, to institute the infringement proceedings provided for by Article 227 of the Treaty.

3. The Commission can announce a Community initiative on the subject of the proposed national measure or announces its finding that such initiative exists. 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.

The obligation to observe the standstill periods

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 the second indent of the second subparagraph of point 11 of Article 1,*

– *without prejudice to paragraphs 3, 4 and 5, for six months the adoption of any other draft technical regulation (except for draft rules on services),*

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;

– *without prejudice to paragraphs 4 and 5, for four months the adoption of any draft rule on services, 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 services or to the freedom of establishment of service operators within the internal market.

With regard to draft rules on services, detailed opinions from the Commission or Member States may not affect any cultural policy measures, in particular in the audiovisual sphere, which Member States might adopt in accordance with Community law, taking into account of their linguistic diversity, their specific national and regional characteristics and their cultural heritage.

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.

With respect to rules on services, the Member States concerned shall indicate, where appropriate, the reasons why the detailed opinions cannot be taken into account.

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.[68]

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.

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.

One should point out that the same 'additional one-month rule' applies in the event of a detailed opinion concerning draft rules on Information Society services.

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 and/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

[68] 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 linked with financial or fiscal measures (see Article 10(4)).

these measures are suited to eliminate the barriers to the free movement of goods, the free movement of services or the freedom of establishment of service operators which may have resulted from the adoption of the text, or whether the justification given for retaining the text is acceptable.

3. With the exclusion of draft rules relating to services, 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 of proposing or adopting a directive, regulation or decision on the matter 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 paragraph 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 249 (former 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.

In the field of Information Society services, the Commission cannot require postponement of the adoption of a draft simply by stating its intention to propose or adopt a binding Community act relating to the subject of the text. The fact that the Commission is in the process of drawing up a draft Community act is not sufficient to justify a waiting period of twelve months for the Member State concerned.

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. Contrary to the preceding case, this effect applies also in the field of Information Society services.

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 co-operation[69] and co-decision,[70] 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 postpones the adoption of national legislation 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, together with the Parliament in case of co-decision, or when the Commission adopts the announced binding Community act.

7. Paragraphs 1 to 5 shall not apply in 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 and, for rules on services, also for public policy, notably the protection of minors, 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 or*
- *for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons, a Member State is obliged to enact and implement rules on financial services immediately.*

In the communication referred to in Article 8, the Member State shall give reasons for 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.

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 pre-

[69] Procedure established by the Single European Act in 1986 and then introduced as Article 189c of the EC Treaty by the Maastricht Treaty. (Today Article 252).

[70] Article 189b, introduced into the EC Treaty by the Maastricht Treaty. (Today Article 251).

pare technical regulations for immediate introduction, without having time to consult the Commission and the other Member States beforehand.

Concerning rules on services, Member States can invoke the urgency clause also for urgent reasons, occasioned by serious and unforeseeable circumstances relating to public policy, notably the protection of minors. This new concept reflects the special importance attached by the Community legislator to the protection of minors in the context of the new services.

The urgency clause may also be invoked, where rules relating to financial services are concerned, for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons. This special and less strict form of urgency clause is provided for exclusively in the field of Information Society financial services on account of certain risks and requirements specific to this sector.

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 (apart from financial services) 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 to trade 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 launch the infringement procedure referred to in Article 226 of the Treaty against the Member State concerned for breach of the obligations provided by the Directive.

Exceptions to the obligation to notify or observe standstill periods

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 or rules on services;*

– *fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services 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 98/34/EC 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 twenty-five 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.

Several judgments have clarified the scope of the exception laid down in the first indent of Article 10(1) of Directive 98/34/EC, whereby Member States are not obliged to notify texts by means of which they comply with binding Community acts which result in the adoption of technical specifications or rules on Information Society services.

In the joined Albers, Van den Berkmortel and Nuchelmans cases[71], the Court considered that in issuing the prohibition on administering Clenbuterol to fattening cattle, the Netherlands honoured its obligations under Directive 86/469/EEC concerning the examination of animals and fresh meat for the presence of residues, and was therefore exempt, under Article 10, from the duty of notification.

