COMMISSION OF THE EUROPEAN COMMUNITIES



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# **REPORT FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE**

# THE OPERATION OF DIRECTIVE 98/34/EC FROM 1995 TO 1998

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## **REPORT FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE**

## THE OPERATION OF DIRECTIVE 98/34/EC FROM 1995 TO 1998

## 1. SUMMARY

This report on the application of Directive  $98/34/EC^1$  from 1995 to 1998 is intended to inform the European Parliament, the Council and the Economic and Social Committee in accordance with Article 11 of the Directive.

It is divided into three parts: the information procedure for standards (brief description of the procedure, statistical analysis, quality of notifications and use made of the information, requests to European standardisation bodies to draw up standards); the notification procedure for technical rules within the European Community (how the procedure has developed, information exchanged, reactions from the Commission and the Member States, subsequent procedure, factors which contributed to the increase in the number of drafts notified, action taken to provide businesses with more information); and the procedure for the exchange of information on technical rules between the Community and the EFTA countries.

This report describes the role of Directive 98/34/EC during the period in question, and the way in which it prevents barriers to intra-Community trade. It reflects the results of the dialogue between the Commission and the Member States, and among the Member States, and of the establishment of an information network linking European and national standardisation bodies.

This report is intended to raise awareness of this procedure in the European Union and to encourage businesses to make greater use of the procedure set up by the Directive.

## 2. INTRODUCTION

- 1. This report on the application of Directive 98/34/EC from 1995 to 1998 is intended to inform the European Parliament, the Council and the Economic and Social Committee in accordance with Article 11 of Directive 83/189/EEC, as amended by Directives 88/182/EEC and 94/10/EC and consolidated by Directive 98/34/EC.
- 2. The purpose of Directive 98/34/EC is to prevent the appearance of barriers to intra-Community trade; this basic instrument for the completion of the internal market has fulfilled its purpose by initiating a dialogue between the Commission and the Member States, by promoting cooperation among the Member States, and by setting up an information network linking European and national standardisation bodies.

<sup>&</sup>lt;sup>1</sup> Directive 83/189/EEC was amended by Directives 88/182/EEC and 94/10/EC and then consolidated by Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, page 37). The latter entered into force on 5 August 1998 and repealed the earlier Directives. For the sake of simplicity, this report therefore refers to Directive 98/34/EC rather than to Directive 83/189/EC.

- 3. The changes made to the Directive, in particular those made during the period covered by this report, and the case-law of the Court of Justice have contributed to this result and have enhanced the transparency, dialogue, preventive approach and reciprocal control which characterised the system from the start.
- 4. The report on the operation of this instrument from 1995 to 1998 is divided into three parts.
- 4.1. The information procedure for standards

After a brief description of the procedure for standards, this section explains how it worked from 1995 to 1998 and analyses the statistics. It also discusses the quality of the notifications, the use made thereof, and the mandates given to the European standardisation bodies, i.e. the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI). This section ends with details of improvements which have been or could be made.

4.2. The notification procedure for technical rules within the European Community

This section describes how the procedure established by Directive 98/34/EC for national technical regulations has developed. It examines the information flows, including the various reactions from the Commission and the Member States, the possible further procedures, and the results. Particular attention is paid to the factors which contributed to the increase in the number of drafts notified and to the action taken to provide businesses with more information.

4.3. The exchange of information on technical rules between the Community and the EFTA countries.

The Agreement on the European Economic Area (EEA Agreement) entered into force in 1994. It incorporates the provisions of Directive 98/34/EC in an adapted form. Although the Swiss Confederation is not a party to the EEA Agreement, it continues to participate in the exchange of information with the Community by voluntarily following the practice introduced by the Agreement between the Member States of EFTA and the European Economic Community laying down a procedure for the exchange of information in the field of technical regulations.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> Council Decision 90/518/EEC of 24 September 1990 concerning the conclusion of an Agreement between the European Economic Community, on the one hand, and the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Kingdom of Norway, the Kingdom of Sweden and the Swiss Confederation, on the other, laying down a procedure for the exchange of information in the field of technical regulations, OJ L 291, 23.10.1990. This Agreement was concluded for a period of two years and expired on 1 November 1992. It was extended for the period from November 1992 to December 1993 by bilateral agreements in the form of exchanges of letters.

This section analyses the exchange of information between these countries and the Community.

## 3. PART I: THE INFORMATION PROCEDURE FOR STANDARDS

#### 3.1. Introduction

5. This section reports on the information procedure for standards established by Articles 2 to 7 of Directive 98/34/EC. These provide for the national standardisation bodies to notify the Commission, the European standardisation bodies and the other national standardisation bodies of any new subjects for which they have decided to prepare or amend a standard. After a brief description of the procedure, this section explains how it worked from 1995 to 1998 and analyses the statistics. It also discusses the quality of the notifications, the use made thereof, and the mandates given to the European standardisation bodies, i. e. the European Committee for Standardisation (CEN). the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI). This section ends with details of improvements which have been or could be made.

#### **3.2.** Brief description of the procedure

6. In practice, the information procedure for standards began on 1 January 1985. Since the adoption of Directive 94/10/EC amending Directive 83/189/EEC, the notification obligation has applied exclusively to new standardisation work started. It no longer applies to other updates to the national standardisation programmes, namely drafts for public scrutiny or the adoption of national standards.

The national standardisation bodies, which are members of CEN and CENELEC (including bodies from the EFTA countries), send the necessary information to the Central Secretariats of CEN and CENELEC. The information gathered is sent periodically to the Commission and to all members of CEN and CENELEC, who are responsible for distributing it to the sectors concerned in order to sound out their reactions. The information is also examined by the relevant authorities within CEN and CENELEC (Central Secretariats, Technical Boards, etc.) and by the Commission departments.

Appropriate annual contracts were concluded between the European Commission and CEN and CENELEC on technical operation of the information procedure for standards.

7. The European Telecommunications Standards Institute (ETSI) automatically takes part in the information procedure for standards. In practice, however, its role is limited to receiving and examining the information submitted by CEN and CENELEC members via both Central Secretariats. In fact, ETSI is not made up of national standardisation bodies, as defined in Article 1 of Directive 98/34/EC. Information on draft national technical specifications in the field of telecommunications is channelled, in principle, either via the information procedure for technical regulations in the case of legislation, or via CEN and CENELEC members in the case of voluntary measures. As mentioned in the previous report, it can be assumed that national standardisation activities in the field of telecommunications should be limited, since the ETSI programmes cover a wide range of subjects, all of which are covered by the internal standstill rule. In practice, this section of the report therefore focuses solely on activities notified by the CEN and CENELEC members listed in Annex II to Directive 98/34/EC.

## **3.3.** Operation of the information procedure from 1995 to 1998

8. As stated in the previous report, as early as 1993 CEN introduced the simplified procedure proposed by the Commission in 1992 and on which Directive 94/10/EC was based. This simplification has enabled the CEN Central Secretariat to exert closer control over the flow of information and to examine the presentation and content of certain notifications in greater detail. It has also made it possible to obtain full, realistic statistics on new activities.

In October 1996 CEN introduced the ICS classification for the notifications, the ISO's international classification of the various fields - of industry in particular - covered by the standards. By 1998 the ICS classification had already been added to around 22% of notifications.

Since the beginning of 1993 the full texts of draft standards for public scrutiny have been exchanged, case by case, by mutual agreement between the bodies concerned in the spirit of the participation provided for by Article 3 of Directive 98/34/EC.

9. CENELEC has been concentrating on its internal procedure, known as the "Vilamoura" procedure, followed, where appropriate, by the information procedure laid down by Directive 98/34/EC. The Vilamoura procedure requires each CENELEC member to notify every standardisation activity wanted and/or planned as early as possible, even at a preliminary stage. A reaction within three months from just one other member is enough to activate a standstill period, which only the highest technical authority within CENELEC (the Technical Board) can lift. Only if this authority finds it inappropriate to work at European level will it authorise the notified activity at national level, which then becomes a national initiative under the terms of Directive 98/34/EC. Notifications of these initiatives are then distributed every quarter to the larger circle of participants named in Directive 98/34/EC.

As a result of CENELEC's special procedure, and the fact that CENELEC covers only the electrotechnical sector, the number of notifications from its members under Directive 98/34/EC has remained fairly low. The statistics in this report are therefore principally for the activities of CEN members.

At the express request of the Commission in December 1996, CENELEC confirmed that the combined procedure described above was working well, and also confirmed the commitment shown by its members. However, it is regrettable that the information from the Vilamoura procedure is not released outside, as it is in the procedure introduced by the Directive, but is circulated mainly among CENELEC members. Compilation of all the notifications in a single register would improve transparency and is, therefore, one possibility to explore.

10. The statistics published in the CEN and CENELEC annual reports supply an overview of the standardisation activities notified from 1995 to 1998.

The statistics on new work reflect the latest trends in standardisation activities. These statistics can be examined from three complementary angles:

- breakdown by level (national, European or international) and activity trends at each level;
- breakdown by country;
- breakdown by sector and subsector.
- 11. As indicated in previous reports, the statistics must be interpreted with some caution for the following reasons:
  - the pre-1993 statistics take no account of the relatively high number of new activities notified directly at the public scrutiny stage; moreover, these late notifications were contrary to CEN/CENELEC regulations;
  - a new activity launched at European level might cover a much wider field than an activity at national level;
  - because of different working methods not all CEN and CENELEC members notify new standardisation work at the same stage.

The accession of three new Member States on 1 January 1995 complicates the comparison of statistics from before and after that date.

The statistics set out in the annexes disregard notifications from France for regularisation purposes in the course of 1995. The number of such regularisations was estimated from the information received from AFNOR (62% of the total of 1 342).

## **3.4.** Trends in standardisation activities

- 12. Bearing these reservations in mind, a number of comments can be made on the trends in international, European and national standardisation based on Tables I, II, III and IV annexed to this report.
  - The total number of new activities launched at these three levels has remained stable since 1993 at around 4 500, after two years of rapid growth in 1991 and 1992.
  - At national level, the number of new initiatives averaged 1 620 per year from 1995 to 1998, down from 2 000 per year from 1992 to 1994. The proportion of very specific work within this number held steady at around 95%.
  - The number of new initiatives at European level has fallen sharply since 1993 in comparison with the two previous years in both the electrical and non-electrical sectors.
  - At international level, the downward trend is continuing (average of 1 122 initiatives per year compared with 2 189 per year from 1992 to 1994).
  - Tables IIIa to IIId show that on average 50% of new national activities were from Germany and France. In 1998 the figure for France was in line with the share of notifications from the other top three Member States (i.e. 10%).

- The top ten subsectors for national activities are shown in Tables IVa to IVd. They show a high level of activity in the fields of aeronautics and chemicals in 1995. In 1996 and 1997 new national activities focused mainly on foodstuffs and small machine tools. Foodstuffs remained the leading sector in 1998.

## **3.5.** Quality of the notifications from the national standardisation bodies

- 13. In its previous reports the Commission indicated that there were still problems with the notification deadlines and the intrinsic quality of the information supplied. The Commission insisted on additional efforts at national and European level to remedy this situation. Since the start of the report period (1995/98) such efforts have been made, bringing with them an improvement in the quality of notifications. This progress, which has not always been easy, is the fruit of constant efforts by the CEN Central Secretariat and its national correspondents.
- 14. First, the CEN Central Secretariat clearly defined the internal rules necessary to keep notifications accurate, clear and reliable in a user's guide for its members published in May 1995. This also explained how one member could participate in another member's activities. A month later a training seminar was held for all correspondents to exchange experience. This was followed up by bilateral contacts on notifications of dubious quality. A help desk was set up within the Central Secretariat to deal with questions from suppliers of data.
- 15. Despite these measures, around 20% of notifications were still submitted late in 1998, compared with 23% in 1994. The main improvement is that in 1998 only 14% of these late notifications were received at the end of the public scrutiny stage. Further efforts are essential to avoid jeopardising the principles of the information procedure laid down in the Directive. In particular, late notification can hinder direct participation in the work of other standardisation bodies and the submission of comments at an early stage.
- 16. The description of the draft is still not sufficiently precise, although there was some improvement between 1995 and 1998. In 1995 some 55% of notifications contained no description other than the title. By 1998 this percentage was down to around 31%, which is still high. These were principally notifications from the United Kingdom, France, Finland and Austria. The other main inaccuracies in the notifications were misclassification of the sector of activity, although there was improvement on this point between 1995 and 1998. Also, the Commission departments have doubts about whether some of the new activities are not linked to European or international work.
- 17. No detailed analysis similar to the analysis by the CEN Central Secretariat is available from CENELEC. However, bearing in mind the internal Vilamoura procedure, with its relatively strict rules on notification, and the lower volumes involved, the quality of notifications from CENELEC members can be considered satisfactory at least.

#### **3.6.** Use of the information received through the procedure

18. The 1992-94 report recommended a study of the dissemination at national level of the information gleaned from the procedure, as no detailed information was available on this subject. In May 1995 the CEN Central Secretariat sent a survey to its correspondents. Several national bodies replied. It emerged that in Denmark a fee is

charged for subscribing to the monthly register and that notifications are examined mainly by the standardisation body. In Germany the information is circulated to 60 or so relevant trade associations which are responsible for disseminating it to their members. In France systematic dissemination and broad consultation of industry are the striking features. The Italian standardisation body disseminates the data to its industries and affiliates. Its technical staff are also kept informed of the activities notified sector by sector. In Portugal the information is passed on to members of the standardisation organisation, but in Sweden and the United Kingdom there seems to be only marginal interest in the information.

- 19. As was also highlighted in previous reports, application of Article 4 of the Directive, i.e. involvement in national activities and requests to draw up European standards, remains marginal. Table V confirms these observations:
  - the number of comments made by the standardisation bodies remains very low in comparison with the number of notifications received;
  - requests to participate in other members' activities even seem to be decreasing;
  - with one or two exceptions, requests to draw up European standards are non-existent.

