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

ON THE OPERATION OF DIRECTIVE (EU) 2015/1535 FROM 2014 TO 2015

{SWD(2017) 465 final}

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EXECUTIVE SUMMARY

This report analyses the application of one of the cornerstones of the internal market from 2014 to 2015: the notification procedure laid down by Directive (EU) 2015/1535¹ (hereinafter referred to as the "*Single Market Transparency Directive*"). The report highlights the important contribution of the notification procedure to the functioning of the Single Market and to the implementation of the Better Regulation policy².

Directive (EU) 2015/1535 was adopted on 9 September 2015 and repealed and replaced Directive 98/34/EC. Since Directive 98/34/EC had been substantially amended several times (notably to include Information Society services and to remove technical standards from its scope), a decision was taken to codify it in the interest of clarity.

The notification to the Commission of national technical regulations prior to their adoption has continued 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 including in certain emerging sectors and improving the quality of national technical regulations - in terms of transparency, legibility and effectiveness - in non-harmonised or partly harmonised areas. The greater clarity in the legal framework of the Member States can help economic operators to adapt to the new rules and thus reduce the cost of accessing the regulations and apply them correctly. This is possible also thanks to the fact that technical regulations notified to the Commission are translated into 23 official languages of the EU³.

¹ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification; OJ L 241, 17.9.2015, p. 1–15).

² 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 *Smart Regulation in the European Union*; COM(2010)543 and COM(2016) 615 final, *Better Regulation: Delivering better results for a stronger Union*.

³ Irish translation is not available.

INTRODUCTION

The notification procedure for national technical regulations allows the Commission and the Member States of the EU to examine before adoption the technical regulations Member States intend to introduce for products (industrial, agricultural and fishery) and for Information Society services (see Annex 1 of the Commission Staff Working Document accompanying this Report). 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 3).

The main purpose of the notification procedure is to prevent the creation of new barriers to the internal market before they have been put in place and have produced any negative effects.

The internal market is one of the Commission's 10 priorities and the Commission considers a better functioning Single Market as an engine for building a stronger EU economy and "*Europe's best asset in times of increasing globalisation*".⁴ For this reason, together with the Member States the Commission endeavours to unlock the full potential of the Single Market "*so that citizens, business and public authorities can access goods and services for the best quality, price or service*".⁵ As stated in the Single Market Strategy, "*[T]he Single Market is arguably among European Union's greatest achievements*"⁶ and the Commission considers it a priority to remove remaining regulatory and non-regulatory barriers to the Single Market for goods and services. The European Commission has decided to give the Single Market a new boost with a number of ambitious and pragmatic actions in key areas for the EU internal market such as circular economy, collaborative economy, the Digital Single Market, the Capital Market Union and taxation.

In its Communication "*Upgrading the Single Market: more opportunities for people and business*"⁷ the Commission has stressed that "*[g]oods generate around 75 % of intra-EU trade [and that in] 2014, trade in goods between EU Member States was valued at EUR 2 900 billion*", thus highlighting the important role played by trade in goods in the general context of trade in the Single Market (intra-EU trade in goods represented 20.6% of EU GDP in 2015). The need to strengthen the free movement of goods and to provide businesses a more predictable regulatory framework is reiterated in the Commission staff working document accompanying this Communication. The Single Market Transparency Directive contributes directly or indirectly to several follow-up initiatives of the Single Market Strategy.

Given the centrality of the Single Market Transparency Directive in the proper functioning of the Single Market for goods and for Information Society services, this report is adopted together with the "Goods Package". The aim of the package is to boost the Single Market and exploit its full potential by reinforcing trust in the Single Market for the benefit of all, citizens and business. Specifically, initiatives will be presented to make mutual recognition function better and to enhance the enforcement of common EU product safety rules.

The Single Market Transparency Directive is the most open and transparent instrument of the Single Market. It is a unique system which prevents the emergence of new barriers to the

⁴ https://ec.europa.eu/priorities/sites/beta-political/files/juncker-political-guidelines-speech_en_0.pdf

⁵ See *President Juncker's Political Guidelines, A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change. Political Guidelines for the next European Commission*, https://ec.europa.eu/priorities/internal-market_en.

⁶ *A Single Market Strategy for Europe - Analysis and Evidence Accompanying the document Upgrading the Single Market: more opportunities for people and business*, SWD/2015/0202 final.

⁷ See *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 - Upgrading the Single Market: more opportunities for people and business*, COM(2015) 550 final.

Single Market by putting the focus on transparency, dialogue, prevention and better regulation. Not only it provides that Member States participate on an equal footing with the Commission in this procedure, but it also enables stakeholders themselves to have access to all national technical regulations under preparation, which are translated in 23 official languages of the EU. Economic operators can therefore anticipate the creation of obstacles to trade and, by taking an active role in the notification process, can concretely prevent unnecessary and costly administrative burdens from affecting their business.

The Single Market Transparency Directive also plays an important role in the compliance dialogue meetings with Member States⁸, which are part of the culture of compliance and smart enforcement work strand of the Single Market Strategy⁹. The Commission sees these meetings as an opportunity for a dialogue to improve transposition, implementation and application of EU law. The dialogues are also an occasion to discuss together with Member States how to proactively address the challenges of EU law enforcement. In this context, the dialogue under the Single Market Transparency Directive, combined with other indicators, enables the Commission to better identify the problematic sectors and structural problems in the Member States.

