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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 FROM 2011 TO 2013

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EXECUTIVE SUMMARY

This report analyses the application of the procedures laid down by Directive 98/34/EC¹ from 2011 to 2013 as regards technical regulations and for 2011 and 2012 as regards standards (the standardisation part of Directive 98/34/EC was repealed as of 1 January 2013 by Regulation (EU) No 1025/2012 on European standardisation², in order to better address future challenges in European standardisation). It highlights the important contribution of the notification procedure to the functioning of the single market and to the implementation of the Better Regulation policy³.

The standardisation part consists of the information procedure on standards, the Commission requests to the European Standards Organisations (ESOs)⁴ 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, which in turn promotes 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 standardisation bodies 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 again 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 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 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 reduce the cost of accessing the regulations and applying them correctly.

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 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, OJ L 316, 14.11.2012, p. 12–33.

³ 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, *Third strategic review of Better Regulation in the European Union*, COM(2009) 15 and *Smart Regulation in the European Union*; COM(2010)543.

⁴ 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 (mandates⁵), and formal objections against standards supporting New Approach Directives. It provides and explains statistics for the period 2011-2012, as the standardisation part of Directive 98/34/EC was repealed as of 1 January 2013 by Regulation (EU) No 1025/2012 on European standardisation.

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 Directive 98/34/EC). The notification system was 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).

1.1. Operation of the procedure from 2011 to 2012

The procedure continued to operate successfully from 2011 to 2012. From the reports provided by CEN and CENELEC each year, it is possible to see that the annual average of national measures remained relatively stable in 2011 and 2012. Annex 2 gives a breakdown of notifications by Member State.

Comparing the statistics of 2011-2012 with the previous periods, the number of notifications made by the EU27 countries continued to be stable with between 1750 and 2000 notifications per year (not considering the exceptional situation in 2010).

The sectoral breakdown (Annex 3) shows that the construction sector, in its broadest sense, continues to dominate the national notifications in CEN. Food products and petroleum products have also been a significant area in CEN. In CENELEC, electrical accessories, electric cables, and electrical installations in buildings have been significant subsectors both in 2011 and 2012.

The information disseminated under the procedure continued 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 rather exceptional situation of 2010 the number of notifications has been relatively stable, or even decreasing since 2006. This applies also to the Member States which joined the EU in 2004 and 2007 and could be interpreted as a sign of good integration in the system as the standardisation activity appears to be moving from the national to the European level. In general the procedure is well applied and works correctly.

1.2. Conclusion

The information procedure still plays an important role in encouraging national standardisation bodies to bring their initiatives to the European level, thus encouraging the

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

single market and European harmonisation. Notifications from EU 12 Member States are stable which can be considered as a good sign of their integration in the system.

As of 1 January 2013, the standardisation part of Directive 98/34/EC was repealed by Regulation (EU) No 1025/2012 on European standardisation in order to better address future challenges in European standardisation. This relates in particular to the increased development of standards for services, the evolution of standardisation deliverables other than formal standards, and increased requirements on the inclusiveness of the European standardisation system. Regulation (EU) No 1025/2012 however maintains a similar information procedure operated under Directive 98/34/EC, even though with minor changes.

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.

1.3. Operation of the mandating process 2011-2012

In the reporting period, a total of 43 mandates were issued to the ESOs, with 8 amendment mandates. The ratio of amendments is relatively higher compared to that of previous years (see Annex 4). Also the number of mandates concerning New Approach Directives (13, plus the 8 amendments) has increased compared to the previous period.

The mandating process functions well. The informal consultation carried out before the documents are circulated to the members of the Committee on Standards and Technical Regulations 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 during the reporting period. This brings greater transparency to the informal consultation.

In order to increase transparency further, DG Internal Market, Industry, Entrepreneurship and SMEs maintains a database of mandates. It contains all mandates issued in the past with the numbering series M/xxx. This database is publicly accessible on the internet at:

<http://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.welcome>

The practice of giving a follow-up to all the mandate consultations to the Committee on Standards and Technical Regulations by means of an updated list has continued throughout the period.

