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

**THE OPERATION OF DIRECTIVE 98/34/EC IN 2009 AND 2010**

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## EXECUTIVE SUMMARY

This report analyses the application in 2009 and 2010 of the procedures laid down by Directive 98/34/EC<sup>1</sup> for standardisation and technical regulations. It highlights the important contribution of standardisation and of the notification procedure for technical regulations to the functioning of the single market and to the implementation of the Better Regulation policy<sup>2</sup>.

The standardisation part consists of the information procedure on standards, the Commission requests to the European Standards Organisations (ESOs)<sup>3</sup> 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 single market. The information procedure has brought transparency to standards at national and thus also European level and has encouraged National Standards Bodies (NSBs) to continue to take initiatives at 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 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. In this respect, the notification procedure has been an important tool for guiding national regulatory activity in certain 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 the Member States has helped economic operators to reduce the cost of accessing the regulations and applying them correctly.

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<sup>1</sup> Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations 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).

<sup>2</sup> 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; *Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment*, COM(2005) 535 final; *A strategic view of Better Regulation in the European Union*, COM(2006) 689; *Second strategic review of Better Regulation in the European Union*, COM(2008) 32 and *Third strategic review of Better Regulation in the European Union*, COM(2009) 15.

<sup>3</sup> CEN (European Committee for Standardisation), CENELEC (European Committee for Electrotechnical Standardisation) and ETSI (European Telecommunications Standards Institute).

## **PART I: STANDARDISATION**

### **1. INTRODUCTION**

This section describes the operation of the standardisation part of Directive 98/34/EC covering three main activities: the information procedure on standards, Commission requests to the European Standards Organisations for standardisation work (mandates<sup>4</sup>) and formal objections against standards supporting New Approach Directives. It provides explained statistics for the period 2009-2010.

### **2. INFORMATION PROCEDURE**

The information procedure in the field of standards is designed to monitor the new standardisation activities introduced by the NSBs (as recognised under the Directive). The notification system has 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 in 2009 and 2010***

The procedure has continued to operate successfully in 2009 and 2010. From the reports provided by CEN and CENELEC each year, it is possible to see that the annual average of national measures has increased substantially in 2010. This increase is attributable mainly to ELOT<sup>5</sup> who passed from an annual average number of notifications of 1.25 for the period 2006-2009 to 464 in 2010 and to UNI<sup>6</sup> who in 2010 doubled its usual number of notifications. Annex 2 gives a breakdown of notifications by State.

Excluding the atypical number of notifications made by ELOT in 2010 and comparing the statistics of 2009-2010 with the previous period, the number of notification made by the EU-15 countries is stable at around 1500 notifications per year and the number of notifications from the EU-12 countries has dropped from 400 to 230 (see Annex 3).

The exceptional number of notifications made by ELOT comes from a decision of the Greek Ministry of Public Works to change the status of around 460 technical specifications (public and private) on National Technical Specifications. As a consequence ELOT undertook a major project to redraft the existing texts into the proper form of a National Technical Specification and check and update all references to European Standards. ELOT announced this action through the procedures of Directive 98/34/EC.

The increase of UNI notifications in 2010 is mainly due to the improvement of UNI standard elaboration and publication processes. This upward trend allowed UNI to better manage the revision of national existing standards, which are also subject to the notification. As a matter of fact, in 2010 more than 60% of UNI notifications were revisions of Italian existing standards.

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

<sup>5</sup> ELOT - Hellenic Organisation for Standardisation

<sup>6</sup> UNI - Ente Nazionale Italiano di Unificazione

The sectoral breakdown (Annex 4) shows that the construction sector, in its broadest sense, dominates the national notifications, with structures, and fire protection at the top. Food products have also been a significant area.

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.

Apart from the exceptional situation of 2010 the number of notifications has been decreasing since 2006. EU-12 countries have reduced the number of notifications during the period 2009-2010 which could be interpreted as a sign of good integration in the system as more European standards are developed compared with the national ones. In general the procedure is well applied and works correctly. The break of tendency in 2010 is not expected to continue in 2011 as it is linked to specific events.

## **2.2. Conclusion**

The information procedure still plays an important role in encouraging national standardisation bodies to bring their initiatives to European level, thus encouraging the single market and European harmonisation. Notifications from new Member States are stable which can be considered as a good sign of their integration in the system.

## **3. MANDATES**

Standardisation “mandates” are a well-established Commission tool to obtain technical specifications that support European legislation and/or policy. They are requests 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 in 2009 and 2010**

In the reporting period, a total of 41 mandates were issued to the ESOs, with 4 amendment mandates. The ratio of amendments is similar to that of previous years (see Annex 5). The number of mandates concerning New Approach Directives (9, plus the 4 amendments) has fallen compared to the previous period.