Taking into account the role of the Single Market Transparency Directive in preventing the creation of barriers on the single market of goods, in the framework of the Services Package the Commission recently presented a legislative proposal for a self standing notification instrument in the area of services. This aims to modernise the existing notification procedure under the Services Directive¹⁰ and will allow for more upstream verification of the justification and proportionality of new national regulations potentially restricting the free movement of services as well as addressing compliance through the dialogue with the Member States before the proposed legislation has been adopted¹¹.

Given its wide scope, which covers all products, industrial, agricultural and fishery, and Information Society services, the Single Market Transparency Directive also helps in promoting the free movement of goods and services in emerging sectors of the digital economy and for preventing the creation of barriers to trade in the EU Digital Single Market. The Single Market Transparency Directive notification procedure helps to create a stronger and more connected Digital Single Market. With respect to the collaborative economy, the Single Market Transparency Directive seeks to prevent the adoption by Member States of unjustified and disproportionate market access requirements.¹²

⁸ Compliance dialogue are structured / strategic meetings with Member States organised on a regular basis to take stock of the state of the Single Market integration in that Member State, in particular the state of play of transposition and ongoing infringement proceedings.

⁹ See paragraph "*Ensure a culture of compliance and smart enforcement to help deliver a true Single Market*" of the Single Market Strategy, http://ec.europa.eu/growth/single-market/strategy_en.

¹⁰ 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

¹¹ See *Proposal for a directive on the enforcement of the Directive 2006/123/EC on services in the internal market, laying down a notification procedure for authorisation schemes and requirements related to services*, COM(2016) 821.

¹² See *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 European agenda for the collaborative economy*, COM(2016) 356 final.

1. DEVELOPMENTS 2014-2015

1.1. Use of the notification procedure within the context of "Better regulation" and to improve competitiveness

Already in its 2002 Communication "*Better regulation for growth and jobs in the EU*"¹³ the Commission highlighted that the preventive control mechanism established by the Single Market Transparency Directive contributes to improving the quality of national regulations on products and Information Society services. The cooperation between the Commission and the Member States within the context of the notification procedure aims to ensure a clearer regulatory framework for economic operators.

In the framework of the Commission's action plan to simplify and improve the regulatory environment¹⁴, Member States have been invited to submit impact studies (or their conclusions) together with notified drafts technical regulations under the Single Market Transparency Directive, where such studies have been carried out internally. By carrying out these impact studies, Member States are encouraged to reflect in advance on the most appropriate instrument to be used, and the Commission can better check the necessity and proportionality of the measures proposed. In the reporting period, Member States submitted impact studies in relation to 356 notifications (almost 25% of the total of notifications). This represents a slight increase compared to the previous two years, when Member States submitted 314 impact studies out of 1439 notifications (approximately 22% of the total of notifications).

1.2. Use of the notification procedure to boost mutual recognition

The Single Market Transparency Directive contributes to better mutual recognition. The evaluation of national regulations, before their adoption, in the light of Articles 34-36 TFEU and of the mutual recognition principle and the recommendations of the Commission to insert a single market clause in notified draft national rules, where necessary, helps in reducing the risk of these rules raising regulatory barriers to trade. This preventive mechanism could be complemented by a corrective mechanism, in case authorities, when taking decisions based on national rules in individual cases, misapply the principle of mutual recognition. For this reason, the report is adopted together with the "Goods package", which contains a Single Market Strategy follow-up initiative to give a major boost to mutual recognition in the area of goods. It aims to introduce the use by economic operators of a voluntary mutual recognition declaration and to facilitate the smooth implementation of the mutual recognition principle. This should ensure that national regulations do not create unjustified barriers to trade through their full life cycle.

1.3. Improvements to the notification procedure

One of the objectives of the Single Market Transparency Directive is to inform economic operators, including small and medium-sized enterprises (SMEs), in advance of planned technical regulation in the Member States, to allow them to make their voices heard and to adapt early their activities to future technical regulations.¹⁵ The high number of contributions on notifications sent by stakeholders shows that this right of scrutiny is used extensively and helps the Commission and national authorities to detect barriers to trade.

In an ever-evolving effort towards transparency and efficiency, in 2015 the Commission worked on a new functionality on the Technical Regulation Information System (TRIS)

¹³ See *supra*, footnote 2.

¹⁴ See *supra*, footnote 2.

¹⁵ See whereas clause number 7 of the Single Market Transparency Directive.

website.¹⁶ This new functionality was put in place in June 2016 and allows any person to use the TRIS website to submit contributions on any notification during the standstill period provided for under Article 6 of the Single Market Transparency Directive.

Contributors have the possibility to make their contribution confidential and available only to the Commission services. The new "*Contributions*" tool also provides a way to quickly and easily gain access to contributions from other stakeholders provided they have not been marked as confidential, giving more visibility to contributions also outside the Commission.

All contributions submitted through this new mechanism will be immediately forwarded to the Commission's competent services, representing an increase in the efficiency of the contribution process. In the meantime, contributors receive an automatic acknowledgement of receipt through the Contribution Acceptance receipt sent by email.

1.4. Jurisprudence on the Single Market Transparency Directive

In the reference period the Court of Justice of the European Union (CJEU) issued two main rulings referring to the Single Market Transparency Directive and its obligations which help to clarify some aspects of the Directive and to better define some of its requirements.

In case C-307/13 (*Ivansson and Others*),¹⁷ the Court stated that, if a change to the timetable for the implementation of a national measure is made and if this is significant in nature, the draft technical regulation is subject to the obligation of communication to the Commission, as laid down in the third subparagraph of Article 5(1) of the Single Market Transparency Directive ("*Member States shall communicate the draft technical regulation again to the Commission [...] if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive*"). The Court added that a failure to observe such an obligation constitutes a procedural defect in the adoption of the technical regulation concerned, and renders this technical regulation inapplicable and therefore unenforceable against individuals.

