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**REPORT FROM THE COMMISSION
TO THE COUNCIL, THE EUROPEAN PARLIAMENT
AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
THE OPERATION OF DIRECTIVE 98/34/EC FROM 1999 TO 2001**

EXECUTIVE SUMMARY

The present report presents the results of the application of Directive 98/34/EC laying down a procedure for the provision of information in the field of technical regulations and standards and of rules on information society services. It covers the period 1999 to 2001. It is divided into three parts: the information procedure for standards, the notification procedure for technical regulations and finally, the annexes referring to standards and technical regulations.

The report provides an assessment of the role of Directive 98/34/EC during the period in question. It is intended to raise awareness of these procedures set up by the Directive and to encourage businesses to make even more use of it.

1. STANDARDS

The procedure, in the field of standards, is designed to monitor the new standardisation activities introduced by the national standardisation bodies (as recognised under Directive 98/34/EC). This report gives a brief description of the procedure in the field of standards, provides an assessment and proposes improvements.

The report concludes that it would be useful to examine the value and direct and indirect usefulness of this procedure for the different players on the market. It is first up to all the parties concerned to consider these aspects and make an assessment. However, it should be noted that it is highly likely that the absence of the mechanism for monitoring national activities could again create the danger of disruption on the internal market. Therefore, this procedure must certainly be continued, but it is necessary to allocate greater resources to it and to strengthen it at European and national levels in order to increase its effectiveness.

One further question that could be asked concerns the legal framework. European standardisation has developed considerably since the procedure was set up in 1983. There has been a massive movement of expert resources from national to European level since then. European standardisation now covers a wide variety of fields which were previously within the scope of national standards. It may also be assumed that the standardisation bodies now automatically check whether their national standardisation intentions should be submitted directly at European or even international level. It would therefore be useful to consider reducing the legal framework of the information procedure for standards when Directive 98/34/EC is revised.

1. TECHNICAL REGULATIONS

By setting up a notification procedure for national technical regulations, Directive 98/34/EC has created a genuine observatory for the internal market, since it allows the Commission, the Member States and economic operators to find out about national regulatory initiatives.

This report provides a brief description of the procedure in the field of technical rules, the information exchanged, and the reactions of the Commission and the Member States. It also includes the results achieved, infringements of Directive 98/34/EC and case law in this area, the measures taken to improve the functioning of the procedure and, finally, its application at international level.

Looking to the future, the notification procedure could be extended both as regards contents and geographical coverage. Since services play an increasingly important role in our economies, the Commission has undertaken to begin studying the suitability of extending Directive 98/34/EC to services other than those of the information society. This appears particularly necessary since the Commission has already noted in its analysis of drafts covering several high technology sectors such as genetic treatment and the use of stem cells, that the Member States are increasingly linking the processing and handling of products to requirements imposed on service providers.

The other challenge for Directive 98/34/EC is enlargement. A first step has already been taken with Turkey, which has had the possibility since 1 January 2001 of participating in the notification procedure under a simplified arrangement. Given the importance of the Directive for the creation of an enlarged internal market, the Commission is currently studying ways of including the participation of candidate countries in the notification procedure prior to their accession, on the lines of the EFTA countries.

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Introduction

1. GENERAL OVERVIEW

The purpose of this report on the application of Directive 98/34/EC¹ from 1999 to 2001 is 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, the notification procedure for technical regulations and finally, the annexes referring to standards and technical regulations.

The report provides an assessment of the role of Directive 98/34/EC during the period in question. It is intended to raise awareness of these procedures set up by the Directive and to encourage businesses to make even more use of it.

2. STANDARDS

The procedure, in the field of standards, is designed to monitor the new standardisation activities introduced by the national standardisation bodies (as recognised under Directive 98/34/EC). Systems have been set up mainly to allow other bodies to comment, participate in the work or request an initiative to be taken at European level.

Despite the fact that only limited use is made of any of these systems, it should be stressed that the very existence of the procedure has constrained national initiatives and to some extent changed the approach of the national standardisation bodies. Human resources are increasingly being concentrated on European work rather than national activities.

This report provides a brief description of the procedure in the field of standards, provides an assessment and proposes improvements.

3. TECHNICAL REGULATIONS

By setting up a notification procedure for national technical regulations, Directive 98/34/EC has created a genuine observatory for the internal market, since it allows the Commission, the Member States and economic operators to find out about the regulatory initiatives taken by Member States. The Directive is also in line with the efforts of the Council, the Member States and the Commission to improve the quality of legislation at both Community and national levels. The Directive has therefore made a tangible contribution to improving national law-making. Prior analysis of draft national rules and regulations prevents many barriers to trade before they can have a negative effect. Likewise they allow the Commission to identify the areas where there is a real need for harmonisation.

¹ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, amended by Directive 98/48/EEC laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, OJ L 204 of 21.07.1998. In this report, the references to the provisions of Directive 98/34/EC refer to the version of the Directive as amended by Directive 98/48/EC.

Looking to the future, the notification procedure could be extended both as regards substance and geographical coverage. As regards substance, account could be taken of services other than those relating to the information society because services play an increasingly important role in our economies. As for geographical coverage, the enlargement of the European Union requires this to be increased.

This report provides a brief description of the procedure in the field of technical rules, the information exchanged, the reactions of the Commission and the Member States. It also includes the results achieved, infringements of Directive 98/34/EC and case law in this area, the measures taken to improve the functioning of the procedure and, finally, its application at international level.

Part I: Information procedure for standards

1. INTRODUCTION

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 1999 to 2001 and analyses the statistics. It also discusses the quality of the notifications, the use made of them, 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.

2. BRIEF DESCRIPTION OF THE PROCEDURE

2.1. Role of CEN and CENELEC

The information procedure for standards began in practice on 1 January 1985. Since the adoption of Directive 94/10/EC², amending Directive 83/189/EEC³, the notification obligation concerns only new standardisation activities. It no longer applies to other updates to the national standardisation programmes, namely drafts for public enquiry 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 CEN Management Centre (CEN/CMC, previously known as the CEN Central Secretariat) and the Central Secretariat of 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 (CEN/CMC and the Central Secretariat of CENELEC, Technical Boards, etc.) and by the Commission departments.

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

2.2. Role of ETSI

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 the secretariats of these two bodies. In fact, ETSI is not made up of national standardisation bodies, as defined

² 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 of 10.02.1996.

³ 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 of 26.04.1983.

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 CEN and CENELEC members listed in Annex II to Directive 98/34/EC.

3. OPERATION OF THE INFORMATION PROCEDURE FROM 1999 TO 2001

3.1 Handling of notifications

As stated in the previous report, CEN already started using a simplified procedure in 1993. This is the procedure provided for in the proposal made by the Commission in 1992, on which Directive 94/10/EC was based. This simplification has enabled the CEN Management Centre 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.

Since the beginning of 1993 the full texts of draft standards have been exchanged for public enquiry on a case by case basis and by mutual agreement between the bodies concerned. This is in the spirit of the participation provided for by Article 3 of Directive 98/34/EC.

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.

However, it is regrettable that the information from the Vilamoura procedure is not released outside, as is the case 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.

3.2 Statistics

The statistics published in CEN and CENELEC annual reports supply an overview of the standardisation activities notified from 1999 to 2001.

As a result of CENELEC's Vilamoura 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.

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 sub-sector.

As indicated in previous reports, the statistics must be interpreted with some caution for the following reasons:

- 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.

3.3 Trends in new standardisation activities

Bearing these reservations in mind, a number of comments can be made on the trends in international, European and national standardisation based on the tables in Annexes 1.1 to 1.10 of this report.

- The total number of new initiatives launched for all of these three levels has stabilised since 1999 at around 3 815 units compared with the average of 4 664 units for the 1995-1998 period covered by the previous report.
- At national level, the number of new initiatives averaged 1 400 per year from 1999 to 2001, down from 1 620 per year in the 1995-1998 period. The proportion of very specific work within this number held steady at around 98%. On average, 30% of notifications were declared as revisions or amendments to existing national standards.
- The number of new initiatives at European level fell considerably from 1998 compared with the previous two years. It averaged at 1 587 per year in the 1999-2001 period, whereas in the 1995-1998 period the average was 1 922 per year.
- At international level, the downward trend is also continuing: an average of 828 initiatives per year for the years 1999/2001 compared with 1.122 for the years 1995/1998.
- Tables 1.5 to 1.7 (see annexes) show that on average 30% of new national activities were in Germany. There was also a relatively high number of new initiatives in Austria.
- The top ten sub-sectors for national activities are shown in tables 1.8 to 1.10. Foodstuffs remained the leading sector for new national standardisation initiatives in each financial year. The Commission is of the opinion that European standardisation should be increased in this field. National activities remain important in the construction sector. Given that there are several standardisation mandates in this field for European initiatives, application of the standstill rule is debatable.

4. QUALITY OF THE NOTIFICATIONS FROM THE NATIONAL STANDARDISATION BODIES

4.1 CEN

In its previous reports the Commission indicated that there were still problems with notification deadlines and the intrinsic quality of the information supplied. The Commission insisted on several occasions that further effort should be made at national and European level to remedy this situation. Since 1995 such efforts have been made systematically, 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.

First, in 1995 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. This also explained how one member could participate in another member's activities. Other measures followed, particularly in the 1995-1998 period, such as the creation of a help desk in the CEN central unit to provide help on any issue regarding the units of CEN members responsible for notifying new subjects.

Despite these measures, around 22% of notifications were still submitted late in 1999. In 2000 and 2001 this figure improved (falling to 16% and 15% respectively). However, for this group of late notifications, there was a reduction in the possibilities of intervention by the parties concerned. For example, in 2001, around one third of late notifications were not communicated until 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.

Precise descriptions of drafts are also lacking. In 1998 some 31% of notifications contained no description other than the title. In the 1999-2001 period this had increased to an average of 36%. These were principally notifications from Austria, France and the United Kingdom. The number of other quality-related problems found first fell in 1999 and 2000 (88 and 66 cases reported respectively) then rose considerably in 2001 (136 cases). The inaccuracy of the data mainly consisted of wrong classification of the sector/sub-sector of activity.

4.2 CENELEC

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, the quality of notifications from CENELEC members can be considered good.

5. USE OF THE INFORMATION RECEIVED THROUGH THE PROCEDURE

5.1 Dissemination of information

The Commission does not have accurate, up-to-date information on the national dissemination of information on notifications, despite the reminders it gave to CEN members on 17 January 2002 and 13 June 2002 at the meetings of the enlarged Committee set up by Directive 98/34/EC. Consequently the only conclusions that can be drawn are those of the survey launched by the CEN Management Centre in 1995. 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, as the German standards institution (DIN) confirmed in January 2002, the information is circulated to 60 or so relevant trade associations which are responsible for disseminating it to their members. In France, systematic dissemination of information and broad consultation of industry are the main 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.

5.2 Application of Article 4 of Directive 98/34/EC

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. The table in Annex 1.11 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;
- requests to draw up European standards are non-existent apart from three cases in 1999 and two requests in 2000. It is not clear precisely how these requests were followed up.

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

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. This procedure was used in the case of 40 and 35 notifications in 1999 and 2000 respectively. Of these, 17 and 6 initiatives respectively were transferred to European level, while 20 and 27 were developed at national level with the participation of one or more other countries. In 2001 just 18 notifications were made under this procedure, 7 of which were taken up at European level.

5.3 Application of Article 7 of Directive 98/34/EC

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.

At the CEN Management Centre, some 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. This was 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 Commission queried 29 notifications, which concerned the fields of construction, machines and personal protective equipment.

5.4 Conclusions regarding the use of information

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, since 1998, 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 reiterates its opinion that further measures are needed to make more efficient use of the information at national level. Despite the great efforts made by the CEN Management Centre, 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. For example, the notifications could be put on a website, if possible with unrestricted, free access. There could also be a module on the website to collect comments or requests for information by the parties concerned. The collection - and if possible the evaluation of the comments - could be carried out by the national body of the country of origin of the comments. In this case, the role of coordination at national level by the CEN members could be maintained.

6. INFORMATION ON STANDARDISATION ACTIVITIES IN GENERAL

6.1 Need for information by all the parties concerned

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 when standards are drawn up.

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.

6.2 Websites promoted by the Commission

At the request of the Commission, in 1998 the three standardisation bodies started the computer work needed to establish a shared website. 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.

The shared site will also provide easy access to each of the sites of the three European standardisation bodies and the Commission sites. The full text of the Directives concerned and the references of the harmonised standards implementing the Directives are already on these sites, along with other information. The address of this shared site is: <http://www.NewApproach.org>. The site is a great success, as the access statistics reveal: around 9 000 different people a month visit the site and about 40 000 pages a month are consulted. The site giving the references of the harmonised standards published in the OJ regarding the New Approach Directives is also enjoying great success. The address is: <http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/index.html>

6.3 Information products of European standardisation bodies

The three European standardisation bodies have continued to issue a number of publications (on paper and in electronic format) explaining their present activities, describing standards adopted and listing national transpositions. They have also each created their own Internet site, with automatic pointers to their members' sites.

7. PROGRAMMING AND STANDARDISATION MANDATES

Pursuant to Article 6(3) of Directive 98/34/EC, the Standing Committee set up under the Directive expressed favourable opinions on 24, 16 and 7 mandates in 1999, 2000 and 2001 respectively. A large number (27) of these 47 mandates concern the implementation of New Approach Directives, in particular Directive 89/106/EEC relating to construction products. Various other standardisation mandates have also been issued to support other Community policies (see Annexes 1.12 to 14):

- Seven requests were made for standardisation in the field of consumer protection policy.
- Six mandates concerned energy policy (reduction of consumption and alternative sources).
- Four mandates were given, principally to CEN, in support of Directives on the environment.
- There was also a special mandate in 2001 concerning technologies for humanitarian demining.

This summary shows that the Commission is making increasing use of standardisation to implement the different Community policies. This approach whereby broader use is made of standardisation in the various Community policies is further confirmed by the Conclusions of the Council of 1 March 2002 (OJ of 15 March 2002 - paragraph three of the Conclusions).

8. ACTION TO IMPROVE THE PROCEDURE

8.1 Improvements at European level

In the field of standardisation, Directive 94/10/EC considerably simplified the procedure laid down in Directive 83/189/EEC (these texts were consolidated by Directive 98/34/EC). This made it possible to control the volume of notifications and consequently process them and examine their quality and content.

Several measures have been taken by the CEN Management Centre, mainly since 1995, to improve the quality of the data notified. These include 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 Management Centre 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.

CEN's analysis of the quality of notifications submitted from 1999 to 2001, 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. In particular, a reduction in the quality of notifications in 2001 shows that great vigilance is required. A strict quality assurance system must therefore be constantly applied and any new action in this field is welcome. Possible measures, which were already proposed in the previous report, include more frequent reporting on the quality of the data received. A detailed examination could be made of the problems most frequently encountered and those which are of greatest importance. This should allow targeted action, either by country or according to the nature of the problem, such as the project description.

8.2 Improvements at national level regarding notifications

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.

8.3 Improvement at national level regarding the dissemination of information

With regard to the use made of the information, the current dissemination system still needs to be reviewed. The introduction of new technologies based on websites both for notifications and for disseminating the consolidated information must be envisaged to facilitate communication 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 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 the sectors interested in the information from the standards procedure. European or national awareness-raising measures for these sectors could also be envisaged.

