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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 2002 TO 2005

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EXECUTIVE SUMMARY

This report analyses the application of the procedures laid down by Directive 98/34/EC¹ (“the Directive”) for standardisation and technical regulations from 2002-2005. The report highlights the important contribution of standardisation and the notification procedure to make the internal market work by improving the national regulatory environment².

The standardisation part consists of the information procedure on standards, Commission requests to the European Standards Organisations for standardisation work (mandates) and formal objections against standards. Each of these activities has proved to be an important element in the functioning of the internal market. The information procedure has brought transparency in standardisation at national and thus also European level and has encouraged National Standards Bodies to continue to take initiatives to the European level, in turn promoting European harmonisation. Formal objections have enabled Member States and the Commission to ensure that standards meet the goals of regulation when used for the purposes of ‘New Approach’ legislation. Mandates have provided the means by which the relationship between the Commission services and standardisers is determined; the interface between the policy level and its technical expression.

In the field of technical regulations, the notification to the Commission of national technical regulations prior to their adoption, both in the areas of goods and of Information Society Services, has proved to be an effective instrument of prevention of barriers to trade and of cooperation between the Commission and the Member States and among the Member States themselves. The preventive and dialogue-based approach characterising the notification procedure was particularly useful in preparing the enlargement of the internal market to 10 new Member States in 2004. The notification procedure has also been an important tool for guiding national regulatory activity in certain emerging sectors and for improving the quality of national technical regulations - in terms of increased transparency, readability and effectiveness - in non-harmonised or partly harmonised areas. The greater clarity in the legal framework of each Member State has helped economic operators to access markets and to apply new regulations easily.

PART I: STANDARDISATION

1. INTRODUCTION

This section describes the standardisation³ part of the Directive covering three main activities, the information procedure on standards, Commission requests to the European Standards

¹ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204 of 21.07.1998), as amended by Directive 98/48/EC (OJ L 217 of 05.08.1998).

² See *Action plan for improving the regulatory environment*, COM(2002) 278 final. See also *Better Regulation for Growth and Jobs in the European Union*, COM(2005) 97 final.

³ For more information on European standardisation policy see:
http://ec.europa.eu/enterprise/standards_policy/index_en.htm

Organisations (ESOs⁴) for standardisation work (mandates⁵) and formal objections against standards primarily under New Approach directives⁶, gives statistics for 2002-2005 and provides analysis of the functioning of this part of the Directive.

2. INFORMATION PROCEDURE

The procedure in the field of standards is designed to monitor the new standardisation activities introduced by the National Standardisation Bodies (NSBs; as recognised under the Directive). 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 (see Annex 1).

2.1. Operation of the procedure 2002-2005

The procedure has continued to operate successfully from 2002 to 2005. From the reports provided by CEN and CENELEC each year, it is possible to see that the annual average of national measures notified continued to drop from previous reports. The 1995-1998 average was 1922 per year and for 1999-2001 was 1587 per year. For this reporting period the annual average is 1537 (Annex 2). However, the figures for individual years show the effect of the new CEN and CENELEC members from the EU-10.

Annex 3 gives a breakdown by state of the notifications. The sectoral breakdown (Annex 4) shows that it is the construction sector in the broadest sense that dominates the national notifications, with structures, buildings and construction, concrete and metal structures all featuring regularly in the top ten areas for notifications. Other significant areas are those of food products and water quality.

The information disseminated under the procedure continues to give rise to requests for further information by the Commission services, as well as queries regarding the standstill (Article 7) arising either from notifications or other sources.

Due to the enlargement on 1st May 2004 the NSBs of the ten new Member States became full members of CEN and CENELEC and the notifications increased gradually during the reporting period (see Annex 3). From 2003 to 2005 the number of notifications from the EU-15 has shown an upward trend. The addition of the EU-10 has caused overall figures to rise further. Post-enlargement, the contribution of the new Member States is 15-20% of the total of notified national initiatives. These Member States are already applying the procedure and contributing to the national work of standardisation in Europe.

Through the publishing of national standardisation initiatives, the information procedure encourages all stakeholders to consider the possibilities for extending the work to European level. In this way, the information procedure encourages the NSBs to bring their initiatives to European level, thus promoting the internal market and European harmonisation.

In the new area of standardisation for services, the number of national initiatives notified is rather high (although not featuring in the annual top ten). This has led to an examination of

⁴ EN (European Committee for Standardisation), CENELEC (European Committee for Electrotechnical Standardisation) and ETSI (European Telecommunications Standards Institute).

⁵ Mandates are requests representing an invitation to ESOs that may be accepted under certain conditions.