Conversely, the Court specified, in the Unilever judgment[72] that Article 10 of the Directive may not be invoked when a provision of a directive allows the Member State sufficient room for manoeuvre. This was the case in point. Italy had asserted that Council Directive 79/112/EEC on the labelling of foodstuffs imposed the obligation to include in the labelling, particulars of the place of origin or provenance of the product in cases where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff. According to the Court, this provision is drafted in general terms which leaves sufficient room for manoeuvre for it to be concluded that national rules on labelling relating to the origin of olive oil cannot be regarded as national provisions conforming to a binding Community act within the meaning of the first indent of Article 10(1) of the Notification Directive.

This restrictive interpretation of the first indent of Article 10(1) of the Directive was confirmed by the Court in 'the Canal Satélite Digital' judgment[73]. In this judgment, the Court reiterated that Article 10 of Directive 98/34/EC shows that Articles 8 and 9 do not apply to laws, regulations or administrative provisions of Member States, or to voluntary agreements entered into by them, whereby Member States comply with binding Community measures which result in the adoption of technical specifications. To the extent that the national legislation at issue in the main proceedings transposed Directive 95/47/EC on the use of standards for the transmission of television signals, and to that extent only, there would be no obligation to notify under the Notification Directive. However, having regard to the content of Directive 95/47, the Court considered that the national legislation in question, in so far as it established a system of prior administrative authorisation, - which in fact is not provided by Directive 95/47/EC - could not qualify as legislation whereby the Member State complies with a binding Community measure resulting in the adoption of technical specifications.

The same reasoning applies to measures adopted to conform with an international agreement which contains specific provisions for the implementation of which no possibility of divergence is laid down. Measures adopted to conform with an agreement to which all the Member States are party come

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71 Case C-425/97 *'Albers'*, Case C-426/97 *'Van den Berkmortel'*, Case C-427/97 *'Nuchelmans'* [1999] ECR I-2947.

72 Case C-443/98 *'Unilever'* [2000] ECR I-7535.

73 Case C-390/99 *'Canal Satélite Digital'* [2002] ECR I-607.

within this exception; if these are measures adopted to conform with an international agreement to which not *all* the Member States are party, they must be notified.

– 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 95 of the Treaty. This Article lays down in paragraph 10 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 30, 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;[74]

The Member States do not have to notify draft national technical regulations relating to the application of Article 12 (1) of the Directive on general product safety.

This Article provides that *'where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX*[75]*. It shall also inform the Commission without delay of modification or withdrawal of any such measure or action (…)'.*

– 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 point 11 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

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, for instance through a detailed opinion or comments, from the Commission (for example, a request for the inclusion of a mutual recognition clause, based on Article 28 of the Treaty), since these measures are precisely in accordance with the objective of Directive 98/34/EC.

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[74] Directive of 29 June 1992 on general product safety, OJ L 228, 11.8.1992, p. 24. This Directive has been repealed by Directive 2001/95/EC of 3 December 2001 on general product safety. The relevant article is Article 12(1) of Directive 2001/95/EC.

[75] RAPEX, whose legal basis is Directive 2001/95/EC on General Product Safety, serves as a single rapid alert system for dangerous consumer products. All non-food products intended for consumers or likely under reasonably foreseeable conditions to be used by consumers are included within the scope of RAPEX, with the exception of pharmaceutical and medical products.

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 the second indent of the second subparagraph of point 11 of Article 1.

4. Article 9 shall not apply to the technical specifications or other requirements or the rules on services referred to in the third indent of the second subparagraph of point 11 of Article 1.

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 or rules on services 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 measures linked to the fiscal system of the Member States.

As far as draft regulations concerning 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), the blockage and the standstill obligations applicable to draft national regulations concerning a subject covered by current or imminent Community work, do not apply to voluntary agreements.

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It may be concluded from the reading of Articles 8, 9 and 10 of Directive 98/34/EC that the information procedure applicable to technical regulations is quite complex. The handbook produced by the Commission departments explains in detail how the procedure operates in practice.[76]

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 and by the saving of time and of much more complex procedures, both at Community and national levels, which would result from *ex post* procedures purely limited at removing already existing regulatory obstacles.

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 226 of the Treaty, as already mentioned.

When the Member State concerned does not comply, the procedure leads to a judgment of failure to fulfil obligations by the Court of Justice.[77]

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

[76] Standing Committee Document 94/94 - final of 8 June 1995 and Standing Committee Document S-42/98 (def).

[77] Reference is made to these judgments in Point V of the bibliography.

them.[78] Furthermore, the Unilever judgment laid down that even a measure which is notified but which is subsequently adopted during the standstill period laid down in Article 9 of Directive 98/34/EC, cannot be enforced against individuals.[79]

[78] Case C-194/94 *'CIA Security'* [1996] ECR I-2201 and Case C-226/97 '*Lemmens'* [1998] ECR I-3711.