1.4. Trends in mandates

In the reporting period, mandates were issued in support of a broad spectrum of legislation. The most significant areas include legislation on construction products, ecodesign, consumer protection, and environmental protection. The breadth of legislative areas shows the importance conferred on the model.

The subject matter for mandates continues to broaden. At the same time, mandates issued for the New Approach Directives are still very important, and their number has actually increased compared to the previous reporting periods. Mandates in other policy areas continue to be numerous, in particular consumer protection and the environment.

The number of mandates supporting legislation outside the New Approach (see Annex 4) has remained relatively high compared with the last period and shows that this co-regulatory model continues to be adopted across a broad range of EU policies. Mandates supporting Directive 2009/125/EC (the Ecodesign Directive) have been a major contributor in this field.

Six mandates⁶ were issued during the period 2011–2012 in support of the Ecodesign Directive. These mandates are aimed at products such as household dishwashers, lamps, air conditioners, pumps or fans.

This trend for the use of mandates in support of legislation outside the New Approach and in new areas 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 2011 'A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020'⁷.

The number of mandates supporting European policy continued to drop and is for the second consecutive time slightly inferior compared to the previous reporting period. Nevertheless, amongst the five policy mandates are some key initiatives to promote interoperability such as the mandate on smart grids or the mandate on the space industry.

No mandate for standardisation in the service sector was issued during this period.

1.5. Conclusion

The process of mandating is well-established and is today governed by Regulation (EU) No 1025/2012. The informal consultation of the ESOs and all interested parties (in particular those European stakeholders representing the users of future standards) prior to the consultation of the Committee on Standards and Technical Regulations is essential.

To improve transparency in the functioning of the Committee on Standards and Technical Regulations, the Commission services continued in the reporting period in the practice introduced in 2006 to invite the European standardisation stakeholders ANEC, ECOS, ETUI-REHS and NORMAPME, to participate in its enlarged meeting.

The process of mandating has proved to be instrumental in enlarging the role of standardisation in new areas of EU legislation and policy.

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 on Standards and Technical Regulations is consulted (see Annex 1 for the details of the procedure).

⁶ Mandates M481, M485, M488, M495, M498 and M500 make reference to the Directive 2005/32/EC
⁷ COM(2011) 311 final of 01.06.2011.

1.6. Operation of the procedure from 2011 to 2012

Compared to previous years, the number of objections that have given rise to Commission Decisions has slightly decreased during the reporting period. Only one Decision was adopted by the Commission which restricted the presumption of conformity. This Decision however concerned two formal objections against an identical harmonised standard (see Annex 5).

1.7. Conclusion

The procedure in general has worked adequately. Compared to the previous reporting period, the process from receiving the objection to issuing the Decision was shortened significantly in 2011 and 2012.

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 on Standards and Technical Regulations at each meeting.

5. NEW LEGISLATIVE FRAMEWORK

As of 1 January 2013, the standardisation part of Directive 98/34/EC was repealed by Regulation (EU) No 1025/2012 on European standardisation which introduced significant changes with respect to the information procedure, mandating procedure and formal objections.

A specific report on the implementation of the Regulation (EU) No 1025/2012 for the period from 2013 to 2015 will be presented to the European Parliament and to the Council in accordance with Article 24(3) of the Regulation.

PART II: TECHNICAL REGULATIONS

1. DEVELOPMENTS 2011-2013

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 6). It applies in a simplified manner to the European Free Trade Association (EFTA) Member States which are signatories to the Agreement on the European Economic Area (EEA) and to Switzerland and Turkey (see Annex 9).

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, including small and medium-sized enterprises (SMEs), 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 helps to improve the quality of national and EU regulations in line with the "*Better regulation*" approach.
- It contributes to improving competitiveness of enterprises in the context of industrial policy.

1.8. Use of the procedure within the context of "*Better regulation*"

In its Communication "*Better regulation for growth and jobs in the EU*"⁸ 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.

In the framework of the Commission's action plan to simplify and improve the regulatory environment⁹, Member States have been invited to submit impact studies (or their

⁸ See *supra*, footnote 3.

