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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 2006-2008

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EXECUTIVE SUMMARY

This report analyses the application between 2006 and 2008 of the procedures laid down by Directive 98/34/EC¹ for standardisation and technical regulations. It highlights their important contribution to the implementation of better regulation and to the functioning of the single market.

The standardisation part consists of the information procedure on standards, Commission requests to the European Standards Organisations (ESOs²) for standardisation work (“mandates”) and formal objections against standards. They have proved to be an important element in the functioning of the single market. The information procedure has brought transparency in standards and has encouraged National Standards Bodies (NSBs) to continue to take initiatives to promote 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 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 as well as improving the regulatory framework. Moreover, at the end of 2008, this procedure showed to be useful in preventing the emergence within the internal market of protectionist measures which might have been proposed by Member States in the context of the economic and financial crisis.³ The notification procedure has also been an important tool for guiding national regulatory activity in emerging sectors and 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 reduce the cost of accessing the regulations and applying them correctly.

PART I: STANDARDISATION

1. INTRODUCTION

This section describes the standardisation part of the Directive covering the information procedure on standards, Commission requests to ESOs for standardisation work (mandates⁴)

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

³ *Communication from the Commission to the European Council – A European Economic Recovery Plan* 26 November 2008, COM(2008) 800 final.

⁴ Mandates are requests representing an invitation to ESOs that may be accepted under certain conditions.

and formal objections against standards primarily under New Approach directives, gives statistics for 2006-2008 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 NSBs. 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 from 2006 to 2008

The procedure has continued to operate successfully. It follows from the reports provided by CEN and CENELEC each year that the annual average of national measures notified remains stable. Annex 3 displays figures from 1991 showing an increase of notifications at each enlargement.

The sectoral breakdown (Annex 4) shows that it is the construction sector which dominates the national notifications. Other significant areas are food products, water quality and road building and maintenance.

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

2.2 Conclusion

The information procedure still plays an important role in encouraging national standardisation bodies to bring their initiatives to European level. Enlargement has led to an increase in notifications from new Member States, which will stabilise and even fall as they become more fully integrated, thus following the trend led by older Member States.

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 2006-2008

A total of 62 mandates were issued to the ESOs. The number of mandates concerning New Approach Directives has fallen compared to the previous period (Annex 5).

The mandating process functions well. The informal consultation carried out before the Committee means that a mandate has normally consensual agreement before the formal consultation.

The European standardisation stakeholders – ANEC (European association for the coordination 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 (European Trade Union Institute) were well-integrated into the process by the end of the reporting period. This brings greater transparency to the informal consultation.

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.

3.2 Trends in mandates

The subject matter for mandates continues to broaden. The proportion of the number of mandates issued for the New Approach Directives is 38%, very similar to the last reporting period. Mandates in other policy areas continue to be numerous (see Annex 6), in particular consumer protection and the environment, but also transport and energy.

Mandates in support of lead markets

Two mandates were issued since the beginning of the lead market initiative in 2007. These mandates concern bio-based products and demonstrate the extent to which the Commission believes in the potential role of standards in this important policy area.

Standards in support of legislation

Mandates were issued in support of a broad spectrum of legislation, proving the importance conferred to the model. Some examples include: legislation on cosmetics, vehicle repairs and maintenance, food products, animal feed and general product safety, as well as the environment. The number of mandates supporting new areas of European policy has doubled compared to the previous reporting period. Some examples are the mandates on supply chain security, accessibility to the built environment or the space industry programme.

The first mandate supporting the eco-design Directive was issued at the end of 2008. This was highlighted in the communication from the Commission on the integration of environmental aspects into European standardisation (COM(2004) 130 final), which emphasised the role that standards can play to develop the Commission's policy in terms of environmental protection and sustainable development.

The number of mandates supporting legislation outside the New Approach (see Annex 5) remains large (some 35% overall) and shows that this model has been adopted across a broad range of Commission services.

In 2006 a mandate on the relationship with costumers contact centers was issued. Service sector is a new growing area for standardisation. This trend for the use of mandates in support of legislation outside the New Approach and in new areas of policy reflects the situation that European standardisation is increasingly used in support of the better regulation policy. This has been recognised and encouraged by the Commission's Communication of 2004 on the role of European standardisation in the framework of European policies and legislation⁵.

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 the relevant parties prior to the Committee consultation is essential and should continue.

To improve transparency in the functioning of the Committee, the Commission services have from 2006 invited the European standardisation stakeholders, ANEC, ECOS, ETUI and NORMAPME, to participate in its enlarged meeting.

⁵ COM(2004) 674 final of 18.10.2004.