9. CONCLUSIONS AND PROSPECTS

The reduction in the number of new national standardisation activities has continued. The first reason for this was the simplified procedure introduced years ago, which requires only strictly new national activities to be notified. The second reason for this reduction was an actual fall

in new national initiatives. However, the level of such activity is still high, above all in Germany. Over the report period, an average of 1 400 national initiatives per year were started compared with 1 587 at European level. For all the CEN members, the fields where there is still a high level of national standardisation are foodstuffs, construction products and aeronautics.

The various measures taken by the CEN Management Centre, 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. Targeted measures regarding quality assurance would also be appropriate.

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 applied for using this procedure in order to verify the standstill declared when a (European) standardisation mandate is issued seem insufficient. The information procedure for standards is not, therefore, proving to be directly efficient. Furthermore, the last questionnaire on this subject showed that only a few countries actively disseminate the information. General dissemination in user-friendly form is needed. Combined with a system for collecting comments and requests, this should increase the effectiveness of the procedure in the field of standards.

It would also be useful to examine the value and direct and indirect usefulness of this procedure for the different players on the market. It is first up to all the parties concerned to consider these aspects and make an assessment. However, it should be noted that it is highly likely that the absence of the mechanism for monitoring national activities could again create the danger of disruption on the internal market. On this basis, this procedure must certainly be continued, but greater resources need to be allocated to it to strengthen it at European and national levels in order to increase its effectiveness.

One further question that could be asked concerns the legal framework. European standardisation has developed considerably since the procedure was set up in 1983. There has been a massive movement of expert resources from national to European level since then. European standardisation now covers a wide variety of fields which were previously within the scope of national standards. It may also be assumed that standardisers now automatically check whether their national standardisation intentions should be submitted directly at European or even international level. It would therefore be useful to consider reducing the legal framework of the information procedure for standards when Directive 98/34/EC is revised.

Part II : The information procedure for technical regulations

1. INTRODUCTION

The following pages describe how the information procedure established by Directive 98/34/EC for technical regulations has developed. This system, which was set up in 1983 under Directive 83/189/EEC, has maintained 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.

Since 5 August 1999, the procedure set up by Directive 98/34/EC has been extended to information society services⁴. In future, the Directive will play an even greater role with the enlargement of the European Union. In this respect, the Directive could prove a decisive instrument for ensuring that enlarged internal market operates smoothly.

2. BRIEF DESCRIPTION OF THE PROCEDURE

The following description of the 98/34/EC procedure is divided in two parts. The first provides a general presentation of the procedure in the field of products, while the second describes the specific details of the rules on information society services; the procedure for this sector differs slightly from that applicable to products.

2.1. General presentation of procedure 98/34/EC in the field of products

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 regulation 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.

The following cases may arise:

- The Member States and/or the Commission do not wish to give a reaction. In this case, the notifying Member State can adopt the draft regulation as soon as the three-month standstill period has elapsed.
- 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.

⁴ It was extended under Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EEC laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 217 of 05.08.1998.

- 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 its communication. 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.

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 application of the emergency procedure is justified.

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.

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.

2.2. Specific features of the procedure for the information society services sector

Directive 98/48/EC, which has been applicable since 5 August 1999, substantially extended the scope of Directive 98/34/EC. Given the rapid development of information society services and the national regulatory activity accompanying this development, it has been considered appropriate to also introduce a notification system for this type of service⁵.

⁵ For further information on the application of the notification procedure to information society services, see the recent Commission report entitled "Evaluation of the application of Directive 98/34/EC in the field of information society services" COM(2003) 69 final of 13.2.2003, and the Vade mecum to Directive 98/48/EC (http://europa.eu.int/comm/enterprise/tris/vade9848/index_en.pdf).

Field of Application

According to Article 1(2) of Directive 98/34/EC (as amended by Directive 98/48/EC) the services concerned are "any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services". Consequently radio broadcasting services and the television broadcasting services referred to in Article 1a) of Directive 89/552/EEC on the pursuit of television broadcasting services are excluded from the field of application because they are not provided at the individual request of a recipient of services.

There are certain exceptions to this field of application (Article 1(2) and (5) of Directive 98/34/EC). The Directive does not apply to rules on matters covered by Community legislation on telecommunications services, as defined by Directive 90/387/EEC on the establishment of the internal market for telecommunications services through the implementation of open network provision, or to the rules on matters covered by Community legislation on financial services. Finally, the rules on regulated markets, within the meaning of Directive 93/22/EEC on investment services in the securities field, are excluded from the notification obligation (for this sector all that remains is the obligation to communicate the texts adopted).

It should therefore be borne in mind that telecommunications services and financial services are not, as such, excluded from the field of application of Directive 98/34/EC. Some exceptions have simply been provided for in the terms laid down because in these two fields, a large number of matters are being harmonised and fall within a regulatory framework which is already sufficiently well-defined at Community level. The exclusion of regulated markets lies in the need to adopt without delay regulatory instruments which deal with on-line services relating to highly mobile and very fluid financial markets, where situations may change suddenly and unpredictably.

Article 1(5) of Directive 98/34/EC defines rules on services as "a requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point 2 [information society services], in particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point".

The concept of a "requirement of a general nature" therefore implies the exclusion of measures which, instead of laying down abstract and general requirements, are of direct and individual concern to certain specific recipients, such as administrative or judicial decisions in individual cases (e.g. the granting of licences to one or more specific operators).

A rule is not "specifically" aimed at the services concerned when it "affects such services only in an implicit or incidental manner" (second indent, fifth subparagraph of Article 1(5)). The Directive therefore requires notification of regulatory drafts which, given their grounds, content and purpose, directly and openly concern, entirely or in part, information society services. It is therefore not only regulatory texts which as a whole deal with information society services that are covered, but also regulations of which only a part (an article or even a paragraph) deals with an information society service (see second indent, fifth subparagraph of Article 1(5)). As is the case for technical rules, rules on *de facto* compulsory services are to be notified.

The following are examples of measures likely to constitute rules on information society services:

- measures concerning the conditions of access to an on-line activity;
- measures concerning the conditions for exercising an on-line activity;
- measures concerning the provider of on-line services;
- measures concerning the provision of on-line services;
- measures concerning the receiver of on-line services;
- measures concerning de facto mandatory services (e.g. a rule referring to non-regulatory texts or a professional code of practice for the supply of services on line, compliance with which confers a presumption of conformity; a voluntary agreement to which a public authority is a contracting party and the aim of which is compliance with the rules on services; etc.).

Rules of procedure

The rules of procedure applicable to draft rules on information society services broadly follow those applicable to draft rules on products. However, there are certain differences:

- First, as regards detailed opinions (Article 9 (2)), these may be issued if the Commission or a Member State consider that the draft "may create obstacles to the free movement of services or to the freedom of establishment of service operators within the internal market". In the case of rules on products, the Member State concerned must postpone the adoption of its project for six months from the date of communication. In the case of rules on services, this is reduced to four months.
- Secondly, although in the product sector Member States are obliged to postpone the adoption of a draft technical regulation for twelve months if the Commission announces its intention to propose or adopt a binding Community act or if it finds that the draft concerns a matter which is covered by a proposal for a Community act presented to the Council (Article 9(3) and (4)), in the case of regulations on services, a standstill period of twelve months is possible only in the second scenario (Article 9(4)). Furthermore, the standstill period is possible only if the notified project contains provisions which do not comply with the Commission's proposal (recital 23 of Directive 98/48/EC).
- Thirdly, the emergency procedure (Article 9 (7)) may be applied for regulations on information society services, not only "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" (the same circumstances as those already laid down for products), but also "for urgent reasons occasioned by serious and unforeseeable circumstances relating to [...] public policy, notably the protection of minors". Finally, the urgency clause for information society services may also be invoked for regulations on financial services, "for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons."

3. STATISTICAL OVERVIEW

The following chapter provides a statistical overview of the trends in the number of notifications received and their breakdown by Member State and sector. Data will also be presented on the different types of reaction (i.e. comments, detailed opinions and “blocking”). One final point will deal with the use of the urgency procedure provided for in Directive 98/34/EC.

3.1. Volume of notifications

The table in Annex 2.1 shows that the Commission received 591 draft technical regulations in 1999, 751 in 2000 and 530 in 2001. The general trend in the number of notifications received each year by the Commission is upward from 1999 to 2000 (+24.3%). However, in 2001 the number dropped mainly as a result of the considerable reduction in the number of drafts notified in the telecommunications sector (from 186 in 2000 to 47 in 2001). This was because the Member States had already notified a large number of radio interfaces in 2000, following the entry into force of Directive 99/5/EC on radio equipment and telecommunications terminal equipment.⁶

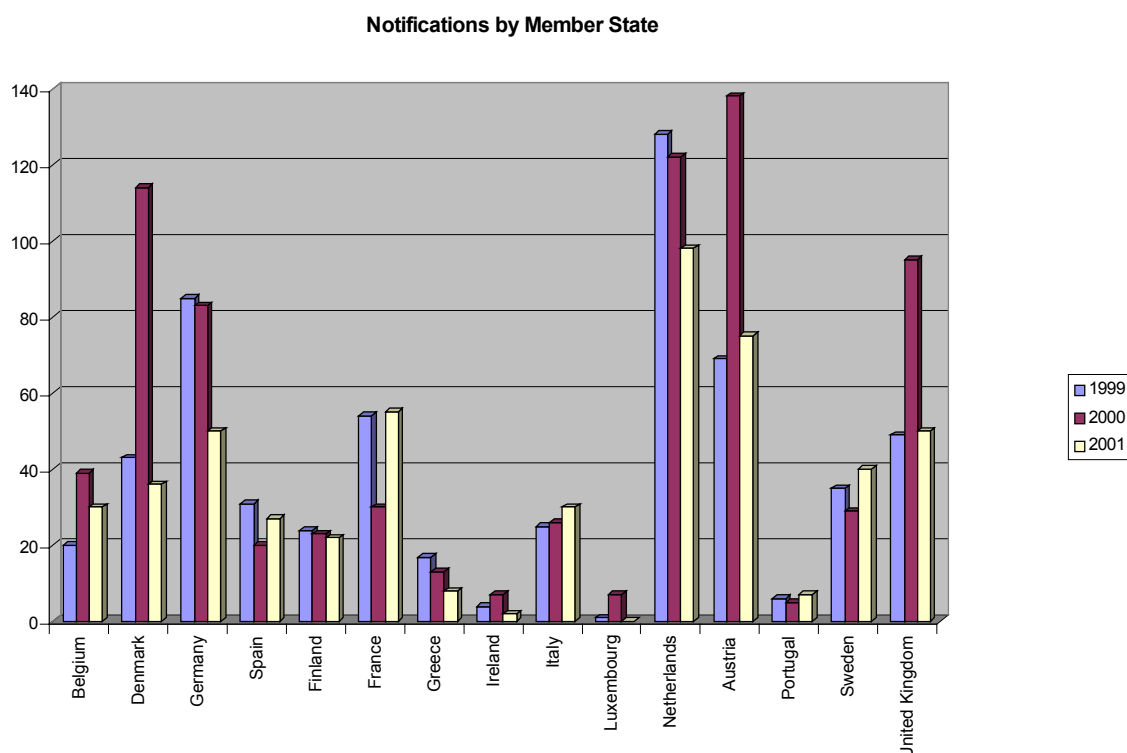
Generally speaking, a spate of "re-regulation" is apparent in the Member States, mainly as a result of technological advances and the desire to increase controls in the field of health, in particular regarding foodstuffs (*in dubio pro dubio*).

3.2. Breakdown by country

Figure 1 (and Table 2.2 in the Annex) shows that from 1999 to 2001 most draft rules were notified by the Netherlands and Austria. In 2000, there was a marked increase in the number of notifications from Denmark and the United Kingdom (Denmark: 43 in 1999 and 114 in 2000; UK 49 in 1999 and 95 in 2000). The increase in the number of notifications by Denmark and the United Kingdom that year is mainly due to the increase in notifications in the telecommunications and transport sectors. In 2001, however, the statistics are more similar again to those of 1999: the Netherlands returns to first place (with 98 notifications), while France and Germany remain among the four countries which notify the most drafts (with 55 and 50 notifications respectively). One trend has continued since 1999, namely the large number of notifications sent by Austria (69 in 1999, 138 in 2000 and 75 in 2001).

⁶ These interfaces should be notified to the Commission under Article 4 of Directive 99/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, OJ L 91 of 7.04.1999.

Figure 1



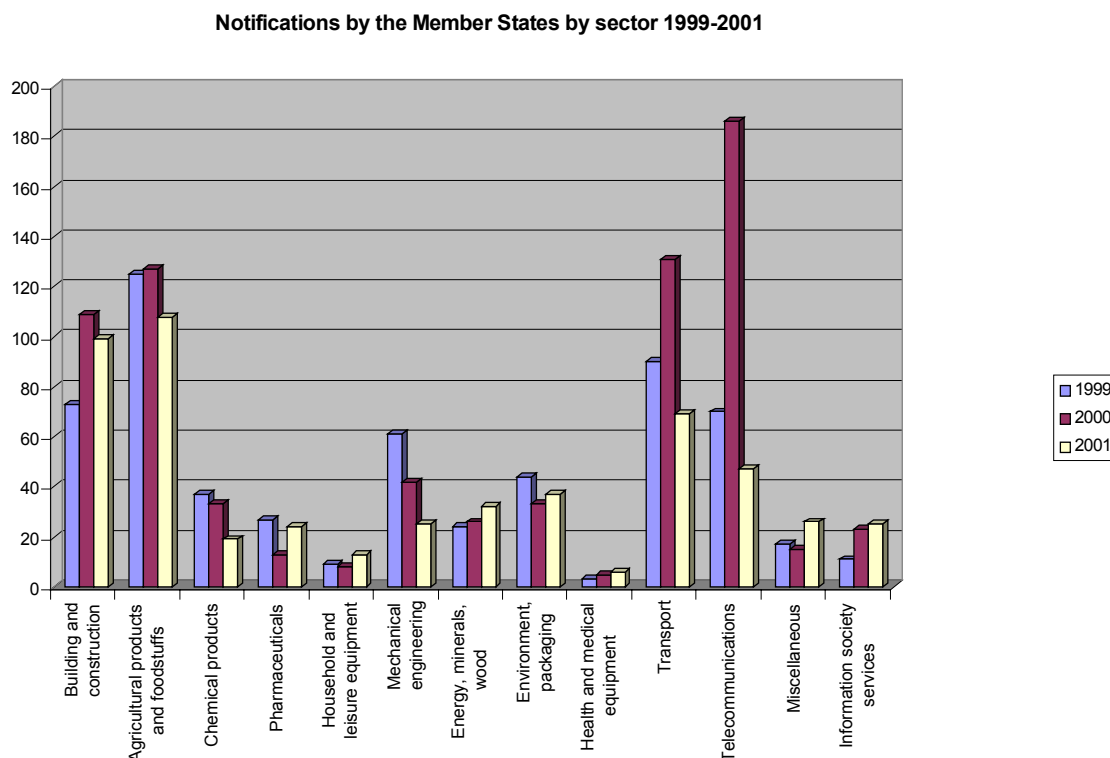
3.3 Breakdown by sector

A breakdown by sector (see Figure 2 and the three tables in Annex 2.3⁷) shows that, as in the 1995-98 period, most notifications received between 1999 and 2001 concerned the following five sectors: agricultural products and foodstuffs (18.9%), telecommunications (15.9%), transport (15.2%), building and construction (14.7%), and mechanical engineering (6.7%). However, for the first time since 1992, these five sectors account for under 75% of total notifications, mainly because of the growing importance of the environment (5.9% of total notifications between 1999 and 2001).