⁹ See *supra*, footnote 3.

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 will 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.

1.9. Use of the procedure to improve competitiveness

In the framework of the EU 2020 strategy, a new approach of the industrial policy based on competitiveness analysis of legislation has been proposed.

In this context, in the latest update of the Communication on Industrial Policy of 10 October 2012 - ***Communication of the Commission to the European Parliament, to the Council, to the European Social and Economic Committee and to the Committee of the Regions - A stronger European industry at the service of economic growth and re-launch - COM (2012)582 final*** – the Commission underlined that:

“Governance and regulatory obstacles to the Internal Market also arise from policy areas that are regulated by Member States, for example technical rules, refusals to apply mutual recognition and mismatches between the 27 different sets of taxation rules. An upstream analysis of draft technical rules can prevent the emergence of regulatory obstacles. This is precisely the objective of the 98/34 notification procedure, which requires draft legislation containing technical rules on products and information society services to be communicated to the Commission before they are adopted. The preventive nature of this procedure has avoided a large number of contraventions of free movement of goods rules. This notification procedure can also be used, however, to improve national legislation in line with "Better Regulation" principles and through benchmarking. Its potential can be further exploited by recommending that Member States use competitiveness proofing in the context of national impact assessments.”.

The Communication of the Commission on industrial policy makes an explicit reference to Directive 98/34/EC which, beside to its role as an instrument for prevention of obstacles to intra-EU trade has the task to encourage Member States to proceed to a competitiveness analysis of national legislation.

This approach was endorsed by the Committee on Industry, Research and Energy of the European Parliament in its ***Report of 18 December 2013 on reindustrialising Europe to promote competitiveness and sustainability ((2013/2006(INI))*** where it encouraged further exploitation of the potential of the 98/34 notification procedure and suggested that the

Member States introduce competitiveness proofing in impact assessments conducted at the drafting stages of national legislative processes, in the wider framework of the ‘Single Market Test’ called for in Parliament’s resolution of 7 February 2013 with recommendations to the Commission on the governance of the Single Market.

In this context, Member States, as of March 2014, have been invited to prepare on a regular basis a competitiveness analysis of the national legislation notified under the scope of the procedure established by Directive 98/34/EC.

1.10. Improvements in managing the 98/34 procedure

The Commission continued conducting various campaigns during 2011-2013 to increase transparency and dialogue with the national authorities. The TRIS (*Technical Regulations Information System*) database has seen continuous improvement.

The Commission worked on the revamping of the TRIS public website, (<http://ec.europa.eu/growth/tools-databases/tris/en/>), to explain the 98/34 procedure in a more accessible way and to reach a wider audience, especially SMEs. The website ensures public access to the notified drafts, in the 23 official languages of the EU, and to essential information regarding the procedure. A constant increase in the number of on-line consultations has been observed: from 2011 to 2013 the number of searches rose by 10% to reach approximately 212,000 searches in 2013 (see Annex 10). More than 4300 economic operators subscribed to the TRIS mailing list, which is a rise of 25% since 2010.

In 2012-2013, the Commission also produced a video on the 98/34 procedure. The message was to explain in a simple and attractive way the functioning of the procedure and its benefits for enterprises, to encourage active participation by enterprises, especially SMEs, and explain how they can make best use of the existing tools (websites, databases, alert systems). This video was published on 11 September 2013 and is accessible using the following link - <http://www.youtube.com/watch?v=ziuAklsNKdI>. It has been promoted on social networks and was viewed 2675 times by stakeholders since its publication.

2. APPLICATION OF THE 98/34 PROCEDURE

1.11. Effectiveness: general overview

► Volume of notifications and sectors involved

From 2011 to 2013, the Commission received 2114 notifications (675 in 2011, 734 in 2012 and 705 in 2013).