For the sake of transparency the services of the Commission will consider the possibility of organising a written procedure inspired by internet forums. The objective will be to ensure that all committee members can read the observations of the other members, rendering this type of consultation similar to that held at the Committee meeting.

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.

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).

4.1 Operation of the procedure from 2006 to 2008

The number of objections raised by the Commission during the reporting period has been low (11). In only two cases, the Decision was to maintain the presumption of conformity; in 9 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 and pressure equipment.

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 2006-2008

The notification procedure (“the procedure”) allows the Commission and the Member States 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 States which are signatories to the Agreement on the European Economic Area and to Switzerland and Turkey (see Annex 11).

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 the detection of protectionist measures which might be drawn up by Member States under exceptional circumstances, such as an economic and financial crisis.
- It allows Member States to ascertain the degree of compatibility of notified drafts with Community legislation, including directives.
- Over the years, the active participation of the Member States in assessing notified drafts has generated an effective dialogue between them and the Commission.
- Economic operators can make their voices heard and can adapt their activities in good time to future technical regulations. This right of scrutiny is used extensively by economic operators, helping the Commission and national authorities to detect any barriers to trade.

1.1 The notification procedure in an enlarged internal market

The procedure made an important contribution to the smooth functioning of the internal market during the enlargement of the EU to include 10 “new” Member States in 2004. The positive results of this, observed in 2005, have since been confirmed by the receipt from these 10 Member States of 122 notifications in 2006, 131 notifications in 2007 and 109 notifications in 2008.

Furthermore, the procedure extended to Bulgaria and Romania (EU-27). The 2 new Member States provided themselves with the administrative capacity, technical structure and knowledge necessary for the application of the Directive: 33 drafts notified between 1 January 2007 and 31 December 2008.

Once again, the Directive has shown that it is an effective tool in ensuring the smooth functioning of the internal market for both products and information society services.

1.2 Use of the procedure within the context of “Better regulation”

Following the Commission’s action plan to simplify and improve the regulatory environment, several initiatives have been taken in the framework of the notification procedure over the reporting period. Member States have been invited to submit impact studies together with

notified drafts. These impact studies encourage Member States to reflect in advance on the most appropriate instrument to be used, and allow the Commission to check the necessity of the measures proposed, taking into account any barriers to the functioning of the internal market.

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 need 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: clarity, consistency, transparency and legal certainty in the application of the texts;
 - the possibility of accessing all regulations in a given sector through the publication both on paper and on-line 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.
- **1.2.1 Improvements in managing the 98/34 procedure**

The Commission conducted various campaigns to increase transparency and dialogue with the national authorities. The operation of the TRIS (“*Technical Regulations Information System*”) database has seen continuous improvement and a new version should be launched by early 2010 at the latest, which will reduce the processing time of notifications and will allow connection between TRIS and national databases. Since 2007 the Commission has reformulated point 7 of the notification message to clarify whether, in the context of the “one-stop shop”, a notification made under the Directive may be considered valid under another EU legislative act.

The Commission ensures public access to the notified drafts, in the 23 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: from 2006 to 2008 the number of searches rose by 7.5% to reach approximately 140,000 searches in 2008 (see Annex 12).

2. APPLICATION OF THE 98/34 PROCEDURE

2.1 Effectiveness: general overview

► Volume of notifications and sectors involved

Between 2006 and 2008, the total number of notified drafts (1,979) increased compared to 1,782 between 2003 and 2005. Enlargement (EU-27) contributed to this increase. Certain weaknesses were observed in the implementation of some Member States’ commitment to notify draft technical regulations (see Annex 10.2).

The construction sector saw the highest number of notifications. Many related to measures taken by Member States in order to make buildings more energy efficient. **Agricultural products and foodstuffs** followed. In this sector, measures were related to food hygiene, to the co-existence of genetically modified organisms with conventional crops, to the composition and labelling of foodstuffs. Notifications increased significantly in the **telecommunications** and **transport sectors**. Several notifications were received in the **games of chance sector** (on-line gambling), the **chemicals sector** (dangerous substances and phytopharmaceutical products) the **environment** (reduction in the use of plastic bags, waste and the quality of biofuels) (see Annexes 10.1 to 10.3).

► **Issues examined**

In the **non-harmonised areas**, subject to compliance with Articles 28-30 (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. The Commission continued to invite Member States to insert mutual recognition clauses into each draft technical regulation.

In **harmonised areas**, the reactions were intended to ensure that national measures were necessary, justified and compatible with EU secondary legislation.