It can therefore once again be concluded from these statistics that the mechanisms provided by Article 4 of the Directive are not being used.

- 20. In the electrotechnical sector, allowance should be made for application of the Vilamoura procedure. This provides for at least the same type of participation in each new initiative launched by a member as allowed by Article 4 of Directive 98/34/EC. In 1997 this procedure was applied to 33 notifications, of which 14 were transferred to European level and 5 others were left to be developed at national level, with the participation of one or more other countries. In 1998 just 13 notifications were made under this procedure, 3 of which were taken up at European level.
- 21. Application of the standstill rule in Article 7 of Directive 98/34/EC was monitored at two levels, by CEN/CENELEC and by the Commission.

Within the CEN Central Secretariat, notifications are periodically examined by technical experts. No statistics are available on the number of cases handled, but it could be useful to submit them to the Commission.

The Commission departments continued to examine the notifications received, both to monitor the standstill in cases where mandates had been given to the European standardisation bodies and to examine whether it would be appropriate to transfer the notified activity to European level. The number of cases queried was cut from 16 in 1996 to 2 in 1997 because of a lack of resources.

- 22. To close this section on the use made of the information received, two remarks can be made:
  - The simplification of the procedure brought about by Directive 94/10/EC has created the conditions required for more efficient use of the information, by considerably reducing the volume of data and concentrating on the relevant information. However, this simplification has improved neither the

dissemination of the information at national level nor the application of Article 4. Use of the information seems to depend, above all, on the general attitude of CEN members to the information procedure. For example, France has a policy of active dissemination of the information gathered.

- The Commission believes that further measures could be taken to make more efficient use of the information at national level. Despite the great efforts made by the CEN Central Secretariat, systematic, tenacious efforts are still needed, particularly to improve the notifications at source. Dissemination of the information at national level could be improved by using advanced technologies and demonstrating the benefits of this procedure to industry.

#### **3.7.** Information on standardisation activities in general

23. Information on new national standardisation activities is only part of the mass of information on standardisation activities. There is also the more general question of information about the national standards adopted and all standardisation in progress or completed at European and international levels.

An effort is still needed to improve information and to take greater account of the interests of consumers and environmental protection.

As it has indicated on several occasions, the Commission considers it necessary to give all sectors concerned access to appropriate information on standardisation activities on reasonable terms. Accessibility and transparency should be basic characteristics of the standardisation system. Constant efforts should be made at national and European level to meet the information requirements of all interested parties.

24. At the start of 1995 a study was made of the knowledge and information needs of small and medium-sized enterprises in Europe, with particular regard to standardisation. This Euromanagement study was funded by the Commission and conducted by AFNOR, the French standardisation body.

It highlighted the enormous difficulties encountered by SMEs in gaining access to information on standardisation. To remedy this situation, in July 1996 the Commission launched a profile- and awareness-raising programme. This evolving programme was designed in close cooperation with the three European standardisation bodies based on an agreement between them and the Commission. The biggest project in this programme is the INES project started in 1997 and partfunded by the Commission, which is intended, inter alia, to open up access to various CEN documents via the Internet. Other forms of information were also produced between 1995 and 1998 including a video, a brochure and a series of articles for publications for SMEs.

25. At the request of the Commission, in 1998 the three standardisation bodies started the computer work needed to establish a shared web site. This single gateway on the Internet should allow all outside users access to information on standardisation activities in progress or already completed at European level under the "new approach" Directives.

This shared site will also provide easy access to the individual sites of the three European standardisation bodies and to the Commission sites, where, amongst other things, the full text of the Directives concerned and particulars of the harmonised standards implementing them can be found. The address of this shared site is: http://www.NewApproach.org.

- 26. At the same time the three European standardisation bodies continued to issue a number of publications explaining their present activities, describing standards adopted and listing national standards transposing European standards. They also started their own project to set up a website.
- 27. The PERINORM information service, distributed monthly on CD-ROM, contains bibliographic references for adopted standards as well as for standards at the public scrutiny stage. It covers several countries as well as CEN and CENELEC at European level and ISO and IEC at international level. The Commission financed subscriptions to this service for several dozen Euro Information Centres, considered to be those most affected by this field and covering a wide geographical area.

Other CD-ROMs are available on the market containing, inter alia, the full text of international, CEN and CENELEC standards.

#### **3.8. Programming and standardisation mandates**

28. Pursuant to Article 6(3) of the Directive, the Standing Committee expressed favourable opinions on 33, 18, 21 and 18 mandates in 1995, 1996, 1997 and 1998 respectively. 26 of these 90 mandates were to implement "new approach" Directives. Others were principally in support of other Community policies (see Tables VIa, VIb, VIc and VId in the Annex).

In 1996, 1997 and 1998 several key mandates were issued under the Directive on Construction Products.

- Eleven mandates were issued on information technology and telecommunications in 1995.
- Seven requests were made for standardisation in the field of consumer protection policy.
- Eight mandates were given, principally to CEN, in support of Directives on the environment.
- Eleven mandates concerned energy policy (reduction of consumption and alternative sources).
- There were two requests for standardisation relating to transport policy.

This shows that the Commission is turning increasingly to standardisation to implement various Community policies, as it had announced in its Communication of 30 October 1995 on the broader use of standardisation in Community policy (COM (95) 412 final).

#### **3.9.** Action to improve the procedure

- 29. In the case of standardisation, Directive 94/10/EC introduced a highly simplified procedure compared with the arrangements in Directive 83/189/EEC, thereby making it possible to examine the quality of notifications more closely.
- 30. Several measures were taken by the CEN Central Secretariat, mainly in 1995, to improve the quality of the data notified: the establishment of detailed rules, an awareness-raising seminar and establishment of a central quality assurance system. CEN's annual reports systematically examine in detail the quality of the notifications received, thus allowing an extremely useful quality assessment. It is not known if specific measures have been taken at national level to improve quality. However, it must be stressed that the action taken by the CEN Central Secretariat would not have borne fruit without the active cooperation of CEN members. CENELEC's Vilamoura procedure is quite strict on the quality of data, however limited the volume.
- 31. CEN's analysis of the quality of notifications submitted from 1995 to 1998, together with the assessment of the use made of the information collected during this period, show, however, that progress on quality has been relatively slow. A strict quality assurance system must therefore be maintained and any new action in this field is welcome. Potential measures include more frequent reports on the quality of the data received and detailed examination of the most frequent and most serious problems. The objective is to take targeted action, for example country by country.
- 32. At national level, it is primarily a matter for the Member States to take measures to enable their national standardisation body to comply fully with the obligations imposed in the new rules laid down in the Directive and with the rules established within the European standardisation bodies.

The national bodies, in turn, should examine the need to revise and adapt their notification systems, with particular emphasis on quality and timely submission. The analysis once again confirms persistent weaknesses on this point.

33. With regard to the use made of the information, the current dissemination system must be reviewed. The introduction of new technologies for notifications and for disseminating the consolidated information must be envisaged to facilitate communications and make the information more attractive. The Commission also recommends that the information on new activities of CENELEC members should form an integral part of the CEN information. This does not require the two systems to be integrated or the CENELEC procedure to be adapted, but it will provide a full overview for potential users and make the CENELEC procedure more transparent for outsiders.

Revision of CEN's current dissemination system should also generate renewed interest on the part of all relevant sectors in the information from the procedure for standards. European or national awareness-raising measures for these sectors could also be envisaged.

## 3.10. Conclusions

34. The approximately 25% reduction in the number of new national standardisation activities since 1993, compared with the previous period, was confirmed. The first

reason for this was the simplified procedure introduced by Directive 94/10/EC, which requires only strictly new national activities to be notified. The second reason for this reduction was an actual fall in new national initiatives. The level of such activity is still high, above all in Germany. Over the report period, an average of 1 620 national initiatives per year were started compared with 1 900 at European level. Foodstuffs, construction products and small machine tools were the main fields concerned.

- 35. The various measures taken by the CEN Central Secretariat, in close cooperation with the national standardisation bodies, have improved the quality of notifications, but less than expected. Constant efforts and resources are needed to ensure data quality. This quality is a sine qua non for better use of the information and can be promoted by applying new technologies to improve communications and the presentation of the information collected.
- 36. Use of the information gathered under Article 4 of Directive 98/34/EC remains marginal, particularly participation in national activities and requests to transfer activities to the European level. Moreover, the resources seem insufficient to use this procedure to verify the standstill declared when a standardisation mandate is issued. The information procedure for standards is, therefore, not efficient enough. The 1995 questionnaire showed that only a few countries actively disseminate the information. General dissemination in user-friendly form is needed. Examination of the benefits and relevance of this procedure to the individual parties is also desirable. However, it must be stressed that removal of this mechanism for monitoring national activities could create new, significant risks of disruption of the internal market. It is up to all parties concerned to consider the usefulness of this procedure and ways of reinforcing it if it remains in place, but also the consequences were it to be removed.

## 4. PART II: THE NOTIFICATION PROCEDURE FOR TECHNICAL RULES WITHIN THE EUROPEAN COMMUNITY

## 4.1. Introduction

- 37. In the early 1980s the Commission took advantage of the judgment of the Court of Justice in the "Cassis de Dijon" case to launch a new policy to complete the internal market resting on three pillars:
  - acceptance in each Member State of products legally manufactured in the rest of the Community ("mutual recognition");
  - harmonisation restricted to major economic sectors, particularly those affecting health, safety and the environment;
  - a preventive approach to the monitoring of national regulations.

Since 1984 Directive  $83/189/EEC^3$  has obliged the Member States of the European Union to notify the Commission and the other Member States of all draft technical rules relating to products before they are adopted in national law; this procedure was extended to cover the rules affecting the information society from 5 August 1999.

38. This revolutionary system has retained all its originality. It prevents the creation of new barriers to trade within the internal market and emphasises transparency, dialogue, preventive measures and mutual control.

The procedure has been amended a number of times: first in 1988 (by Directive  $88/182/\text{EEC}^4$ ), then in 1994 (by Directive  $94/10/\text{EC}^5$ ), mainly to extend its scope. Since then it has covered all products, both agricultural and industrial, and a wide variety of rules.

The procedure for the notification of technical rules was consolidated by Directive 98/34/EC,<sup>6</sup> which repealed the earlier Directives. The consolidated Directive entered into force on 10 August 1998.

Directive 98/34/EC was in turn amended by Directive 98/48/EC,<sup>7</sup> which extended the procedure to information society services from 5 August 1999.

<sup>&</sup>lt;sup>3</sup> Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 109, 26.4.1983.

<sup>&</sup>lt;sup>4</sup> Council Directive 88/182/EEC of 22 March 1988 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 81, 26.3.1988.

<sup>&</sup>lt;sup>5</sup> Directive 94/10/EC of the European Parliament and the Council of 23 March 1994 materially amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 100, 19.4.1994.

<sup>&</sup>lt;sup>6</sup> Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204, 21.7.1998.

<sup>&</sup>lt;sup>7</sup> Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 217, 5.8.1998.

## 4.2. Description of the procedure

- 4.2.1. Brief description of the procedure applicable to technical rules set up by Directive 98/34/EC
- 39. Pursuant to Article 8(1) of Directive 98/34/EC, the Member States are required to communicate to the Commission any draft technical regulation.

The notifying Member State may not adopt the technical rule for three months from the date of notification of the draft to the Commission. This standstill period allows the other Member States and the Commission to examine the notified draft and to react appropriately. The outcome of this consultation procedure between the notifying Member State, the other Member States and the Commission determines the fate of the draft technical rule.

- If there is no reaction from the Member States and the Commission, the notifying Member State can adopt the draft regulation as soon as the three-month standstill period has passed.
- If another Member State and/or the Commission makes comments pursuant to Article 8(2) of the Directive, the notifying Member State must take such comments into account as far as possible in the subsequent preparation of the technical regulation.
- Where a Member State and/or the Commission considers that the draft measure envisaged may create obstacles to the free movement of goods, it may deliver a detailed opinion as provided for in Article 9(2) of the Directive. In this case, the Member State concerned must postpone the adoption of the measure for six months from the date of notification and must inform the Commission of the action it proposes to take in response to the detailed opinion.
- Where the Commission announces its intention to propose or adopt a binding Community act in the field concerned by the notified draft, or where it finds that the notified draft concerns a matter which is covered by a proposal for a binding Community act presented to the Council, Article 9(3) and (4) of the Directive requires the notifying Member State to postpone the adoption of the technical rule for twelve months from the date of notification. Article 9(5) of the Directive provides for this standstill period to be extended to eighteen months if the Council adopts a common position during that twelve-month period. Such extended standstill periods automatically lapse if the Commission withdraws its proposal or decides not to make a proposal, or when the Community act has been adopted.
- 40. Article 9(7) of the Directive allows national measures to be adopted immediately in certain urgent cases. If a Member State wishes to adopt a technical rule 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, it can ask for this procedure to apply and is not required to observe the standstill requirement. The notification must state the reasons which warrant the urgency of the measures taken, and the Commission then rules whether the emergency procedure is justified.

41. Article 8(3) provides that the definitive text of the regulation must be communicated to the Commission without delay.

The Commission plays a decisive role in the procedure. It is responsible for distributing to the Member States not only the notified drafts but also the other messages circulating between the Commission and the Member States or among the Member States. It also provides translations of these texts in order to facilitate the smooth operation of the procedure.

- 42. The Standing Committee of representatives of the Member States (set up by Article 5 of the Directive) is an advisory body which meets about four times a year. It plays an important part in supervising the procedure and examining the various issues arising from the notifications.
- 4.2.2. Changes made by Directive 94/10/EC to the procedure set up by Directive 83/189/EEC
- 43. Directive 94/10/EC, which applies from 1 July 1995, materially amended the notification procedure for the second time. The amendments were intended to clarify certain terms, to adapt the Directive to practical needs, and to extend its scope.