Like in the previous reporting period, the construction sector saw the highest number of notifications over the reporting period. Many measures related to energy efficiency of buildings and concrete structures, road pavements and constituent materials, fire safety of buildings. Construction was again followed by **agricultural products, foodstuffs and beverages**. In this sector, several measures concerned food hygiene, the composition and labelling of foodstuffs and beverages, food packaging, minimum price for alcoholic beverages, composition and marketing of alcoholic and non-alcoholic beverages. Notifications increased in the **telecommunications sector** (radio equipment and telecommunications terminal equipment, radio interfaces, hardware and software for the collection, management and use of data gathered by electronic mechanisms installed on board vehicles (black box)) and in the **environment sector** (packaging and packaging waste, recyclable products, processing of biodegradable waste) (see Annex 8.3).

► 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 (TFEU), the Commission's reactions were intended to draw Member States' attention to potential obstacles to trade which could be created by an unnecessary measure disproportionate to the objective 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 the **harmonised areas**, the reactions were intended to ensure that national measures were necessary, justified and compatible with EU secondary legislation.

- In 2011, 2012 and 2013 Member States notified 512 draft technical regulations in the field of **construction**. These drafts concerned all types of construction products, *inter alia*, bridge structures and concrete road structures, pitched roof coverings for buildings, fire-fighting and rescue equipment, thermal insulation, synthetic fill materials, concrete structures, electrical installations on and in concrete structures, metallic materials in contact with drinking water.

In particular, the Commission examined draft technical regulations setting additional technical requirements or tests for construction products impeding the free movement of products labelled with the CE mark. The notified drafts were examined principally under Directive 89/106/EEC on construction products¹⁰ and Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC¹¹.

The Commission also examined draft legislation prohibiting the installation of fossil oil furnaces and natural gas furnaces in new buildings except when oil and gas furnaces use only renewable energy. The notified draft was examined under Directive 2009/142/EC on gas appliances (GAD)¹² and Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels¹³.

Technical regulations relating to energy efficiency of buildings were assessed under Directive 2012/27/EU on energy efficiency¹⁴, Directive 2010/31/EU on the energy

¹⁰ 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.

¹¹ Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 88, 4.4.2011, p. 5–43.

¹² Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels, OJ L 330, 16.12.2009, p. 10–27.

¹³ Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels, OJ L 167, 22.6.1992, p. 17–28.

¹⁴ Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC, OJ L 315, 14.11.2012, p. 1–56.

performance of buildings¹⁵ and Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products¹⁶.

- In the foodstuffs and agricultural sectors, from 2011 to 2013 Member States notified 393 draft technical regulations. These drafts concerned, *inter alia*, materials coming into contact with foodstuff, energy drinks, trans fats in food products, wine and spirits, labelling of foodstuff, in particular nutritional declarations, quality marks, the well-being of fur animals and the marketing of fur products.

Certain Member States notified draft regulations imposing restrictions on or prohibition of food packaging containing bisphenol A and in particular packaging for foods intended for children between 0 and 3 years, as well as concerning health warning to be affixed to packaging containing bisphenol A. These notifications have been examined under the Treaty provisions on the free movement of goods and Regulation (EC) No 1935/2004 concerning materials and articles intended to come into contact with food.¹⁷

During the relevant period the Commission examined many notifications concerning the hygiene of foodstuffs and issued detailed opinions and comments on the basis of Regulations (EC) No 852/2004 on the hygiene of foodstuffs¹⁸, (EC) No 853/2004 laying down specific hygiene rules for food of animal origin¹⁹ and (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption²⁰.

Other notifications concerned the labelling of foodstuff and the Commission assessed their compatibility with Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs²¹ and Regulation (EU) No 1169/2011 on the provision of food information to consumers.²²

- In the Information Society services sector there were 99 notifications. Numerous notifications were in the area of gambling, while others concerned, *inter alia*,

¹⁵ 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.

¹⁶ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products, OJ L 285, 31.10.2009, p. 10–35.

¹⁷ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p. 4–17.

¹⁸ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1–54.

¹⁹ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, OJ L 139, 30.4.2004, p. 55–205.

²⁰ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, OJ L 139, 30.4.2004, p. 206–320.

²¹ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29–42.

²² Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18–63.

copyright in the digital environment, on demand audio-visual media services, electronic commerce, electronic signature and other trust services.