⁷

In these figures and tables, the health/medical equipment sector essentially covers medical devices.

Figure 2



Although, in percentage terms, the agricultural products and foodstuffs sector varied in the 1999-2001 period (from 21.1% in 1999 to 16.9% in 2000, then back to 19.1% in 2001) it remained at a high level in terms of the total number of notifications (125, 127 and 108 notifications in 1999, 2000 and 2001 respectively) and even took the lead in 2001. After dropping back between 1996 and 1998, telecommunications grew considerably, taking the lead in 2000; it then fell back again in 2001. The transport sector remained stable at a high level. The building and construction sector rose considerably in percentage terms (12.3%, 14.5% and 18.7% in 1999, 2000 and 2001 respectively). Mechanical engineering however fell sharply (from 10.3% in 1999 to 4.4% in 2001), following a short upturn in 1998 (17%).

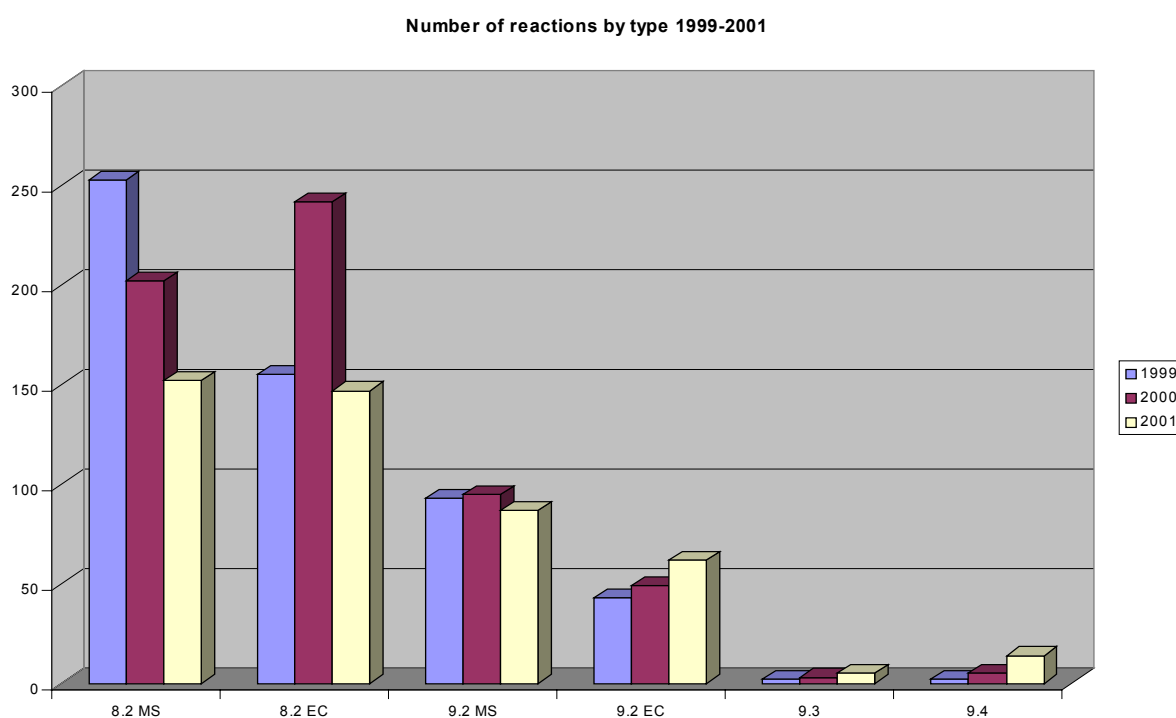
This confirms that in the 1999-2001 period, the Member States mainly legislated to take account of technological advances and to increase controls in the foodstuffs sector. Safety needs have also been apparent in the transport sector.

Alongside the technological progress, the procedure has been started in the information society services sector: 23 drafts were notified in this field in 2000 and 25 in 2001⁸. They covered complex subjects such as electronic signatures, the combating of computer-related crime, electronic commerce, the protection of minors in communications and domain names. These are sectors in which technological and legal advances fully justify the introduction of an effective prior information mechanism, administrative partnership and monitoring, particularly with a view to ensuring fundamental freedoms and rights.

3.4. Breakdown by reaction

As a general rule there was a reduction in the percentage of notifications that provoked a reaction on the part of the Commission. The reactions were in the form of comments, detailed opinions or announcements of intention to propose, adopt or present a Community act (see Figure 3). A notification quite often caused a combination of reactions by the Commission.

Figure 3



Key

- 8.2 : comments
- 9.2 : detailed opinion
- 9.3 + 9.4: blocking

⁸ It is difficult to compare with 1999, since Directive 98/48/EC, which extended Directive 98/34/EC to information society services did not apply until 5 August 1999.

For the 1995, 1996, 1997 and 1998 period, the rate of reactions by the Commission amounted to 49.7%, 63.1%, 46.5% and 38.5% respectively. The trend continued in 1999 when the rate fell to 34.2%. Although the total figure had slightly increased in 2000 to 39.8%, the types of reaction should be looked at.

In 2000, the Commission made comments on 32.2% of the notifications received compared with 26.2% in 1999 and 27% in 1998; it sent detailed opinions on only 6.5% in 2000 compared with 7.2% in 1999, producing an average of 6.8% (the rate had been 14.6% for the 1995-1998 period and 31% for the 1992-1994 period). This drop may be the result of the Commission's information efforts over a number of years in the Member States.

An improvement in the quality of the technical regulations notified is also visible in the total number of detailed opinions delivered by the Member States; this fell from 15.7% of notified drafts in 1999 to 12.6% in 2000.

On the other hand, for 2001, the trend towards a constant improvement in the quality of legislation ceases to become apparent. The number of reactions by the Commission increased considerably. It delivered detailed opinions on 11.7% of the notifications received (the average between 1999 and 2000 was 6.8%). It also sent comments on 27.7% of notifications. The Member States, for their part, delivered detailed opinions from 16.9% of the notifications (compared with 12.6% in 2000).

This trend appears to be due, among other things, to the fact that the Member States are attempting to take into account technological developments by proposing new legislation which is increasingly complex and, therefore, creates obstacles to the free movement of products and the free provision of information society services.

From 1999 to 2001, the Commission applied Article 9(3) to (5) of Directive 98/34/EC in 31 cases. These provisions oblige a Member State to observe a standstill period starting from the time the draft is communicated, if the Commission announces its intention to propose or adopt a binding Community act in accordance with Article 249 (ex Article 189) of the Treaty, or it announces its finding that the draft concerns a matter covered by such a proposal. There were 4 such standstill periods in 1999, 8 in 2000 and 19 in 2001. Of the 31 applications of Article 9(3), (4) or (5) of Directive 98/34/EC, 14 concerned the agricultural products and foodstuffs sector.

3.5. Use of the emergency procedure

From 1999 to 2001, the Member States invoked the emergency procedure 103 times. The measures notified in this way accounted for 5.4% of total notifications. This is about the same number as in the 1995 to 1998 period.

Urgency was invoked mainly in the agricultural and foodstuffs sector (52 times) and in the transport sector (14 times), followed by the chemical industry (7 times). If the number of notifications by sector is compared with the number of times urgency is invoked (see Table 2.4 annexed), the sectors where proportionally greater use is made of this procedure are health and medical equipment (21.4%), followed by agri-foodstuffs (14.5%), then pharmaceutical products (9.4%) and information society services (8.5%).

It can be seen that urgency is invoked mainly in fields which directly concern the protection of health or where there is rapid technological change resulting in a problem of public security (information society services), particularly in the period following 11 September 2001.

The Commission considered that the use of the emergency procedure was justified in 15 cases in 1999, 13 cases in 2000 and 24 cases in 2001, resulting in an average acceptance rate of 50.5%. The rate of acceptance has therefore steadily fallen since 1996 (from 80% in 1996 to 68% in 1997 and 52.7% in 1998). There are many complex reasons for this drop. Nevertheless, it is clear that particularly in the agricultural and foodstuffs sector (over 50% of the total number of urgent cases) that the Member States have invoked urgency in matters which were already regulated exhaustively at Community level.

4. RISKS OF BARRIERS TO THE INTERNAL MARKET DETECTED THROUGH THE NOTIFICATION PROCEDURE

A general picture of these barriers may be obtained from a statistical overview and a more specific description of the problems posed in relation to Articles 28 and 30 and Articles 43 and 49 of the EC Treaty, and in relation to secondary legislation.

4.1 General picture

A comparison between the number of notifications per sector and the reactions of the Commission or the Member States results in the following conclusions for 1999 (see also the first table of Annex 2.5):

- The sectors for which the Commission and the Member States delivered most detailed opinions are those of health and medical equipment, followed by chemical products, household and leisure equipment and agricultural products and foodstuffs.
- If the comments and detailed opinions are taken into account as a whole for 1999, in first place appears health and medical equipment, followed by chemical products, the environment and agricultural products and foodstuffs.

The situation is similar for 2000 (see the second table in Annex 2.5), although information society services appear for the first time:

- The areas in which most detailed opinions were delivered by the Commission and the Member States were, in first place, household and leisure equipment, followed by information society services, agricultural products and foodstuffs and, finally, health and medical equipment.
- Looking again at detailed opinions and comments as a whole, health and medical equipment appear in first place, followed by chemical products, agricultural products and foodstuffs and, finally, household and leisure equipment.

The situation is similar for 2001, although for the first time miscellaneous products are of significance (see also the third table of Annex 2.5).

- The areas in which most detailed opinions were delivered by the Commission and the Member States were health and medical equipment, followed by chemical products, miscellaneous products, and building and construction.

- If an analysis is carried out again of detailed opinions and comments as a whole, health and medical equipment appear in first place, followed by chemical products, the environment, and, finally, miscellaneous products.

This comparison leads to the conclusion that most barriers occur in the following sectors: health and medical equipment, chemical products, and agricultural products and foodstuffs. Conversely, the sectors with the fewest problems are pharmaceuticals and transport.

Another basis for comparison by which to gain an overview is the type of legal basis invoked by the Commission in its detailed opinions. In 1999 the situation was as follows: ⁹

- 17 detailed opinions were delivered on the basis of secondary legislation (6 of which on the basis of Directive 89/336/CEE¹⁰ relating to electromagnetic compatibility);
- 30 detailed opinions were addressed to the Member States on the basis of Articles 28 and 30 of the EC Treaty (21 of which because of the absence of the mutual recognition clause or because of an inadequate clause and 9 because the measure was considered disproportionate to the objective pursued).

For 2000:

- 17 detailed opinions were delivered on the basis of secondary legislation;
- 29 detailed opinions were based on Articles 28 and 30 of the EC Treaty (18 of which because of the absence of the mutual recognition clause or because of an inadequate clause and 11 because the measure was considered disproportionate to the objective pursued);
- 10 detailed opinions were addressed to the Member States on the basis of Articles 43 and 49 of the EC Treaty (these concerned information society services).

For 2001:

- 33 detailed opinions were sent to the Member States on the basis of secondary legislation (6 of which on the basis of Directive 73/23/EEC¹¹ on low-voltage equipment and 5 on the basis of Directive 97/23/EC¹² on pressure equipment);
- 30 detailed opinions were based on Articles 28 and 30 of the EC Treaty (20 of which because of the absence of the mutual recognition clause or because of an inadequate clause and 10 because the measure was considered disproportionate).

In total 67 detailed opinions (40.4%) were based on secondary legislation and 99 (59.6%) on Articles 28 and 30 and Articles 43 and 49 of the EC Treaty. This shows that although the notification procedure does not apply to the measures by which the Member States comply with binding Community acts which result in the adoption of technical specifications or to regulations on services (see the first indent of Article 10(1) of Directive 98/34/EC), the notified texts often concern, directly or indirectly, secondary Community legislation.

⁹ A detailed opinion may have more than one legal basis, which explains why the figures often add up to more than the total number of detailed opinions delivered each year.

¹⁰ OJ L 139 of 23.05.1989.

¹¹ OJ L 77 of 26.03.1973.

¹² OJ L 181 of 9.07.1997.

4.2. Incompatibility of notified drafts with Articles 28 and 30 and Articles 43 and 49 of the EC Treaty

An examination of the detailed opinions addressed by the Commission to the Member States on the basis of Articles 28 and 30 of the EC Treaty shows that, with a few exceptions, most of the barriers to trade identified are related to the principle of mutual recognition and the drafting of clauses whose presence in notified drafts is a condition sine qua non for the correct application of this principle.

In the *field of pharmaceuticals and medical equipment*, the Commission has delivered only a few detailed opinions concerning mutual recognition clauses, either because the subject was covered by a directive (in particular Directive 93/42/EC on medical devices) or the complaint concerned certain discriminatory procedures regarding parallel imports of medicinal products.

In the *environment and chemical products sector*, mutual recognition clauses cannot apply in all cases. For drafts where such clauses are necessary, the Commission noted in some cases that the clauses laid down were inadequate, since they were limited to certain standards, made European standards compulsory or were subject to certain preconditions (e.g. that the reference of the standard of another Member State should be included in an official State publication). In addition, some drafts were deemed contrary to Article 28 of the EC Treaty, since they created barriers disproportionate to the objectives sought. In this respect, the failure to provide scientific data (an infringement of Article 8(1) of Directive 98/34/EC) to support certain prohibitions in the chemical sector made it difficult for the Commission in many cases to analyse the proportionality of the proposed measures.

The drafts notified in the *agricultural field* were rarely in breach of Article 28 of the Treaty and only occasionally concerned the problem of mutual recognition, other than for secondary aspects (use of specific equipment, etc.). In the *foodstuffs sector*, problems arose particularly in relation to the addition of vitamins and minerals to foodstuffs. Some Member States refused to add mutual recognition clauses, arguing that the addition of vitamins and minerals at certain levels could cause problems for human health. These problems should, nevertheless, be solved with the adoption of the draft regulation on fortified foods which the Commission is currently drawing up and publication of which is expected this year.

In the *field of information society services*, the notifications showed that often the Member States make the same requirements as those already fulfilled by the service provider in the Member State of origin. This was considered by the Commission as contrary to the principles of free movement of services and freedom of establishment (Articles 43 and 49 of the EC Treaty). It is useful to note that national initiatives have emerged in a new area, namely that of domain names (on the Internet). In this respect, it is clear that the Member States are beginning to adapt their legislation to technological developments. The Commission has intervened to ensure that this development is consistent throughout the Member States and to thus prevent the creation of barriers to the performance of cross-border activities.

The detailed opinions sent by the Commission in the *construction sector* often refer to the request for the inclusion of mutual recognition clauses in fields considered by the Member States as pertaining to safety or personal protection (e.g. fire protection, amusement parks, playgrounds, old people's homes, etc.). In this sector problems of mutual recognition often arise because Member States intend to make European or national standards compulsory.