⁶ For Directives under the New Approach see www.newapproach.org

those areas by the Commission services, for example when preparing the standardisation mandate on customer call centres towards the end of 2005. There were already several initiatives identified at national level in this area and these were drawn together as far as possible when drawing up the mandate.

2.2. Conclusion

The number of national initiatives notified under the information procedure is still significant. As in the sector of services, the notifications can be monitored to encourage standardisation work to be brought to European level wherever possible, thus encouraging European harmonisation.

The EU-10 are already playing their expected role in the information procedure, so it can be seen that the system should function well for the future.

3. MANDATES

Standardisation mandates are a well-established Commission tool to obtain technical specifications that support European legislation and/or policy. They are a request to the ESOs for standardisation work and provide a reference framework for that work (see Annex 1). They are indispensable in cases where standards support legislation, for example in the context of the New Approach Directives.

3.1. Operation of the mandating process 2002-2005

In the reporting period, a total of 55 mandates were issued to the ESOs, with 10 amendment mandates in the construction sector in addition to this (see Annex 5). As with previous reporting periods, a large number of the mandates concerned New Approach directives (20, plus the 10 amendments). Of the mandates issued, 46 were standardisation mandates, 8 were programming mandates and 1 was a study mandate.

The Standing Committee set up pursuant to Article 5 of the Directive ('the Committee') was consulted twice on standards under the General Product Safety Directive (2001/95/EC) without a mandate, the references of which would be published in the OJ to give a presumption of conformity with that Directive.

The mandating process is now well-established and functions well. The informal consultation carried out before the documents are circulated to the Committee members means that a mandate normally has consensual agreement before the formal consultation starts.

The European standardisation stakeholders ANEC (European association for the co-ordination of consumer representation in standardisation), ECOS (European Environmental Citizens Organisation for Standardisation), NORMAPME (European Office of Crafts, trades and Small and Medium-sized Enterprises for Standardisation) and ETUI-REHS (European Trade Union Institute – Research, Education, Health and Safety) were well-integrated into the process by the end of the reporting period. This brings greater transparency to the informal consultation.

Database of mandates

In order to increase transparency further, DG ENTR has developed a database of mandates. It contains the mandates with the numbering series M/xxx. This database was made accessible to the public through the internet in 2005 at:

http://ec.europa.eu/enterprise/standards_policy/mandates/index.htm

The practice of giving a follow-up to all the mandate consultations to the Committee by means of an updated list has continued throughout the period. The progress of the mandated work is followed up by the sectoral services of the Commission. In certain cases, the ESOs request funding for the mandated work and subventions can be granted subject to the priority of the work and the appropriate evaluations.

3.2. Trends in mandates

The number of mandates issued has shown an increasing trend.

The subject matter for mandates continues to broaden. Whilst many are still issued for New Approach directives, the percentage has fallen in relative terms since the last reporting period, from 57% to 36%. Mandates in other policy areas continue to be important (see Annex 6), in particular environment where 12 mandates were issued, but also transport (5) and consumer protection (4).

Mandates in support of environmental legislation and policy

One-fifth of the mandates issued 2002-2005 concerned the environment. From biowaste to biofuels, waste from electronic equipment to energy-using products, this demonstrates the role that the Commission believes standards can play in this important policy area.

This has been emphasised in the Commission Communication on the integration of environmental aspects into European standardisation (COM (2004) 130 final), which stressed the role that standardisation can play in advancing the Commission's policy of protecting the environment and sustainable development.

Through the reporting period, mandates have been issued **to support a broad range of legislation**. This includes legislation on the European single sky, cosmetics, intermodal loading units and road tolls, conventional rail systems, foodstuffs, animal feeds and general product safety, as well as the environment.

The number of mandates supporting legislation outside the New Approach (see Annex 5) is large (some 50% overall) and shows that this co-regulatory model has been adopted across a broad range of the Commission services.

The breadth of legislative areas shows the commitment to the co-regulatory model provided by standardisation. The use of such a model encourages a regulatory approach which does not inflate the Community acquis with overly detailed rules through leaving to industry and interested parties the task of developing standards that can give technical expression to legislation, thus following **the principles of better regulation**.

Mandates have also increasingly been used to support new areas of European policy. Examples include the study mandate on hydrogen fuel cells, the programming mandate on crime risk in products and services and the standardisation mandate on film archiving.

A mandate was issued for the first time in 2003 for standardisation in the service sector. This was followed by two more mandates in 2005, with another being consulted at the Committee meeting at the end of the reporting period. This is a new growth area for national, European and international standardisation. The process of mandating links here to the information procedure, as initiatives on service standardisation at national level were examined in drawing up the mandate on customer contact centres (see point 2.1 above).

