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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 THE SINGLE MARKET TRANSPARENCY DIRECTIVE
FROM 2016 TO 2020**

{SWD(2022) 297 final}

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EXECUTIVE SUMMARY

This report is drafted and submitted in compliance with Article 8 of Directive (EU) 2015/1535¹ (the ‘Single Market Transparency Directive’). It analyses the results of the application of one of the cornerstones of the single market from 2016 to 2020: the notification procedure laid down by the Single Market Transparency Directive. The report highlights the notification procedure’s important contribution to the functioning of the single market and to implementing the Better Regulation guidelines and toolbox², as well as its pivotal role during the COVID-19 pandemic.

Notifying the Commission of national technical regulations before their adoption has continued to be an important tool to address the emergence of barriers to trade, with the aim to prevent them. It has also continued to be a good channel to ensure cooperation between the Commission and the Member States and among the Member States themselves. This is particularly important in critical and unforeseen circumstances such as during the COVID-19 pandemic. Also, technical regulations are notified to the Commission and the final texts of the notified measures are translated into 23 official languages of the EU³.

Additionally, the implementation of the Single Market Transparency Directive requires the Commission to follow up and monitor all notifications raising concerns as to their compatibility with EU law. In that context, the Commission pays particular attention to measures having the highest impact on the single market⁴.

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, OJ L 241, 17.9.2015, p. 1.

² *Action plan for improving the regulatory environment*, COM(2002) 278. See also *Better Regulation for Growth and Jobs in the European Union*, COM(2005) 97; *Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment*, COM(2005) 535; *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 *Better Regulation: Delivering better results for a stronger Union*, COM(2016) 615.

³ Irish translation is not available.

⁴ https://ec.europa.eu/info/sites/info/files/communication-enforcement-implementation-single-market-rules_en_0.pdf

INTRODUCTION

As ‘an engine for building a stronger and fairer EU economy’, the single market is a key part of the Commission’s six priorities for 2019-2024⁵. The single market has improved prosperity and opportunities for businesses and the public in Europe. A well-functioning single market stimulates competition and trade, improves efficiency, raises quality and helps reduce prices for businesses and consumers⁶.

As part of the Commission’s March 2020 new industry strategy package⁷, a communication on barriers⁸ and an action plan on single market enforcement⁹ were adopted to further improve competitiveness and facilitate the integration of companies of all sizes in EU and global value chains. Action 10 of the Commission action plan on single market enforcement refers to the Single Market Transparency Directive. In that context, ‘in line with the more strategic approach for the Commission’s enforcement actions, the implementation of the Single Market Transparency Directive is built on four axes:

- (i) Member States notify to the Commission all draft technical regulations concerning goods and information society services;
- (ii) the Commission follows up on all notifications raising concerns as to the their compatibility with EU law;
- (iii) in calibrating its follow-up, the Commission pays particular attention to measures having the highest impact on the single market;
- (iv) the Commission monitors legislation which was subject to a Commission reaction under the Single Market Transparency Directive and which, in the absence of appropriate adjustments, may give rise to infringement proceedings’.

The Commission puts a clear focus on prevention and enforcement in relation to cases with the most significant impact on the single market economically or in some other way.

The Single Market Transparency Directive aims to prevent the emergence of new barriers in the single market by focusing on transparency, dialogue, prevention and better regulation. Member States can participate on an equal footing with the Commission in this procedure. Stakeholders have access to both national technical regulations under preparation and the final texts of the notified measures, translated in 23 official languages of the EU. Therefore, economic operators can anticipate the creation of obstacles to trade and avoid unnecessary and costly administrative burdens affecting their business.

The notification procedure for national technical regulations under the Single Market Transparency Directive allows the Commission and the Member States to examine, before their adoption, the technical regulations any Member State intends to introduce for products (industrial, agricultural and fishery) and information society services (see Annex 1 to the Commission staff working document accompanying this report). The procedure applies in a simplified manner to European Free Trade Association (EFTA) states which are parties to the Agreement on the European Economic Area (EEA), to Switzerland, and to Turkey (see Annex 4).

⁵ https://ec.europa.eu/info/strategy/priorities-2019-2024/economy-works-people/internal-market_en

⁶ https://ec.europa.eu/commission/presscorner/detail/en/fs_20_427

⁷ https://ec.europa.eu/commission/presscorner/detail/en/ip_20_416

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A0093%3AFIN>

⁹ See footnote 4.

The Single Market Transparency Directive also plays a key role in the ‘country knowledge’ dialogue meetings with Member States and stakeholders¹⁰. Such meetings are part of the single market strategy’s efforts to ensure a culture of compliance and smart enforcement¹¹. The Commission sees these meetings as an opportunity for dialogue to improve the implementation of the Single Market Transparency Directive. In this context, the dialogue under the Directive, combined with other indicators, enables the Commission to better identify the problematic sectors and structural problems in the Member States.