[79] Case C-443/98 '*Unilever'* [2000] ECR I-7535.

Chapter IV

The Standing Committee

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.

The Committee shall meet in a specific composition to examine questions concerning Information Society services.

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 consolidated 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.

8. With respect to rules on services, the Commission and the Committee may consult natural or legal persons from industry or

academia, and where possible representative bodies, capable of delivering an expert opinion on the social and societal aims and consequences of any draft rule on services, and take notice of their advice whenever requested to do so.

Articles 5 and 6 describe the composition and role of the Standing Committee, which is referred to repeatedly in the provisions of Directive 98/34/EC.

The Committee is composed of representatives of the Member States' national authorities and chaired by a representative of the Commission. It has competence for standards and technical regulations,[80] and constitutes the 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 and also in developing an administrative network between national authorities.

The operating rules of this body have been agreed by the Member States and the Commission, since the Directive 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 four 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 98/34/EC, and specific powers limited to each of them.

1. General powers

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.

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 98/34/EC, 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, the

[80] Hence its title: 'Standards and Technical Regulations Committee' or '98/34/EC Committee'.

Council and the European Economic and Social Committee 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 draft or a proposal for a decision, 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 the Notification directive.[81] It draws up a list of national authorities, other than central governments, whose technical regulations fall within the scope of the Directive and examines any draft amendment to this list. 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 98/34/EC procedure with the notification procedures provided for by other Community acts; certain notified draft technical regulations are placed on the agenda with a view to finding solutions to specific problems raised.

Apart from the 98/34/EC 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 98/34/EC, with a view to settling practical problems encountered in the application of the information procedure, finding solutions which will enable infringement proceedings launched by the Commission for non-notification of draft national regulations to be closed, or avoiding such proceedings.

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 I and respectively II of the Directive, and on the presentation format of national and European standards programmes.

It must also be consulted on any request (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.), and standards in other European fields/policies with a view to implement these policies (energy, 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 Commit-

[81] 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.

tee on the relevance and timeliness of undertaking standardisation work on a European level.

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 full application of European standards.

The Standing Committee also reviews progress of mandated work and discusses several problems relating to standardisation in the framework of Directive 98/34/EC.

Moreover this standing Committee is also consulted on possible shortcoming in mandated standards, as stipulated in New Approach Directives. This procedure is known as the procedure for formal objections against an harmonised standard.[82]

[82] See the Vademecum on European Standardization:
http://europa.eu.int/comm/enterprise/standards_policy/vademecum/index.htm

Chapter V

The Application of the Directive

Chapter V: The Application of the Directive

Reports and statistics

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.

Not later than two years from the 5th of August 1999, the Commission shall submit to the European Parliament and the Council an evaluation of the application of Directive 98/34/EC in particular in the light of technological and market developments for the services referred to in point 2 of Article 1. Not later than three years from the above mentioned date, the Commission shall, if necessary, make proposals to the European Parliament and to the Council for a revision of the said Directive.

To this end, the Commission shall take into account any observations that might be communicated to it by Member States.

This Article sets out the Commission's obligations in respect of guaranteeing the transparency of information on the application of Directive 98/34/EC, 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 reports which the Commission must submit to the European Parliament, the Council of Ministers and the European Economic and Social Committee describe the operation of the Directive during the reference period.[83] A specific report from the Commission to the European Parliament and the Council on the evaluation of the application of Directive 98/34/EC in the field of Information Society services was published in 2003 to take stock of the situation since the Directive was extended to this sector in August 1999.[84]

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 98/34/EC, are also directly accessible, since they are published every year in the Official Journal of the European Union (OJEU).[85]

Reference to the Directive at the time of adoption of technical regulations

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 98/34/EC 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.

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[83] The last report, published under the reference COM(2003) 200 final, 23 May 2003 covers the period 1999 – 2001.

[84] COM(2003) 69 final, 13.2.2003.

[85] This publication obligation was laid down by Directive 94/10/EC, in force since 1 July 1995. Statistics relating to technical regulations notified in 2004 under Directive 98/34/EC were published in OJ C 158, 29.6.2005, p. 20. The statistics can also be consulted on the Website of the Commission dedicated to Directive 98/34/EC.