- Since 2011, Member States have notified a series of technical regulations concerning measuring instruments. These drafts concerned various types of measuring devices such as gas, electricity and heat meters, taximeters or prism refractometers and provided for specific requirements which these instruments have to fulfil. The notifications on gas, electricity and heat meters and taximeters were mainly analysed under Directive 2004/22/EC on measuring instruments²³. The novelty consisted of projects of new smart metering systems, also falling under Directive 2004/22/EC, which are quite complex due to the needs of the combination of engineering with IT and communication, data privacy and security aspects.
- In the chemicals sector the Commission received 76 notifications. Some of them regarded the annual declaration of nanoparticle substances as well as draft legislation banning the import and sale of products containing certain phthalates intended for indoor use or which may come into contact with skin or mucous membranes. The notified drafts were mainly examined under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)²⁴.
- In the environment sector the Commission examined 141 draft regulations. Some notified drafts established conditions for the use of environmental claims on plastic objects and packaging while others prohibited the marketing of non-biodegradable shopping bags. These notifications have been mainly analysed in the light of Directive 94/62/EC on packaging and packaging waste²⁵.

The 98/34 procedure has also allowed the Commission to intervene in sectors where harmonisation was envisaged or under way at European Union level and thus has prevented Member States from introducing divergent national measures. Pursuant to Articles 9(3) and 9(4) of Directive 98/34/EC, the Commission has blocked the adoption of notified draft legislation for twelve months from the date of notification in the fields of: type-approval requirements for masses and dimensions of motor vehicles and their trailers; marketing and use of explosives precursors; the indication of the origin of olive oil on the label and the methods for such indication; compounds terms for spirit drinks; electronic identification and trust services for electronic transactions; fertilisers allowed in organic production. Through this type of intervention, not only has the Commission avoided the fragmentation of the market in areas where harmonisation was envisaged or under way, but it has also granted greater certainty and stability in the legal framework of Member States and of the European Union to the benefit of economic operators and of the competitiveness of European enterprises.

► **Reactions**

²³ Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments, OJ L 135, 30.4.2004, p. 1–80.

²⁴ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1–849.

²⁵ 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.

The Commission issued detailed opinions in relation to 208 notifications, which represents 9.8% of the total number of drafts notified by the Member States over the reporting period. This figure shows a 29.2% increase in the number of detailed opinions issued by the Commission compared to the previous three years. For their part, the Member States issued 205 detailed opinions. Of the 910 comments issued during the reporting period, 425 were made by the Commission and 485 by the Member States (see Annexes 8.4 and 8.6).

In 12 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 because there was European Union harmonisation work under way in the area (see Annex 8.5).

1.12. Use of the urgency procedure

Out of a total of 2114 notifications, the Member States made 87 requests to apply the urgency procedure to notified drafts. The Commission confirmed its strict interpretation of the exceptional conditions required by Directive 98/34/EC, 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 was not sufficiently established or was based on purely economic grounds or national administrative delay as well as in cases where no unforeseeable circumstances were demonstrated. The urgency procedure was deemed justified in 56 cases, in particular concerning psychotropic substances, control of narcotics, radioactive waste, infection of bees, poisonings caused by methanol intoxication, explosive precursors, protection of cash transports, prohibition of products that are harmful to health, prohibition of the possession and use of fireworks not intended for private individuals. (see Annex 8.7).

1.13. Notification of 'fiscal or financial incentive measures'

According to Directive 98/34, Member States have to notify fiscal and financial incentives, i.e. technical regulations which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical regulations. The specificity of such technical regulations is that the standstill period does not apply.

During the period 2011-2013 Member States notified 112 draft regulations as '*fiscal or financial measures*'. The Commission observes that often national legislation is misclassified as '*fiscal or financial measure*' in the meaning of Directive 98/34/EC when it contains any fiscal or financial measures but not the incentive to comply with such technical regulations. In order to help Member States to correctly classify these technical regulations the Commission drafted Guidelines on the definition and notification of '*fiscal or financial measures*' for the purposes of Directive 98/34/EC.