In case C-98/14 (*Berlington Hungary and Others*)¹⁸ the Court ruled that a tax legislation such as that at issue which is not accompanied by any technical specification or any other requirement with which it is purportedly intended to ensure compliance, cannot be described as a "*de facto technical regulation*" (Article 1(f) of the Single Market Transparency Directive) and that the concept of "*de facto technical regulations*" refers, not to the tax measures themselves, but to the technical specifications or other requirements linked to them.

The Court also stated that the provisions of national legislation that prohibit the operation of slot machines outside casinos constitute "*technical regulations*" within the meaning of Article 1(f) of the Single Market Transparency Directive, the drafts of which must be communicated in accordance with the first subparagraph of Article 5(1) of the Single Market Transparency Directive. The Court held that "*a national measure which restricts the organisation of certain games of chance to casinos only constitutes a 'technical regulation', within the meaning of*

¹⁶ <http://ec.europa.eu/growth/tools-databases/tris/en/>.

¹⁷ The case was brought to the Court in the context of a request for a preliminary ruling concerning the interpretation of the third subparagraph of Article 8(1) of then Directive 98/34/EC, (OJ 1998 L 204, p. 37) on the obligation to communicate to the Commission any changes to the drafts previously notified to the Commission under the above-mentioned Directive, that have the effect of significantly altering the scope of, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

¹⁸ The case was brought to the Court in the context of a request for a preliminary ruling concerning, amongst others, the interpretation Articles 1, 8 and 9 of then Directive 98/34/EC. The case concerned regulation in the areas of slot machines.

Article [1(f) of the Single Market Transparency Directive], in so far as it can significantly influence the nature or the marketing of the products used in that context".

The Court also held that Articles 5 and 6 of the Single Market Transparency Directive, which illustrate the procedural steps of the notification procedure, "*are not intended to confer rights on individuals, in such a way that their infringement by a Member State gives rise to a right of individuals to obtain from that Member State compensation for the damage suffered as a result of that infringement on the basis of EU law*".

These judgements provided better clarity on the interpretation of Articles 1, 5 and 6 of the Single Market Transparency Directive and notably on the notification of changes to previously notified laws, the concept of technical regulation and the fact that procedural breaches do not give rise to compensation claims. This will help Member States and the Commission in better applying the Single Market Transparency Directive.

2. APPLICATION OF THE NOTIFICATION PROCEDURE

1.5. Effectiveness: general overview

► Volume of notifications and sectors involved

From 2014 to 2015, the Commission received 1382 notifications (655 in 2014, 727 in 2015)¹⁹. This represents a small decrease with respect to the previous two years (1484 notifications).

Marked differences in the number of notifications among Member States have been noticed, with some Member States carrying out on average more than 50 notifications per year and others notifying less than 10 notifications per year. If this gap can be partly explained with a different setting of the State organisation (e.g. presence of regional/local authorities with regulatory powers), lack of awareness or with a higher/lower degree of regulatory activity, this wide discrepancy raises doubts about the full compliance with the notification obligations by some Member States. This can also be explained by the fact that some national regulatory authorities do not take into account the Single Market Transparency Directive notification process, and notably the required stand-still of three months, when planning their regulatory decision making process.

¹⁹ These figures do not include notifications from EFTA countries which are signatories of the EEA Agreement (Norway, Lichtenstein and Iceland), Turkey and Switzerland. In the reporting period 85 notifications were carried out by these countries (44 by EFTA/EEA countries, 22 by Turkey and 19 by Switzerland). Please see Annex 3 for more information about these notifications.

Member States	2014	2015
Austria	38	43
Belgium	20	20
Bulgaria	6	13
Croatia	10	4
Cyprus	14	3
Czech Republic	26	37
Denmark	29	39
Estonia	18	17
Finland	34	37
France	49	69
Germany	50	61
Greece	7	8
Hungary	24	22
Ireland	6	2
Italy	29	20
Latvia	15	21
Lithuania	4	8
Luxembourg	2	1
Malta	5	1
Netherlands	59	44
Poland	25	36
Portugal	7	22
Romania	24	17
Slovakia	23	35
Slovenia	8	6
Spain	21	30
Sweden	38	32
United Kingdom	64	79
Total	655	727

A correlation between the size of the Member States and the number of notifications can be observed, with the biggest Member States notifying, in general, more than the medium and small ones. This can be partly explained with a higher number of regional and local authorities which have an obligation to notify their draft technical regulations. However, this is not always the case: for instance, in some cases medium-sized Member States notified more than some bigger Member States.

As 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, and fire safety of buildings.

Like in the previous reporting period, this sector was again followed by notifications in the area of **agricultural products, fishery and aquaculture products and other foodstuffs**. In this category, 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, quality and origin marks.

Numerous notifications were also made 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)).

A number of notifications concerned **gambling** products and services.

Finally, a number of notifications related to the **environment sector** (mainly packaging and packaging waste, recyclable products, processing of biodegradable waste) (see Annex 2.3).

► Issues addressed by the Commission in its reactions

In the **non-harmonised areas** which, in absence of secondary legislation, are subject to compliance with Articles 34 to 36 (free movement of goods) and 49 and 56 (right of establishment and freedom to provide services) TFEU, the Commission's reactions were intended to draw Member States' attention to potential obstacles to trade after assessing the necessity and the proportionality of the measure in line with the case-law of the Court of Justice. Thus the Commission aimed to ensure 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.