For the sake of consistency, the scope of the Directive was extended in two respects: (i) the concept of "technical specification", which Directive 88/182/EEC had already extended to include production methods and procedures for agricultural products, foodstuffs and medicinal products, was extended to include production methods and processes in general (Article 1(2)); (ii) the Community legislator added the new concept of "other requirement", meaning a requirement other than a technical specification (Article 1(3)).

- 44. "Other requirements" include all specifications which can be imposed on a product during its life cycle, from conditions of use to the management or disposal of the waste it generates, for the purpose of protecting, in particular, consumers or the environment. The "other conditions" listed in the Directive ("conditions of use, recycling, reuse or disposal") are given merely as examples. Other similar measures must therefore also be notified, provided they can significantly influence the composition or nature of the product or its marketing. This amendment closed up a whole series of loopholes which allowed Member States to avoid the preventive monitoring of certain technical rules which might affect the marketing or use of products.
- 45. A new subparagraph of Article 1(9) gives three examples of "de facto technical regulations" whose classification as technical regulations had previously been disputed. To avoid impinging on the fiscal autonomy of the Member States, and to ensure the flexibility inherent in voluntary agreements, there are specific standstill arrangements for certain de facto technical regulations. Thus the Community legislator has exempted notified fiscal and financial measures from the standstill requirement; voluntary agreements are subject to a reduced standstill period of four months.

In practice, the number of notifications of fiscal and financial measures designed to encourage compliance with a technical specification by means of financial incentives is increasing. The fact that a public authority must be a contracting party to voluntary agreements for them to be covered by the Directive has left the Member States a degree of discretion in determining whether or not they are obliged to notify such measures. In reality, it is exceptional for a State to sign a voluntary agreement; so, in spite of their obvious impact on the free movement of goods, many voluntary agreements fall outside the scope of the procedure set up by the Directive.

- 46. The standstill period imposed when a binding Community act is proposed (Article 9(3), (4) and (5)) was extended, as the mechanism established by the original version had produced highly unsatisfactory results. Thus the twelve-month standstill period, starting on the date of notification of the draft, can be extended to eighteen months where the Council adopts a common position during the initial twelve-month period. Thanks to this change, the percentage of cases in which the legislator adopted a binding Community act before the end of the extended standstill period quadrupled compared with the 1992-94 period.
- 47. Another change concerns the transparency of the information procedure: the definitive text of a technical regulation, which previously had to be communicated only at the express request of another Member State or the Commission, must now always be communicated (Article 8(3)). This change facilitates the last stage of the procedure, i.e. the final monitoring of the adopted texts.

The same concern for transparency prompted the Community legislator to amend the provisions on the confidentiality of the information communicated under the procedure. Pursuant to Article 8(4), information supplied as part of a compulsory notification is no longer confidential except at the express request of the notifying Member State. The new Article 12 requires the Member States to refer to the Directive either in the definitive text of a technical rule or on the occasion of its adoption.

48. Other major changes to the Directive include the obligation to submit a risk analysis in certain cases (Article 8(1)); the requirement to notify significant changes to a previously notified draft (Article 8(1)); the introduction of a single contact point for notifications under different procedures (Article 8(5)); the automatic lapsing of the extended standstill period when the relevant binding Community act is adopted (Article 9(6); the need for a "serious and unforeseeable" risk to justify recourse to the emergency procedure and the Commission ruling on whether recourse to the procedure is justified (Article 9(7)); certain exceptions to the notification requirements (Article 10(1).

## **4.3.** Application of the procedure

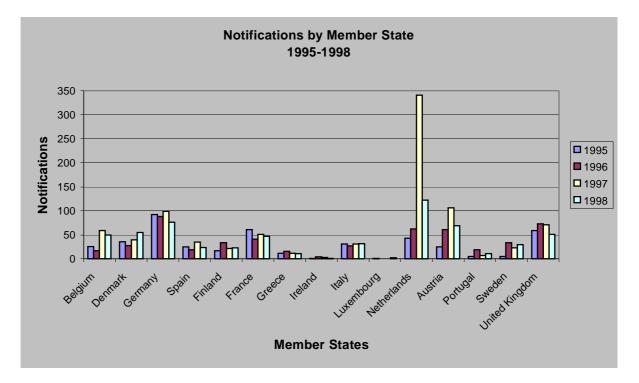
- 4.3.1. Volume of notifications
- 4.3.1.1. General trend
- 49. Table VII in the Annex shows that the Commission received 439 draft technical regulations in 1995, 523 in 1996, 900 in 1997 and 604 in 1998. If we exclude 1997 which we will discuss later we can see that there is a general upward trend in the number of notifications received each year (an increase of 37% between 1995 and 1998). The extremely high number of notifications in 1997 was due to the "catch-up" operation by the Dutch authorities following the judgment of the Court of Justice in

the "CIA Security International" case: the Dutch authorities notified 227 draft technical regulations with a view to their readoption. Even disregarding these Dutch notifications, there was a remarkable growth in the number of notifications in 1997, probably due to three factors: the accession of Austria, Finland and Sweden to the European Union; the entry into force of Directive 94/10/EC, which extended the scope of Directive 83/189/EEC; and the judgment in the "CIA Security" case, which prompted Member States to apply the Directive with greater care.

Apart from these factors, the large number of notifications is explained by the nature of the notified drafts. Many consisted of partial technical adaptations of existing technical rules which had already been notified. The degree of Community harmonisation varies from sector to sector. In some fields, such as foodstuffs, there is only partial harmonisation. In others, harmonisation is nearing completion, for example telecommunications, where the new Directive 99/5/EC of 9 March 1999 on radio equipment and telecommunications terminal equipment applies to radio equipment from 8 April 2000. The transport sector is covered by numerous international conventions. Standardisation work has still not been completed in a number of sectors, such as construction products where, in the absence of harmonised European standards, the Member States continue to legislate at national level to lay down product requirements.

- 4.3.1.2. Breakdown by country
- 50. Figure 1 (and Table VIII in the Annex) shows that from 1995 to 1998 most draft rules were notified by the Netherlands, Germany, Austria and the United Kingdom. Unlike previous years, Germany, the United Kingdom and France no longer account for the majority of notifications. In 1995, 1996, 1997 and 1998 the joint share of these Member States fell to between 24% and 48%. On the other hand, there was a marked increase in the number of notifications from Austria and the Netherlands. In 1997, for the first time, Austria (106) and the Netherlands (341 or 114) notified more draft technical regulations than Germany (99), the United Kingdom (71) and France (51). There was a particularly marked increase in the number of drafts notified by Belgium and Denmark in 1997 and 1998.

### 51. Figure 1

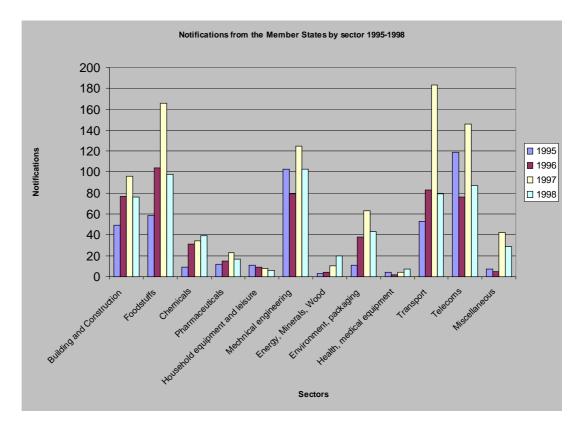


- 4.3.1.3. Breakdown by sector
- 52. A breakdown by sector (see Figure 2 and Tables IX to XII in the Annex) shows that, as was also the case in 1992-94, more than 75% of notifications received from 1995 to 1998 concerned the following five sectors: telecommunications (17.3%), agriculture and foodstuffs (17.2%), transport (16.1%), mechanical engineering (16.6%), and building and construction (12.1%). Transport is becoming increasingly important, and even topped the list for the first time in 1997, while mechanical engineering topped the list in 1998. The dominance of telecommunications noted in 1993 and 1994 continued in 1995 (27.1%), but weakened in 1996 (14.5%), 1997 (16.2%) and 1998 (14.4%). Mechanical engineering, which had been declining (from 23.5% in 1995 to 13.9% in 1997), recovered in 1998 to 17%, while building and construction was stable (between 11% and 14%).
- 53. In terms of national preferences the situation changed very little: building and construction was, as usual, dominated by notifications from Germany and Austria (32.8% and 19.7% respectively of all notifications in this sector); agriculture and foodstuffs were the leading sector in the Netherlands, which accounted for 37.3% of all notifications in this sector; traditionally this sector has also been important in Italy (30.5% of Italian notifications) and France (20.5% of French notifications).

Pharmaceuticals seem to be of particular interest to France and the United Kingdom, which together contributed 41.7% of notifications in this sector. France was also the source of a quarter of all notifications in the leisure goods sector. The Netherlands accounted for a remarkable proportion of notifications in the environment and transport sectors (41.9% and 35.4% respectively), the latter accounting for 29.4% of all Greek notifications.

Mechanical engineering, still dominated by German notifications (almost a quarter of all notifications in this sector and a quarter of all German notifications), also appears to be important in Finland (35.4% of Finnish notifications).

Telecommunications accounted for 38.9% of Danish notifications, 30.9% of Belgian notifications, 28.7% of Austrian notifications and 21.9% of German notifications.



## 54. Figure 2

#### 4.3.2. Use of the emergency procedure

55. From 1995 to 1998, the Member States invoked the emergency procedure 131 times. Measures notified under the emergency procedure between 1995 and 1998 accounted for some 5% of all notifications.

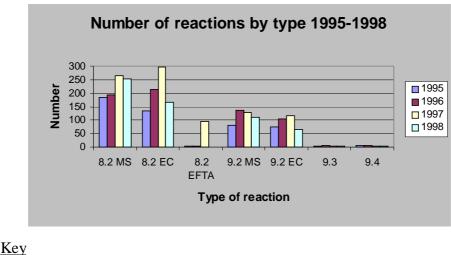
The temporary increase in the number of measures notified under the emergency procedure in 1996 (40 cases) was due to the BSE crisis, during which the United Kingdom used the procedure in 24 cases. Another area in which urgency was invoked several times was the transport of cash: in 1997 the urgency criteria were considered to have been satisfied in five cases concerning Belgium, compared with one case, also concerning Belgium, accepted in 1996 and one other in 1998. Other areas in which urgency was invoked include plant-based products or preparations, child safety (banning of foods mixed with objects, pseudo-toys, lighters shaped like mobile telephones, decorative objects and dangerous products which are attractive to children, play and recreation areas), the fuel supply system, vehicle identification in order to reduce pollution and equipment used to detect radar and laser equipment in vehicles.

56. Between 1992 and 1994 the Commission considered that the use of the emergency procedure was justified in 25% of cases. This figure rose sharply to 33% in 1995, 80% in 1996, 68% in 1997 and 52.7% in 1998.

The United Kingdom and Belgium (34 notifications each) and France (23 notifications) accounted for more than 70% of all notifications under the emergency procedure.

- 4.3.3. Commission reactions
- 4.3.3.1. General trend
- 57. The percentage of notifications eliciting a reaction from the Commission is falling. In 1992, 1993 and 1994, the Commission reacted to 60% of notifications; in 1995, 1996, 1997 and 1998 the Commission reacted to 49.7%, 63.1%, 46.5% and 38.5% of notifications respectively, giving an average of 49.4%. These reactions take the form of comments, detailed opinions or the announcement of the intention to propose a directive (see Figure 3). It is not uncommon for a notification to elicit several reactions from the Commission,

Figure 3



comments
detailed opinion
standstill

- 4.3.3.2. Detailed opinions
  - (i) Statistics
- 58. From 1995 to 1998, the Commission delivered 360 detailed opinions regarding notified drafts. The downward trend in the percentage of drafts which elicit a detailed opinion from the Commission continued. In 1990 and 1991, the Commission had delivered a detailed opinion in respect of 37% of drafts; In 1992, 1993 and 1994, this rate was 31%, and for the period covered by this report it was 14.6%.

(ii) Reasons:

#### Article 28 of the EC Treaty and the principle of mutual recognition

- 59. The absence of provisions ensuring compliance with the principle of mutual recognition continued to be the point that the Commission raised most frequently in the detailed opinions which it delivered regarding drafts notified by the Member States in 1995, 1996 and 1997. 6% of drafts notified in 1995 (29 cases) elicited a detailed opinion on the grounds of violation of the principle of mutual recognition. In 1996 (56 cases) and 1997 (92 cases), this rate increased to about 10%, while in 1998 (27 cases) it fell to 4.5%.
- 60. However, the way this question is approached has changed. Years of experience of the notification procedure have given the Member States a good understanding of the principle of mutual recognition. As a result as is shown also by the rather low rate of detailed opinions compared with the number of measures notified the Commission can now more frequently than in the past simply ask the Member States, in the comments it makes, largely for educational purposes, to make improvements to the clauses which they have drafted to apply the principle of mutual recognition.

The Commission now draws the Member States' attention to the need to provide businesses with precise and full information so that they can take advantage of the rights conferred on them by Articles 28 et seq. of the Treaty. Thus, for example, the Member States generally notify draft technical specifications which form part of more general rules governing type-approval or checks on product conformity. Insofar as these general rules provide for the acceptance of products legally manufactured and/or marketed in the other Member States, the notified draft technical specifications are already covered by the mutual recognition provided for in the basic rules. For the sake of clarity and legal certainty, the Commission asks the Member States, where appropriate, to summarise or refer to the provisions of the basic rules on mutual recognition in notified drafts. The Commission also regularly reminds the national authorities that the principle of mutual recognition also applies to tests, to certificates attesting that products conform to national rules and to the national bodies authorised to issue such certificates.