- Notifications in the area of **construction** were analysed principally under Directive 89/106/EEC on construction products and the harmonised standards adopted in the context of this Directive as well as Directive 2002/91/EC on the energy performance of buildings.
- Several Member States 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 the light of Directive 2001/18/EC (deliberate release of GMOs), Regulation (EC) Nos. 1829/2003 on genetically modified food and feed and 1830/2003 on the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC, these texts have provided examples of regulatory solutions for other Member States.
- On 1 January 2006, Regulation Nos. 852/2004 (**hygiene** of foodstuffs), 853/2004 (specific hygiene rules for food of animal origin) and 854/2004 (official controls on products of animal origin intended for human consumption) entered into force. These regulations authorise Member States to take certain measures at national level, which were notified in the framework of the 98/34 procedure and subject to detailed opinions and/or observations.
- Several Member States notified drafts concerning health claims on and labelling of **foodstuffs**, and the additives, colourings and preservatives contained therein.
- Equally numerous were 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.
- An analysis of the intense regulatory activity at national level in the non-harmonized **games of chance** sector has highlighted aspects of free movement within the internal market and national public policy.

- The procedure has also allowed intervention in the sectors where harmonisation was envisaged at Community level and has prevented Member States from introducing divergent national measures.

► **Reactions**

The Commission issued detailed opinions in relation to 179 notifications, which represents 9.04% of the total number of drafts notified over the reporting period (1,979). This figure shows a fall compared to the previous reporting period, suggesting that the Member States are legislating increasingly with the Community in mind and taking into account the requirements of an effectively functioning internal market. For their part, the Member States issued 142 detailed opinions. Of the 894 observations issued during the reporting period, 418 were made by the Commission and 476 by the Member States (see Annexes 10.4 and 10.6).

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 Annexes 10.5).

In addition, the Commission drew the attention of the Member States to the need to ensure compatibility with the rules of the Agreement on technical barriers to trade when the measures concerned were also notified to the World Trade Organisation.

2.2 Use of the urgency procedure

Out of a total of 1,979 notifications, the Member States made 49 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 justified in 14 cases (see Annex 10.7).

2.3 Follow-up to Commission reactions

For 2006-2008, 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 83.7% over the period). This percentage is the main indicator used to assess Member States' commitment to meeting their obligations under the procedure. The Commission observes that the responses were mainly satisfactory (an average of 64.3% 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 10.8).

2.4 Dialogue with the Member States

The regular meetings of the Committee on Standards and Technical Regulations allowed views to be exchanged on points of general interest and also on specific aspects of the procedure.

Discussions particularly concerned the enlargement to Bulgaria and Romania, public access to documents relating to the 98/34 procedure pursuant to Regulation (EC) No 1049/2001⁶the overlap between the procedure and other Community notification procedures (“one-stop shop”), the developments in the management of the TRIS database and Member States’ obligations to respond to detailed opinions and communicate the definitive texts.

Seminars were also held in several Member States, allowing direct dialogue between the Commission and the national authorities involved in the procedure and helping the latter to become familiar with the often highly technical elements of the procedure. In addition, a conference to mark the 25th anniversary of the Directive was held in November 2008. This event was an opportunity to showcase the performance of the 98/34 mechanism and discuss prospects for the future, including how to better use the mechanism to favour the competitiveness of enterprises, in particular SMEs. It was also a chance to note the expectations of the economic operators, particularly their desire to have access to the documents exchanged under the procedure. On the same day, a new booklet entitled “Preventing obstacles to trade in the internal market – Directive 98/34” was published in all the official languages of the EU and widely distributed in the Member States (ISBN 978-92-79-09847-5).

2.5 *Infringements against the Directive*

The number of infringement proceedings (Article 226 of the EC Treaty) brought against Member States for breach of obligations under the Directive remained low during the period in question: fourteen in 2006, nine in 2007 and five in 2008.

2.6 *Conclusion*

Between 2006 and 2008, the utility of the procedure has been fully confirmed in terms of effectiveness, transparency and administrative cooperation. The fact that, in relation to the number of technical draft regulations notified, the number of infringement proceedings remains minimal shows that the correct application of Community legislation can be ensured through a preventive approach and the close partnership between the Commission and the Member States as well as between the Member States themselves.

This networking approach and the high degree of cooperation between the Commission and the 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 to detect the need to supplement or reinforce them.

When applying the 98/34 directive the Commission will remain vigilant as regards the principles of better regulation and the need to sustain a favourable environment for the competitiveness of the European economy. Therefore notified drafts continue to be available electronically, free of charge and in all the official languages of the EU. Moreover efforts will continue to provide economic operators with a legal framework that is as clear as possible,

⁶ Regulation (EC) no 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145/43 of 31.5.2001).

will continue to seek to avoid "goldplating" and provide with comments, aiming at enhancing the competitiveness of European enterprises in the EU and abroad, taking into account the links between this procedure and that established by the Agreement on technical barriers to trade (TBT) in the context of the World Trade Organisation (WTO).