As regards *mechanical engineering*, problems of mutual recognition arise particularly as regards electronic taxi meters. Since a proposal for a directive on this type of taxi meter was submitted by the Commission on 15 September 2000 (COM(2000) 566 final), the problems raised by these notifications should be settled in the future.

The majority of detailed opinions addressed to the Member States regarding *transport* concerned the absence or poor drafting of the mutual recognition clause. In this field, the Commission pointed out that the principle of mutual recognition applied not only to technical manufacturing specifications, but also to the control procedures applicable to the products.

Often the Member States believe that they do not have to include a mutual recognition clause in notified texts if they refer to standards. On several occasions, the Commission has stated that, where a European standard is compulsory, a mutual recognition clause for products from other Member States of the European Union and from the EFTA countries that belong to the European Economic Area must be included in the text.

One particular case of mutual recognition concerned the transposition of certain regulations of the Economic Commission for Europe of the United Nations (ECE/UN) in the field of motor vehicles. Under Article 6 of Council Decision 97/836/EC¹³, by which the Community acceded to the agreement governing the drafting of ECE/UN regulations, the Member States may subscribe to ECE/UN regulations by which the Community is not yet bound. In this case they are obliged to include a mutual recognition clause, since otherwise vehicles from other Member States which have not yet subscribed to the ECE/UN regulation could be prevented from entering the markets of the Member States which have already subscribed. This obligation was mentioned by the Commission in several notifications.

In the *field of energy*, few drafts were the subject of Commission reactions on the basis of Articles 28 and 30 of the EC Treaty (given the application of Directive 96/92/EC¹⁴ concerning the internal market in electricity). These reactions mainly concerned the conditions of access to the national electricity network of other Member States.

Since most notifications in the *field of telecommunications* are related to the fact that the requirements go beyond what is laid down in Directive 89/336/EEC on electromagnetic compatibility or in Directive 99/5/EC¹⁵ on radio equipment and telecommunications terminal equipment, the question of mutual recognition clauses rarely arises as these additional requirements have in most cases been considered by the Commission as incompatible with these directives.

4.3. Incompatibility of notified drafts with secondary legislation

In the *field of pharmaceuticals and medical equipment*, it was the drafts on medical equipment that gave rise to most reactions. The problems were often due to incorrect interpretation of Directive 93/42/EC¹⁶ concerning medical devices, as amended by Directive 98/79/EC¹⁷. This is also why in certain cases the Commission pointed out that drafts were not notifiable in relation to Directive 98/34/EC but should have been notified according to specific articles of Directive 93/42/EC.

¹³ OJ L 346 of 17.12.1997.

¹⁴ OJ L 27 of 30.01.1997.

¹⁵ OJ L 91 of 7.04.1999.

¹⁶ OJ L 169 of 12.07.1993.

¹⁷ OJ L 331 of 7.12.1998.

In the *environment and chemical products sector*, the Commission drew the Member States' attention to the incompatibility of notified drafts with certain directives and regulations. Most such cases concerned incompatibility with waste directives, such as Directive 91/689/EEC¹⁸ on hazardous waste and Directive 75/442/EC¹⁹ on waste. Similarly, a notification concerning the recovery, recycling, regeneration and destruction of halons, chlorofluorocarbons and hydrochlorofluorocarbons was deemed contrary to Regulation (EC) No 2037/2000²⁰ on substances that deplete the ozone layer.

Agricultural products and foodstuffs is a heading under which appear drafts covering a wide variety of subjects, ranging from combating bovine spongiform encephalopathy to the regulatory size of a grain of rice. The Commission's reactions to "agricultural" notifications generally concern the incorrect application of a directive concerning human or animal health, phytosanitary products, animal welfare, seeds and seedlings, ornamental plants, or a regulation related to the common organisation of markets. The Member States often invoke the precautionary principle to justify measures which go beyond what is laid down in Community legislation. In these cases, the Commission has systematically requested the data used by the Member States to justify the invoking of this principle.

There are a large number of notifications for the *construction sector*, but during the reference period there were not many reactions by the Commission in relation to Directive 89/106/EEC²¹ relating to construction products. Most of the reactions in this sector concern mutual recognition clauses (see point 4.2 above).

As regards *information society services*, a first problem concerns notifications in which the Member States do not confine themselves - under the terms of Article 10 of Directive 98/34/EC²² - to simply transposing Directive 1999/93/EC²³ on electronic signature and Directive 2000/31/EC²⁴ on electronic commerce. The notification procedure has made it possible to check whether the Member States impose additional charges compared with those provided for under the Directives. In most cases, in its detailed opinions and comments on these two Directives the Commission focused on defending the free movement of services and freedom of establishment. This gave it the opportunity to have the idea respected that information society services cannot be obstructed beyond what is allowed under the Directives.

The second category of detailed opinions delivered by the Commission concerns the protection of personal data in relation to the management of information society services. Through its detailed opinions, the Commission has allowed the development of adequate protection of the processing of personal data throughout the Member States, referring to the European Convention on Human Rights and Community directives on the protection of personal data.

Finally, this Directive prevents the Member States from extending the field of application of their national drafts beyond their borders, for instance in the domain names sector.

¹⁸ OJ L 377 of 31.12.1991.

¹⁹ OJ L 194 of 25.07.1975.

²⁰ OJ L 244 of 29.09.2000.

²¹ OJ L 40 of 11.02.1989.

²² See also the Canal Satellite Digital judgement of 22 January 2002 - C-390/99, point 48, not yet published in the reports of cases before the Court.

²³ OJ L 13 of 19.01.2000.

²⁴ OJ L 178 of 17.07.2000.

The drafts notified by the Member States in *the field of mechanical engineering and household equipment* generally give rise to difficulties regarding the mutual recognition clause. Nevertheless, there were also problems regarding the correct application of Directive 73/23/EEC on low voltage equipment and Directive 97/23/EC on pressure equipment. The problems encountered in this field often arose from the fact that the Member States made national or European standards compulsory although these two Directives allow economic operators the option of using other technical solutions if they meet the essential requirements that they define.

In the *field of transport*, the Commission has received a large number of notifications regarding motor vehicles. However, few of these have raised serious problems. As regards transport by sea and inland waterway, the Commission delivered detailed opinions for incompatibility with Directive 97/70/EC²⁵ on the safety of fishing vessels and Directive 82/714/EEC²⁶ on inland waterway vessels.

In the *field of energy*, the Commission noted that some technical rules contained in the regulations on the management of networks in the Member States were discriminatory and therefore in breach of Directive 96/92/EC on the internal market in electricity, which lays down that minimum technical design and operational requirements for the connection to the system of generating installations, distribution systems, interconnector circuits and direct lines must ensure the interoperability of systems and be objective and non-discriminatory.

Most of the notifications in the *field of telecommunications* concern interface requirements for radiocommunications and terminal equipment. The Commission reactions generally concentrated on the fact that the notified drafts laid down additional requirements which were not provided for in Directive 89/336/EEC on electromagnetic compatibility and Directive 99/5/EC on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. The Commission also noted that some drafts made European or international standards compulsory, thus contravening these two New Approach directives.

4.4. Analysis of the reactions of the Member States

An examination of the detailed opinions which the Member States exchange shows that as a general rule they react on similar points to those raised by the Commission (for example, by invoking Articles 28 and 30 of the EC Treaty as regards the environment and by invoking Directives 73/23/EEC and 97/23/EC as regards mechanical engineering).

Nevertheless, there is one big difference between the reactions of the Commission and those of the Member States: often the Member States require certain technical amendments to notified drafts (in all the areas analysed below) whereas the Commission calls for the inclusion of a mutual recognition clause. The Member States appear to call for these technical amendments to ensure that the notified drafts are as closely in line as possible with the technical requirements of their own legislation.

In the field of *pharmaceuticals and medical equipment*, the Member States have mainly delivered detailed opinions for the incompatibility of the notified drafts with Directive 93/42/EEC on medical devices.

²⁵ OJ L 34 of 9.02. 1998.

²⁶ OJ L 301 of 28.10.1982.

In the *environment and chemical products sector*, the Member States reacted in particular to the prohibitions on the sale and/or manufacture of certain chemical substances. In their reactions, the Member States considered, on the basis of Articles 28 and 30 of the Treaty, that these prohibitions were disproportionate, since in their opinions other less restrictive measures were possible; in some cases they considered the scientific data provided by the Member States that submitted the notification as inadequate. Some drafts were also considered contrary to Directive 94/62/EC²⁷ on packaging and packaging waste.

In the *agricultural products and foodstuffs sector*, a large number of detailed opinions concerned the incompatibility of the notified drafts with certain agricultural and foodstuffs directives. In non-harmonised fields, in some cases (for instance the addition of vitamins and minerals to foodstuffs) the introduction of a mutual recognition clause was requested in the detailed opinions.

In the *construction sector*, the Member State which had made the notification was often requested to introduce a mutual recognition clause in order to ensure the free movement of goods. In some cases the notifying Member State is also requested to introduce a reference to harmonised standards in implementation of Directive 89/106/EEC on construction products.

In the *field of information society services*, the Member States did not issue any detailed opinions in the 1999-2001 period, which appears to have been due to the fact that the administrative departments responsible for technical files in the Member States were not used to making use of the possibilities offered by the notification procedure in the field of services and probably had not yet drawn up well-defined positions on issues relating to a new, developing sector such as that of information society services.

As regards the *mechanical engineering sector* a large part of the detailed opinions are based on Directive 97/23/EC on pressure equipment and Directive 73/23/EEC on low voltage equipment.

In the *field of transport*, a small number of notifications led the Member States to deliver a detailed opinion. They generally called for technical adaptations in their detailed opinions.

The *energy sector* gave rise to virtually no reactions on the part of the Member States. The few reactions that did occur concerned ensuring the interconnection of electricity systems.

Similarly in the *field of telecommunications*, there were virtually no reactions by the Member States. The detailed opinions delivered by the Member States in this area mainly stressed the incompatibility of notified drafts with Directive 99/5/EC on radio equipment and telecommunications terminal equipment.

5. RESULTS

The results achieved and hence the effectiveness of the procedure introduced by Directive 98/34/EC can be analysed in particular through the follow-up carried out by the Member States to the detailed opinions and comments made, including the withdrawal of drafts by the Member States. The effectiveness of the Directive also lies in the possibility of imposing a standstill period on national drafts as provided for by Articles 9(3), (4) and (5) of

²⁷ OJ L 365 of 31.12.1994.

the Directive. It may also be analysed in terms of the real needs for harmonisation at Community level that have been identified.

5.1. Follow-up to detailed opinions

An analysis of the follow-up given by the Member States to the detailed opinions delivered by the Commission under the notification procedure shows the effectiveness of this procedure. Below are a few indicative figures. They only concern the cases in which the procedure has been completed, that is, where the Member State has stated that a follow-up would be given to the detailed opinions delivered by the Commission and where the Commission has in turn commented on the Member State's reply²⁸.

Years 1999 and 2000:

Year	Total number of finalised procedures	Positive Commission position	Negative Commission position
1999	29	24	5
2000	26	18	8

The figures show that initially in 84.2% of cases a solution in accordance with internal market rules could be found. In addition, of the 15.8% of cases (13 notifications) where the Commission did not give a positive response, according to the information sent to the Commission by the Member States, only 5 of the 13 drafts in question were adopted.

Of these five notifications, following the amendments finally made by the Member States, the Commission was of the opinion that in three cases the texts in question were no longer in breach of Community law. In the remaining two cases, the Commission was of the opinion that the text was still in breach of Community law and consequently announced the possible opening of infringement proceedings on the basis of Article 226 of the Treaty. In other words, of the 55 drafts that were considered to be in breach of internal market rules at the beginning of the procedure, only two texts (i.e. 3.6%) were adopted with contents that, according to the Commission, continued to infringe those provisions.

An analysis by sector (see table 2.6 of the annex) shows that the areas where there appeared to be the most problems in terms of the follow-up given to the Commission's detailed opinions are the agri-foodstuffs sector, pharmaceuticals and the environment.

Given the small number of procedures that have been finalised for notifications in 2001, it is not yet possible at this stage to produce an analysis for that year.

5.2. Follow-up to comments

In the case of the comments made by the Commission or the Member States on notified drafts, Directive 98/34/EC does not lay down an obligation for the Member State addressed to state how it intends to react to the comments. Nevertheless, Member States often say what action they intend to take. The positive results achieved by the notification procedure may,

²⁸ These figures do not include notifications which were shelved because a notifying Member State withdrew a draft. See point 5.3 of this report for an analysis of withdrawn drafts.

therefore, also be measured in terms of the number of responses that the Member States make to the comments, which demonstrates the intensity of the dialogue and the transparency achieved.

For 1999 and 2000, of the 852 comments made by the Commission and the Member States, 510 received a response by the Member States, i.e. a response rate of 60%. In 1999, the rate was 63% and in 2000 it was 57%. This difference may be explained mainly by the fact that in some cases the Member States carry out a detailed study on how to follow up the comments; it therefore cannot be ruled out that responses may yet be received in 2002 on the notifications for 2001. This is why an analysis of the follow-up given to the comments on notifications in 2001 would produce a false image at this stage.

As regards the content of responses to comments, generally speaking Member States take account of the comments made by the Commission and the other Member States.

5.3. Drafts withdrawn

The results achieved via Directive 98/34/EC may also be analysed on the basis of the drafts withdrawn by the Member States. From a statistical point of view, in 1999 out of a total of 591 notifications, 29 were withdrawn by the Member States (4.9%) in 2000 out of a total of 751 notifications 54 (7.2%) were withdrawn and in 2001 out of a total of 530 notifications, 24 (4.5%) were withdrawn.

A breakdown of withdrawals by sector for the years 1999 to 2001 shows that they were mainly in the telecommunications, transport and construction sectors. The drafts withdrawn are broken down as follows:

57 telecommunications; 10 transport; 10 construction; 9 agricultural products and foodstuffs; 6 energy and minerals; 5 chemical products; 2 environment; 2 miscellaneous; 1 mechanical engineering, 1 pharmaceuticals; 1 information society services.

An analysis of these withdrawals shows first that they were due to the fact that comments and/or detailed opinions had been sent or discussions had been held with the Commission.

As regards content, the Member States withdrew their notifications in most cases because they incorrectly applied Community directives (such as Directive 99/5/EC on radio equipment and telecommunications terminal equipment, Directive 95/16/EC²⁹ on lifts, Directive 97/70/EC on the safety of fishing vessels, Directive 96/92/EC on common rules for the internal market in electricity, etc). In other cases, the drafts were withdrawn following an announcement by the Commission of a Community draft covering the same field (e.g. the proposal for a Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment or the proposal for a directive on measuring instruments). In some specific cases, following a dialogue which took place in accordance with Directive 98/34/EC, the Member State felt it more appropriate to submit a new draft.