61. The Commission asks the Member States not only to ensure mutual recognition of products from other Member States providing a level of protection of the legitimate interests at stake equivalent to that provided for in the notified drafts, but also to make sure that the technical requirements for products are reasonable. It is not enough for the Member States to accept products from other Member States which are "equivalent" to theirs. Insofar as such acceptance is based on a finding of equivalence to the national requirements, it is important to ensure that the national requirements are not themselves excessive, as otherwise products which satisfy the legitimate objectives of the rules of the Member State of destination (health protection, safety, etc.) would still face unjustified barriers to access to that country's market.

Thus in some cases the Commission sets the level of protection which it considers reasonable by reference to the solutions which it adopts in its harmonisation proposals, after consulting experts. 62. The Commission has also had occasion to deliver detailed opinions regarding other requirements which are liable to create barriers to trade not directly linked to mutual recognition. These include import authorisation requirements, excessive marking requirements, rules making the use of quality descriptions subject to criteria linked to origin, or requirements relating to certain type-approval procedures (e.g. the requirement to have a representative established in the Member State in which the product is to be marketed in order to have access to such a procedure).

#### Secondary legislation

63. One of the grounds on which the Commission delivers detailed opinions is failure of a notified draft to comply with a Community directive or regulation which main purpose is to abolish obstacles to the free movement of goods.

Twelve detailed opinions were based on infringement of Directive 89/336/EEC on electromagnetic compatibility in 1995, eleven in 1996, two in 1997 and four in 1998. In 1995, five detailed opinions were based on infringements of each of the following Directives: 73/23/EEC on low-voltage equipment, 87/404/EEC on simple pressure vessels and 91/263/EEC on telecommunications terminal equipment, whereas all three Directives together only gave rise to five detailed opinions in 1996 and 1997. In 1998, two detailed opinions were based on infringements of Directive 98/13/EC on telecommunications terminal equipments of Directive 98/13/EC on telecommunications terminal equipment.

Other detailed opinions were based on infringements of other secondary legislation, particularly in the fields of foodstuffs (6 in 1995, 10 in 1996, 16 in 1997 and 6 in 1998) and vehicles.

The Commission also received 46 notifications concerning packaging and packaging waste during this period. The Netherlands notified 9 drafts and Denmark 5, while Finland, France, Spain and Sweden each notified 4 drafts.

The Commission considered ten of these drafts (including eight in 1996) to be contrary to Directive 94/62/EC on packaging and packaging waste, Article 16 of which provides that before adopting such measures the Member States must notify the drafts of measures which they intend to adopt to the Commission under the procedure set up by Directive 98/34/EC. If the proposed measure is also a technical matter within the meaning of Directive 98/34/EC, the Member State concerned may indicate, when following the notification procedures referred to in Directive 94/62/EC, that the notification is equally valid for Directive 98/34/EC.

In order to ensure the smooth operation of this procedure, the Commission has set up a single contact point for the notification of all such drafts. The Committees set up by Directives 98/34/EC and 94/62/EC were informed of this single contact point in 1995.

64. The upward trend in the number of detailed opinions based on complaints other than violation of the principle of mutual recognition in 1992, 1993 and 1994 was reversed in the period 1995-98. The percentage of detailed opinions relating to subjects other than mutual recognition fell from 63% in 1994 to 61% in 1995, 46.2% in 1996, 21.4% in 1997 and 30% in 1998.

- (iii) <u>Further action</u>:
- 65. The second subparagraph of Article 9(2) of the Directive requires the Member State to which a detailed opinion is addressed to inform the Commission of "the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction."
- 66. The Member State must indicate whether it intends to abandon the draft text, to justify its adoption, or to amend it to make it conform to Community law. The Commission's reaction must indicate whether the Member State's reply is satisfactory, i.e. whether it eliminates all possibility of infringement of Community law. To ensure that this dialogue proceeds smoothly, the Commission regularly enters a list of notifications in respect of which the Member States have not provided a reply on the agenda of the Committee set up by Directive 98/34/EC for discussion.

The way in which the national authorities respond to the detailed opinions delivered by the Commission has improved since 1995, to the extent that the Member States responded to virtually all detailed opinions relating to drafts notified in 1998. Less than 10% of such responses required further discussion between the Commission and the Member State concerned.

- 4.3.3.3. Comments
  - (i) Statistics:
- 67. From 1995 to 1998, the Commission made comments on 33% of all notifications. This percentage is significantly lower than from 1992 to 1994 (46%) and in 1990 and 1991 (42%).
  - (ii) Reasons:
- 68. In general, the comments made by the Commission give an overall political or legal assessment of the measure, express its position on the subject, or remind Member States of their obligations, e.g. under an infringement proceeding or an earlier notification.
- 69. The Commission has in particular made comments reminding the Member States of their obligation under Article 12 of the Directive. Following the judgment in the CIA Security International case, the compulsory reference to the Directive either in the text of a technical regulation or at the time of its publication has assumed crucial importance for the protection of the rights of individuals. The Commission has therefore systematically asked for such a reference to be made.

The Commission also chose to make comments where it considered a more stringent reaction entailing the extension of the standstill period to be inappropriate. In addition to cases of incomplete mutual recognition clauses, this concerned cases where the binding Community act had already been adopted, but did not yet apply, and cases where such an act was unlikely to be adopted within eighteen months, the maximum standstill period on account of a Community harmonisation initiative.

Comments were also used to complain about texts which were already in force and which were either referred to in the notified draft or formed its legal basis. The

notification procedure provides the Commission with an opportunity to discover such texts and to assess their effects on the Community.

The Commission also made comments to inform the Member States about standardisation work being carried on by the European standardisation bodies in the field in question. In such cases the Commission's reaction has to be limited to comments, as this type of "European harmonisation" does not prevent the Member States from adopting technical rules on the same subject, even if such rules inevitably hamper the work of the European harmonisation bodies.

Fairly often during the 1995-98 period, the Commission had to remind the Member States in its comments that the principle of "mutual recognition" derived from Article 28 of the EC Treaty, as interpreted by the Court of Justice, also applies to products originating in EFTA Member States which are contracting parties to the Agreement on the European Economic Area.

- 4.3.3.4. Intention to propose, adopt or present to the Council a proposal for a binding Community act standstill decision
- 70. When the Commission applies Article 9(3) and (4) of the Directive, the Member State cannot adopt its draft until one year after the date of notification. As this period proved to be too short between 1992 and 1994, the Community act on account of which a standstill had been imposed was adopted before the end of the standstill period in only six cases Directive 94/10/EC modified the procedure slightly: the standstill period starts on the date of notification and, to compensate for the cumbersome nature of the cooperation and co-decision procedures, is automatically extended by six months when the Council adopts a common position. The new procedure made it possible to adopt a binding Community act before the end of the standstill period in 10 cases (6 in 1995, 4 in 1996, none in 1997 or 1998). This is equivalent to 38% of the cases in which Article 9(3), (4) or (5) is applied compared with 9% in the period from 1992 to 1994 which shows how useful the amendments made in this respect by Directive 94/10/EC are.
- 71. From 1995 to 1998, the Commission applied Article 9(3), (4) or (5) of Directive 98/34/EC in 30 cases. The Commission imposed a standstill in ten cases in 1995, twelve in 1996, four in 1997 and four in 1998.

Most (7) of the standstill periods imposed in 1995 were due to the future Directive 96/98/EC on marine equipment, which was adopted on 20 December 1996. The other standstill periods imposed in 1995 concerned foodstuffs (2) and articles of precious metals (1). In 1996, standstill periods were imposed on six national drafts because they were covered by Community drafts which eventually resulted in the adoption of Directive 96/98/EC on marine equipment and Directive 98/18/EC on passenger ships. Other drafts concerned fuel quality (auto-oil programme), buses, pesticide residues (draft amendment of Directive 91/414/EEC on plant protection products) and the transport of live animals. In 1997, there were two drafts concerning fuel quality, one concerning ecological farm products and one concerning recreational craft. In 1998 a standstill period was imposed on two draft national regulations on account of the Regulation on the marketing standards for olive oil, then under preparation, which was adopted one week after the end of the standstill period; another standstill period was imposed on a draft relating to inland navigation and the last concerned ecological foodstuffs.

Seven of the ten cases in which Article 9(3), (4) and (5) of the Directive applied concerned transport in 1995, and eleven out of twelve in 1996.

### 4.3.4. Reactions of the Member States

- 72. Some 41% of notified drafts elicited comments from other Member States in 1995, 36% in 1996, 29% in 1997 and 42% in 1998. Some 18% of notifications elicited detailed opinions in 1995, 26% in 1996, 14% in 1997 and 18% in 1998.
- 73. The fields which elicited the most detailed opinions from other Member States in 1995 and 1996 were the environment, followed by mechanical engineering, electrical engineering, and motor vehicles. In 1997, most objections concerned the environment and chemicals, followed by foodstuffs and construction. In 1998, the environment and chemicals again prompted the most reactions, followed by foodstuffs.

## 4.3.5. Handling of infringements

- 74. Between 1995 and 1998, the Commission initiated 103 infringement proceedings for failure to comply with Directive 98/34/EC, either for failing to notify draft measures or for adopting them before the end of the standstill period. The Commission was informed of the national measures either by the private body which it had commissioned to hunt out national technical rules adopted in violation of Directive 98/34/EC, or by businesses affected by them. To allow businesses to find out about notified texts and the dates of the initial standstill period, the Commission publishes the titles of notified national drafts and the corresponding standstill periods in the Official Journal of the European Communities each week.
- 75. In line with the Commission's position, repeatedly expressed at meetings of the Committee (see point 4.3.6.1 below) and at bilateral meetings between the Commission and the central units in the Member States responsible for applying the procedure (see point 4.3.6.3 below), the majority of Member States abandon the disputed act and/or notify a new draft. During the reference period, this solution allowed the infringement proceeding to be terminated in virtually all cases. The Court of Justice delivered judgments in four cases (C-273/94, C-289/94, C-279/94 and C-145/97, see point 4.4.2.1 of this report). From 1992 to 1994, nine cases were brought before the Court.
- *4.3.6. Subsequent procedure*
- 4.3.6.1. Meetings of the Committee set up by Directive 98/34/EC
- 76. The Committee set up by Article 5 of Directive 98/34/EC (consisting of representatives appointed by the Member States and chaired by a representative of the Commission) discussed points of general interest and specific points of interest to certain parties.

The Committee met thirteen times between 1995 and 1998 (four in 1995, four in 1996, three in 1997 and two in 1998), which, due to budgetary constraints, was markedly less than the sixteen meetings held between 1992 and 1994. They discussed inter alia practical and budgetary aspects of the implementation of the

procedure set up by Directive 98/34/EC, the action to be taken to enhance transparency, and possible amendments to the Directive.

- 77. Discussions on the practical aspects of the way the procedure is implemented covered the degree of transposition of Directive 94/10/EC; the final drafting of the new Vade mecum, which forms the basis for cooperation between the central units and the Commission; solutions to the problem of overlapping procedures (single point of contact); the handling of notifications in the field of pharmacopoeia; the electronic transmission of notifications and messages; the obligation to reply to detailed opinions; and the obligation to automatically send the definitive texts. The main budgetary aspect discussed was the cost of translations.
- 78. The Committee devoted a great deal of time to discussing measures to enhance the transparency of the procedure set up by Directive 98/34/EC, including the preparation of a brochure explaining the notification procedure to a wide audience<sup>8</sup>, the possible publication in the Official Journal of summaries of notified drafts, together with explanatory notices, and the action taken following the judgment in the CIA Security case (explanations given at "package meetings" in the Member States; invitation to the Member States to ask the Commission for its opinion on whether or not a planned national measure needed to be notified; sending to the Member States of the particulars of texts which appeared prima facie to contain technical rules, for comment). The Technical Regulation Information System (TRIS) website was also discussed and at the time of drafting this report the website is up and running and can be consulted at http://europa.eu.int/comm/enterprise/tris.
- 79. The future development of the notification procedure was discussed during debates about the participation of Turkey and the Central and Eastern European countries in the information exchange system and the introduction of a transparency mechanism for the information society. The latter came into being on 20 July 1998, following the adoption of Directive 98/48/EC. The Committee also discussed the transposition of the Directive.
- 80. The Committee served as a forum for discussions of the relationship between Article 28 of the EC Treaty and Article 16 of Directive 89/106/EEC on construction products, and on Decision No 3052/95/EC of the European Parliament and of the Council establishing an information procedure on measures derogating from the principle of the free movement of goods.<sup>9</sup>
- 81. The Committee also discussed individual notified drafts and the problems raised by their application.
- 4.3.6.2. Package meetings
- 82. The practice of holding "package meetings" introduced a few years ago has enabled the Commission to maintain contacts with the national authorities responsible for drawing up technical regulations. The topics discussed at these meetings include

 <sup>&</sup>lt;sup>8</sup> This brochure is published by the Office for Official Publication of the European Communities in all official Community languages : ISBN 92-828-2786-0.
 <sup>9</sup> Device No. 2057/05/TCC of the Device Publication of the Committee in all official Communities in all official Communities in all official Community languages : ISBN 92-828-2786-0.

<sup>&</sup>lt;sup>9</sup> Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community (OJ L 321, 30.12.1995, p.1).

notifications by the country concerned, links with infringement proceedings based on EC Treaty provisions relating to the free movement of goods, and developments relating to the operation of the Directive. At these package meetings the Commission was able to discuss the consequences of the judgment in the CIA Security case with the Member State authorities.

- 4.3.6.3. Meetings with the central units of the Member States
- 83. The Commission made an effort to continue a dialogue with the national authorities responsible for applying Directive 98/34/EC during the period 1995-98. These meetings took place at the meetings of the Committee set up by the Directive or at the package meetings referred to above. They enabled the Commission to terminate numerous infringement proceedings which it had initiated for failure to comply with the notification requirement laid down in the Directive. They also provided an opportunity to discuss the practical problems which can arise in the application of the procedure and enabled the central units to meet representatives of the Commission departments responsible for managing the Directive.
- 4.3.6.4. Ad hoc meetings
- 84. The Commission actively investigates certain dossiers which it suspects may infringe Community law and which may give rise to disputes between Member States and businesses, or between Member States. Ad hoc meetings, organised by the Commission, have helped the parties concerned to reach agreement on the disputed points. During the period covered by this report, meetings were held concerning fields as varied as wrecked cars, satellite television, advertising of tobacco products, ro-ro ferries, weights and measures, etc.