These trends for the use of mandates in support of legislation outside the New Approach and in new areas of policy reflect the situation that **European standardisation is increasingly used in support of the Commission's better regulation policy**. This has been recognised in, and indeed encouraged by, the Commission Communication of 2004 on 'The role of European standardisation in the framework of European policies and legislation'⁷.

3.3. Conclusion

The process of mandating is well-established, but care must be taken to ensure it continues to operate smoothly. To this end, the informal consultation of all relevant parties prior to the Committee consultation is essential and should be reinforced.

To improve transparency in the functioning of the Committee, the Commission services are also actively considering the possibility of inviting the European standardisation stakeholders, ANEC, ECOS, ETUI-REHS and NORMAPME, to participate in its enlarged meeting.

In order to improve transparency the consultations by written procedure will be opened up so that all Committee members can see the comments of the others, making this kind of consultation similar to a consultation carried out during the meeting of the Committee.

The process of mandating has proved to be instrumental in enlarging the role of standardisation in new areas of EU legislation and policy. This is also reflected by the fact that a number of new EU legislative acts refer to the Directive.

Vademecum on European standardisation

The procedure of handling mandates, formal objections against harmonised standards and the publication of the references of harmonised standards are all contained within the *Vademecum* on European standardisation, along with a number of other relevant documents.

The Commission consulted the Committee and other interested parties on the *Vademecum* prior to its publication.

The *Vademecum* is published on the Europa website at:

http://ec.europa.eu/enterprise/standards_policy/vademecum/index.htm

⁷ COM(2004) 674 final of 18.10.2004.

4. FORMAL OBJECTIONS

The New Approach directives contain safeguards for cases where a harmonised standard cannot enable products to meet the essential requirements of the directives concerned. When such cases occur, the Member States or the Commission may introduce a formal objection to the standard in question on which the Committee is consulted (see Annex 1 for the details of the procedure).

4.1. Operation of the procedure 2002-2005

The number of objections that have given rise to Commission Decisions during the reporting period has been low (8). In 5 cases the Decision was to maintain the presumption of conformity; in 3 cases it was fully or partially withdrawn (see Annex 7).

However, when taking into account the notification of new objections, the number of formal objections is on the rise. The main areas are under the directives on machinery, toys, construction products and medical devices.

In a number of cases, problems of the compatibility of standards have been discussed in the Committee and have given rise to requests for amendment of harmonised standards without the necessity for a formal objection.

4.2. Conclusion

Although the process from receiving the objection to issuing of the Decision is quite time-consuming, the procedure in general has worked adequately.

In a similar way to the mandates, and for the sake of transparency, the Commission will make decisions on formal objections public in a consolidated way, and make available an updated table of the actions in relation to the formal objections to the Committee at each meeting.

PART II: TECHNICAL REGULATIONS

1. DEVELOPMENTS 2002-2005

The notification procedure for national technical regulations (“the procedure”) allows the Commission and the Member States of the EU to examine preventively the technical regulations Member States intend to introduce for products (industrial, agricultural and fishery) and for Information Society services (see Annex 8). It applies in a simplified manner to the EFTA Member States which are signatories to the Agreement on the European Economic Area and to Switzerland and Turkey (see Annex 12).

The major benefits of the procedure

- It allows new barriers to the internal market to be detected even before they have any negative effects, thus avoiding long and costly infringement proceedings.
- It allows Member States to ascertain the degree of compatibility of notified drafts with Community legislation, including directives.
- The active participation of the Member States in assessing notified drafts has, over the years, enabled the establishment of an effective dialogue between them and the Commission.
- All interested parties, including consumers, are promptly informed of national regulatory initiatives and economic operators can adapt their activities in good time to future technical regulations.

1.1. Geographical coverage

The procedure made an important contribution to ensure the respect of the internal market rules during the enlargement of the EU. The dialogue established since 2002 with the applicant countries led to the introduction of a simplified procedure giving these countries the administrative capacity, technical structure and knowledge needed to apply the Directive even before the date of accession (see Annex 10).

Moreover, to ensure that the Directive was correctly transposed, seminars were organised in some of these countries to study the procedure and to discuss the measures already put in place by the national authorities.

From 1 May 2004, all the new Member States have been able to fully apply the procedure and translations of notified drafts have been available in the 20 official languages of the EU.

The initiative’s success is shown by the number of notifications from the 10 new Member States: 64 between 1 May 2004 and 31 December 2004 and 196 in 2005 (26.5% of the total number of notifications from the 25 Member States).