5.4. “Blocking” of national initiatives

The results achieved may also be measured on the basis of the application of paragraphs 3 to 5 of Article 9 of Directive 98/34/EC, which obliges the Member States to observe a standstill period of one year (or up to eighteen months) from the time when the drafts are

²⁹ OJ L 213 of 7.09.1995.

communicated to the Commission. As a result, Directive 98/34/EC has promoted harmonisation at Community level by preventing the adoption of national measures which could have frozen the position of some Member States while common solutions were being sought:

- Eight drafts were blocked because the Commission had submitted a proposal for a regulation on the animal-health requirements applicable to non-commercial movement of pet animals (COM(2000) 529 final).
- Two drafts were blocked because they dealt with a subject covered in the proposal for a Decision amending Decision 91/516/EEC establishing a list of ingredients whose use is prohibited in compound feedingstuffs. This amendment was adopted on 5 April 2000 (Decision 2000/285/EC).
- Two drafts were blocked because a Community proposal on food supplements was being drawn up (COM(2000) 222 final). This Directive was adopted on 10 June 2002 (Directive 2002/46/EC).
- One draft was blocked because of work on a proposal for a regulation on fortified foods.
- One draft was blocked because the draft regulation on the labelling of fishery and aquaculture products³⁰ was invoked.
- Work on the proposal for a Directive on measuring instruments (COM(2000) 566 final) led to the blocking of six drafts.
- Three drafts had been blocked on the basis of a proposal for a Directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human (COM(2001) 404 final).
- A blocking was imposed on two drafts because they were covered by a proposal for a directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (COM(2000) 347 final).
- A blocking was imposed on one draft because a Community draft amending Directive 92/61/EEC relating to the type-approval of two or three-wheel motor vehicles was being drawn up (COM(1999) 276 final).
- One national draft was blocked because it was covered by a Community draft that led to Directive 2000/31/EC on electronic commerce.

This list shows that certain Community drafts have given rise to the blocking of several national drafts (e.g. the proposal for a directive on measuring instruments); indeed some Member States were considering legislating in this field (which proves the value of European harmonisation) and it was therefore particularly useful to prevent the adoption of national laws, which were often diverging and could have hampered the Council's discussions.

³⁰ Adoption by the comitology procedure, which is why there is no COM number.

5.5. Identification of harmonisation needs

The Directive also makes it possible to identify the real needs for harmonisation at Community level. On the basis of the notification procedure, harmonisation proceedings began concerning, for instance, the restriction on the use of phthalates, heavy metals, the labelling of the caffeine content of non-alcoholic drinks, fortified foods, food supplements and compound feedingstuffs.

In the field of information society services, there was a plethora of national legislative initiatives in the field of domain names (Internet) which could require consideration regarding the need for possible harmonisation.

6. HANDLING OF INFRINGEMENTS

Between 1999 and the end of 2001, the Commission initiated 20 infringement proceedings for failure to comply with Directive 98/34/EC, either for failing to notify national measures or for adopting them before the end of the standstill period. The Commission was either informed of the national legislation by the economic operators concerned or its own services discovered it.

In line with the Commission's position, repeatedly expressed at meetings of the Committee (see point 8.2 below), at bilateral meetings and at "package" meetings (see point 8.3 below), the majority of Member States abandon the disputed text and/or notify a new draft which, after undergoing the notification procedure, is adopted and at the same time the disputed text is repealed. During the reference period, this solution allowed the infringement proceedings to be terminated in virtually all cases. Problems continued, nevertheless, in the field of information society services (see point 6.2 below). At the end of 2001, a total of 16 infringement proceedings were still in progress for breach of Directive 98/34/EC.

6.1. Infringements in the field of products

Following the judgement of 30 April 1996 on CIA Security International³¹, which confirmed the position defended by the Commission in its communication 86/C 245/05³² on the inapplicability of the technical regulations adopted in breach of the notification obligation, the Member States have started notifying their draft technical regulations as a matter of course and the Commission has been able to stop the systematic opening of infringement proceedings.

There are consequently only a few ongoing infringements in the field of products.

6.2. Infringements in the information society services sector

Since 5 August 1999, regulations on information society services have to be notified under Directive 98/34/EC. In this sector, the number of texts adopted by the Member States without notification is still high at the moment. In 2000 and 2001, the Commission opened 7 infringement proceedings for failure to observe the notification procedure.

³¹ C-194/94, ECR p.I-2201. For further information on this judgement, see the Commission report on the operation of Directive 98/34/EC from 1995 to 1998, COM(2000) 429 final, of 7 July 2000, points 91 and 92.

³² OJ No C 245/4 of 1 October 1986.

The legislation adopted by the Member States can be classified in two categories: that regulating fields covered by Community directives and that regulating the non-harmonised areas.

The first category refers mainly to regulations concerning electronic signatures and electronic commerce. As regards the second category of texts, these concern electronic communication, the electronic transmission of documents and telecommunications services other than those covered by Directive 89/552/EEC. These are also texts concerning Internet domain names and national measures aimed at creating a legal framework for the use of electronic billing.

To clarify the problems regarding the application and interpretation of Directive 98/48/EC, the Commission considered it important to set up dialogue with the Member States based mainly on bilateral meetings. Following these meetings, the Commission was able to terminate the infringement proceedings, since the national authorities had withdrawn the disputed texts.

7. COURT OF JUSTICE CASE-LAW

Between 1999 and 2001, the Court of Justice delivered eight judgements on Directive 98/34/EC, six of which were in response to references for preliminary rulings from national courts and two following infringement proceedings by the Commission. Apart from this distinction concerning the type of proceedings, there are two categories of judgement: those dealing with procedural matters and those concerning the field of application of the Directive and the definition of its concepts.

7.1. Judgements on procedural matters

Unenforceability of a technical regulation

In this context, mention should first be made of the judgement of the Court of Justice of 26 September 2000, Unilever,³³ in which the Court extended the conclusions of its judgement CIA Security International to the failure to observe the standstill period provided for in Directive 98/34/EC. In the case CIA Security International, the Court had already stated that failure to observe the notification obligation made the technical regulation unenforceable. In the Unilever judgement, it stated that adoption of a measure which had been notified, but for which the deadlines laid down in Directive 98/34/EC had not been observed, also rendered the technical regulations it contained unenforceable.

The case in question concerned a draft Italian law regulating labelling indicating the geographical origin of different types of olive oil. This draft law had been properly notified. The Commission had then applied a standstill period of one year in accordance with Article 9(3) of the Directive, since the draft covered a field in which it intended to begin harmonisation work. Without waiting for the end of the standstill period, Italy had adopted its draft.

³³ C-443/98, ECR p. I-7535.

The Court's judgement is particularly significant since it concerned a dispute between two companies. The company Central Food, which had ordered the olive oil from Unilever, did not accept delivery, arguing that the products were not labelled in accordance with Italian law. Unilever, on the other hand, invoked the fact that Italy had not observed the deadlines provided for in the notification procedure. The Court stressed that "Whilst it is true that a directive cannot of itself impose obligations on an individual and cannot therefore be relied on as such against an individual, that case-law does not apply in proceedings between individuals where non-compliance with Article 8 or Article 9 of Directive 83/189, which constitutes a substantial procedural defect, renders a technical regulation adopted in breach of either of those articles inapplicable".

Link between detailed opinions and notice

As regards procedure, mention should also be made of the Court Order of 13 September 2000, *Commission v. Netherlands*³⁴ which gave details regarding the link between detailed opinions within the meaning of Directive 98/34/EC and notice issued on the basis of Article 226 of the EC Treaty under infringement procedures.

The Order concerned a decree concerning the treatment of bivalve molluscs from foreign waters, which had been adopted by the Dutch authorities, without amendment of the notified draft despite the Commission's detailed opinion. Following the adoption of the text, the Commission sent the Dutch authorities a reasoned opinion on the basis of Article 169 (now 226) of the EC Treaty, since the disputed regulation was, in its opinion, in breach of Article 30 and 36 (now Article 28 and 30) of the EC Treaty.

The Commission was of the opinion that a detailed opinion within the meaning of Article 9(1) of Directive 83/189/EEC (now 98/34/EC) constituted formal notice, meeting the requirements of Article 169 of the Treaty (now Article 226 EC) and that it was therefore possible to move on immediately from a detailed opinion to a reasoned opinion. In the Order, the Court of Justice specified that a detailed opinion cannot be considered as the equivalent of a letter of formal notice, as the Member State to which it is addressed cannot have infringed Community law, since the measure exists only in draft form.

This judgement was confirmed by the Court in its judgement of 15 February 2001, *Commission v. France*, on national legislation concerning rubber materials and rubber articles entering into contact with foodstuffs, food products and beverages³⁵.

Since then, the Commission has increased the monitoring of texts adopted after notification, in order to begin infringement proceedings immediately if there is a breach of Community law (very rare infringements, as was seen in point 5.1).

7.2. Judgements concerning the field of application of the Directive and definition of concepts

Exemptions provided for in Article 10 of Directive 98/34/EC

Several judgements have clarified the exemption provided for in the first indent of Article 10(1) of Directive 98/34/EC, according to which Member States do not have to notify

³⁴ C-341/97, ECR p. I-6611.

³⁵ C-230/99, ECR 2001, p. I-1169.

the texts by which they comply with binding Community acts which result in the adoption of technical specifications or rules on information society services.

In the joint case *Albers, Van den Berkmortel and Nuchelmans*³⁶, the Court was of the opinion that by adopting rules prohibiting the administration of clenbuterol to fattening cattle, the Netherlands had honoured its obligations pursuant to Directive 86/469/EEC concerning the examination of animals and fresh meat for the presence of residues and was therefore exempt, under Article 10 of the Directive, from the notification obligation.

On the other hand, in the *Unilever* judgement (see point 7.1 above) the Court stated that Article 10 of the Directive could not be invoked when a provision of a directive allowed the Member States sufficiently wide room for manoeuvre. This was the case here. Italy had submitted that Directive 79/112/EEC relating to the labelling of foodstuffs required that the place of origin or provenance of the product be indicated on the label in cases where omission of such information would be liable to mislead consumers as to the real origin or provenance of the foodstuff. According to the Court, this provision is drafted in general terms, which leave sufficient room for manoeuvre for it to be concluded that national rules on labelling relating to the origin of olive oils cannot be regarded as national provisions conforming to a binding Community act within the meaning of the first indent of Article 10(1) of Directive 83/189.

This restrictive interpretation of the first indent of Article 10(1) was confirmed by the Court in the *Canal Satellite Digital* judgement³⁷.

Concept of technical regulation and technical specification

In the *Colim* judgement³⁸ of 3 June 1999, the Court emphasised that although the obligation to give certain information on a product to the consumer via labelling on the product or by attaching documents (instructions for use and guarantee certificate) constitutes a technical regulation within the meaning of the Directive, this is not the case for the obligation to give this information in a certain language. "Unlike the first obligation, which concerns the product directly, the second is intended merely to specify the language in which the first must be carried out." The case in question concerned the Belgian Law on Trade Practices and Consumer Information and Protection.

The judgement of the Court of 16 November 2000 in the *Donkersteeg* case³⁹ dealt with whether a national law requiring every farmer to have the pigs on his holding vaccinated against Aujeszky's disease was a technical regulation. According to the Court, this law is a technical specification within the meaning of the Directive, as the vaccination is linked to the actual production of the agricultural product concerned and therefore defines a procedure in the production of that product. Nevertheless, it is not, according to the Court, a technical regulation within the meaning of the Directive, since to be classified as a technical regulation, the observance of these technical specifications must, according to the Directive, be compulsory *de jure* or *de facto*. However, the Dutch decree in question did not impose any restriction on either the marketing or use of the products concerned when, in contravention of the provision, the pigs had not been vaccinated.

³⁶ C-425/97, ECR 1999, p. I-2947.

³⁷ C-390/99, not yet published in European Court Reports.

³⁸ C-33/97, ECR 1999, p. I-3175.

³⁹ C-37/99, ECR 2000, p. I-10223.

The judgement of the Court of 12 October 2000 in the Snellers case⁴⁰ concerned the authorisation of a vehicle for use on the public highway. The matter concerned Dutch rules determining the date on which a vehicle was first authorised for use on the public highway. According to the Court, these could not constitute technical specifications within the meaning of the Directive, since such specifications have to refer to the product as such. However, the Dutch rules simply defined criteria for determining the date on which a vehicle was first authorised for use on the public highway and did not define any characteristic required of the product, i.e. the vehicle, as such.

In its judgement of 8 March 2001 on the van der Burg case⁴¹, the Court clarified the relationship between publicity and technical regulation. The case concerned a Dutch decree prohibiting commercial advertising for transmitting equipment of a non-approved type. The question was whether such a prohibition constituted a technical regulation within the meaning of the Directive. The Court stated that the relationship between an advertising ban such as the one in question and technical regulations to be satisfied by the transmitting equipment was not sufficient for the prohibition to be classified as a technical specification and hence as a technical regulation. The Court emphasised that the decree merely prohibited a marketing method, without laying down the characteristics required of a product, in this case transmitting equipment.

8. ACTION TO IMPROVE THE PROCEDURE

The Commission has carried out a variety of measures to improve the notification procedure. These concern on the one hand improving the access of businesses to the information provided by the procedure and on the other improving the exchange of information between the Commission and the Member States.

8.1. Transparency

To improve the access of economic operators to draft technical regulations, in 2000 the Commission created an Internet site on the notification procedure⁴². This site provides access to information on the drafts notified by the EU Member States since 1984 and on the measures communicated by the EFTA members of the European Economic Area. It also provides explanations on how the procedure works and provides access to the case law of the Court of Justice in this area. The purpose of the site is to ensure that Directive 98/34/EC fully fulfils its role as regards transparency and eliminating barriers to the smooth operating of the internal market.

To publicise the new Internet site and provide information on the notification procedure, the Commission has published a brochure providing a brief explanation of the objectives of the procedure and how it works. The brochure also contains the addresses of the national bodies responsible for the procedure in their country.

Since the new Internet site was created, the Commission has noted a considerable increase in the number of comments made by economic operators. It intends to further improve the information provided to these operators in order to ensure maximum transparency of the

⁴⁰ C-314/98, ECR 2000, p. I-8633.

⁴¹ C-278/99, ECR 2001, p. I-2015.

⁴² The site, which is called TRIS (Technical Regulations Information System), can be consulted at the following address: <http://europa.eu.int/comm/enterprise/tris>.

notified drafts. It is essential for businesses to know about them, on the one hand in order to adapt their products in advance to new national regulations and on the other so that they can alert their governments and the Commission to any unjustified barriers which would result from the adoption of the drafts.

8.2. Meetings of the Committee set up by Directive 98/34/EC

Eleven meetings of the Committee set up under Article 5 of Directive 98/34/EC (composed of representatives appointed by the Member States and chaired by a Commission representative) took place between 1999 and 2001. Discussions concentrated on the various aspects set out below.

Improving the exchange of information

As regards the practical aspects of implementing the procedure, discussions were held on the progress made in transposing Directive 98/48/EC and on the drawing up of the Vade-mecum on cooperation between the central units and the Commission departments regarding this Directive, the electronic transmission of notified drafts and messages and the obligation to reply to detailed opinions and to systematically submit the final texts. Discussions were also held on the creation of an electronic system (extranet) which provides the Member States with direct access to the Commission database on the operation of Directive 98/34/EC. At the time this report was written, this system had been created, which should greatly facilitate communication between the Commission and the Member States regarding the procedure.

Impact studies

The Committee also examined the value of adding impact studies to notified drafts. The discussion related to the Lisbon European Council of March 2000, which had asked the Commission, the Council and the Member States to "set out - by 2001 - a strategy for further coordination action to simplify the regulatory environment at both national and Community level".