The mandating process 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. This brings greater transparency to the informal consultation.

#### **Database of mandates**

In order to increase transparency further, DG Enterprise and Industry of the Commission 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](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.

## **European standards production**

The scope of Directive 98/34/EC and of this report is limited to mandates and does not cover the standards production process itself. Nevertheless, it is important to mention that the entire system relies on the capacity of the ESOs to produce standards of high quality, with a broad consensus and on time.

Recently the European Commission has adopted the Standardisation package<sup>7</sup> which consists of a legislation proposal, a strategic communication and an impact assessment. One of the goals is to modernize the European standardisation system so that it becomes faster, more efficient, inclusive and open. Despite progress made by the ESOs during recent years, the Commission has set a goal to cut development time by 50% by 2020. As an example, in 2005 the average time for drafting a standard was of 6.20 years for CEN, 3.45 years for CENELEC and only 1.08 years for ETSI. The situation in 2009 was 2.42 years for CEN, 2.34 years for CENELEC and 1.79 years for ETSI.

With a view to promote earlier availability of mandated standards, the Commission is revising its internal procedures to make the mandating procedure faster and more transparent so that the ESOs, together with other interested parties, can better anticipate future standardisation work. In order to encourage the ESOs to continue their efforts in improving their processes, the Commission is negotiating with them on performance indicators like "on time development", "inclusiveness" and "quality" which will be linked to the future financial support to be given by the Commission. The Commission will also carry out an independent review of the standardization system to assess progress against strategic objectives and evaluate the performance of the current governance in the European standardisation system in 2013 at the latest.

### **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 31%, which shows a drop from the last reporting period. Mandates in other policy areas continue to be numerous, in particular consumer protection, environment and energy.

### **Standards in support of legislation**

In the reporting period, mandates were issued in support of a broad spectrum of legislation. Some examples include: legislation on construction products, ecodesign, general product safety or low voltage. The breadth of legislative areas shows the importance conferred on the model.

The number of mandates supporting European policy is slightly inferior compared to the previous reporting period. The mobile phone charger or the electrical vehicle charger mandates are good examples of policy mandates to promote interoperability.

The number of mandates supporting legislation outside the New Approach (see Annex 5) has significantly increased on average per year compared with the last period (from 35% to 54%) and shows that this co-regulatory model continues to be adopted across a broad range of

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<sup>7</sup> COM(2011) 311 final of 1.6.2011, COM(2011) 315 final of 1.6.2011, SEC(2011) 671 final of 1.6.2011

Commission services. Mandates supporting the eco-design Directive have been the major contributor to this increase.

Up to nine mandates<sup>8</sup> were issued during the period 2009–2010 in support of the eco-design Directive. These mandates are aimed at products such as dishwashing machines, household refrigerating appliances, circulators and electric motors.

No mandate for standardisation in the service sector has been issued for this period.

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 in, and indeed encouraged by, the Commission Communication of 2004 on the role of European standardisation in the framework of European policies and legislation<sup>9</sup>.

### **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 the ESOs and all interested parties, in particular those European stakeholders representing the users of future standards, 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-REHS and NORMAPME, to participate in its enlarged meeting.

For the sake of transparency, and thanks to the technological advantages that will be incorporated into the CIRCA<sup>10</sup> system, the services of the Commission will in future 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.

To enable wider and more effective use of mandates as a policy tool, the mandating process should be more responsive – the ESOs should respond earlier if requested European standards are market relevant, if they accept a mandate and on which conditions they accept it. Therefore, future modifications to the mandating process should make sure that clear deadlines are set for replies of the ESOs so that the Commission services have time to develop alternative solutions if the ESOs are unable or unwilling to develop European standards.

### ***Vademecum on European standardisation***

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<sup>8</sup> Mandates M450 M451, M458, M459, M462, M469, M470, M476 and M477 makes reference to the Directive 2005/32/EC

<sup>9</sup> COM(2004) 674 final of 18.10.2004.

<sup>10</sup> CIRCA is a collaborative workspace with partners of the European Institutions. More information can be found in the following URL: <http://circa.europa.eu/>

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

#### **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 in 2009 and 2010**

The number of objections that have given rise to Commission Decisions during the reporting period has been on average per year equivalent to the last period with a total of 7. In three cases, the Decision maintained the presumption of conformity; in four cases, the presumption of conformity was restricted or withdrawn (see Annex 6).

##### **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 makes decisions on formal objections public in a consolidated way, and makes an updated table of the actions in relation to the formal objections available to the Committee at each meeting.