Although this reference is not an absolute guarantee of compliance by the Member State with the provisions of the Directive, it does at least establish a 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).

Timetable and application methods

Directive 83/189/EEC was adopted on 28 March 1983 and entered into force on 1 April 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 and was brought about by Directive 94/10/EC.

The procedure was then codified by Directive 98/34/EC of 22 June 1998 and modified by Directive 98/48/EC of 20 July 1998, mainly to extend its application to Information Society services. This extension came into force on 5 August 1999.

The manner in which these Directives were transposed was left, as for any other Directive, to the discretion of the Member States in accordance with Article 249 of the Treaty which states that '*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*'.[86]

Directive 98/34/EC 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.

[86] As opposed to a regulation which 'shall be binding in its entirety' and 'directly applicable in all Member States'.

Chapter VI

Access to information by private individuals and industry and the remedies available to them

Chapter VI: Access to information by private individuals and industry and the remedies available to them

Although the implementation of Directive 98/34/EC 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, the real beneficiaries of the notification procedure, including all the categories of recipients of Information Society services (companies, professionals, consumers, etc.), to inform themselves of all the initiatives planned by the national standardisation bodies and of 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 other Member states, 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, in order to facilitate the access to products and to Information Society services at crossborder level. 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 98/34/EC 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 and undertakings of the European Union under Directive 98/34/EC are to be exercised in full, private individuals and businesses 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 Union, Series C

– Each year the Commission publishes a list in the Official Journal of the European Union 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 OJEU 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).[87]

[87] See the statistics on technical regulations notified in 2004 under Directive 98/34/EC, OJ C 158, 29.6.2005, p. 20.

– Each week, the Commission publishes in the OJEU the titles of draft national technical regulations notified under the 98/34/EC 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 Official Journal of the European Union, Series C).

2. Other sources of information

– In order to facilitate industry's access to national technical regulations, the Commission has developed a comprehensive database of all notified draft texts called TRIS (Technical Regulations Information System) which is accessible to the public on the Europa website.[88]

  In addition to the search system, the general public can use the automatic Alert System via this Website. All one needs to do is register and select one or several notification categories. TRIS will automatically e-mail the subscriber as soon as a new notified text in the chosen category or categories has been received. If a draft under examination subsequently causes the subscriber problems or is likely to hinder trade relations in the European Union, he/she is invited to forward any comments and make any concerns known either to the Commission or to the authorities responsible in his/her particular Member State.

– Interested parties may also obtain the text of draft technical regulations from the central units of the Member States (listed in Annex 1 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 2 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.[89]

– The Commission issues press releases to inform private individuals and companies of infringement proceedings against texts of technical regulations adopted in breach of the Directive. This information can be used by a private individual or a company before a national authority, in support of the principle of non-applicability of a technical regulation adopted in breach of Directive 98/34/EC.

3. The inapplicability of the 'non notified' technical regulations

The above cited sources of information enable private individuals and other interested parties 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 and the 'Unilever' judgment, delivered under the preliminary ruling procedure by the Court of Justice, are key elements in the protection of private individu-

[88] http://europa.eu.int/comm/enterprise/tris/

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

als against failure on the part of Member States to fulfil their obligations under Directive 98/34/EC.[90]

These judgments specify the consequences of the adoption of a technical regulation in breach of the obligations laid down by Directive 98/34/EC: 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 or which *has* been notified but has been adopted during and not after the expiration of the standstill period laid down by the Directive.

Private individuals and enterprises 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 national 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 which had been already adopted by the Commission in 1986[91] and enhances the protection of the interests of private individuals and enterprises in this respect.

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[90] Judgment of 30th 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 *'CIA Security'* [1996] ECR I-2201 and Judgment of 26th September 2000 'Interpretation of Council Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations – Obligations of notification and postponement of adoption – Applicability in civil proceedings', delivered in Case C-443/98 *'Unilever'* [2000] ECR I-7535.'

[91] 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.

Conclusion

Conclusion

In the context of the 2005 renewed Lisbon strategy and as part of its Better Regulation programme, the Commission announced its intention to launch a comprehensive initiative to ensure that the regulatory framework in the EU meets the requirements of the twenty-first century. Closer cooperation with the Member States to ensure that better regulation principles are applied consistently throughout the EU and the reinforcement of the constructive dialogue between all regulators at the EU and national level and with stakeholders were identified as key action lines in this respect.