When national measures partially fall under **harmonised areas**, the reactions were intended to ensure that national measures were compatible with EU secondary legislation.

- In 2014-2015 Member States notified 303 (151 in 2014 and 152 in 2015) 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 Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC²⁰.

The Commission 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)²¹ and Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels²².

Technical regulations relating to energy efficiency of buildings were assessed under Directive 2012/27/EU on energy efficiency²³, Directive 2010/31/EU on the energy

²⁰ 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.

²¹ 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.

²² 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.

²³ 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 buildings²⁴ and Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products²⁵.

The Commission also examined draft legislation concerning requirements for motorway communications equipment. The notified draft was examined under Directive 1999/5/EC²⁶, Directive 2006/95/EC²⁷ and Directive 2004/108/EC²⁸.

- In the **agricultural, fishery and foodstuff sectors**, from 2014 to 2015 Member States notified 266 (133 in 2014 and 133 in 2015) draft technical regulations. These drafts concerned, *inter alia*, materials coming into contact with foodstuffs, energy drinks, trans fats in food products, wine and spirits, quality marks for foodstuffs, the well-being of animals and the marketing of fur products.

Certain Member States notified draft regulations setting up marks linking the quality of a product with its origin. These notifications have been examined under the Treaty provisions on the free movement of goods and Regulation (EU) No 1151/2012 of the European Parliament and the Council on quality schemes for agricultural products and foodstuffs.²⁹

During the relevant period, the Commission examined many notifications concerning the hygiene of foodstuffs and issued detailed opinions and comments concerning their compliance with Regulation (EC) No 852/2004 on the hygiene of foodstuffs³⁰, Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin³¹ and Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption³².

Other notifications concerned the labelling of foodstuff and the Commission assessed their compatibility with Regulation (EU) No 1169/2011 on the provision of food information to consumers,³³ in particular with the provisions on nutritional declarations, or other sector-specific provisions on consumer information.³⁴

²⁴ 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.

²⁵ 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.

²⁶ Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, OJ L 91 of 7.4.1999, p. 10–28.

²⁷ Directive 2006/95/EC of the European Parliament and of The Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, OJ L 374 of 27.12.2006, , p. 10–19

²⁸ Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility, OJ L 390 of 31.12.2004, p. 24–37.

²⁹ Regulation (EU) No 1151/2012 of the European Parliament and the Council on quality schemes for agricultural products and foodstuffs, OJ L 343, 14.12.2012, p. 1–29.

³⁰ 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.

³¹ 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.

³² 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.

³³ 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

- In the **Information Society services sector** there were 69 (25 in 2014 and 44 in 2015) notifications. Numerous notifications were in the area of gambling, while others concerned, *inter alia*, copyright in the digital environment, on demand audio-visual media services, electronic commerce, electronic signature and other trust services.
- In the **metrology** sector there were 67 notifications (37 in 2014 and 30 in 2015). 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 instruments³⁵. 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 69 (33 in 2014 and 36 in 2015) notifications. The bulk of the notifications concerned biocidal products, fertilisers, plant protection products and products falling under the scope of REACH and were mainly examined under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("*REACH*")³⁶, the Biocidal Products Regulation³⁷ and Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market³⁸.
- In the **environmental sector** the Commission examined 86 (42 in 2014 and 44 in 2015) draft regulations. Some notified drafts concerned packaging waste and raised both problems of compatibility with the EU harmonised legislation, particularly Directive 94/62/EC on packaging and packaging waste³⁹ (for example with regard to the requirements for banning lightweight plastic carrier bags), and with Articles 34-36 TFEU, for the non-harmonised aspects (for instance with regard

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.

³⁴ Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000, OJ L 354, 28.12.2013, p. 1–21.

³⁵ 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.

³⁶ 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, 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.

³⁷ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123.

³⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, GU L 309 del 24.11.2009, p. 1–50.

³⁹ 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.

to the mutual recognition clause or the use of national standards for disposable plastic bags or disposable plastic cups, glasses and plates).

The notification 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 6(3) and 6(4) of the Single Market Transparency Directive, the Commission has requested the notifying Member State to postpone the adoption of notified draft legislation for twelve months from the date of notification in the fields of: electronic signatures, electronic archiving, electronic recorded delivery, electronic time-stamping and certification services (notification 2013/584/B and 2013/585/B) and requirements for milk and milk products, ice creams and edible fats and oils (notification 2015/169/CZ).

Thus, the Single Market Transparency Directive helps to avoid the fragmentation of the Single Market in areas where harmonisation is envisaged or under way and aims to give greater certainty and stability in the legal framework to the economic operators.

► Positive examples, showcasing the impact of the Single Market Transparency Directive

- In 2014 the Commission issued a detailed opinion on an Italian notification concerning a regional logo which linked the origin of a wide range of products with their quality. The Commission argued that this measure would have been contrary to Article 34 TFEU as it could have encouraged consumers to buy national products to the detriment of imported ones. Following a dialogue, the Italian authorities removed the barrier by eliminating the reference to the origin of the products covered by the notified draft.
- In 2014 Hungary notified a draft measure setting inspections to ensure that operators have paid VAT on wine products without geographical indication marketed in Hungary. These inspections were subject to the payment of a fee. The Commission issued a detailed opinion arguing that the payment of a VAT inspection fee was contrary to Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products⁴⁰. Following the adoption of the measure by the Hungarian authorities, the Commission started an investigation which was finally closed due to the fact that the contested measure ceased to have effect from 31 July 2017 (due to lack of extension by the Hungarian authorities). The notification procedure, therefore, proved useful in the identification of a barrier to trade which was eventually removed through an investigation.
- In 2015 the French authorities notified the Commission a draft measure defining a logotype to be used with industrial and craft products protected by geographical indications. The Commission issued a detailed opinion on the grounds that establishing the logotype, which consisted of a blue and red outline around the initials "IG" [indication géographique – geographical indication], with the word "FRANCE", was liable to constitute a measure having equivalent effect under Article 34 TFEU. In particular, the Commission considered that this logotype underlining the French origin of the products concerned would go beyond the objective of authenticating the specific local or regional origin of a product and could therefore encourage consumers to purchase products bearing this logo, to the exclusion of products from other Member

⁴⁰ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, OJ L 347, 20.12.2013, p. 671–854.