## PART II: TECHNICAL REGULATIONS

### 1. DEVELOPMENTS IN 2009 AND 2010

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 7). 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 10).

#### **The major benefits of the procedure**

- It allows new barriers to the internal market to be detected 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 European Union legislation.
- It allows an effective dialogue between Member States and the Commission when assessing notified drafts.
- It is a benchmarking tool allowing Member States to draw on the ideas of their partners in order to solve common problems regarding technical regulations.
- It allows economic operators to make their voices heard and to 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.
- It contributes to the application of the subsidiarity principle.
- It is a regulatory instrument which can be used to identify areas where harmonisation is necessary.
- It is an instrument for industrial policy

#### **1.1. Use of the procedure within the context of “Better regulation”**

In its Communication *“Better regulation for growth and jobs in the EU”*<sup>11</sup> the Commission has highlighted that the preventive control mechanism established by Directive 98/34/EC is crucial for improving national regulations on products and Information Society services.

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<sup>11</sup> See *supra*, footnote 2.

In the framework of the Commission's action plan to simplify and improve the regulatory environment<sup>12</sup>, Member States have been invited to submit impact studies (or their conclusions) together with notified drafts, where such studies have been carried out internally. The analysis of these impact studies encourages the Member States to reflect in advance on the most appropriate instrument to be used, and allows the Commission to check the necessity and proportionality of the measures proposed.

The cooperation between the Commission and the Member States within the context of the 98/34/EC notification procedure helps to improve the clarity and consistency of the notified draft national legislations. This cooperation is to be intensified with a view to ensuring a clear and legible regulatory framework for economic operators while guaranteeing a high level of protection for public health, consumers and the environment.

The national authorities are 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 and avoidance of procedures imposing unnecessarily complex and onerous administrative burdens on economic operators, particularly when placing a product on the market.

### ***1.2. Improvements in managing the 98/34 procedure***

The Commission continued conducting various campaigns during 2009-2010 to increase transparency and dialogue with the national authorities. The operation of the TRIS (*“Technical Regulations Information System”*) database has seen continuous improvement and the new version TRIS v2.0 has been launched in 2010, with the aim of reducing the processing time of notifications and messages and allowing a direct connection between TRIS and national databases in Member States.

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: in 2009 and 2010 the number of searches rose by 23.4% to reach approximately 192,000 searches in 2010 (see Annex 11).

## **2. APPLICATION OF THE 98/34 PROCEDURE**

### ***2.1. Effectiveness: general overview***

#### **► Volume of notifications and sectors involved**

In 2009 and 2010, the total number of notified drafts increased in comparison with the previous period (1,525 notifications for 2009 and 2010 as opposed to 1,979 for 2006, 2007 and 2008).

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<sup>12</sup> See *supra*, footnote 2.

**The construction sector again saw the highest number of notifications** over the reporting period. Many measures related to energy efficiency of buildings and labelling of construction and decoration products regarding their volatile pollutant emissions. Construction was followed by **agricultural products and foodstuffs**. In this sector, several measures concerned food hygiene, genetically modified organisms, the composition and labelling of foodstuffs and beverages. Notifications increased significantly in the **transport sector** where many notifications related to traffic signals, vehicle safety, tractors and motor vehicle devices. Several notifications were received in the **telecommunication sector**, mainly concerning radio interfaces, and in the **environment sector** (eco-contribution on plastic bags, management of waste batteries and accumulators and labelling of reusable drink packaging) (see Annexes 9.3).

### ► Issues examined

In the **non-harmonised areas**, subject to compliance with Articles 34-36 (free movement of goods) and 49 and 56 (right of establishment and freedom to provide services) of the Treaty on the Functioning of the European Union, the Commission's reactions were intended to warn Member States of potential obstacles to trade which could be created by unnecessary measures disproportionate to the objectives pursued. Thus the Commission ensured compliance with these principles and in addition continued to invite Member States to insert mutual recognition clauses into each draft technical regulation falling outside the harmonised area.

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

- Since 2009, Member States have notified a high number of draft technical regulations in the field of **construction**. These drafts concerned all types of construction products (dangerous substances, wooden materials, fire fighting equipments, supporting structures made from concrete, reinforced concrete, heat generators etc.), their properties (mechanical resistance and stability, fire resistance, insulating properties, etc.) and their labelling (in particular, labelling on volatile pollutant emissions). They were analysed principally under Directive 89/106/EEC<sup>13</sup> on construction products and the harmonised standards adopted in the context of this Directive as well as Directive 2002/91/EC<sup>14</sup> on the energy performance of buildings, repealed by Directive 2010/31/EU<sup>15</sup>.