It is clear from a review of more than twenty years' experience with the implementation of the Notification Procedure during which time the Commission has screened more than 10.000 draft national measures that significant progress has been made in preventing the emergence of new barriers to trade, simultaneously saving onerous legal, administrative and economic costs. In this respect the 98/34 Notification procedure may be considered a precursor for better regulation as it has proved to be an effective instrument of industrial policy and competitiveness which has created various channels of communication between all the main stakeholders. Consequently, it represents a model of regulatory transparency and administrative cooperation whose scope of application might be further extended and provide similar benefits in other sectors.

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 co-operation, which now govern their activities in the field of technical standards and regulations. Similarly, even if more recently, in the area of services this mechanism has played an important educational role in the case of national authorities, notably as regards the need to make a clear legal distinction between operators acting under the freedom of establishment and those only wishing to provide crossborder services.

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.

In more or less 95% of the cases where the Commission reacted in order to bring the national draft regulations into conformity with Community law, Member States agreed to carry out the necessary changes and to align their legislation with EC law, thus avoiding the launching of the more cumbersome infringement procedures by the Commission. The cooperation and discussion fostered between Member States through the 98/34 procedure is evidenced by the fact that between 2002 and 2004, for instance, Member States exchanged 230 detailed opinions

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 98/34/EC is the key instrument of Community policy to combat barriers to trade which has made this possible.

Despite its success, the procedure laid down by Directive 98/34/EC could still be improved. This 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.

With regard to the procedure for the provision of information applicable to technical regulations and rules on Information Society services, 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 appreciates industry's increased participation in the examination of draft measures. Some European federations exercise a high degree of 'legislative vigilance' and are very active in defending their legitimate interests by informing the Commission or the national authorities about certain drafts which, if adopted, would create technical barriers. The involvement of individual enterprises and particularly small and medium-sized businesses, which are often more reserved, could be improved. They should not hesitate to seek information and speak up, even in a confidential way, 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 has taken some important steps to facilitate the participation of industry. In principle, notified drafts are translated into all Community languages and are then available free of charge to the public on the Europa site, via the TRIS (Technical Regulations Information System) database. Furthermore, the Commission has set up an automatic alert system to which the public may subscribe. This permits economic operators to be automatically notified by TRIS via e-mail as soon as a new notified text is received in the product or Information Society services category or categories selected.

Directive 98/34/EC is at a turning point: the adoption of Directive 98/48/EC on Information Society services and the accession of ten new Member States to the Union on 1 May 2004 have radically changed the application of the legislation, the geographical scope of which will continue to expand.

The next big challenge concerns the probable extension of the 98/34 Notification Procedure. Following a Commission Report which analysed barriers to the freedom to provide services and the freedom of establishment in the Internal Market[92], the Commission is currently working on a proposal concerning the possible extension of Directive 98/34/EC to cover services other than Information Society services in order to ensure that this increasingly important and largely predominant area of the EC economy will no longer fall outside the preventive control set up by this procedure.

[92] COM(2002) 441 final.

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Judgment of 12 October 2000, Snellers, Case C-314/98, ECR I - 8633

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Judgment of 8 March 2001, Van der Burg, Case C-278/99, ECR I - 2015

Judgment of 22 January 2002, Canal Satélite Digital SL, Case C-390/99, ECR I - 607

Judgment of 6 June 2002, Sapod Audic/Eco-Emballage SA, Case C-159/00, ECR I - 5031

Judgment of 21 April 2005, Lars Erik Staffan Lindberg, Case C-267/03

Judgment of 2 June 2005, Mediakabel, Case C-89/04

Judgment of 8 september 2005, Lidl Italia, Case C-303/04

Annexes

Annex 1

CONTACT POINTS AT THE COMMISSION AND IN THE MEMBER STATES FOR THE 'TECHNICAL REGULATIONS' ASPECT OF THE DIRECTIVE.

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This booklet is intended as a guide to the system set up to prevent barriers to the free movement of products as well as the freedom of establishment and the freedom to provide services as far as Information Society services are concerned. The booklet provides a commentary on Directive 98/34/EC, the legislation adopted to implement this mechanism. It covers the amendments subsequently introduced on 20 July 1998 by Directive 98/48/EC which brought about an important change to the procedure by extending it to rules on Information Society services. 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.

This booklet has been prepared by the Commission departments and does not commit the Commission in any way. The text of Directive 98/34/EC, as amended by Directive 98/48/EC, is alone legally binding. The original language of this booklet is English.

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