States. The French authorities took these objections on board and amended the draft logotype in a manner which was considered acceptable by the Commission.

- In 2015 France notified a draft technical regulation setting out the expected performance of personal protective equipment (PPE) used to protect operators and workers from synthesised plant protection products and proposed appropriate tests. The Commission issued a detailed opinion expressing its concerns on the mutual recognition clause contained in the notified draft. According to the notified draft, any other means could be used to demonstrate that suits comply with the essential health and safety requirements of Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment⁴¹ (PPP Directive), provided that these means guaranteed the same level of protection for operators and workers as the test conditions and information requirements described in the French draft. The Commission was of the opinion that this provision rendered in practice the test conditions and information requirements of the notified text mandatory, in breach of Article 4(1) of the PPE Directive: "*Member States may not prohibit, restrict or hinder the placing on the market of PPE or PPE components which comply with the provisions of this Directive and which bear the CE marking attesting their conformity to all the provisions of this Directive, including the certification procedures in Chapter II*". The French authorities modified the text accordingly, addressing the concerns expressed by the Commission.
- In 2014 the United Kingdom notified a draft providing that motorway communications equipment should comply with the Low Voltage Directive (LVD)⁴², the Radio & Telecommunication Terminal Equipment Directive (R&TTE)⁴³, and the Electromagnetic Compatibility Directive (EMC)⁴⁴, and, in addition, with a number of harmonised voluntary standards. The Commission issued a detailed opinion reminding that if products fall within the scope of specific EU harmonising legislation providing for the CE marking (such as the LVD, EMC, R&TTE), they shall comply with that legislation and shall not be subject to those provisions of the notified draft that regulate the same risks. The United Kingdom modified the draft by removing any requirement to comply with voluntary harmonised standards under CE marking directives throughout the notified draft.

► **Most common tackled barriers**

One of the purposes of the Single Market Transparency Directive is to allow the identification of areas of recurrent obstacles to the free movement of goods and the freedom to provide Information Society services and the detection of harmonisation needs with the aim of ensuring a smoother functioning of the single market⁴⁵.

⁴¹ Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, OJ L 399, 30.12.1989, p. 18–38.

⁴² Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits, OJ L 96, 29.3.2014, p. 357–374.

⁴³ Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, OJ L 091, 07.04.1999 p. 10–28.

⁴⁴ Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC, OJ L 390, 31.12.2004, p. 24–37.

⁴⁵ See recital number 15 of the Single Market Transparency Directive.

In this respect, the Commission identified in the period under analysis several recurrent barriers in the notified draft legislation, of which the most pertinent ones are listed below..

Mutual recognition clauses

The Commission reacted frequently to notifications of draft technical regulations in which the mutual recognition clause was not included or was not drafted in line with the standard laid down in the "*Interpretative Communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition*" (2003/C 265/02). Some Member States justified the absence of the mutual recognition clause in their drafts on the basis of the inclusion of a general mutual recognition clause in the basic legislation. In those cases, the Commission nonetheless recommended to the notifying Member States to include in the notified drafts a direct reference to the mutual recognition clause in the basic legislation in order to ensure the necessary legal certainty for business operators.

Improper legal drafting technique - Repetition of provisions of EU Regulations

One of the most frequent issues addressed by the Commission in the detailed opinions issued on the basis of EU regulations applicable in the food hygiene area, was a practice whereby the notified draft technical regulations repeated, often partially and in an incomplete way, the provisions laid down in the applicable EU regulations. According to the Treaty on the Functioning of the European Union, a regulation has general application, is binding in its entirety and is directly applicable in all Member States (Article 288 TFEU). Thus, Member States may not lay down rules in the area governed by directly applicable EU legislation, even identical ones, as they would interfere with the correct application of the EU legislation and cause uncertainty as to the complete application of the relevant EU law.

Incorrect implementation of the exemptions provided for in the food hygiene regulations

Several potential breaches have also been identified in respect of the implementation by the notifying Member States of the exceptions and the flexibility clauses contained in the three Regulations (e.g. Article 1(3) and (5) and Article 10(3) of Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin). Member States wrongly implemented or went beyond what is allowed by these exemptions.

Unjustified barriers related to Information Society services

In the area of Information Society services the Commission identified recurrent problems in notified drafts concerning gambling. These led to the issuance of 14 detailed opinions (6 in 2014 and 8 in 2015) the main grounds of which concerned unjustified or disproportionate restrictions to the free provision of services and freedom of establishment under Articles 49 and 56 TFEU. For example, the Commission made remarks concerning the conditions for granting the monopoly and licenses to gambling operators, the establishment requirements in a given Member State of the service provider or of its ICT infrastructure or regarding the blocking of websites.