#### 4.4. Factors which contributed to the high number of notifications

#### 4.4.1. Various factors

85. The high number of notifications between 1995 and 1998 cannot be attributed exclusively to the accession of Austria, Finland and Sweden. The entry into force of Directive 94/10/EC and the rich case-law of the Court of Justice were the main factors which led the Member States to notify more than 2 400 draft technical rules to the Commission.

The judgment in the CIA Security case, which confirmed the Commission's position on the inapplicability of technical rules adopted in violation of Directive 83/189/EEC, demonstrated the importance of the information procedure and helped raise awareness of it. The operation undertaken by the Dutch Government in the summer of 1997 to catch up with notifications of technical rules was undoubtedly a result of this judgment. This operation resulted in a substantial rise in the number of notifications in 1997.

#### 4.4.2. Court of Justice case-law

86. Between 1995 and 1998, the Court of Justice delivered eight judgments concerning Directive 98/34/EC: four in response to Commission requests for rulings that a Member State had violated its obligations under Community law and four in response to references for preliminary rulings from national judges. These judgments

essentially concern the concept of a "technical rule"; they clarify the scope of the obligation to notify and the consequences of any failure to notify.

- 4.4.2.1. Judgments declaring a Member State to have failed to fulfil its obligations
- 87. The judgment of 11 January 1996 (Case C-273/94, *Commission v Netherlands* [1996] ECR I-31) concerned a Dutch regulation which added an alternative production method to the existing Dutch legislation on margarine. The Court seized this opportunity to dismiss the widely held view that a technical rule whose purpose or effect was to liberalise trade did not need to be notified. The legislation in question established a new technical rule and as such it was subject to the Directive, even though the new rule constituted a relaxation of the existing rules.
- 88. The necessary link between the technical specification and the marketing of the products concerned, and the scope of the exception regarding transposition measures, were clarified in the judgment of 17 September 1996 (Case C-289/94 *Commission v Italy* [1996] ECR I-4405). In this case, the Italian Government refused to notify provisions on the quality of waters in which molluscs are raised on the grounds that these measures were intended to transpose certain provisions of Community law and that they concerned only the waters and not the molluscs raised in them.

The Court dismissed both arguments, because the rules in question were very closely linked to the marketing of the product, as only goods produced in accordance with the provisions could be marketed, so compliance with the provisions had a direct impact on the marketing of the molluscs. The Court ruled that the exception regarding transposition measures did not apply, because the scope of the national rules in question was far narrower than the scope of the Community rules.

89. In its judgment of 16 September 1997 (Case C-279/94 *Commission v Italy* [1997] ECR I-4743), the Court made three points concerning the definition of a technical rule. A provision prohibiting the marketing and use of a substance is a technical regulation, and this was already the case before the clarification made by Directive 94/10/EC. However, a regulation imposing limits on the concentration of asbestos fibres in the air does not define a characteristic required of a product, and does not in principle fall within the definition of a technical specification; nevertheless, this does not rule out the possibility of establishing that such a regulation may have consequences as regards the characteristics of a product. Finally, the Court reiterated that a technical regulation is subject to the notification procedure only if it is new, i.e. it must produce distinct legal effects in relation to the previously existing arrangements.

With regard to the procedure, the Court ruled that the notification and standstill obligations do not always go together: the full text of the measure must be notified, but only the technical regulations which it contains are subject to the standstill period.

90. In its judgment of 7 May 1998 (Case C-145/97 *Commission v Belgium* [1998] ECR I-2643), the Court ruled that pursuant to Article 8 of the Directive, the Member States must communicate not only the draft text containing technical regulations, but also the text of the basic legislative or regulatory provisions principally and directly concerned. The aim of this provision is to enable the Commission to have as much

information as possible in order to enable it to exercise as effectively as possible the powers conferred on it by the Directive.

- 4.4.2.2. Judgments in cases referred for a preliminary ruling
- 91. The judgment of 30 April 1996 (Case C-194/94 *CIA Security International SA v Signalson SA and Securitel SPRL* [1996] ECR I-2201) is without doubt the most important judgment delivered by the Court during the period covered by this report. In this judgment, the Court agreed with the assertion made by the Commission in its communication of 1986 that a breach of the obligation to notify renders the technical regulations inapplicable so that they may not be enforced against individuals.

The Court based this conclusion on the fact that Articles 8 and 9 of the Directive are precise (in that the technical rules must be notified before they are adopted) and unconditional, and must therefore be interpreted as meaning that individuals may rely on them before national courts. Comparing the procedure established by Directive 83/189/EEC with a simple information procedure, the Court stressed that the aim of the Directive is not simply to inform the Commission, but to eliminate or restrict obstacles to trade, to inform other States of technical regulations envisaged by a State, to give the Commission and the other Member States time to react and to propose amendments for lessening restrictions to the free movement of goods arising from the envisaged measure, and to afford the Commission time to propose a harmonising directive. The Court concluded that breach of the obligation to notify constitutes a substantial procedural defect such as to render the technical regulations in question inapplicable to individuals. Where an individual correctly relies on the breach of such an obligation before the national court, the latter must decline to apply a national technical regulation which has not been notified.

- 92. In addition to these very important clarifications, the Court ruled that the Directive does not apply to rules laying down conditions governing the establishment of firms, nor to rules which merely serve to enable technical regulations to be adopted.
- 93. In its judgment of 20 June 1996 (Joined Cases C-418/93, C-419/93, C-420/93, C-421/93, C-460/93, C-461/93, C-462/93, C-464/93, C-9/94, C-10/94, C-11/94, C-14/94, C-15/94, C-23/94, C-24/94 and C-332/94 [1996] ECR I-2975), the Court found that the obligation to notify does not apply to national regulations which do not lay down the characteristics required of a product but are confined to regulating the closing times of shops.
- 94. The judgment of 20 March 1997 (Case C-13/96 Bic Benelux SA v Belgian State [1997] ECR I-1755) concerned a marking to be placed on products informing the consumer that they are subject to environmental tax. The Court seized this opportunity to stress that the underlying purpose of a national measure has no bearing on whether or not that measure constitutes a technical regulation. Consequently, the fact that a national measure does not implement a technical standard which may itself constitute a barrier to the free movement of goods or was adopted in order to protect the environment does not mean that the measure cannot be a technical regulation. Since the marking in issue was intended to inform the public of the effects of a product on the environment, like any other quality label, the Court concluded that it could not be regarded as exclusively a fiscal accompanying measure.

- 95. In the judgment of 16 June 1998 (Case C-226/97 *Lemmens* [1998] ECR I-3711), the question arose as to whether provisions applying to a product (breath-analysis apparatus) when used by a particular user (the police) for a specific purpose (breath analysis) must be notified. The Court ruled that certain measures may impose, in respect of a product intended for a particular group of users, technical specifications whose content depends on the specific objective pursued by that group. Where these specifications are too remote in terms of their relationship with the production and marketing of the product, they cannot be classified as technical regulations. However, where the technical specifications must be complied with in order to sell the product to a major user of that product on the market in question, they constitute technical regulations; that was the case here.
- 96. The Court also ruled that the Directive applies equally to regulations which fall within the scope of criminal law; its scope is not limited to products intended to be used otherwise than in connection with the exercise of public authority.

## 4.4.3. The Dutch operation to catch up on unnotified technical rules

97. Following the judgment in the CIA Security International case, the Dutch Government drew up a list of national regulations which should perhaps have been notified to the Commission pursuant to Directive 83/189/EEC. Of the 400 dossiers which it announced, the Dutch Government unilaterally withdrew 96, and it withdrew a further 77 following discussions with the Commission departments under a "prenotification" exercise (verification of the need to notify the texts in question). Of the 227 texts thus notified, 70 were considered unimportant, and the rest were considered important. The notifications covered a wide range of fields, from gaming machines to judges' robes; most drafts concerned sea transport, metrology, agriculture or motor vehicles. The exercise showed that a large number of texts which had been adopted without passing through the filter of Directive 83/189/EEC contained provisions which were contrary to Community law; these provisions were corrected under this operation.

#### 4.5. Action to improve transparency and provide businesses with more information

98. The Directive has fulfilled its purpose as an instrument of transparency by providing information to all parties concerned by technical rules, i.e. companies, Member States and the Commission. The amending Directives have merely enhanced this task of ensuring transparency and information.

However, businesses which can find out about initiatives taken in the countries in which they market or wish to market their products and which could, therefore, help to eliminate barriers to the free movement of goods at source, or at least adapt their products to the new requirements in good time, still do not take full advantage of the possibilities open to them. While certain European federations are now aware of the advantages of the information procedure, the involvement of individual companies, and particularly small and medium-sized companies, in the examination of notified drafts still seems too marginal.

99. With a view to increasing transparency and the availability of information to European citizens, the Commission has made available a number of sources of information:

Each year the Commission publishes in the Official Journal statistics on notifications received, reactions to such notifications and infringement proceedings for failure to comply with the obligations resulting from the Directive.<sup>10</sup>

Each week the Commission publishes in the Official Journal the titles of draft national technical regulations which have been notified to it under the notification procedure and the dates on which the initial three-month standstill period laid down in the Directive ends for each notified draft. Where the Commission considers the emergency procedure to be justified, this information is also published in the Official Journal. Publication of this list is intended primarily to allow individuals to find out about notifications and to check that technical regulations which they are required to comply with have indeed been notified in advance.

With the same concern for transparency, the Commission has taken great care to ensure that the Member States fulfil their obligations under Article 12 of the Directive. A technical regulation not containing a reference to Directive 98/34/EC may give rise to doubts as to whether it was notified in draft form and, following the Court's judgment in the CIA Security case, as to its applicability once adopted.

Press releases intended to inform the public of infringement proceedings against technical regulations adopted in breach of the Directive are published regularly. Individuals can rely on this information before a national authority in support of the principle that a technical regulation adopted in breach of Directive 98/34/EC is unenforceable.

100. To make it easier for businesses to access national technical regulations and draft technical regulations, the Commission has studied the possibility of setting up a website on the notification procedure for national technical regulations. This site will provide access to general information about Directive 98/34/EC. Drafts notified since July 1995 by the Member States of the European Community and by EFTA States which are members of the European Economic Area will also be available on this site. It will be a valuable tool providing information on technical regulations planned or adopted in all the Member States. The objective will be to ensure that Directive 98/34/EC creates full transparency and is an effective tool for eliminating at source barriers to the smooth operation of the internal market. It will also help to strengthen the dialogue between businesses, the Member States and the Commission in the field of technical regulations.<sup>11</sup>

In order to raise awareness of the Directive, the Commission has produced a brochure containing an article-by-article commentary explaining the information procedure clearly in simple layman's language to the business circles concerned, the general public, and the Member States. This brochure,<sup>12</sup> which has been translated into all the official languages of the European Union, will also be available on the TRIS website.

<sup>&</sup>lt;sup>10</sup> Statistics for 1995 published in OJ C 309, 18.10.1996, p. 2.

Statistics for 1996 published in OJ C 311, 11.10.1997, p. 2.

Statistics for 1997 published in OJ C 281, 10.9.1998, p. 3.

Statistics for 1998 published in OJ C 228, 11.8.1999, p. 7.

At the time of drafting this report, the Technical Regulation Information System (TRIS) website is up and running and can be consulted at http://europa.eu.int/comm/enterprise/tris.

<sup>&</sup>lt;sup>12</sup> ISBN 92-828-2786-O.

#### 4.6. Conclusions and prospects

- 101. The years 1995, 1996, 1997 and 1998 saw a substantial rise in the number of notifications, even discounting the Dutch catch-up operation in 1997. This is partly due to the accession of three new Member States in 1995, but also to the amendment of the Directive and the case-law of the Court of Justice. Telecommunications, agriculture and foodstuffs, transport, mechanical engineering and construction continued to account for the bulk of notifications during this period.
- 102. During this period, the total number of Commission detailed opinions fell, due to the improved quality of the national texts notified, which are more in line with Community law. This demonstrates the didactic nature of the Directive, which has resulted in notified texts being drafted with increasingly regard for Community rules. While the Member States have become accustomed to paying greater heed to the principle of mutual recognition, the Commission has still had to act to ensure compliance with the provisions of the Directives on electromagnetic compatibility, low-voltage equipment, telecommunications terminal equipment, and packaging and packaging waste.
- 103. In its Communication to the Council and the European Parliament on mutual recognition in the context of the follow-up to the action plan for the single market (COM(1999) 299 final) of 16 June 1999, the Commission confirmed the importance which it attaches to Directive 98/34/EC as an instrument for promoting mutual recognition and preventing the creation of obstacles to the free movement of goods and, since August 1999, information society services.

In response to this Communication, the Council itself called on the Member States to develop appropriate measures in order to provide economic operators and citizens with an effective framework for mutual recognition, inter alia by implementing the notification procedure. The Council also invited the Commission to take the appropriate measures and initiatives in this field, relying as much as possible on administrative cooperation.

- 104. Directive 98/34/EC has been supplemented by the application from 1 January 1997 of the procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community set up by Decision No 3052/95/EC of the European Parliament and of the Council.
- 105. In future, the role of the Directive will also be stressed in the field of services, in the context of the information society.
- 106. With a view to enlargement, the applicant countries have shown a keen interest in Directive 98/34/EC and are willing to incorporate it into their domestic legal systems. Thus the Directive could play its didactic role for the free movement of goods within the internal market by encouraging the national authorities to become more Community-minded.
- 107. Turkey is now associated with the work of the committee set up by Directive 98/34/EC, and its experts started attending meetings in 1999.