1.14. Follow-up to Commission reactions

From 2011 to 2013, 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 86% over the period). This percentage is the main indicator used to assess Member States' commitment to meeting their obligations under the procedure. The number of completely satisfactory responses was higher in comparison with the previous reporting period (an average of 48.4% over the period 2011-2013 in comparison with 32.5% over the period 2009-2010) (see Annex 8.8), showing an increased compliance of Members States with the internal market legal framework following the Commission's reaction. The effect of Commission's reactions was even more remarkable in the case of notified draft technical regulations which were withdrawn following the delivery of a detailed opinion (24 cases for the reporting period). For other notified draft technical regulations the dialogue is still on-going.

1.15. Follow-up to the notification procedure

For all other cases where the potential breaches of the EU internal market law have not been entirely cleared within the framework of the 98/34/EC procedure, the Commission conducted further investigations which in some cases, eventually led, to EU Pilots or to infringement proceedings (Article 258 of the TFEU) on subjects such as quality and transparency of the supply chain for virgin olive oils, taxation of food products with high sugar, salt, and/or caffeine content, environmental protection product charges, traditional food production, wine and spirits, banning of products intended for indoor use which contain certain types of phthalates, products made of leather, hide and fur, minimum content of fruit juice that must be contained in non-alcoholic fruit-based beverages and plastic bags.

Two of the infringement proceedings brought against Member States during the reporting period were grounded on the breach of obligations under Directive 98/34/EC.

1.16. 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.

As regards technical regulations, the discussions particularly concerned the role of notifications for national competitiveness issues and competitiveness proofing; access to documents of the Commission under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents²⁶; the obligation for Member States to communicate to the Commission the final text of a notified technical regulation; and the legal consequences of the delivery of a detailed opinion under Article 9(2) of Directive 98/34/EC.

The Commission made presentations concerning Regulation (EU) No 1169/2011 on the provision of food information to consumers; the review of Regulation (EC) No 1907/2006 (REACH); the Product Safety and Market Surveillance Package; the evaluation report of Directive 2006/123/EC on services in the internal market²⁷; the state of play of the internal market in the construction sector; issues related to technical regulations in the area of renewable energy sources; notifications about metrology and notifications in the railway sector, in particular notification obligations in the framework of Directive 2004/49/EC on safety on the Community's railways²⁸ and Directive 2008/57/EC on the interoperability of the rail system within the Community²⁹.

Guidelines on the definition and notification of '*fiscal or financial measures*' for the purposes of Directive 98/34/EC, and guidelines on the "*One-stop-shop for the 98/34 notification procedure and for the notification procedures laid down in specific EU rules*" were presented by the Commission.

²⁶ 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, 31.5.2001, p. 43-48.

²⁷ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ L 376, 27.12.2006, p. 36-68.

²⁸ Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification, OJ L 164, 30.4.2004, p. 44-113.

²⁹ Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community, OJ L 191, 18.7.2008, p. 1-45.

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.

1.17. *Requests for access to documents issued under Directive 98/34*

From 2011 to 2013 the Commission received 272 requests for access to documents issued in the framework of the 98/34 procedure. The major part of them concerned detailed opinions and comments delivered by the Commission. In 167 of the cases, access to the requested documents was given. In the other cases, access to documents was refused while the dialogue with the Member States, aimed at removing the potential obstacle to trade, was ongoing.

1.18. *Conclusion*

During the period 2011-2013, the usefulness 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 substantially reduced the risk of national regulatory activities being carried out in a way that would create technical barriers to the free movement of goods within the internal market. The high number of detailed opinions and comments issued during the reporting period demonstrates that there is still a risk of fragmentation of the internal market for goods. On average 86% of the detailed opinions issued by the Commission during the period were replied to by the Member States concerned and dialogues followed to remove any incompatibility with EU law and ensure the free movement of goods within the internal market, thus avoiding infringement procedures.

The 98/34 procedure has also confirmed its usefulness in providing the possibility to identify areas where harmonisation at EU level might be an option.

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 and other stakeholders 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). Further promotion of the Directive and its stronger implementation together with a stronger link with follow-up policy and legislative actions are crucial in order to fully achieve its objectives.