Other recurring issues in the detailed opinions concerning gambling related to the compliance with the Data Protection Directive 95/46/EC, restrictions to the free movement of goods (Article 34-36 TFEU) and breach of product-related secondary legislation such as Regulation (EC) No 765/2008 on marketing of products, accreditation and market surveillance, the Machinery Directive 2006/42/EC, Directive 1999/5/EC on radio equipment and telecommunications terminal equipment, Directive 2014/30/EU on Electromagnetic Compatibility and the Low Voltage Directive 2014/35/EU. For example, the Commission

raised concerns regarding requiring CE marking, assessment by conformity assessment bodies or non-recognition of foreign conformity assessment bodies.

Standards – making them mandatory, requiring additional test methods

Another recurring issue is a practice whereby national legislation seeks to make voluntary European harmonised standards compulsory by inserting them into national law.

In this context, under the New Approach directives, only "*essential requirements*" listed in the harmonising Directives are mandatory. European harmonised standards are one of the ways of guaranteeing the presumption of conformity with the mandatory essential requirements and should thus remain voluntary.

This practice by the Member States would create barriers to trade within the internal market since products complying with the essential requirements of New Approach Directives but not with the European harmonised standards, could not freely circulate in the Member State in question.

Moreover, some Member States intended to develop and to require additional (non-standardised) test methods to those provided for by harmonised standards while, additional national methods cannot be imposed by Member States in the light of the case law of the CJEU as well as primary and secondary EU legislation. National (even voluntary) procedures linked to the verification/testing of characteristics not harmonised in harmonised standards are therefore not allowed.

All of the above-mentioned recurrent practices have been discussed with the Member States in the framework of the Standing Committee of Technical Regulations, which meets twice per year. In addition, these recurrent practices will be also discussed in the context of bilateral compliance meetings with the Member States.

► **Reactions**

The Single Market Transparency Directive allows for a formal and structured exchange of information between the Member States and the Commission and among Member States to take place when assessing notified drafts. The intensity of this exchange of information is demonstrated by the high number of reactions sent by the Commission and the Member States to the notifications and by the replies of the notifying Member States and the subsequent exchange of messages. Thanks to this exchange of information, the Member States have also the possibility to ascertain the degree of compatibility of notified drafts with European Union legislation. When necessary, the Commission's services also meet at expert level with representatives of the Member States to clarify outstanding issues. The Commission can also send to the Member States requests for supplementary information in order to clarify the scope of the notified technical regulations.

The intensity of this dialogue is shown in the table below which indicates the number of notifications per Member State for each year of the period considered and the comments and detailed opinion issued by the Commission regarding those notifications⁴⁶.

⁴⁶ This table uses a different methodology from the rest of the report for the calculation of the number of detailed opinions and comments issued by the Commission. While the rest of the report refers to detailed opinions and comments issued in the course of the relevant period (2014 and 2015), the table refers to detailed opinions and comments issued with regard to notifications carried out in 2014 and 2015. Therefore, the table includes detailed opinions and comments issued in the beginning of 2016 for notifications made in the end of 2015. Likewise, the table does not include detailed opinions and comments issued in the beginning of 2014 for notifications made in the end of 2013.

Member States	2014			2015		
	Notifications	Comments	D.O.	Notifications	Comments	D.O.
Austria	38	10	2	43	14	1
Belgium	20	3	2	20	1	2
Bulgaria	6	0	1	13	1	4
Croatia	10	2	1	4	2	0
Cyprus	14	5	2	3	1	0
Czech Republic	26	4	0	37	11	6
Denmark	29	6	3	39	5	4
Estonia	18	9	0	17	3	2
Finland	34	2	1	37	13	2
France	49	15	5	69	8	15
Germany	50	6	5	61	7	4
Greece	7	3	0	8	3	3
Hungary	24	10	5	22	5	3
Ireland	6	2	1	2	0	1
Italy	29	7	4	20	2	4
Latvia	15	2	2	21	3	2
Lithuania	4	3	7	8	1	9
Luxembourg	2	0	0	1	0	0
Malta	5	3	1	1	1	0
Netherlands	59	11	0	44	5	2
Poland	25	3	3	36	8	2
Portugal	7	4	2	22	4	3
Romania	24	11	3	17	9	2
Slovakia	23	7	2	35	9	2
Slovenia	8	1	2	6	1	1
Spain	21	9	3	30	8	4
Sweden	38	6	1	32	6	0
United Kingdom	64	9	4	79	10	4
Total	655	153	62	727	141	82

In the period considered the Commission issued 141 detailed opinions (60 from 2014, 81 from 2015), which represents 10.2% of the total number of drafts notified by the Member States over the reporting period. This figure shows a 10% decrease in the number of detailed opinions issued by the Commission compared to the previous two years. For their part, the Member States issued 131 detailed opinions (64 from 2014 and 67 from 2015), which represents a decrease compared to the previous two years (157 detailed opinions). Of the 589 comments issued during the reporting period (634 had been issued in the previous two years), 352 were made by the Commission (161 in 2014 and 191 in 2015) and 237 by the Member States (112 in 2014 and 125 in relation to notifications from 2015) (see Annexes 2.4 and 2.6).

The table below shows the number of reactions (comments and detailed opinions) issued by each Member State in the reporting period. The numbers in the table provide some indications on the participation of Member States in the dialogue triggered by the notification and on the specific interests of some Member States whose reactions are more concentrated in specific sectors. Austria, France, Germany, Italy, Poland, Spain and the United Kingdom are among the most active Member States. An analysis of the reactions per Member State and by sector shows a particular interest of Austria, France, Italy, Slovakia and Spain for the agriculture,

fishery and foodstuffs sector; of Germany for the telecoms sector; of Poland for the mechanics sector; and of Malta for the domestic and leisure equipment sector (mostly linked with gambling machines).