#### 5. PART III: EXCHANGE OF INFORMATION ON TECHNICAL RULES BETWEEN THE COMMUNITY AND THE EFTA COUNTRIES

#### 5.1. Introduction

108. The Agreement between the Member States of EFTA and of the EEC laying down a procedure for the exchange of information in the field of technical regulations entered into force in November 1990 (Council Decision 90/518/EEC<sup>13</sup>) for an initial period of two years. The Agreement accordingly expired on 1 November 1992. The Agreement on the European Economic Area (EEA), which takes over the notification procedure with arrangements similar to those of the previous Agreement, did not enter into force until 1 January 1994; in the interval, the Agreement concluded by Council Decision 90/518/EEC was extended by means of bilateral agreements in the form of an exchange of letters.

In order to avoid any barriers to trade between the Member States of the two groups, the 1990 Agreement established a link between the information procedure based on Directive 98/34/EC and the equivalent procedure between the EFTA countries.

The Agreement on the EEA, which has applied since 1 January 1994, includes Directive 83/189/EEC, amended as appropriate, in Annex II, Part XIX.

- 109. The Community and Switzerland have continued to apply the information exchange procedure since the entry into force of the Agreement on the EEA, even though the Swiss Confederation is not a signatory to the Agreement.
- 110. Since Austria, Finland and Sweden acceded to the Community, the simplified procedure for the exchange of information on technical regulations between the Member States of the EEC and EFTA has applied between the Member States of the Community on the one hand and Iceland, Liechtenstein, Norway, and, on a voluntary basis, Switzerland, on the other. The number of notifications under this system has accordingly declined.

#### 5.2. Description of the procedure

- 111. During 1992 and 1993, all messages relating to the information procedure between the Member States of the Community and the Member States of EFTA were exchanged between the Commission of the European Communities and the EFTA Council. Since 1994, the exchange of information between the Member States of the Community and the Member States of EFTA has gone via the Commission and the EFTA Surveillance Authority set up by the Agreement on the EEA.
- 112. There is a three-month standstill period, during which the notifying State cannot adopt the text, starting on the date of receipt of the draft regulation by the EFTA Surveillance Authority (for notifications from EFTA Member States) or the Commission (for notifications from Community Member States). The EFTA Surveillance Authority and the Community may make comments on the draft technical regulations notified under this procedure. The Commission draws up

<sup>&</sup>lt;sup>13</sup> Decision of 24 September 1990, published in OJ L 291, 23.10.1990.

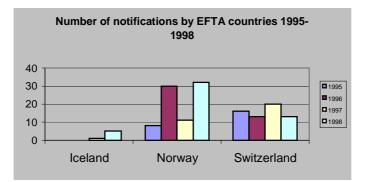
comments on behalf of the Community, in consultation with the Member States, and communicates them to the EFTA Surveillance Authority, which forwards them to its Member States.

The Agreement contains no provisions regarding the extension of the standstill period. The only possibility for continuing the procedure once comments have been made is to hold regular consultations on the comments made by all contracting parties or to call ad hoc additional meetings to discuss specific cases.

#### **5.3.** Application of the procedure

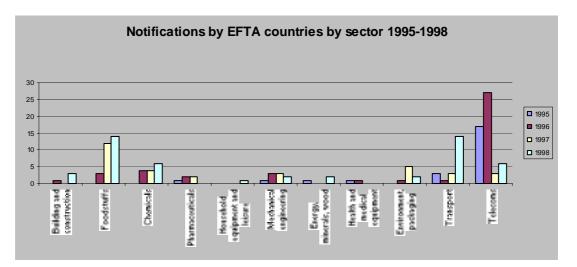
- 5.3.1. Volume of notifications and breakdown by sector
- 113. Figure 4 and Table XIII in the Annex show that the accession of Austria, Finland and Sweden has considerably reduced the number of notifications from EFTA countries. Between 1995 and 1998, the Commission received 149 draft technical regulations from EFTA Member States, compared with 344 in 1992, 1993 and 1994. Eighty-one notifications were from Norway, 62 from Switzerland and 6 from Iceland.

Figure 4



A breakdown by sector (Figure 5 and Table XIV in the Annex) shows that telecommunications was the most important sector during this period, as was also the case in 1992-94; in 1995, 70% of all notifications concerned telecommunications; this figure was still 62% in 1996. There was a drop in notifications in this sector in 1997 (just three notifications, or less than 10%), rising slightly to 12% in 1998. Agricultural products and foodstuffs was the leading sector in 1997, accounting for 37.5% of all notifications. In 1998, this sector and transport each accounted for 28% of notifications.

#### Figure 5



#### 5.3.2. Reactions

- 5.3.2.1. Community comments on EFTA notifications
- 114. From 1995 to 1998, the Community made comments on 75 EFTA notifications (50%), which represents a slight fall on the 66% of EFTA notifications which prompted the Community to make comments from 1992 to 1994. These comments were the subject of a consultation procedure with the Community Member States.
- 115. Notifications made by Austria, Sweden and Finland in 1994 for which the standstill period ended after 1 January 1995, i.e. after the date of accession of these States to the European Union, were treated as notifications from Member States. This means that the notifications could, in principle, elicit a detailed opinion from the Commission or from other Member States. The Commission delivered 15 detailed opinions early in 1995 relating to notifications from the new Member States. Notifications from new Member States were also the subject of one detailed opinion and six comments from existing Member States.
- 116. The comments made by the Community concerned above all problems of compatibility with Community secondary legislation, in particular Directives 73/23/EC (low-voltage equipment), 77/535/EEC (methods of sampling and analysis for fertilisers), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility) and 91/263/EEC (telecommunications terminal equipment).
- 117. Other comments drew the attention of the EFTA countries to aspects of proportionality and/or the need to include in their technical regulations the mutual recognition clauses needed to avoid creating technical barriers to trade and to ensure compliance with Articles 11, 12 and 13 of the Agreement on the European Economic Area; However, only 10% of EFTA notifications prompted a reaction from the Community regarding these aspects. This sharp fall is evidence of a trend towards an effective mutual recognition system in relations with the EFTA countries.

In its comments, the Community also referred to work in progress at Community level (future Directives 96/98/EC on marine equipment and 98/18/EC on passenger ships) or within the European standardisation bodies, and to international agreements

(Stockholm Agreement and SOLAS Convention). Other comments referred to Community provisions relating to the labelling of animal feedingstuffs containing genetically modified organisms or the provisions of the Agreement on the EEA pursuant to which the contracting parties are to examine any difficulties that might arise in their trade in agricultural products and endeavour to seek appropriate solutions. The Community also referred to the obligation pursuant to Article 12 of Directive 98/34/EC to refer to the Directive when a technical regulation is published.

- 5.3.2.2. EFTA comments on Community notifications
- 118. EFTA commented on four Community notifications in 1995, three in 1996, four in 1997 and one in 1998. The new Member States made five comments early in 1995.

Most of the EFTA comments referred to the standardisation work of the European bodies. They also referred to legislation in force in certain EFTA countries, to their intention to apply international agreements (such as the Stockholm Agreement concerning specific stability requirements for ro-ro passenger ships) and to barriers which the drafts might create to trade in products legally manufactured in one or more EFTA countries (e.g. the Dutch notification on sustainable wood for the wood industry). They also supported initiatives taken by the authorities of the Member States (as in the case of the French notification limiting the sound levels of personal stereos).

#### 5.4. Conclusions and prospects

119. The 1995-98 period was marked by a fall in the number of notifications compared with the 1992-94 period, due to the accession of Austria, Finland and Sweden to the Community. Telecommunications remained the main sector. Community reactions to drafts notified by the EFTA countries continued to be motivated by the desire for these countries to abide by the provisions of Community law. Cooperation under the procedure was excellent.

#### 6. ANNEXES

#### 6.1. Table I - Breakdown of new standardisation activities started each year between 1991 and 1998

Yea	r	19	91	19	92	19	93	19	94	19	95	19	96	19	97	19	98
Lev	el	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
a.	National activities																
a.1	Connected with European or international activities	241	2.4	542	5.2	109	1.7	119	23.5	74	1.4	62	1.4	71	1.5	49	1.1
a.2	Specific*	1952	19.1	1744	16.5	2019	31.3	1511	29.8	1839	35.4	1531	34.3	1356	28.1	1497	35.8
a.3	Total (a.1 + a.2)	2193	21.5	2286	21.4	2128	33.0	1630	32.2	1913	36.8	1593	35.7	1427	29.6	1546	36.9
b.	European activities	5887	57.6	5014	47.5	2466	38.2	1985	39.8	2091	40.3	1643	36.8	2270	47.2	1684	40.2
c.	International activities	2130	20.9	3252	30.8	1860	28.8	1454	28.6	1190	22.9	1223	27.4	1116	23.2	958	22.9
d.	Total $(a + b + c)$	10210	100	10552	100	6454	100	5069	100	5194	100	4459	100	4813	100	4188	100

#### **CEN/CENELEC** members in the EU

Source: Notifications to the CEN/CENELEC.

<sup>(\*)</sup> Note that these figures could be overestimated as not all CEN/CENELEC members automatically report any links with European or international activities.

#### 6.2. Table II a - Breakdown of new standardisation activities started in 1995

	Field	Non-electrical (1)		Electrical (2)		Total (3) = $(1) + (2)$		Non-electrical share <u>(1) x 100</u> (3)
	Level	No	%	No	%	No	%	%
a.	National activities							
a.1	Connected with European or international projects	74	1,9	0	0	74	1,4	100
a.2	Specific*	1823	46,5	16	1,3	1839	35,4	99,2
a.3	Total (a.1 + a.2)	1897	48,4	16	1,3	1913	36,8	99,2
b.	European activities	1291	33,0	800	62,6	2091	40,3	61,7
c.	International activities	728	18,6	462	36,1	1190	22,9	61,2
d.	Total $(a + b + c)$	3916	100	1278	100	5194	100	75,4

#### **CEN/CENELEC** members in the EU

Source: Notifications to the CEN/CENELEC.

#### 6.3. Table II b - Breakdown of new standardisation activities started in 1996

	Field	Non-electrical (1)		Electrical (2)		Total (3) = $(1) + (2)$		Non-electrical share <u>(1) x 100</u> (3)
	Level	No	%	No	%	No	%	%
a.	National activities							
a.1	Connected							
	with European	62	1,9	0	0	62	1,4	100
	or international projects							
a.2	Specific*	1514	46,1	17	1,4	1531	34,3	98,9
a.3	Total (a.1 + a.2)	1776	48,0	17	1,4	1593	35,7	98,9
b.	European activities	911	27,8	732	62,1	1643	36,8	55,4
c.	International activities	794	24,2	429	36,5	1223	27,4	64 ,9
d.	Total $(\mathbf{a} + \mathbf{b} + \mathbf{c})$	3281	100	1178	100	4459	100	73,6

#### **CEN/CENELEC** members in the EU

Source: Notifications to the CEN/CENELEC.

#### 6.4. Table II c - Breakdown of new standardisation activities started in 1997

Field	Non-electrical (1)		Electrical (2)		Total (3) = $(1) + (2)$		Non-electrical share <u>(1) x 100</u> (3)
Level	No	%	No	%	No	%	%
a. National activities a.1 Connected with European or international projects	68	1,9	3	0,2	71	1,5	95,8
a.2Specific*	1345	36,9	11	1,0	1356	28,1	99,2
a.3Total (a.1 + a.2)	1413	38,8	14	1,2	1427	29,6	99,0
b. European activities	1558	42,8	712	60,9	2270	47,2	68,6
c. International activities	673	18,4	443	37,9	1116	23,2	60,3
<b>d.</b> Total (a + b + c)	3644	100	1169	100	4813	100	75,7

#### **CEN/CENELEC** members in the EU

Source: Notifications to the CEN/CENELEC.

#### 6.5. Table II d - Breakdown of new standardisation activities started in 1998

Field		lectrical 1)	Elect (2			otal 1) + (2)	Non-electrical share <u>(1) x 100</u> (3)
Level	No	%	No	%	No	%	%
a. National activities a.1 Connected with European or international projects	49	1,5	0	0,0	49	1,1	100,0
a.2 Specific*	1487	45,0	10	1,1	1497	35,8	99,3
a.3 Total (a.1 + a.2)	1536	46,5	10	1,1	1546	36,9	99,3
b. European activities	1077	32,5	607	69,0	1684	40,2	64,0
c. International activities	695	21,0	263	29,9	958	22,9	72,5
<b>d.</b> Total (a + b + c)	3308	100	880	100	4188	100	79,0

#### **CEN/CENELEC** members in the EU

Source: Notifications to the CEN/CENELEC.

Field	Non-el	lectrical	Elect	rical	Tot	tal
Country	No	%	No	%	No	%
a. DE	468	24,4	3	18	471	24,4
b. FR	564	29,5	2	13	566	29,3
c. UK	313	16,3	5	31	318	16,5
d. IT	216	11,3	0	0	216	11,2
e. ESP	125	6,5	0	0	125	6,5
f. Other EU countries	211	11,0	6	38	217	11,2
g. EU total	1897	99,1	16	100	1913	99,1
h. EFTA countries	18	0,9	0	0	18	0,9
i. Grand total (g+h)	1915	100	16	100	1931	100

6.6. Table III a - Breakdown by country of new national standardisation activities notified in 1995

- 1. Comparisons between the various countries must be made with some caution, since the exact stage at which a new draft is notified by the INFOPRO system has not been harmonised.
- 2. These figures reflect the number of notifications managed by the central unit. Any questions relating to the exact number of new activities started at national level should be sent to the relevant national standardisation body.
- 3. The figures for France (AFNOR) exclude 778 notifications for "regularisation" purposes. This number of regularisations has been estimated at 62% of the total number of notifications.