1.2. Use of the procedure within the context of “better regulation”

Following the Commission’s action plan to simplify and improve the regulatory environment⁸ several initiatives have been taken in the framework of the notification procedure over the reporting period. To ensure that comprehensive information is available when notified drafts are examined and to facilitate their understanding and evaluation, Member States have been invited to submit impact studies (or their conclusions) together with notified drafts, where such studies have been carried out. Analysing these impact studies also encourages the Member States to reflect in advance on the most appropriate instrument to be used.

The Commission also intensified its efforts in line with better regulation principles to ensure the clarity and consistency of the notified drafts and to identify any unnecessarily complex or onerous procedures that have to be simplified to help economic operators while guaranteeing a high level of protection for public health, consumers and the environment.

The national authorities have been encouraged to consider the following aspects in particular:

- the wording of drafts
- the possibility of accessing all regulations in a given sector through the publication of consolidated versions of the texts
- the identification of procedures imposing unnecessarily complex and onerous administrative burdens on economic operators, particularly when placing a product on the market or regulating the exercise of on-line activities.

1.3. Improvements in managing the procedure

The Commission conducted various campaigns during 2002-2005 to increase transparency and dialogue with the national authorities. Firstly, the operation of the TRIS (“*Technical Regulations Information System*”) database was improved so that, since 2002, all documents have been sent electronically in a standardised format. Secondly, Member States must mention in the notification message any impact studies which have been carried out (see paragraph 1.2 above). Finally, they are also required to indicate whether their drafts may affect international trade and must therefore be notified under the WTO’s TBT and/or SPS Agreements. This information allows the Commission to connect the Community and international dimensions of notified drafts, to assess their implications better and to defend the interests of European industry within the WTO more effectively.

The Commission ensures public access to the notified drafts, in the 20 official languages of the EU, and to the essential information on the conduct of the procedure through the website <http://ec.europa.eu/enterprise/tris>. A constant increase in the number of on-line consultations has been observed: the monthly number of searches increased from 4 459 in 2003 to 11 109 in 2005 (see Annex 13).

To allow interested parties to respond effectively to the competent authorities, a mailing list system was introduced in 2003. Based on a simple on-line registration, draft regulations notified by Member States, in the respective areas of interest, are sent automatically by e-

⁸ See *supra*, footnote 2

mail. The number of registrations has increased (420 subscribers at the end of 2003 and 1 300 at the end of 2005).

2. APPLICATION OF THE NOTIFICATION PROCEDURE

2.1. Effectiveness: general overview

► Volume of notifications and sectors involved

Between 2002 and 2004 (EU-15) the total number of notified drafts fell slightly compared to the previous period (1 487 as opposed to 1 872 between 1999 and 2001) - around 500 notifications per year. Enlargement (EU-25) contributed to an increase in the number of notifications to 739 in 2005.

One of the factors explaining the high number of drafts notified by Member States is the effect of the case-law of the Court of Justice since the “*CIA Security International*”⁹ judgment, namely the unenforceability against third parties of technical regulations not notified in advance to the Commission (for recent case-law, see Annex 9).

As in the past, **agricultural products and foodstuffs** is the sector which saw the highest number of notifications during the reporting period. The subjects covered included labelling of foodstuffs, food supplements, traceability and the origin of products and also measures on the co-existence of GMOs with conventional and organic crops. Notifications increased significantly in the **telecommunications, transport, construction** and, particularly in 2005, **energy** and **mechanical engineering** sectors. In the field of **Information Society** services, the notifications mainly concerned electronic signature, electronic commerce and domain names (see Annexes 11.1 to 11.3).

► Issues examined

In **non-harmonised areas** subject to compliance with Articles 28 to 30 (free movement of goods) and 43 and 49 (right of establishment and freedom to provide services) of the EC Treaty, the Commission’s reactions were intended to warn Member States of potential obstacles to trade which could be created by an unnecessary measure disproportionate to the objective pursued. In addition, the Commission invited Member States to insert a mutual recognition clause in each draft technical regulation following its interpretative communication on compliance with the mutual recognition principle in the product sector¹⁰.

⁹ Case C-194/94 *CIA Security International SA v Signalson SA and Securitel SPRL* [1996] ECR I-2201.

¹⁰ *Facilitating the access of products to the markets of other Member States: the practical application of mutual recognition* (2003/C 265/02), OJ C 265/2 of 04.11.2003.

In **harmonised areas**, the reactions were intended to ensure that national measures going beyond the simple transposition of directives were justified and compatible with Community law.