	Construction	Agriculture, Fisheries and Foodstuffs	Transport	Energy, Minerals, Wood	Telecoms	Mechanics	98/48/EC Services	Environment	Domestic And Leisure Equipment	Pharmaceuticals And Cosmetics	Chemicals	Goods and Misc. Products	Health, Medical Equipment
Austria	2	10	1	1	0	5	1	3	3	2	2	1	0
Belgium	0	3	0	0	0	0	0	0	0	0	0	0	0
Bulgaria	2	0	0	0	0	1	0	1	0	0	0	5	0
Croatia	0	4	0	0	0	0	0	1	0	0	0	0	0
Czech Republic	0	8	0	0	0	2	0	0	0	0	0	5	0
Denmark	0	4	0	1	0	0	0	0	0	1	0	0	0
Estonia	0	3	0	0	0	0	0	0	0	0	0	1	0
Finland	0	2	0	3	0	0	0	1	0	0	0	0	0
France	3	9	0	3	0	4	1	1	0	1	1	2	0
Germany	4	4	1	0	35	2	0	0	0	8	0	2	0
Greece	0	0	0	0	0	0	0	0	0	0	0	5	0
Hungary	0	8	0	0	0	1	0	0	0	0	1	2	0
Ireland	0	2	0	0	0	0	0	0	0	0	0	2	0
Italy	0	11	2	0	2	1	0	1	0	0	2	6	0
Lithuania	0	0	0	0	0	0	0	0	0	0	0	3	0
Malta	0	0	0	0	0	0	1	0	10	0	0	0	0
Netherlands	0	1	0	0	0	0	0	0	0	0	3	0	0
Poland	6	5	1	0	0	10	0	2	0	0	3	8	0
Portugal	0	1	0	0	0	0	0	1	0	0	0	5	0
Romania	1	1	0	0	0	1	0	0	0	0	0	5	0
Slovakia	0	13	0	0	0	0	0	0	0	0	0	7	0
Slovenia	0	8	0	0	0	0	0	0	0	0	0	0	0
Spain	3	25	0	1	0	0	0	1	0	0	0	7	0
Sweden	1	3	1	1	0	0	1	1	0	0	0	0	0
United Kingdom	2	4	0	1	0	1	0	4	0	1	2	6	0

Thanks to the access to all notifications and to the messages exchanged within the dialogues, Member States can use the Single Market Transparency Directive as a benchmarking tool. It allows them to draw on the ideas of their partners in order to solve common problems regarding technical regulations and to identify when a draft technical regulation could be in breach of EU law.

In 3 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 2.5).

1.6. Use of the urgency procedure

Out of a total of 1382 notifications, the Member States made 76 (40 in 2014 and 36 in 2015) requests to apply the urgency procedure to notified drafts. The Commission confirmed the strict conditions required by the Single Market Transparency Directive for the urgency procedure to apply, 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 for

cases in which the justification was not sufficiently established or was based on purely economic grounds or national administrative delay as well as in cases for which no unforeseeable circumstances were demonstrated. The urgency procedure was deemed justified in 60 cases (29 in 2014 and 31 cases in 2015), in particular concerning psychotropic substances, control of narcotics, medicinal products, fight against terrorism, firearms, pesticides, infection of bees, prohibition of products that are harmful to health and fireworks (see Annex 2.7).

1.7. Notification of "fiscal or financial incentive measures"

According to the Single Market Transparency Directive, 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 2014-2015 Member States notified 70 (35 in 2014 and 35 in 2015) 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 the Single Market Transparency Directive 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 shared with the Member States Guidelines on the definition and notification of "*fiscal or financial measures*" for the purposes of the Single Market Transparency Directive.

1.8. Follow-up to Commission reactions

According to Article 6(2) of the Single Market Transparency Directive, Member States have to report on the action they propose to take in response to a detailed opinion.

From 2014 to 2015, the ratio between the number of responses given by the Member States and the volume of detailed opinions issued by the Commission was satisfactory, but could be further improved (an average of 79% over the period). The number of completely satisfactory responses was in line with the previous two years (an average of 56% over the period 2014-2015 in comparison with 54% over the period 2012-2013) (see Annex 2.8).

In the period considered the Member States withdrew 43 draft technical regulations. In 12 cases (7 in 2014 and 5 in 2015) the withdrawal followed the delivery of a reaction (detailed opinion or comments) by the Commission. Some of the reasons of these withdrawals are, *inter alia*, the introduction by the notifying Member State of substantial changes to the draft technical regulation which require a new notification (Article 5(1) of the Single Market Transparency Directive) or the simple decision of the national authorities not to go ahead with the adoption of the draft technical regulation.

For other notified draft technical regulations the dialogue is still on-going.

1.9. Follow-up to the notification procedure

For all other cases in which the potential breaches of the EU internal market law have not been entirely removed within the framework of the notification procedure, the Commission conducted further investigations which in some cases, eventually led to launching a pre-infringement dialogue with the Member States (the so-called EU Pilot) and, in some cases, to infringement proceedings (Article 258 of the TFEU) on subjects such as sugar content for jam and marmalade and use of the reserved denomination "*marmalade*", quality and transparency of the supply chain for virgin olive oils, wine and spirits, labelling of beef meat in the context

of a regional quality system, online gambling, fuel quality, gas appliances, the safety of road barriers and packaging and packaging waste.