The Member States responded to this by setting up a high-level advisory group (commonly known as the Mandelkern Group), which presented a report on the simplification of the regulatory environment to the Laeken European Council in December 2001. The report stated, in relation to impact assessments, there was: "Agreement by all Member States that from June 2002 they will submit the relevant national RIA [Regulatory Impact Assessment], where it exists, alongside regulation notified to the Commission and other Member States".

The Commission responded to this appeal in its Communication of 5 December 2001 "Simplifying and improving the regulatory environment" (COM(2001) 726 final) which was presented at the Laeken European Council. In the Communication, the Commission stated that it "expected, in accordance with the recommendations of the Mandelkern Group, that the Member States would systematically append to the regulations notified to the Commission and the other Member States the relevant national statutory impact assessment each time such an assessment had been made".

The Laeken Council stressed in its conclusions that it "welcomes the final report by the high level advisory group (Mandelkern Group) on the quality of regulatory arrangements and the Commission communication on regulatory simplification, [...]".

The Committee members subsequently agreed that these impact studies would be sent together with the notified drafts each time they were carried out. The studies could be submitted either as such or in the form of a summary. The inclusion of such studies with notified drafts should:

- encourage Member States to think at the earliest possible stage in the legislative process about the most appropriate instrument to use;
- make the legislation of the Member States easier to understand and
- make evaluation of the notified drafts by the Member States and the Commission easier.

Decision 3052/95/EC

The Committee also served as a forum for the discussion of questions regarding Decision No 3052/95/EC of the European Parliament and of the Council concerning an information procedure on measures derogating from the principle of the free movement of goods⁴³. The implementation of this decision was also debated on several occasions.

Access to documents

Finally, the Committee also dealt with the question of access to the comments and detailed opinions of the Member States and those of the Commission following the entry into force of Regulation 1049/2001 on public access to European Parliament, Council and Commission documents on 3 December 2001. Discussions on this matter are still in progress.

Future development of the procedure

The future developments of the notification procedure were dealt with during the discussions on the participation of Turkey and the candidate countries in the information exchange system (see point 9). The candidate countries have been attending Committee meetings as observers since October 2001 (Turkey has been associated in the work of the Committee since 1999⁴⁴). The Committee also discussed the accession of the Community to the Moscow Convention on Information and Legal Cooperation concerning "Information Society Services" (see point 9) and the possibilities of extending the procedure to services other than those of the information society.

8.3. Package meetings

The practice of holding "package meetings" (meetings in the capitals to discuss a large number of cases with the ministers concerned) has enabled the Commission to maintain contacts with the national authorities responsible for drawing up technical regulations. The drafts notified by the country concerned are discussed at these meeting as are the changes to be made to them to make them comply with internal market rules, infringements of Directive 98/34/EC and developments concerning the functioning of the procedure. At these meetings,

⁴³ 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 of 30.12.1995.

⁴⁴ See Decision No 2 of the EC-Turkey Association Council of 8 March 1999 concerning the extension of the list of committees referred to in Annex 9 to Decision No 1/95 on implementing the final phase of the Customs Union, OJ L 72 of 18.3.1999.

the Commission departments have also had the opportunity to discuss the development of the case law of the Court with Member State authorities, in particular the consequences of the Unilever judgement (see point 7.1. above).

9. INTERNATIONAL ASPECTS OF THE NOTIFICATION PROCEDURE

The notification procedure is not limited to the Member States of the EU but also applies to EFTA countries and, recently, to Turkey. The Commission is also currently studying the possibility of the participation of the candidate countries in the procedure before accession.

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

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 EC and EFTA (originally set up in 1990 by an agreement between the Community and the EFTA members⁴⁵) 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. Annex II to the Agreement on the EEA includes Directive 98/34/EC, amended as appropriate.

Since 1 March 2001, Directive 98/48/EC, which extends the notification procedure to information society services, also applies to EFTA members of the EEA.⁴⁶

Description of the procedure

Since 1994, the exchange of information between the Member States of the Community and the Member States of EFTA has taken place via the Commission and the EFTA Surveillance Authority set up by the Agreement on the EEA.

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 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.

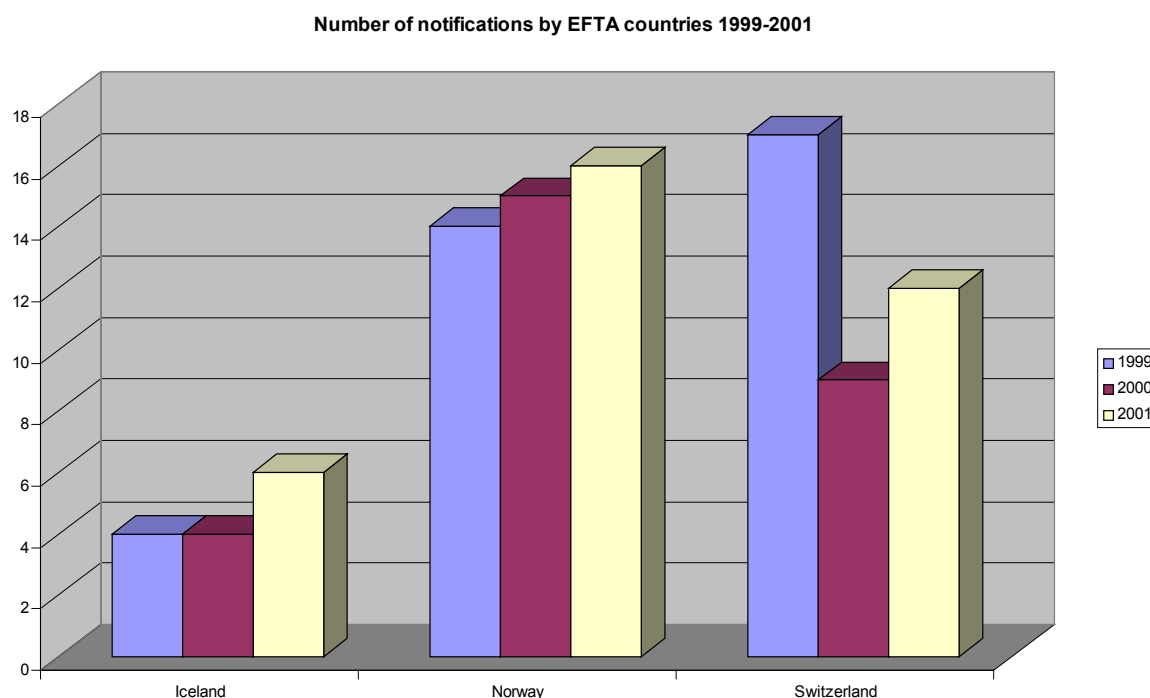
⁴⁵ Council Decision 90/518/EC concerning the conclusion of an Agreement between the European Economic Community, on the one hand, and the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Kingdom of Norway, the Kingdom of Sweden and the Swiss Confederation, on the other, laying down a procedure for the exchange of information in the field of technical regulations of 24 September 1990, OJ L 291 of 23.10.1990.

⁴⁶ Decision of the EEA Joint Committee No 16/2001 of 28 February 2001 amending Annex II (Technical regulations, standards, testing and certification) and Annex XI (Telecommunication services) to the EEA Agreement, OJ L 117 of 26.04.2001.

Volume of notifications and breakdown by sector

Between 1999 and 2001, the Commission received 97 notifications from the EFTA Member States, whereas between 1995 and 1998, the figure amounted to 149. Norway submitted 45 notifications, Switzerland 38 and Iceland 14 (see figure 4). If the number of EFTA notifications is compared with the number of Community notifications for the 1995-1998 period and the 1999-2001 period, the ratio remains virtually unchanged (EFTA notifications equal to 6% of total Community notifications for the 1995-1998 period, compared with 5.1% for the 1999-2001 period).

Figure 4



A breakdown by sector shows that the trend observed in 1997 has continued (see table 2.7 annexed). In 1997, agricultural products and foodstuffs for the first time took the lead in terms of the number of notifications. In the 1999-2001 period, notifications in this sector made up 35% of the total number. In contrast, the number of notifications in the field of telecommunications, which is the second biggest sector, continued to fall. As a result, in the 1999-2001 period, this sector represented only 16.5% of the notifications.

The importance of the agricultural products and foodstuffs sector reflects an identical trend at Community level, namely a spate of "re-regulation" in the Member States, resulting from the various crises in this sector. The EFTA countries on the other hand notified far fewer radio interfaces⁴⁷ than the Member States.

The first three notifications by EFTA countries concerning information society services also took place in 2001.

⁴⁷

These interfaces must be notified to the Commission in accordance with Directive 99/5/EC of the European Parliament and of the Council EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, OJ L 91 of 7.04.1999.

Community comments on EFTA notifications

In the 1999-2001 period, the Community made comments on 56 (57.7%) notifications from EFTA (see table 2.8 annexed), which is slightly up on the 1995-1998 period (50.3%).

The comments sent by the Community to the EFTA members of the European Economic Area Agreement mainly concerned problems of compatibility with secondary Community legislation, in particular Directives 98/95 (genetically modified seed), 88/388/EEC (movement of flavourings), 99/71/EC (pesticide residues on foodstuffs), 77/99/EEC (health marking of meats), 99/5/EC (telecommunications terminal equipment), 96/98/EC (marine equipment) and Directive 2000/31/EC (electronic commerce and other information society services).

In other comments, the attention of these countries was drawn to the aspects of proportionality and the obligation to include and apply in their technical regulations the mutual recognition clauses required in order to prevent the creation of technical barriers to trade and to ensure the observance of Articles 11 to 13 of the Agreement. In this respect mention was made of the case law of the Court of Justice of 22 October 1998 in the case *Commission versus France*⁴⁸, in which the Court stressed the obligation for the Member States to include a mutual recognition clause in legislation on non-harmonised fields.

In its comments, the Commission also referred to ongoing work at Community level: amendment of Directive 98/18/EC on passenger ships, Decision 91/516/EEC on feedingstuffs (amendment adopted on 5 April 2000 in Decision 2000/285/EC), Directive 94/52/EC on environmental protection and the Community draft on food supplements (COM(2000) 222 final) adopted on 10 June 2002. The ongoing work within European standardisation bodies and certain international agreements (SOLAS Convention and IMO circular) were also mentioned.

As regards the notifications from Switzerland, the Community drew the attention of the Swiss authorities to certain differences in approach between Swiss legislation and Community legislation, in particular as regards foodstuffs (labelling of origin of foodstuffs, flavourings, etc.) and telecommunications (Directive 99/5/EC on telecommunication terminal equipment).

Comments by EFTA on Community notifications

Three Community notifications gave rise to comments by the EFTA surveillance authority (2 in 1999, 0 in 2000 and 1 in 2001).

The comments mainly concerned the possible barriers that the drafts in question could create regarding products legally manufactured in EFTA countries (e.g. a Dutch notification on bivalve molluscs).

Conclusions and outlook

In the years 1999 to 2001 the number of notifications remained at the same level as in the 1995-1998 period. The biggest sector is agricultural products and foodstuffs. The reasons for the reactions of the Community regarding drafts notified by EFTA countries remained the desire to ensure that these countries observe Community legislation. There has always been excellent cooperation regarding the procedure.

⁴⁸ C-184/96, ECR 1998, p. I-6197.

In the near future, a *modus vivendi* must be found for Switzerland to participate too in the exchange of information on information society services. So far it has participated in the notification procedure on an informal basis.

9.2. Turkey

Since 1 January 2001, Turkey has participated in the notification procedure in the same way as EFTA countries. The decision for Turkey to participate in the notification procedure was taken in 1997 during the introduction of the final phase of the customs union between the Community and Turkey⁴⁹. A single period of standstill of three months applies, with no possible extension. Turkey may make comments on the Member States' drafts and vice-versa. On the other hand, there is no system of exchange provided for between Turkey and the EFTA countries.

9.3. Enlargement

Given the importance of the Directive for the smooth functioning of the enlarged internal market, the Commission is currently studying ways for the candidate countries to participate in the notification procedure prior to their accession, along the same lines as the EFTA countries and Turkey.

9.4. Council of Europe

The Community will soon accede to the Convention on Information and Legal Cooperation concerning information society services of the Council of Europe⁵⁰. The Convention was open for signature in Moscow on 4 and 5 October 2001. It incorporates part of Directive 98/34/EC in the field of information society services. The aim is to increase transparency and the knowledge of all the member countries of the Council of Europe and the observer states regarding the national regulations planned in connection with information society services, with the possibility of the mutual transmission of comments on notified drafts.

10. CONCLUSIONS AND PROSPECTS

During the reference period of this report, work took place on the subject of governance. In relation to this, openness, participation and efficiency were highlighted as principles to be applied to guarantee the quality of regulations, proportionality and subsidiarity⁵¹.

As an instrument of transparency and partnership at the service of the internal market, Directive 98/34/EC reflects these different principles, as this report shows.

First, *openness*. Businesses, Member States and Commission departments have received information on over 1800 draft technical regulations notified during this period. The information has been presented in a way suited to needs and in all the official languages.

⁴⁹ Decision No 2/97 of the EC-Turkey Association Council of 4 June 1997 establishing the list of Community instruments relating to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey, OJ L 191 of 21.07.1997.

⁵⁰ Convention on Information and Legal Cooperation concerning "Information Society Services" ETS No. 180. For further information: <http://conventions.coe.int/Treaty/EN/cadreprincipal.htm>.

⁵¹ European Governance - A White Paper, COM(2001) 428 final, 25.07.2001, p. 12.

The creation of an Internet site (<http://europa.eu.int/comm/enterprise/tris>) contributed to this, as did a new electronic communication system with the Member States and the Commission departments.

A spate of re-regulation also took place, mainly as a result of technological advances and the desire to increase controls in the fields of health and in particular food. The desire of the Member States to respond to rapid technological development confirmed that it was entirely worth extending the notification procedure to information society services.

Secondly, *participation*. The analysis of notified drafts led the Commission to react in over one third of cases between 1999 and 2001. The Member States, for their part, reacted in almost half of the cases, which shows the intensity of the dialogue that has developed between them.

In 2001, there was a difference compared with previous years regarding the number of detailed opinions delivered by the Commission. Although in 1999 and 2000 the number continued to fall as in previous years, there was an increase in 2001. This seems to be due to the fact that the Member States, in order to keep pace with technological developments, are proposing new laws which are increasingly complex and consequently the source of barriers to the free movement of products and the free movement to provide information society services.

The reactions of the Commission and the Member States are to a large part due to the intervention of businesses. Aware of the possibility of intervention in the national legislative process provided by Directive 98/34/EC, many of them have reacted. They have emphasised the trading problems that could be caused by certain national drafts, particularly in the sectors of drinks packaging, the environment, chemicals and foodstuffs, thus inducing the Commission and their governments to react to safeguard their competitiveness.

It should be noted that although the notification procedure does not apply to measures by which the Member States comply with binding Community acts which lead to adoption of technical specifications or regulations regarding services, the drafts notified nevertheless very often lead the Commission to react on the basis of secondary Community legislation.

Efficiency, also. Directive 98/34/EC has ensured that decisions are taken at the most appropriate level. As stated in this report, in almost thirty cases, the Directive has facilitated harmonisation at Community level by preventing the adoption of national measures which would have hardened the positions of certain Member States while common solutions were being sought.

High among the achievements of the notification procedure appears the *improvement of the quality of national regulations*. By means of the prior analysis of draft texts, the Directive prevents the creation of many barriers before they have a detrimental effect and thus makes a tangible contribution to improving the law-making of the Member States.