Field	Non-e	lectrical	Elect	rical	Tot	tal
Country	No	%	No	%	No	%
a. DE	466	29,1	6	31,6	472	29,2
b. FR	212	13,3	1	5,3	213	13,2
c. UK	166	10,4	0	0	166	10,3
d. IT	237	14,8	0	0	237	14,6
e. ESP	168	10,5	0	0	168	10,4
f. Other EU countries	327	20,4	10	53,0	337	20,8
g. EU total	1576	98,5	17	89,5	1593	98,4
h. EFTA countries	24	1,5	2	10,5	26	1,6
i. Grand total (g+h)	1600	100	19	100	1619	100

6.7. Table III b - Breakdown by country of new national standardisation activities notified in 1996

- 1. Comparisons between the various countries must be made with some caution, since the exact stage at which a new draft is notified by the INFOPRO system has not been harmonised.
- 2. These figures reflect the number of notifications managed by the central unit. Any questions relating to the exact number of new activities started at national level should be sent to the relevant national standardisation body.

Field	Non-e	lectrical	Elect	rical	Tot	al
Country	No	%	No	%	No	%
a. DE	404	28,0	6	40,0	410	28,1
b. FR	25	17,4	2	13,3	254	17,4
c. UK	152	10,5	0	0	152	10,4
d. IT	173	11,8	1	6,7	174	11,9
e. ESP	123	8,5	1	6,7	124	8,5
f. Other EU countries	309	21,4	4	26,6	313	21,4
g. EU total	1413	97,8	14	93,3	1427	97,7
h. EFTA countries	32	2,2	1	6,7	33	2,3
i. Grand total (g+h)	1445	100	15	100	1460	100

6.8. Table III c - Breakdown by country of new national standardisation activities notified in 1997

- 1. Comparisons between the various countries must be made with some caution, since the exact stage at which a new draft is notified by the INFOPRO system has not been harmonised.
- 2. These figures reflect the number of notifications managed by the central unit. Any questions relating to the exact number of new activities started at national level should be sent to the relevant national standardisation body.

Field	Non-el	lectrical	Elect	rical	Tot	al
Country	No	%	No	%	No	%
a. DE	518	32,7	7	70,0	525	33,0
b. FR	174	11,0	0	0	174	10,9
c. UK	160	10,1	0	0	160	10,0
d. IT	161	10,2	0	0	161	10,2
e. ESP	168	10,6	0	0	168	10,5
f. Other EU countries	355	22,4	3	30,0	358	22,4
g. EU total	1536	97,0	10	100	1546	97,0
h. EFTA countries	47	3,0	0	0	47	3,0
i. Grand total (g+h)	1583	100	10	100	1593	100

6.9. Table III d - Breakdown by country of new national standardisation activities notified in 1998

- 1. Comparisons between the various countries must be made with some caution, since the exact stage at which a new draft is notified by the INFOPRO system has not been harmonised.
- 2. These figures reflect the number of notifications managed by the central unit. Any questions relating to the exact number of new activities started at national level should be sent to the relevant national standardisation body.
- 3. CS: Czech Republic.

SUBSECTORS		Number of new activities (EU + EFTA)
Code	Name	
T02	Aeronautics	264 <sup>(*)</sup>
C99	Chemical products - miscellaneous	75 <sup>(*)</sup>
N05	Textiles	64
C01	Foodstuffs	58
109	Small machine tools	56
I11	Machine tools	53
S09	Water quality and water supply	51
B02	Construction	44
B99	Building - miscellaneous aspects	44
N03	Oil products	39
Т03	Road vehicles	40
Total	-	788

### 6.10. Table IV a - Top ten subsectors for new national standardisation activities in 1995

Source: Notifications to the CEN/CENELEC.

- In 1995 the top two subsectors in the electrical engineering sector were:
   electricity cables (code W08): 6 new drafts
  - electrical accessories (code W11): 2 new drafts.
- 2. In the absence of more detailed figures, the totals given are for the EU plus the EFTA countries.
- (\*) Estimate for subsectors T02 and C99, excluding the notifications for regularisation purposes from France.

SUBSECTORS		Number of new activities (EU + EFTA)
Code	Name	
C01	Foodstuffs	119
I09	Small machine tools	66
T01	Shipbuilding and offshore structures	64
S09	Water quality and water supply	58
T02	Aeronautics	53
B03	Concrete	43
B01	Fire protection	42
I19	Nuclear energy	33
N03	Oil products	33
M01	Steel	29
S99	Health - miscellaneous	29
Total		569

# 6.11. Table IV b - Top ten subsectors for new national standardisation activities in 1996

Source: Notifications to the CEN/CENELEC.

- In 1996 the top two subsectors in the electrical engineering sector were:
   electricity cables (code W08): 7 notifications
  - telecommunications cables and wires (code V08): 3 notifications.
- 2. In the absence of more detailed figures, the totals given are for the EU plus the EFTA countries.

SUBSECTORS Code	Name	Number of new activities (EU + EFTA)
C01	Foodstuffs	66
109	Small machine tools	52
Т03	Road vehicles	50
B01	Fire protection	49
B99	Building - miscellaneous aspects	44
105	Steel tubes	43
S09	Water quality and water supply	38
B02	Construction	37
B27	Waterproof materials	33
T02	Aeronautics	31
Total		443

# 6.12. Table IV c - Top ten subsectors for new national standardisation activities in 1997

Source: Notifications to the CEN/CENELEC.

- In 1997 the top two subsectors in the electrical sector were:
   switching and control systems (code W06): 5 notifications
   electrical accessories (code W11): 3 notifications.
- 2. In the absence of more detailed figures, the totals given are for the EU plus the EFTA countries.

SUBSECTORS		Number of new activities (EU + EFTA)
Code	Name	
C01	Foodstuffs	61
T01	Shipbuilding and offshore structures	61
I19	Nuclear energy	58
S09	Water quality and water supply	49
105	Steel tubes	47
S08	Air quality	47
B02	Construction	39
B25	Gas distribution installations	37
Т03	Road vehicles	33
N02	Solid fuels	32
Total		464

# 6.13. Table IV d - Top ten subsectors for new national standardisation activities in 1998

Source: Notifications to the CEN/CENELEC.

- In 1998 the top two subsectors in the electrical sector were:

   fibre optics (code V28): 4 notifications
   overhead electric lines (code W04): 2 notifications.
- 2. In the absence of more detailed figures, the totals given are for the EU plus the EFTA countries and the Czech Republic (CS).

Year	Requests for information	Comments	Requests to participate	Requests for a European standard
1985	5	14	5	0
1986	8	16	10	1
1987	5	74	5	0
1988	0	67	15	0
1989	0	52	16	1
1990	20	78	7	0
1991	0	83	16	0
1992	0	52	5	0
1993	0	34	7	0
1994	5	74	7	1
1995	0	46	4	2
1996	0	63	8	1
1997	0	58	5	0
1998	0	29	3	2

6.14. Table V - Application of Article 4 (requests to participate in national standardisation activities and requests to draw up a European standard)

Source: CEN/CENELEC.

- 1. In the absence of detailed figures, the totals given are for the EU plus the EFTA countries.
- 2. Not all requests for information or to participate and comments were reported to the CEN Central Secretariat.
- 3. Following a reminder by the CEN/CENELEC, some comments dating from 1985/1986 were entered in 1987.
- 4. From 1989 the figures are primarily for the CEN, following the introduction of the Vilamoura system in CENELEC.

### 6.15. Table VI a - Standardisation work entrusted to the European standardisation bodies in 1995

#### 1. Mandates related to New Approach Directives

- Directive 88/378/EEC: standardisation mandate for CEN in the field of organic compounds in toys other than chemical toys.
- Directive 89/336/EEC, Directive 91/263/EEC and Directive 93/97/EEC supplementing Directive 91/263/EEC: standardisation mandate for CEN, CENELEC and ETSI in the field of electromagnetic compatibility requirements.
- Directive 98/79/EC on in vitro diagnostic medical devices: programming mandate for CEN and CENELEC.

#### 2. Mandates in connection with the Directives on public procurement

 Directive 89/440/EEC: standardisation mandate for CEN and CENELEC in the field of qualification of construction enterprises.

### **3.** Mandates in connection with Community policy in the field of information technology and telecommunications

- Corporate telecommunications networks.
- Work programme for aeronautical mobile satellite terminals.
- Multiple 64 kbits/s leased lines.
- General packet radio service on GSM.
- Work programme for electronic toll systems.
- Standards for integrated circuit cards for road toll collection.
- Standards for metal and optical fibre cables and for cabling systems.
- Standards for broadband ISDN/ATM-based networks and metropolitan networks.
- Standards for frame relay.
- Standards for access networks.
- Standards for digital European cordless telecommunications (DECT).
- Standards for GSM and DCS 1800.
- Standards covering the elements involved in the terrestrial flight telecommunications system (TFTS).
- Standards for trans-European trunked radio system (TETRA).

- Standards for mobile satellite services.
- Report on the numbering of telecommunications services.
- Standards for sound, picture and data coding.
- Standards for managing the various elements in a telecommunication management network (TMN).
- Standards for the universal mobile telecommunications system (UMTS).
- Standards for software interfaces to information and communications technologies services.

#### 4. Mandates in connection with other Community policies.

#### 4.1. Consumer protection policy

- Directive 92/59/EEC on general product safety: standardisation mandate for CEN in the field of consumer safety - bunk beds.

#### 4.2. Environmental policy

- Directive 94/55/EC on the transport of dangerous goods: standardisation mandate for CEN.
- Directive 94/62/EC on packaging and packaging waste: standardisation mandate for CEN.
- Directive 94/67/EC and Directive 89/369/EEC: standardisation mandate for CEN for determination of the total emissions of certain heavy metals into the air.

#### 4.3. Energy policy

- Council Decision 93/500/EEC (ALTENER Programme): standardisation mandate for CEN and CENELEC in the field of solar photovoltaic energy systems and components.
- Directive 92/75/EEC: standardisation mandate for CEN and CENELEC for the drafting and adoption of measurement standards for household lighting sources.
- Directive 92/75/EEC: standardisation mandate for CEN and CENELEC for the drafting and adoption of measurement standards for household ovens.
- Directive 92/75/EEC: standardisation mandate for CEN and CENELEC for the drafting and adoption of measurement standards for household water heaters and hot-water storage appliances.
- SAVE and PACE Programmes: standardisation mandate for CEN and CENELEC for the drafting and adoption of measurement standards for ballasts for fluorescent lamps.

### 6.16. Table VI b - Standardisation work entrusted to the European standardisation bodies in 1996

#### 1. Mandates related to New Approach Directives

- Mandate for CEN and CENELEC in the field of construction products: geotextiles.
- Mandate for CEN and CENELEC in the field of construction products: curtain walling.
- Mandate for CEN and CENELEC in the field of construction products: fire alarm and detection systems, fixed explosion suppression systems and products.
- Mandate for CEN and CENELEC in the field of construction products: sanitary appliances.
- Mandate for CEN and CENELEC in the field of construction products: fixed road traffic installations.
- Mandate for CEN and CENELEC in the field of construction products: structural timber products.
- Mandate for CEN and CENELEC for a study on the feasibility of, need for and proposed form of a guideline concerning the selection of personal protective equipment.

#### 2. Mandates in connection with public procurement

- Mandate for CEN and CENELEC for standardisation in the field of equipment and installations for the transmission and distribution of electricity.

### **3.** Mandates in connection with Community policy in the field of information technology and telecommunications

- Mandate for CEN in the field of postal services and equipment.
- Mandate for CEN, CENELEC and ETSI in the field of information technology, consumer electronics and telecommunications: standards for ISDN packet mode services.
- Mandate for CEN, CENELEC and ETSI in the field of information technology, consumer electronics and telecommunications: standards for user access to broadband ISDN networks and services.

#### 4. Mandates in connection with other Community policies.

#### 4.1. Consumer protection policy

- Standardisation mandate for CEN and CENELEC in the field of safety of equipment for fairgrounds and amusement parks.

#### 4.2. Policy on worker protection

- Mandate for CEN in the field of specifications for fire-resistant hydraulic fluids used for power transmission (hydrostatic and hydrokinetic).

#### 4.3. Environmental policy

 Mandate for CEN and CENELEC for the quality assurance of automated measuring systems.

#### 4.4. Transport policy

- Mandate for CEN, CENELEC and ETSI in the field of space technology.
- Mandate for CEN, CENELEC and ETSI in the field of air traffic management equipment and systems.

#### 4.5. Energy policy

- Mandate for CEN for the adoption of standards containing minimum requirement specifications, including test methods for fatty acid methyl esters (FAME) or biodiesel.
- Mandate for CEN and CENELEC for the adoption of measuring standards and test methods for the power of electric motors.

### 6.17. Table VI c - Standardisation work entrusted to the European standardisation bodies in 1997

#### **1.** Mandates related to New Approach Directives

- Mandate for CEN and CENELEC in the field of construction products: woodbased panels.
- -Mandate for CEN and CENELEC in the field of construction products: cements, building limes and other hydraulic binders.
- Mandate for CEN and CENELEC in the field of construction products: reinforcing and prestressing steel for concrete.
- Mandate for CEN and CENELEC in the field of construction products: masonry and related products.
- Mandate for CEN and CENELEC in the field of construction products: horizontal complement for the evaluation of construction products and elements in respect of their resistance to fire.
- Mandate for CEN and CENELEC in the field of construction products: waste water engineering products.
- Mandate for CEN and CENELEC in the field of construction products: floorings.
- Mandate for CEN and CENELEC in the field of in vitro diagnostic medical devices.

#### 2. Mandates in connection with public procurement

(No mandates)

### **3.** Mandates in connection with Community policy in the field of information technology and telecommunications

- Programming and standardisation mandate for CEN, CENELEC and ETSI in the field of health care informatics.
- Mandate for CEN, CENELEC and ETSI in the field of road transport telematics.
- Mandate for CEN, CENELEC and ETSI on European multicultural specificities.
- Mandate for CEN, CENELEC and ETSI on geographic information systems.
- Mandate for CEN, CENELEC and ETSI on consumer interests in the field of electronic commerce.