In the period concerned, the Commission also started EU Pilot cases and where necessary, infringement proceedings concerning, *inter alia*, the breach of obligations under the Single Market Transparency Directive. For all these cases, the Commission drew the attention of the national authorities to their duty to notify and to respect the standstill period provided for in Article 6(2) of the Single Market Transparency Directive. The Commission recalled that the CJEU held that the adoption of technical regulations in breach of "*the obligation to notify constitutes a substantial procedural defect such as to render the technical regulations in question inapplicable to individuals*". Consequently, individuals can resort to national courts which "*must decline to apply a national technical regulation which has not been notified in accordance with the directive*" (Case C-194/94 CIA Security International, paragraphs 44, 48 and 54; Case-226/97 Lemmens, paragraph 33; Case C-303/04 Lidl Italia, paragraphs 23, 24).

1.10. Structured exchanges with the Member States

The regular meetings of the Single Market Transparency Directive Committee allowed views to be exchanged on points of general interest and also on specific aspects of the notification procedure.

As regards technical regulations, the discussions particularly concerned the urgency procedure under the Single Market Transparency Directive; access to documents of the Commission under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents⁴⁷ and confidential notifications; the obligation for Member States to communicate to the Commission the final text of a notified technical regulation; developments on the jurisprudence of the CJEU concerning the Single Market Transparency Directive.

Based on requests from the Member States and on the initiative of the Commission to provide clarification on some recurrent barriers or on new legislation, the Commission made presentations concerning the notification procedure for the Swiss and the EEA notifications; technical regulations in the area of psychoactive substances; the proposal for a regulation on electronic identification and trust services for electronic transactions in the internal market; the relation between REACH and the Single Market Transparency Directive; issues related to the broadcasting exemption from the Single Market Transparency Directive; the mutual recognition clause and Articles 34-36 TFEU; the Fuel Quality Directive⁴⁸; the food hygiene package⁴⁹; the Packaging and Packaging Waste Directive⁵⁰; the notification procedure under Regulation (EU) No 1169/2011⁵¹.

⁴⁷ 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.

⁴⁸ Directive 2009/30/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 98/70/EC as regards the specification of petrol, diesel and gas-oil and introducing a mechanism to monitor and reduce greenhouse gas emissions and amending Council Directive 1999/32/EC as regards the specification of fuel used by inland waterway vessels and repealing Directive 93/12/EEC, OJ L 140, 5.6.2009, p. 88-113.

⁴⁹ 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; 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; Regulation (EC) No 854/2004 of the European Parliament and

Several Member States made presentations on their best practices for notifications under the Single Market Transparency Directive.

Seminars were also held in several Member States, allowing direct dialogue between the Commission and the national authorities involved in the notification procedure and helping the latter to become familiar with the technical elements of the notification procedure.

The Commission has included presentations on the application of the Single Market Transparency Directive in the agendas of the compliance dialogue meetings with Member States which are carried out following the commitment in the Single Market Strategy.

1.11. Requests for access to documents issued under the Single Market Transparency Directive

From 2014 to 2015 the Commission received 236 (98 in 2014 and 138 in 2015) requests for access to documents issued in the framework of the Single Market Transparency Directive. The major part of them concerned detailed opinions and comments delivered by the Commission. In 68 of the cases, access to the requested documents was given. In the other cases, access to documents was refused or partially refused while the dialogue with the Member States, aiming to remove the potential obstacle to trade, was ongoing.

1.12. Transparency

Transparency is a fundamental feature of the notification procedure. The TRIS public website is the window that ensures stakeholders are constantly informed about all draft technical regulations under preparation by Member States and that a dialogue between stakeholders and the Commission services takes place, thanks to the new contribution functionality mentioned in paragraph 1.3.

The success of the TRIS public website is corroborated by numbers:

- At the end of 2015 there were 5,196 subscribers to the TRIS mailing list compared to 4,441 in 2013, with an increase of 17% in the two-year reporting period;
- In the period considered 244,736 searches have been carried out through the TRIS public website compared to 177,147 searches in the period 2012-2013, with an increase of 38%;
- Also, access to notifications by the users has increased from 869,791 occurrences in 2013 to 1,203,299 by the end of 2015, determining a specific increase of 38%.

⁵⁰ 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
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.

⁵¹ 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 Text with EEA relevance, OJ L 304, 22.11.2011, p. 18–63.

3. CONCLUSION

During the period 2014-2015, the usefulness of the procedure has again been confirmed in terms of transparency, administrative cooperation and prevention of technical barriers in the internal market.

The preventive and networking approach of the notification procedure, has 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 an internal market which is rapidly evolving, but is not yet delivering on its full potential.

There is still room for improvement in the application of the procedure, namely concerning the number of notifications from some Member States and their compliance with the notification obligations. A higher number of notifications and a more active participation of Member States in the procedure would favour the prevention of new technical barriers and the identification of systemic issues in each Member State and across the EU. This would help the dialogue with the Commission and would facilitate a more targeted and effective approach to barriers to intra-EU trade.

The high number of detailed opinions and comments issued during the reporting period demonstrates that there is an increasing risk of fragmentation of the internal market for goods. On average 79% of the detailed opinions issued by the Commission were replied to by the Member States concerned and dialogues followed to remove any incompatibility with EU law, thus avoiding infringement procedures.

The importance of the Single Market Transparency Directive is proved by the high interest of stakeholders in the notification procedure, as noted, *inter alia*, in the REFIT Platform opinion on the Directive⁵². This growing interest mirrors the effort to improve the transparency and the efficiency of the TRIS public website.

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

When applying the Single Market Transparency Directive 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 to enhance the competitiveness of European enterprises in the EU and abroad, taking into account the links between the notification 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 Single Market Transparency 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.

⁵² https://ec.europa.eu/info/files/refit-platform-recommendations-internal-market-xii6a-single-market-transparency-directive_en