In particular, the Commission issued detailed opinions and comments concerning draft technical regulations relating to the labelling of construction and decoration products regarding their volatile pollutant emissions. The notified drafts were examined in the light of Directive 1999/45/EC<sup>16</sup> relating to the classification,

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<sup>13</sup> Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (OJ L 40, 11.2.1989, p. 12-26)

<sup>14</sup> Directive 2002/91/EC of the European Parliament and of the Council of 16 December 2002 on the energy performance of buildings (OJ L 1, 4.1.2003, p. 65-71)

<sup>15</sup> Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings (OJ L 153, 18.6.2010, p. 13-35)

<sup>16</sup> Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1-68)

packaging and labeling of dangerous preparations and Regulation (EC) No 1272/2008<sup>17</sup> on classification, labelling and packaging of substances and mixtures.

These drafts have prompted a number of reactions from several Member States who issued detailed opinions raising the issue of compatibility of the measures notified with the principles of the free movement of goods in the internal market.

- Member States notified several drafts on genetically modified organisms (GMOs). The notifications related in particular to the right to place GMOs on the market, to ban or restrict their cultivation and to their dispersal in the environment. They have been analysed in the light of Directive 2001/18/EC<sup>18</sup> on the deliberate release into the environment of genetically modified organisms, Regulation (EC) No 1829/2003<sup>19</sup> on genetically modified food and feed and Regulation (EC) No 1830/2003<sup>20</sup> on the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, and Commission Recommendation on Co-existence measures (2010/C 200/01)<sup>21</sup>.
- In 2009 and 2010, Member States have notified drafts concerning food supplements, materials intended to come into contact with foodstuffs (containers, packaging and utensils manufactured from stainless steels, labelling of gold-plated, silver-plated and related items), mineral, spring and drinking water, equipment for the treatment of water for human consumption, hygiene of foodstuff. Certain Member States notified draft regulations on the restriction or interdiction of the use of Bisphenol A in babies' bottles and materials and objects which are designed or are intended to come into contact with food. In this regard, it is important to point out that Directive 2011/8/EU<sup>22</sup> amending Directive 2002/72/EC<sup>23</sup> as regards the restriction of use of Bisphenol A in plastic infant feeding bottles has been adopted in January 2011 and provides for the prohibition from 1 March 2011 of the manufacture, and from 1 June 2011 of the placing on the market and importation into the European Union, of plastic infant feeding bottles

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<sup>17</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1-1355)

<sup>18</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (OJ L 106, 17.4.2001, p. 1-39)

<sup>19</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1-23)

<sup>20</sup> Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24-28)

<sup>21</sup> Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (OJ C 200/1, 22.7.2010)

<sup>22</sup> Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (OJ L 26, 29.1.2011, p. 11-14)

<sup>23</sup> Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 220, 15.8.2002, p. 18-58)

- In the Information Society services sector numerous were the notifications on radio interfaces; others concerned, inter alia, on-line gambling, pricing of digital books, electronic tax registers, EPoS systems (Electronic Point of Sale) and electronic signature devices, interoperability of information systems.
- In the environment sector the Commission examined in particular draft regulations on the labelling of drink packaging, labelling of batteries, labelling of plastic bags and PVC packaging. These notifications have been analysed in the light of Directive 94/62/EC<sup>24</sup> on packaging and packaging waste and Directive 2006/66/EC<sup>25</sup> on batteries and accumulators and waste batteries and accumulators.
- The procedure has also allowed intervention in the sectors where harmonisation was envisaged at European Union level and has prevented Member States from introducing divergent national measures, as in the case of the promotion of electricity production from liquid biomass, the compulsory mention of the origin of foodstuff on labelling, the importation and transit of seal-based products, the approval standards for test bench equipment for roller brakes for vehicles with a total mass in excess of 3.5 tonnes, labeling and presentation of foodstuff, quality of table grapes, recycling of spent lead acid batteries and accumulators, the production of fermented alcoholic beverages other than beer and wine, and combustion plants and remote heating power stations.

### ► **Reactions**

The Commission issued detailed opinions in relation to 105 notifications, which represents 7% of the total number of drafts notified by the 27 Member States over the reporting period. This figure shows a fall in the number of detailed opinions issued by the Commission compared to the previous reporting period, suggesting that the Member States are legislating increasingly with the European Union legislation and principles in mind and taking into account the requirements of an effectively functioning internal market. For their part, the Member States issued 130 detailed opinions. Of the 616 observations issued during the reporting period, 262 were made by the Commission and 354 by the Member States (see Annexes 9.4 and 9.6).