The results achieved between 1999 and 2001 show that the Directive made it possible to meet the challenge posed by the new wave of regulations. By providing Member States with examples of the best approaches adopted by their counterparts, and even indicating what approaches should be avoided, the notification procedure helped improve the quality of national regulations. An analysis of the replies by the Member States to the detailed opinions sent by the Commission and the subsequent dialogue shows that in almost all cases (96%), the

problems that would have arisen from the adoption of the drafts in their initial version were removed.

Finally, *proportionality and subsidiarity* are on the list of achievements. By improving the quality of national regulations, the notification procedure has made legislative intervention at Community level less often necessary. It has also identified sectors where intervention at European level appeared more appropriate.

Given technological developments, particularly in the scientific field, the notification procedure is increasingly becoming an instrument with which to identify emerging sectors so that the best solutions can be found for them, which may involve a combination of formal rules with other more flexible ones.

Looking to the *future*, the notification procedure could be extended both as regards contents and geographical coverage.

Since services play an increasingly important role in our economies, the Commission has undertaken to begin studying the suitability of extending Directive 98/34/EC to services other than those of the information society⁵². This appears particularly necessary since the Commission has already noted in its analysis of drafts covering several high technology sectors such as genetic treatment and the use of stem cells, that the Member States are increasingly linking the processing and handling of products to requirements imposed on service providers.

The other challenge for Directive 98/34/EC is enlargement. A first step has already been taken with Turkey, which has had the possibility since 1 January 2001 of participating in the notification procedure under a simplified arrangement. The Commission is currently studying ways of including the participation of candidate countries in the notification procedure prior to their accession, in the same way as the EFTA countries, given the importance of the Directive for the creation of an enlarged internal market.

Concerned both with enlargement and the importance of information society services, the Convention on information and legal cooperation concerning information society services of the Council of Europe incorporates, in part, Directive 98/34/EC in this field. Its purpose is to increase transparency and the knowledge of all the Member States of the Council of Europe and the observer States of the national regulations planned in connection with information society services. The Community is soon to accede to this Convention.

Finally, the Commission should continue emphasising the transparency of the notification procedure, in the light of the undertakings it made in the White Paper on Governance.

⁵² An internal market strategy for the services, COM(2000) 888 final, of 29.12.2000, p. 16 and the Working Programme 2001 of the Enterprise DG, second part, p. 82. A contract for the provision of services will also soon be concluded in this respect jointly by the Enterprise DG and the Internal Market DG as part of the internal market strategy for services mentioned.

Part III: Annexes

1. ANNEXES REGARDING STANDARDISATION

1.1. Breakdown of new standardisation activities started each year between 1991 and 1998

CEN/CENELEC members in the EU

Year	1994		1995		1996		1997		1998		1999		2000		2001	
Level	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
a. National activities																
a.1 Connected with European or international activities	119	2,3	74	1,4	62	1,4	71	1,5	49	1,1	43	1,2	35	0,9	28	0,7
a.2 Specific*	1511	29,8	1839	35,4	1531	34,4	1356	28,1	1497	35,8	1262	35,6	1348	33,5	1483	38,3
a.3 Total (a.1 + a.2)	1630	32,2	1913	36,8	1593	35,7	1427	29,6	1546	36,9	1305	36,8	1383	34,4	1512	39,0
b. European activities	1985	39,2	2091	40,3	1643	36,8	2270	47,2	1684	40,2	1505	42,4	1707	42,4	1548	40,0
c. International activities	1454	28,7	1190	22,9	1223	27,4	1116	23,2	958	22,9	739	20,8	935	23,2	811	21,0
d. Total (a + b + c)	5069	100	5194	100	4459	100	4813	100	4188	100	3549	100	4025	100	3870	100

Source: Notifications to CEN/CENELEC.

(*) These figures could be overestimated as not all CEN/CENELEC members automatically report any links with European or international activities.

1.2. Breakdown of new standardisation activities started in 1999

CEN/CENELEC members in the EU

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 drafts	43	1,6	0	0	43	1,2	100
a.2 Specific*	1226	44,3	36	4,6	1262	35,6	97,1
a.3 Total (a.1 + a.2)	1269	45,9	36	4,6	1305	36,8	97,2
b. European activities	911	32,9	594	76,2	1505	42,4	60,5
c. International activities	589	21,2	150	19,2	739	20,8	79,7
d. Total (a + b + c)	2769	100	780	100	3549	100	78,0

Source: Notifications to CEN/CENELEC.

(*) These figures could be overestimated as not all CEN/CENELEC members automatically report any links with European or international activities.

1.3. Breakdown of new standardisation activities started in 2000

CEN/CENELEC members in the EU

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 drafts	35	1,1	0	0	35	0,9	100
a.2 Specific*	1318	41,5	30	3,5	1348	33,5	97,8
a.3 Total (a.1 + a.2)	1353	42,6	30	3,5	1383	34,4	97,8
b. European activities	1091	34,4	616	72,3	1707	42,4	63,9
c. International activities	729	23,0	206	24,2	935	23,2	78,0
d. Total (a + b + c)	3173	100	852	100	4025	100	78,8

Source: Notifications to CEN/CENELEC. (*) These figures could be overestimated as not all CEN/CENELEC members automatically report any links with European or international activities.

1.4 Breakdown of new standardisation activities started in 2001

CEN/CENELEC members in the EU

Field	Non-electrical (1)		Electrical (2)		Total (3) = (1) + (2)		Non-electrical share <u>(1) x 100</u> (3)
	No	%	No	%	No	%	%
a. National activities							
a.1 Connected with European or international drafts	28	1,0	0	0	28	0,7	100
a.2 Specific*	1467	48,8	16	1,9	1483	38,3	98,9
a.3 Total (a.1 + a.2)	1495	49,8	16	1,9	1511	39,0	98,9
b. European activities	875	29,1	673	77,9	1548	40,0	56,5
c. International activities	636	21,1	175	20,2	811	21,0	78,4
d. Total (a + b + c)	3006	100	864	100	3870	100	77,7

Source: Notifications to CEN/CENELEC.

(*) These figures could be overestimated as not all CEN/CENELEC members automatically report any links with European or international activities.

1.5. Breakdown by country of new national standardisation activities notified in 1999

Field	Non-electrical		Electrical		Total	
Country	No	%	No	%	No	%
a. DE	385	28,0	12	32,4	397	28,2
b. ESP	150	10,9	4	10,8	154	10,9
c. FR	229	16,7	2	5,4	231	16,4
d. IT	98	7,2	1	2,7	99	7,0
e. AUS	182	13,2	2	5,4	184	13,0
f. UK	84	6,1	12	32,5	96	6,8
g. Other EU countries	141	10,3	3	8,1	144	10,2
h. EU total	1269	92,4	36	97,3	1305	92,5
i. EFTA countries + CZ	105	7,6	1	2,7	106	7,5
j. Grand total (h+i)	1374	100	37	100	1411	100

Sources: Notifications to CEN/CENELEC.

Notes:

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. CZ: Czech Republic.

1.6. Breakdown by country of new national standardisation activities notified in 2000

Field	Non-electrical		Electrical		Total	
Country	No	%	No	%	No	%
a. DE	406	28,9	6	18,2	408	28,4
b. ESP	158	11,2	3	9,1	161	11,2
c. FR	207	14,7	8	24,2	215	14,9
d. IT	120	8,5	0	0	120	8,3
e. AUS	171	12,1	8	24,2	179	12,5
f. UK	144	10,2	3	9,1	147	10,2
g. Other EU countries	151	10,7	2	6,1	153	10,6
h. EU total	1353	96,3	30	90,9	1383	96,1
i. EFTA countries + CZ	53	3,7	3	9,1	56	3,9
j. Grand total (h+i)	1406	100	33	100	1439	100

Sources: Notifications to CEN/CENELEC.

Notes:

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. CZ: Czech Republic.

1.7. Breakdown by country of new national standardisation activities notified in 2001

Field	Non-electrical		Electrical		Total	
Country	No	%	No	%	No	%
a. DE	514	32,7	3	17,6	517	32,6
b. ESP	233	14,8	2	11,8	235	14,8
c. FR	127	8,1	7	41,2	134	8,4
d. IT	121	7,7	1	5,9	123	7,8
e. AUS	226	14,4	0	0	226	14,2
f. UK	117	7,5	2	11,8	119	7,5
g. Other EU countries	157	10,0	1	5,9	158	10,0
h. EU total	1495	95,2	16	94,1	1511	95,3
i. EFTA countries + CZ	76	4,8	1	5,9	76	4,7
j. Grand total (h+i)	1571	100	17	100	1587	100

Sources: Notifications to CEN/CENELEC.

Notes:

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. CZ: Czech Republic

1.8 Top ten subsectors for new national standardisation activities in 1999

SUBSECTORS		Number of new activities (EU + EFTA + CZ)
Code	Name	
C01	Foodstuffs	80
T02	Aeronautics	63
B03	Concrete	46
B01	Fire protection	43
N14	Plastic tubes	40
S09	Water quality and water supply	40
N03	Oil products	36
B02	Construction	34
B99	Building - miscellaneous aspects	34
C02	Paints and assimilated products	31
Total		447

Source: Notifications to CEN/CENELEC.

CZ: Czech Republic

Notes: In 1999 the top two subsectors in the electrical engineering sector were:

- electricity cables (code W08): 11 new drafts
- electricity cables (code V07): 3 new drafts

1.9. Top ten subsectors for new national standardisation activities in 2000

SUBSECTORS		Number of new activities (EU + EFTA + CZ)
Code	Name	
C01	Foodstuffs	73
T02	Aeronautics	47
N03	Oil products	44
B02	Construction	41
S09	Water quality and water supply	41
B99	Building - miscellaneous aspects	38
H09	Furniture	36
N05	Textiles	36
B01	Fire protection	30
S99	Health - miscellaneous	29
Total		415

Source: Notifications to CEN/CENELEC.

Notes:

In 2000 the top two subsectors in the electrical engineering sector were:

- electrical installations in buildings (code W27): 9 new drafts
- electricity cables (code W08): 7 new drafts

1.10. Top ten subsectors for new national standardisation activities in 2001

SUBSECTORS		Number of new activities (EU + EFTA + CZ)
Code	Name	
C01	Foodstuffs	80
B99	Building - miscellaneous aspects	74
B03	Concrete	70
S09	Water quality and water supply	65
B02	Construction	55
F99	Basic standards	45
I09	Small tools	44
T02	Aeronautics	41
H99	Household goods	35
B01	Fire protection	34
Total		543

Source: Notifications to CEN/CENELEC.

Notes:

In 2001 the top two subsectors in the electrical engineering sector were:

- electronical devices (code V15): 3 new drafts
- alarm systems (code V21): 3 new drafts

1.11 Application of Article 4 (requests to participate in national standardisation activities and requests to draw up a European standard)

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
1999	50		4	3
2000	24		6	2
2001	14		1	0

Source : CEN

Notes:

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

1.12. Standardisation work entrusted to the European standardisation bodies in 1999

1. Mandates related to New Approach Directives

- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on thermal insulating products, doors, windows, shutters, gates and associated hardware; membranes; precast normal/ lightweight/ autoclaved aerated concrete products.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on adhesives used in the construction industry.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on pipes, tanks and piping accessories not coming into contact with water intended for human consumption.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on products for concrete, mortar and grout.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on space heating appliances.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on thermal insulation products, doors, windows, shutters, gates and associated hardware; membranes, precast normal/ lightweight/ autoclaved aerated concrete products; chimneys, flues and specific products; gypsum products; fire detection and alarm systems, fixed firefighting installations, smoke and fire control devices and explosion suppression products.
- Addendum to the mandates for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on circulation fixtures, structural support appliances and floor coverings.
- Mandate for CEN to reviewing the harmonised standard EN 1384 “Helmets for equestrian activities” following the petition in the European Parliament aiming to improve rider safety.
- Mandate for CEN, CENELEC and ETSI with a view to preparing an EN standard similar to the future ISO 9001:2000 standard for application in the regulatory field (application of modules, etc.)
- Mandate for CEN, CENELEC and ETSI concerning the applicability of the Directive on electromagnetic compatibility to aircraft.
- Mandate for CEN, CENELEC and ETSI in the field of Directive 1999/5/EC on radio equipment and telecommunications terminal equipment.
- Mandate in the field of construction products: horizontal complement to the standardisation mandates for CEN and CENELEC concerning the evaluation of construction products in respect of their reaction to fire.

- Mandate in the field of construction products: horizontal complement to the standardisation mandates for CEN and CENELEC concerning the evaluation of construction products in respect of their resistance to fire.
- Mandate for CEN and CENELEC concerning 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
(No mandates)
- 4. Mandates in connection with other Community policies.
 - 4.1. Consumer policy
 - Mandate for CEN, CENELEC and ETSI in the field of consumer safety: ladders.
 - Mandate for CEN, CENELEC and ETSI in the field of the safety and user-friendliness of products for people with special needs (the elderly or disabled).
 - Supplement to the existing mandate for CEN concerning the methods of analysis for materials and articles intended to come into contact with foodstuffs.
 - Mandate for CEN, CENELEC and ETSI related to consumer safety: product information.
 - Mandate for CEN, CENELEC and ETSI related to consumer safety: child safety .
 - 4.2 Environmental policy
 - Mandate for CEN for establishing a standard pertaining to a fuel quality monitoring system.
 - Mandate for CEN related to measuring methods for concentrations of particulate matters with PM 2.5 in ambient air.
 - 4.3 Energy policy
 - Mandate for CEN and CENELEC for drawing up and adopting measurement standards for household gas ovens (document from the IRL delegation).
 - Mandate for CEN and CENELEC relating to the revision and extension of the standard EN 50294 "Methods of measurement of total input power of ballast-lamp circuits".
 - Mandate for CEN and CENELEC regarding the methods for measuring the efficiency of ballast-lamp circuits for discharge lamps and the efficiency of outdoor discharge lamp luminaries.

1.13. Standardisation work entrusted to the European standardisation bodies in 2000

1. Mandates related to New Approach Directives

- Mandate for CEN under Directive 98/37/EC relating to machines with a view to revising standards EN 1726-1 and EN 1459 concerning the safety of industrial trucks.
- Mandate for CEN, CENELEC and ETSI concerning cableway installations designed to carry persons.
- Mandate for CEN for the realisation of harmonised standards in the field of construction products: flat glass, profiled glass and glass block products.
- Mandate for CEN relating to the revision of standard EN ISO 11681-2 on chainsaws for tree-service.
- Mandate for CEN relating to the revision of revision of standard EN 703:1995 on safety of agricultural machines/silage cutters.
- Mandate for CEN, CENELEC and ETSI relating to the safety aspects of the electromagnetic fields generated by certain appliances in connection with Directive 73/23/EEC, Directive 1999/5/EC and Council Recommendation 1999/519/EC of 12 July 1999.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on construction products in contact with water.
- Mandate for CEN and CENELEC concerning the execution of standardisation work for harmonised standards on construction products and in relation to fire performance.
- Supplement to the existing mandate for CEN and CENELEC concerning the performance of standardisation work on harmonised standards for heat insulation products.
- Mandate for CEN relating to the revision of standard EN 795/1996 "Protection against falls from a height – Anchorage devices – Requirements and testing".