#### 4. Mandates in connection with other Community policies.

#### 4.1. Consumer protection policy

- Mandate for CEN in the field of consumer safety: feasibility study on possible standardisation on fire resistance of nightwear.
- Mandate for CEN and CENELEC in the field of consumer safety: baby-walkers.
- Mandate for CEN in the field of consumer safety: oil lamps.
- Mandate for CEN and CENELEC in the field of consumer safety: safety of child care articles.

#### 4.2. Environmental policy

- Mandate for CEN and CENELEC concerning the reference method for the measurement of SO<sub>2</sub>, NO<sub>x</sub>, CO and O<sub>3</sub> in ambient air.
- Mandate for CEN and CENELEC concerning the reference method for the measurement of benzene in ambient air.
- Mandate for CEN and CENELEC concerning the reference method for the measurement of Pb, Cd, As and Ni in ambient air.

#### 4.3. Transport policy

(No mandates)

#### 4.4. Energy policy

 Mandate for CEN and CENELEC for the designation of operational modes and for the measurement methods related to the power consumption of televisions, videocassette recorders, decoders and satellite receivers.

### 6.18. Table VI d - Standardisation work entrusted to the European standardisation bodies in 1998

#### **1.** Mandates related to New Approach Directives

- Mandate for CEN for the conversion of the Eurocodes from ENV prestandards into European EN standards concerning the structural and geotechnical design of buildings and civil engineering works.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on structural metallic products and ancillaries.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on internal and external wall and ceiling finishes.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on roof coverings, rooflights, roof windows and ancillary products.
- Horizontal complement to the mandates for CEN and CENELEC concerning the execution of standardisation work for the evaluation of construction products in respect of their reaction to fire.
- Mandate for CEN and CENELEC concerning the execution of standardisation work on road construction products.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on aggregates.
- Mandate for CEN, CENELEC and ETSI for the elaboration and adoption of standards for railway equipment, related to the interoperability of the trans-European high-speed rail system.

#### 2. Mandates in connection with public procurement

(No mandates)

# **3.** Mandates in connection with Community policy in the field of information technology and telecommunications

- Mandate relating to electronic signature.
- - Mandate relating to educational software.
- Standardisation mandate for CEN, CENELEC and ETSI for harmonised standards for R-GSM terminals.
- Standardisation mandate for CEN, CENELEC and ETSI for harmonised standards for the GSM cordless telephony system.

- Mandate for the European standards bodies in the field of information and communications technologies for elderly and disabled people.

#### 4. Mandates in connection with other Community policies.

#### 4.1 Consumer protection policy

- Mandate for CEN and CENELEC in the field of consumer safety related to the safety of lighters.

#### 4.2 Environmental policy

- Three mandates concerning a manual reference method allowing the calibration of an automated system for measuring emissions of substances.

#### 4.3 Energy policy

- Standardisation mandate for CEN and CENELEC for the designation of operational modes and for the measurement methods related to the power consumption of audio systems.
- Standardisation mandate for CEN and CENELEC for the measurement method for the determination of the efficacy of fluorescent lighting luminaries.
- Standardisation mandate for CEN and CENELEC for the elaboration and adoption of standards for the measurement methods for the determination of the efficiency of individual air conditioners.

Member State	1995	1996	1997	1998
Belgium	26	17	59	50
Denmark	36	28	40	55
Germany	92	88	99	76
Spain	25	19	35	24
Finland	17	34	22	23
France	61	41	51	47
Greece	12	16	12	11
Ireland	1	4	3	1
Italy	31	27	31	32
Luxembourg	1	0	0	2
Netherlands	43	62	341	122
Austria	25	61	106	69
Portugal	5	19	7	11
Sweden	5	34	23	30
United Kingdom	59	73	71	51
EC total	439	523	900	604

6.19. Table VII - Number of notifications of technical rules from each Member State from 1995 to 1998

Member State	%	%	%	%
	1995	1996	1997	1998
Belgium	5,9	2,1	6,5	8,2
Denmark	8,2	5,3	4,4	9,1
Germany	20,9	16,8	11	12,5
Spain	5,6	3,6	3,8	3,9
Finland	3,8	6,5	2,4	3,8
France	13,8	7,8	5,6	7,7
Greece	2,7	3	1,3	1,8
Ireland	0,2	0,7	0,3	0,1
Italy	7	5,1	3,4	5,2
Luxembourg	0,2	-	-	0,3
Netherlands	9,7	11,8	37,8	20,1
Austria	5,6	11,6	11,7	11,4
Portugal	1,1	3,6	0,7	1,8
Sweden	1,1	6,5	2,5	4,9
United Kingdom	13,4	13,9	7,8	8,4

6.20. Table VIII - Percentage of notifications of technical rules from each Member State from 1995 to 1998

SECTOR	В	DK	D	E	FIN	F	GR	IRL	I	L	NL	A	Р	S	U K	EC TOTAL
Building and construction	-	3	14	5	1	1	1	-	4	-	-	11	3	-	6	49
Agricultural products and foodstuffs	5	-	3	4	-	3	4	-	11	-	16	3	1	-	8	58
Chemicals	1	1	1	-	1	-	-	-	-	-	1	2	-	2	-	9
Pharmaceuticals	3	-	-	1	-	2	1	-	-	-	-	-	-	-	5	12
Household and leisure equipment	-	1	1	-	-	3	-	-	-	-	2	1	-	-	3	11
Mechanical engineering	3	5	45	6	8	7	-	1	10	-	4	3	-	-	11	103
Energy, minerals, wood	-	-	-	1	-	-	1	-	-	-	1	-	-	-	-	3
Environment, packaging	-	1	-	-	1	1	-	-	-	1	6	-	-	1	-	11
Health, medical equipment	-	-	-	-	-	3	-	-	-	-	-	1	-	-	-	4
Transport	2	9	2	3	3	8	3	-	3	-	5	3	-	1	11	53
Telecommunications	12	16	24	5	1	33	1	-	2	-	8	1	1	-	15	119
Miscellaneous	-	-	2	-	2	-	1	-	1	-	-	-	-	1	-	7
TOTAL BY MEMBER STATE	26	36	92	25	17	61	12	1	31	1	43	25	5	5	59	439

6.21. Table IX - Breakdown by sector of drafts notified by the Member States of the European Union (1995)

SECTOR	B	DK	D	E	FIN	F	GR	IRL	Ι	L	NL	A	Р	S	U K	EC TOTAL
Building and construction	1	3	28	6	4	4	2	1	1	-	5	11	-	2	9	77
Agricultural products and foodstuffs	2	5	5	1	1	10	5	1	8	-	27	7	6	-	26	104
Chemicals	-	2	5	1	1	3	1	-	4	-	6	3	-	3	2	31
Pharmaceuticals	3	-	1	-	2	4	-	-	-	-	-	-	-	2	3	15
Household and leisure equipment	-	2	1	-	2	1	-	-	-	-	1	2	-	-	-	9
Mechanical engineering	5	5	11	6	13	8	-	-	2	-	6	7	2	3	11	79
Energy, minerals, wood	-	-	1	-	-	-	1	-	-	-	-	-	-	2	-	4
Environment, packaging	2	3	4	1	3	1	2	1	1	-	9	4	1	4	2	38
Health, medical equipment	-	-	1	-	-	-	-	-	1	-	-	-	-	-	-	2
Transport	-	4	11	2	5	1	5	-	7	-	8	12	-	11	17	83
Telecommunications	1	4	20	2	3	8	-	1	2	-	-	15	10	7	3	76
Miscellaneous	3	-	-	-	-	1	-	-	1	-	-	-	-	-	-	5
TOTAL BY MEMBER STATE	17	28	88	19	34	41	16	4	27	-	62	61	19	34	73	523

6.22. Table X - Breakdown by sector of drafts notified by the Member States of the European Union (1996)

SECTOR	В	DK	D	E	FIN	F	GR	IRL	Ι	L	NL	Α	Р	S	UK	EC TOTAL
Building and construction	1	1	26	7	5	3	2	1	1	-	15	28	_	4	2	96
Agricultural products and foodstuffs	7	6	4	8	1	11	4	0	11	-	81	7	-	1	25	166
Chemicals	1	1	3	3	-	-	1	0	6	0	11	3	-	4	1	34
Pharmaceuticals	-	-	6	-	-	4	-	-	1	-	4	2	-	2	4	23
Household and leisure equipment	-	1	0	2	0	3	-	-	-	-	1	-	-	-	1	8
Mechanical engineering	11	3	26	5	6	8	-	-	2	-	40	12	2	5	5	125
Energy, minerals, wood	1	-	-	1	-	6	-	-	-	-	2	-	-	-	-	10
Environment, packaging	4	4	3	-	1	5	1	1	2	-	32	5	3	-	2	63
Health, medical equipment	-	-	1	-	-	-	-	-	-	-	1	-	1	-	1	4
Transport	-	8	7	3	5	2	4	-	3	-	110	9	1	7	24	183
Telecommunications	33	16	23	6	3	7	-	1	4	-	9	38	-	-	6	146
Miscellaneous	1	-	-	-	1	2	-	-	1	-	35	2	-	-	-	42
TOTAL BY MEMBER STATE	59	40	99	35	22	51	12	3	31	-	341	106	7	23	71	900

6.23. Table XI - Breakdown by sector of drafts notified by the Member States of the European Union (1997)

SECTOR	В	DK	D	Ε	FIN	F	GR	IRL	Ι	L	NL	Α	Р	S	UK	EC total
Building and construction	2	-	30	5	3	1	-	-	5	-	14	9	-	1	6	76
Agricultural products and foodstuffs	9	4	6	1	1	15	2	-	7	_	35	2	5	4	7	98
Chemicals	3	8	2	1	-	2	2	-	7	-	4	4	1	3	2	39
Pharmaceuticals	-	1	2	-	-	4	1	-	1	-	2	1	-	3	2	17
Household and leisure equipment	1	-	-	1	-	1	-	-	-	-	-	1	1	1	-	6
Mechanical engineering	18	-	8	9	7	7	2	-	7	-	10	16	2	7	10	103
Energy, minerals, wood	-	2	-	2	-	2	-	-	1	1	5	4	-	1	2	20
Environment, packaging	8	2	3	1	2	2	1	1	1	1	18	2	-	1	-	43
Health, medical equipment	-	-	3	-	-	-	-	-	-	-	1	3	-	-	-	7
Transport	1	9	11	-	7	7	3	-	1	-	18	3	1	8	10	79
Telecommunications	1	26	11	3	3	2	-	-	1	-	6	21	1	1	11	87
Miscellaneous	7	3	-	1	-	4	-	-	1	-	9	3	-	-	1	29
TOTAL BY MEMBER STATE	50	55	76	24	23	47	11	1	32	2	122	69	11	30	51	604

6.24. Table XII - Breakdown by sector of drafts notified by the Member States of the European Union (1998)

COUNTRY	NOTIFICATIONS	EC COMMENTS
Norway	8	6
Switzerland	16	8
TOTAL	24	14

#### 6.25. Table XIII - Comments on drafts notified by Norway and Switzerland in 1995

#### Comments on drafts notified by Norway and Switzerland in 1996

COUNTRY	NOTIFICATIONS	EC COMMENTS
Norway	30	23
Switzerland	13	4
TOTAL	43	27

#### Comments on drafts notified by Iceland, Norway and Switzerland in 1997

COUNTRY	NOTIFICATIONS	EC COMMENTS
Iceland	1	1
Norway	11	5
Switzerland	20	6
TOTAL	32	12

#### Comments on drafts notified by Iceland, Norway and Switzerland in 1998

COUNTRY	NOTIFICATIONS	EC COMMENTS
Iceland	5	4
Norway	32	11
Switzerland	13	7
TOTAL	50	22

SECTOR	NORWAY	SWITZERLAND	TOTAL FOR SECTOR
Pharmaceuticals	-	1	1
Mechanical engineering	1	-	1
Energy, minerals, wood	-	1	1
Health, medical equipment	-	1	1
Transport	1	2	3
Telecommunications	6	11	17
TOTAL FOR COUNTRY	8	16	24

# 6.26. Table XIV - Breakdown by sector of drafts notified by Norway and Switzerland in 1995

SECTOR	NORWAY	SWITZERLAND	TOTAL FOR SECTOR
Building and construction	1	-	1
Foodstuffs	2	1	3
Chemicals	3	1	4
Pharmaceuticals	-	2	2
Mechanical engineering	-	3	3
Health, medical equipment	-	1	1
Environment, packaging	1	-	1
Transport	1	-	1
Telecommunications	22	5	27
TOTAL FOR COUNTRY	30	13	43

Breakdown by sector of drafts notified by Norway and Switzerland in 1996

SECTOR	ICELAND	NORWAY	SWITZERLAN D	TOTAL FOR SECTOR
Building and construction	-	-	-	-
Foodstuffs	-	4	8	12
Chemicals	-	2	2	4
Pharmaceuticals	-	-	2	2
Mechanical engineering	-	-	3	3
Health, medical equipment	-	-	-	-
Environment, packaging	1	1	3	5
Transport	-	1	2	3
Telecommunications	-	3	-	3
TOTAL FOR COUNTRY	1	11	20	32

### Breakdown by sector of drafts notified by Iceland, Norway and Switzerland in 1997

SECTOR	ICELAND	NORWAY	SWITZERLAN D	TOTAL FOR SECTOR
Building and construction	-	-	3	3
Foodstuffs	3	5	6	14
Chemicals	-	6	-	6
Pharmaceuticals	-	-	-	-
Household and leisure equipment	-	1	-	1
Mechanical engineering	1	-	1	2
Energy	-	-	2	2
Health, medical equipment	-	-	-	-
Environment, packaging	1	1	-	2
Transport	-	13	1	14
Telecommunications	-	6	-	6
TOTAL FOR COUNTRY	5	32	13	50

### Breakdown by sector of drafts notified by Iceland, Norway and Switzerland in 1998