In 11 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 European Union harmonisation work underway in the area (see Annexes 9.5).

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.

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<sup>24</sup> European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10-23)

<sup>25</sup> Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266, 26.9.2006, p. 1-14)

## **2.2. Use of the urgency procedure**

Out of a total of 1525 notifications, the Member States made 52 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 29 cases, mainly concerning psychotropic substances, control of narcotics, pollutants, games of chance, security bags and the private security sector (transport of dangerous goods, weapons, safes, alarms, money and valuable items) (see Annex 9.7).

## **2.3. Follow-up to Commission reactions**

In 2009-2010, 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 89.5% 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 number of satisfactory responses was not high (an average of 32.5% over the period) (see Annex 9.8).

## **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.

The discussions particularly concerned the development of the new TRIS database, the quality of the translation of the notified texts, the fiscal measures intended to deal with the economic and financial crisis to be notified under Directive 98/34/EC, the question of the confidentiality of certain notified drafts, the links between Regulation (EC) No 764/2008<sup>26</sup> of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and Directive 98/34/EC.

The guidelines relating respectively to the blockage foreseen in Article 9, paragraphs 3 and 4 and to the urgency procedure laid down in Article 9, paragraph 7, of Directive 98/34/EC were presented by the Commission.

Moreover, the Commission made a presentation of the new TRIS v2.0 database, of the "one-stop-shop" (single entry point for notifications by EU Member States – including when they are obliged to notify documents according to other EU acts) and of the guide for the application of the Treaty provisions governing the free movement of goods.

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 highly technical elements of the procedure.

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<sup>26</sup> Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L 218, 13.8.2008, p. 21-29)

During a seminar held in November 2008 on the occasion of the 25<sup>th</sup> anniversary of Directive 98/34/EC, proposals and suggestions on the functioning of the notification procedure were formulated by Member States and by economic operators. Inspired by those requests, it was decided, on the initiative of the Commission, to set up a Working Group on the functioning of Directive 98/34/EC.

This Working Group examines how the notification procedure worked so far and if and how its functioning could be improved through administrative adjustments or, if necessary, through the introduction of changes to the Directive currently in force.

The group comprises representatives of twelve Member States (the 98/34 Contact Points of Austria, the Czech Republic, Denmark, France, Germany, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia and the United Kingdom) and is chaired by the Commission's service responsible for the management of the 98/34 notification procedure.

The first meeting of the Working Group was held on 12 April 2010 and discussed problems relating, on the one hand, to the three months standstill period of notified draft regulations and its possible reduction and, on the other hand, to the consequences of the case-law of the European Court of Justice "*CIA Security and Unilever*" (unenforceability of non notified regulations) with regard to national texts which comply in substance with EU law, but which were adopted without being notified under the 98/34/EC procedure, or which were adopted during the standstill period, or which were substantially modified during the standstill period.

During the second meeting, held on 29 June 2010 the Working Group dealt with the extension of the initial standstill period by three more months (one month for Information Society services) only when the Commission (and not other Member States) issues a detailed opinion. It also discussed the possibility of providing for a minimum standstill period to be observed for fiscal, financial and urgent measures, in order to allow time for their proper examination.

The third meeting took place on 27 October 2010 and focused on the issue of public access to documents exchanged in the framework of the 98/34/EC procedure and the development of the "one-stop-shop" function of Directive 98/34/EC.

## **2.5. *Infringements against the Directive***

The number of infringement proceedings (Article 258 of the TFUE) brought against Member States for breach of obligations under the Directive remained low during the period in question: three in 2009 and seven in 2010.

## **2.6. *Conclusion***

During 2009 and 2010, the utility of the procedure has again been confirmed in terms of effectiveness, transparency and administrative cooperation.

The preventive and networking approach of the 98/34 procedure has ensured that national regulatory activities have been carried out without creating technical barriers to trade and that European Union harmonisation has occurred only where really needed, in strict compliance with the subsidiarity principle. The fact that the number of infringement proceedings remained low during the reporting period shows that Directive 98/34/EC is an important tool for ensuring the correct application of European Union legislation.

When applying Directive 98/34/EC the Commission remains vigilant regarding the principle of better regulation and the need to sustain a favourable environment for the competitiveness of the European economy. Notified drafts continue to be available electronically, free of charge and in all the official languages of the EU, thus providing the opportunity for economic operators to comment on them.

Efforts will continue in order to ensure a clear legal framework for economic operators aiming at enhancing the competitiveness of European enterprises in the EU and abroad, taking into account the links between the 98/34 procedure and that established by the Agreement on Technical Barriers to Trade (TBT) in the context of the World Trade Organisation (WTO).