2. Mandates in connection with public procurement

(No mandates)

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

(No mandates)

4. Mandates in connection with other Community policies.

4.1. Consumer policy

- Mandate for CEN on fire resistance of nightwear.

- Mandate for CEN in the field of consumer safety : cords and ties on children's clothing.

4.2 Environmental policy

- Mandate for CEN relating to solid biofuels.

4.3 Energy policy

- Mandate for CEN and CENELEC relating to definitions and measurements methods for stand-by losses of domestic appliances.
- Mandate for CENELEC for the revision of standards for definitions and measurement methods for the efficiency of oil-cooled and dry-type transformers.

4.3 Research policy

- Mandate for CEN, CENELEC and ETSI on technologies for humanitarian demining.

1.14. Standardisation work entrusted to the European standardisation bodies in 2001

1. Mandates related to New Approach Directives

- Mandate for CEN relating to the revision of standard EN ISO 848-3:1999 "Safety of woodworking machines".
- Mandate for CEN for the revision of standards in the field of packaging and the waste from packaging in the context of Directive 94/62/EC.
- Mandate for CEN, CENELEC and ETSI concerning electromagnetic compatibility for the telecommunications network in the context of Directive 89/336/EEC.

2. Mandates in connection with public procurement

(No mandates)

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

(No mandates)

4. Mandates in connection with other Community policies.

4.1 Agriculture policy

- Mandate for CEN for the development and adoption of standards for animal feed in connection with Directive 70/373/EEC.

4.2 Environmental policy

- Mandate for CEN for standardised measuring methods for benzo(a)pyrene, in connection with Council Directive 96/62/EC.

4.3 Energy policy

- Mandate for CEN for the development and adoption of measurement standards relating to domestic appliances for the production of hot water and running on gas.

4.4 Internal market policy, aspects other than those related to the New Approach.

- Mandate for CEN, CENELEC and ETSI for the development and adoption of standards in the postal field.

2. ANNEXES CONCERNING TECHNICAL REGULATIONS

2.1. Number of notifications of technical rules from each Member State from 1999 to 2001

Member State	1999	2000	2001
Belgium	20	39	30
Denmark	43	114	36
Germany	85	83	50
Spain	31	20	27
Finland	24	23	22
France	54	30	55
Greece	17	13	8
Ireland	4	7	2
Italy	25	26	30
Luxembourg	1	7	0
Netherlands	128	122	98
Austria	69	138	75
Portugal	6	5	7
Sweden	35	29	40
United Kingdom	49	95	50
EC total	591	751	530

2.2. Percentages of notifications of technical rules from each Member State from 1999 to 2001

Member State	% 1999	% 2000	% 2001
Belgium	3.4	5.2	5.7
Denmark	7.3	15.2	6.8
Germany	14.4	11.0	9.4
Spain	5.2	2.7	5.1
Finland	4.1	3.1	4.1
France	9.1	4.0	10.4
Greece	2.9	1.7	1.5
Ireland	0.7	0.9	0.4
Italy	4.2	3.5	5.7
Luxembourg	0.2	0.9	0
Netherlands	21.6	16.2	18.5
Austria	11.7	18.4	14.2
Portugal	1.0	0.7	1.3
Sweden	5.9	3.9	7.5
United Kingdom	8.3	12.6	9.4

2.3 Breakdown by sector of drafts notified by the Member States of the European Union (1999)

SECTOR	B	DK	D	E	FIN	F	GR	IRL	I	L	NL	A	P	S	UK	EC TOTAL
Building and construction	2	10	10	3	2	1	2	3	0	0	5	30	1	1	3	73
Agricultural products and foodstuffs	2	7	6	6	0	8	7	1	12	0	43	4	2	18	9	125
Chemical products	1	3	1	3	3	8	1	0	2	0	9	3	0	2	1	37
Pharmaceuticals	3	1	5	2	1	3	0	0	1	0	1	1	0	3	6	27
Household and leisure equipment	0	0	0	3	0	0	0	0	1	0	2	2	0	1	0	9
Mechanical engineering	5	2	26	1	2	5	2	0	5	0	1	7	1	2	2	61
Energy, minerals, wood	0	1	0	1	3	5	1	0	0	0	8	4	0	1	0	24
Environment, packaging	2	6	3	1	0	3	0	0	1	0	16	5	1	2	4	44
Health, medical equipment	1	0	0	0	0	1	0	0	0	0	0	1	0	0	0	3
Transport	1	11	10	5	7	9	3	0	1	0	19	6	0	4	14	90
Telecommunications	3	2	22	3	2	8	0	0	1	1	14	5	1	1	7	70
Miscellaneous	0	0	1	0	4	3	0	0	0	0	7	0	0	0	2	17
Information society services	0	0	1	3	0	0	1	0	1	0	3	1	0	0	1	11
TOTAL BY MEMBER STATE	20	43	85	31	24	54	17	4	25	1	128	69	6	35	49	591

2.3. Breakdown by sector of drafts notified by the Member States of the European Union (2000)

SECTOR	B	DK	D	E	FIN	F	GR	IRL	I	L	NL	A	P	S	UK	EC TOTAL
Building and construction	0	26	17	1	5	4	2	0	1	0	6	39	0	3	5	109
Agricultural products and foodstuffs	7	4	9	7	4	12	4	0	10	0	54	1	5	6	4	127
Chemical products	2	2	0	0	3	3	1	0	2	0	12	3	0	3	2	33
Pharmaceuticals	0	1	2	0	0	2	1	0	0	0	0	0	0	1	6	13
Household and leisure equipment	5	1	0	2	0	0	0	0	0	0	0	0	0	0	0	8
Mechanical engineering	4	4	2	4	3	1	0	0	1	0	5	7	0	4	7	42
Energy, minerals, wood	1	2	2	1	0	1	3	0	1	2	8	3	0	1	1	26
Environment, packaging	1	3	0	1	1	1	0	0	2	0	13	5	0	1	5	33
Health, medical equipment	0	1	0	0	0	2	0	0	0	0	0	2	0	0	0	5
Transport	5	22	6	4	5	3	2	0	4	2	13	31	0	8	26	131
Telecommunications	6	47	42	0	1	0	0	5	2	0	2	43	0	1	37	186
Miscellaneous	5	0	0	0	0	0	0	1	0	0	5	3	0	0	1	15
Information society services	3	1	3	0	1	1	0	1	3	3	4	1	0	1	1	23
TOTAL BY MEMBER STATE	39	114	83	20	23	30	13	7	26	7	122	138	5	29	95	751

2.3. Breakdown by sector of drafts notified by the Member States of the European Union (2001)

SECTOR	B	DK	D	E	FIN	F	GR	IRL	I	L	NL	A	P	S	UK	EC TOTAL
Building and construction	3	3	12	5	5	11	1	1	5	0	4	41	1	1	6	99
Agricultural products and foodstuffs	5	8	9	6	0	6	1	0	5	0	37	9	1	13	8	108
Chemical products	0	0	2	2	0	0	0	0	0	0	7	4	1	2	1	19
Pharmaceuticals	1	1	6	0	1	9	0	0	0	0	3	0	0	1	2	24
Household and leisure equipment	3	3	0	1	0	1	0	0	0	0	1	0	0	4	0	13
Mechanical engineering	1	1	2	5	1	3	0	0	4	0	4	0	0	2	2	25
Energy, minerals, wood	3	2	1	0	1	6	2	0	5	0	5	3	1	1	2	32
Environment, packaging	3	3	8	1	0	1	1	1	0	0	10	4	0	1	4	37
Health, medical equipment	0	0	0	1	0	0	0	0	1	0	2	0	0	0	2	6
Transport	6	8	2	1	4	3	3	0	5	0	15	3	1	9	9	69
Telecommunications	0	4	1	0	2	11	0	0	2	0	3	9	0	2	13	47
Miscellaneous	3	2	2	3	2	2	0	0	1	0	6	1	1	3	1	26
Information society services	2	1	5	2	6	2	0	0	2	0	1	1	1	1	1	25
TOTAL BY MEMBER STATE	30	36	50	27	22	55	8	2	30	0	98	75	7	50	40	530

2.4. Number of notifications compared with number of times emergency procedure invoked by sector between 1999 and 2000

SECTOR	Total number	% of total	No of urgent cases	% urgent cases
Building and construction	281	100%	4	1.4%
Agricultural products and foodstuffs	360	100%	52	14.5%
Chemical products	89	100%	7	7.9%
Pharmaceuticals	64	100%	6	9.4%
Household and leisure equipment	30	100%	1	3.3%
Mechanical engineering	128	100%	6	4.7%
Energy, minerals, wood	82	100%	1	1.2%
Environment, packaging	114	100%	3	2.6%
Health, medical equipment	14	100%	3	21.4%
Transport	290	100%	14	4.8%
Telecommunications	303	100%	0	0%
Miscellaneous	58	100%	1	1.7%
Information society services	59	100%	5	8.5%

2.5. Comparison between notifications and reactions by sector (only detailed opinions and comments) - 1999

SECTOR	Number of notifications	Detailed opinion from the Commission	Detailed opinion from the Member States	Comments (Commission and Member States)	% detailed opinions in relation to number of notifications*	% comments in relation to number of notifications*
Building and construction	73	2	1	35	4.1%	47.9%
Agricultural products and foodstuffs	125	12	31	84	34.4%	67.2%
Chemical products	37	3	22	55	67.6%	148.6%
Pharmaceuticals	27	2	2	8	14.8%	29.6%
Household and leisure equipment	9	3	3	3	66.7%	33.3%
Mechanical engineering	61	2	4	39	9.8%	63.9%
Energy, minerals, wood	24	3	4	16	29.2%	66.7%
Environment, packaging	44	1	7	37	18.2%	84.1%
Health, medical equipment	3	0	8	3	266.7%	100%
Transport	90	8	6	46	15.6%	51.1%
Telecommunications	70	6	0	60	8.6%	85.7%
Information society services	11	1	0	10	9.1%	91%
Miscellaneous	17	0	5	12	29.4%	70.6%
Total all sectors	591	43	93	408	 	

* These percentages are explained by the fact one notification can receive several detailed opinions and/or comments

2.5. Comparison between notifications and reactions by sector (only detailed opinions and comments) - 2000

SECTOR	Number of notifications	Detailed opinion from the Commission	Detailed opinion from the Member States	Comments (Commission and Member States)	% detailed opinions in relation to number of notifications*	% comments in relation to number of notifications*
Building and construction	109	4	6	38	9.2%	34.8%
Agricultural products and foodstuffs	127	13	42	92	43.3%	72.4%
Chemical products	33	2	11	29	39.4%	87.9%
Pharmaceuticals	13	1	0	1	7.7%	7.7%
Household and leisure equipment	8	2	3	2	62.5%	25%
Mechanical engineering	42	5	9	22	33.4%	52.4%
Energy, minerals, wood	26	0	5	16	19.2%	61.5%
Environment, packaging	33	4	4	13	24.2%	39.4%
Health, medical equipment	5	0	2	5	40%	100%
Transport	131	5	8	66	9.9%	50.4%
Telecommunications	186	1	1	144	1.1%	77.4%
Information society services	23	11	0	9	47.8%	39.1%
Miscellaneous	15	1	4	7	33.3%	46.7%
Total all sectors	751	49	95	444	 	

* These percentages are explained by the fact one notification may be the subject of several detailed opinions and/or comments.

2.5. Comparison between notifications and reactions by sector (only detailed opinions and comments) - 2001

SECTOR	Number of notifications	Detailed opinion from the Commission	Detailed opinion from the Member States	Comments (Commission and Member States)	% detailed opinions in relation to number of notifications*	% comments in relation to number of notifications*
Building and construction	99	24	20	45	44.4%	45.5%
Agricultural products and foodstuffs	108	6	15	53	19.4%	49.1%
Chemical products	19	2	9	16	57.9%	84.2%
Pharmaceuticals	24	1	0	12	4.2%	50%
Household and leisure equipment	13	4	1	8	38.5%	61.5%
Mechanical engineering	25	3	5	14	32%	56%
Energy, minerals, wood	32	3	3	13	18.7%	40.6%
Environment, packaging	37	3	13	35	43.2%	94.6%
Health, medical equipment	6	1	3	8	66.7%	133.3%
Transport	69	2	5	16	10.1%	23.2%
Telecommunications	47	7	2	45	19.1%	95.7%
Information society services	25	4	0	15	16%	31.9%
Miscellaneous	26	2	11	19	50%	73.1%
Total all sectors	530	62	87	299		

* These percentages are explained by the fact one notification may be the subject of several detailed opinions and/or comments.

2.6. Follow-up to the detailed opinions delivered by the Commission (only finalised procedures) on notifications in 1999 and 2000

SECTOR	Positive position by Commission	% positive position by Commission	Negative position by Commission	% negative position by Commission
Building and construction	3	100%	0	0%
Agricultural products and foodstuffs	9	60%	6	40%
Chemical products	3	100%	0	0%
Pharmaceuticals	1	33.3%	2	66.7%
Household and leisure equipment	4	80%	1	20%
Mechanical engineering	2	100%	0	0%
Energy, minerals, wood	3	100%	0	0%
Environment, packaging	2	66.7%	1	33.3%
Health, medical equipment	_*	_*	_*	_*
Transport	9	90.9%	2	9.1%
Telecommunications	1	100%	0	0%
Miscellaneous	1	100%	0	0%
Information society services	4	80%	1	20%
Total all sectors	42	84.2%	13	15.8%

No detailed opinion was delivered by the Commission in this field in 1999 or 2000.

2.7. Breakdown by sector of drafts notified by Iceland, Norway and Switzerland between 1999 and 2001

SECTOR	Iceland			Norway			Switzerland			Total for sector		
	1999	2000	2001	1999	2000	2001	1999	2000	2001	1999	2000	2001
Building and construction	0	0	0	1	0	0	0	0	0	1	0	0
Agricultural products and foodstuffs	2	4	5	5	1	3	8	1	5	15	6	13
Chemical products	1	0	0	1	1	2	3	1	1	5	2	3
Pharmaceuticals	0	0	0	0	1	0	1	1	3	1	2	3
Household and leisure equipment	0	0	0	1	0	0	0	0	0	1	0	0
Mechanical engineering	0	0	0	2	0	5	2	1	0	4	1	5
Energy, minerals, wood	0	0	0	0	0	1	0	0	1	0	0	2
Environment, packaging	0	0	0	0	1	0	1	1	0	1	2	0
Health, medical equipment	0	0	0	0	0	0	0	0	0	0	0	0
Transport	1	0	0	3	2	0	1	1	1	5	3	1
Telecommunications	0	0	0	1	8	3	0	3	1	1	11	4
Miscellaneous	0	0	0	0	1	0	1	0	0	1	1	0
Information society services	0	0	1	0	0	2	0	0	0	0	0	3
Total all sectors	4	4	6	14	15	16	17	9	12	35	28	34

2.8. Comments on drafts notified by Iceland, Norway and Switzerland in the 1999-2001 period

1999

Country	Notifications	EC comments
Iceland	4	1
Norway	14	8
Switzerland	17	9
Total	35	18

2000

Country	Notifications	EC comments
Iceland	4	2
Norway	15	7
Switzerland	9	6
Total	28	15

2001

Country	Notifications	EC comments
Iceland	6	4
Norway	16	15
Switzerland	12	4
Total	34	23