- Since 2004, several Member States have notified drafts on the co-existence of genetically modified crops with conventional and organic crops and on the control of accidental contamination by **GMOs**. Analysed in light of Directive 2001/18/EC (deliberate release of GMOs), these texts have provided examples of regulatory solutions for other Member States.
- In 2004, several drafts aimed at introducing **blind spot mirrors** for lorries demonstrated the need to speed up the entry into force of common rules in an area already harmonised at Community level by Directive 2003/97/EC.
- This is also true for drafts on substances used as ingredients in **food supplements** which are only partly harmonised at Community level.
- An analysis of the intense regulatory activity at national level in the **games of chance** sector, in which there are no common rules, has highlighted aspects of free movement within the internal market and national public policy.
- Since 2003 there have also been many notifications on **radio interfaces**, a sector in which rapid technological development has resulted in increasingly complex national regulations likely to create barriers within the internal market.

► **Reactions**

The Commission issued 293 detailed opinions, which represents 12.7% of the total number of drafts notified over the reporting period (2 290). In the 1999-2001 period, the figure was 8.2%. For their part, the Member States issued 275 detailed opinions. Of 1 563 comments, 802 were made by the Commission and 761 by the Member States (see Annexes 11.4 and 11.6).

In 22 cases the Commission invited the Member States concerned to postpone the adoption of the notified regulations for one year from the date of their receipt, so as not to compromise Community harmonisation work underway in the area (see Annex 11.5).

2.2. Use of the urgency procedure

From a total of 2 290 notifications, the Member States made 99 requests to apply the urgency procedure to notified drafts. The Commission confirmed its strict interpretation of the exceptional conditions required, namely serious and unforeseeable circumstances relating in particular to the protection of health and safety. As a result, use of the urgency procedure was refused where the justification given was based on purely economic grounds or stemmed from an attempt to make up for national administrative delay. The urgency procedure was deemed to be justified in 49 cases (see Annex 11.7).

2.3. Follow-up to Commission reactions

This is the main indicator for assessing the commitment of the Member States to compliance with their obligations under the procedure. For 2002-2005, the ratio between the number of responses given by Member States and the volume of detailed opinions issued by the Commission was satisfactory (an average of 84.7% over the period) and gradually improved (78.5% in 2002 increasing to 87% in 2005). The responses were mainly satisfactory (an average of 60.6% over the period). Continued dialogue between the Commission and the Member States involved contributed to this by allowing many cases to be resolved within a year of notification (see Annex 11.8).

2.4. Dialogue with the Member States

The regular meetings of the Committee allowed views to be exchanged on points of general interest and also on specific aspects of the procedure. Between 2003 and the accession, the 10 new Member States participated in the Committee's work as observers.

The discussions particularly concerned the enlargement of 1 May 2004, the possible extension of the Directive to services other than Information Society services, public access to documents relating to the 98/34 procedure following the entry into force of Regulation (EC) No 1049/2001, the impact studies for notified drafts and the overlap between the procedure and other Community notification procedures ("one-stop shop").

"Package meetings" and seminars were also held in the Member States, thus allowing direct dialogue between the Commission and national authorities involved in the procedure. In 2005, a conference involving about 200 participants from the Member States and European industry provided an opportunity to find out the expectations of those involved in the procedure and to discuss improvements in its effectiveness.

2.5. Infringements against the Directive

The infringement proceedings (Article 226 of the EC Treaty) brought against Member States were related to the breach of their obligation to notify technical regulations at a draft stage, in accordance with the Directive. The number of these proceedings remained low during the period in question: three in 2002, three in 2003, two in 2004 and four in 2005. The outcome of the infringement proceedings was that the unnotified national regulations were repealed by the Member States. All these proceedings have been closed.

2.6. Conclusion

Between 2002 and 2005, the utility of the procedure has been fully confirmed in terms of effectiveness, transparency and administrative cooperation. Moreover, the high number of draft technical regulations notified by Member States in accordance with the Directive contributes to ensure a correct application of Community legislation through a preventive approach.

The networking approach and the high degree of cooperation between the Commission and Member States have also ensured that national regulatory activities have been carried out without creating technical barriers to trade and that Community harmonisation has occurred only where really needed, in strict compliance with the subsidiarity principle. At the same time, in certain areas where harmonisation measures already exist, the procedure has allowed the need to supplement or reinforce these to be detected.

The intense work undertaken to ensure that the 10 applicant countries would comply with the obligations arising from the Directive on their accession to the EU has helped ensure the correct operation of the enlarged internal market.

Extending the enterprise policy dimension remains a priority in the application of the procedure. Notified drafts are already available electronically, free of charge and in all the official languages of the EU. Efforts will continue to provide economic operators with a legal framework that is as clear as possible without any regulatory excesses.