This report drafted and submitted in compliance with the Single Market Transparency Directive is a snapshot of its operation from 2016 to 2020 both from a qualitative and quantitative angle.

In 2020, the notification procedure under the Single Market Transparency Directive played a crucial role in the management of the COVID-19 pandemic and contributed to a coordinated approach to the health crisis throughout the EU. The spread of the virus caused the disruption of global supply chains. During the pandemic, the integrity of the single market and, more broadly, the preservation of production and distribution value chains ensuring the necessary supplies to our health systems were jeopardised. The Directive provided a framework allowing Member States to act in a coordinated way.

1. DEVELOPMENTS 2016-2020

With 3 553 notifications received in the 5-year period 2016-2020 (see Annex 3.1), the dialogue that unfolded in the context of the Single Market Transparency Directive demonstrated a good level of participation by the Member States, which issued 243 detailed opinions and 475 comments (see Annex 3.6). This was coupled with frequent reactions by the Commission on the notified technical regulations, notably 212 detailed opinions and 816 comments issued by the Commission (see Annex 3.4). The highest number of reactions of the Commission and the EU Member States concerned agriculture, fishing and foodstuffs and construction products.

The introduction of new IT tools over the reference period, as described in the paragraphs below, facilitated economic operators’ participation in the Single Market Transparency Directive procedure.

The case-law of the Court of Justice of the European Union (CJEU) shed light on some interpretative conundrums of the Single Market Transparency Directive. These included the definition of technical regulations, the classification of new intermediation services in emerging sectors related to collaborative economy models, the right of access to documents in relation to the Single Market Transparency Directive procedure and the penalty for non-notification¹².

1.1. Improvements to the notification procedure

One of the Single Market Transparency Directive’s objectives is to inform economic operators, including small and medium-sized enterprises, in advance of planned technical regulations before their adoption by the Member States. This allows economic operators to make their voices heard and to adapt their activities in good time to future technical

¹⁰ The ‘country knowledge’ dialogue consists in structured meetings with the national authorities involved in the notification procedure in each EU Member State and with national stakeholders.

¹¹ 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.

¹² See Annex 2 for further details on CJEU case-law on the Single Market Transparency Directive in 2016-2020.

regulations¹³. The high number of contributions on notifications sent by stakeholders shows that this right of scrutiny is exercised extensively and is helping the Commission and national authorities to detect barriers to trade.

In an ever-evolving effort towards transparency and efficiency, in 2015 the Commission worked to develop a new function on the Technical Regulation Information System (TRIS) website¹⁴. This function was put in place in 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. From 2016-2020, the Commission received 1 618 contributions via this function (144 in 2016, 421 in 2017, 175 in 2018, 281 in 2019 and 597 in 2020).

1.2. Use of the notification procedure within the context of ‘better regulation’ and mutual recognition

In its Communication *Better regulation for growth and jobs in the EU*¹⁵, 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.

The Single Market Transparency Directive also contributes to better mutual recognition. The mutual recognition principle, which derives from the case-law of the CJEU on Articles 34 to 36 TFEU, ensures market access for goods that are not, or are only partly, subject to EU harmonisation legislation. It guarantees that any good lawfully marketed in one Member State can in principle be sold in another. The assessment of national regulations before their adoption helps minimise the risk that these rules raise unjustified regulatory barriers to trade, notably in the light of the mutual recognition principle. This is because the Commission can: (i) correct the text of the single market clauses in drafts notified by the Member States under the Single Market Transparency Directive procedure; and (ii) recommend that the Member States insert the single market clause in notified draft national measures when it is missing in the notified drafts.

2. APPLICATION OF THE NOTIFICATION PROCEDURE

2.1 Effectiveness: general overview

► Volume of notifications and sectors involved

From 2016 to 2020, the Commission received 3 553 notifications (700 in 2016, 676 in 2017, 666 in 2018, 657 in 2019 and 854 in 2020)¹⁶.

Marked differences have been noticed in the number of notifications among Member States, with some carrying out on average more than 50 notifications per year and others notifying less than 10 per year (see Annex 3.2). While this gap can be partly explained with reference to the way the state organisation is structured in different countries (e.g. presence of

¹³ See Recital 7 of the Single Market Transparency Directive.

¹⁴ <http://ec.europa.eu/growth/tools-databases/tris/en/>

¹⁵ See *supra*, footnote 2.

¹⁶ See Annex 3.1. These figures do not include notifications from EFTA countries that are signatories of the EEA Agreement (Norway, Lichtenstein and Iceland), or notifications from Turkey or Switzerland. In the reporting period, the Commission received 232 notifications by these countries (124 by EFTA/EEA countries, 74 by Turkey and 34 by Switzerland). See Annex 4 for more information about these notifications.

regional/local authorities with regulatory powers), by lack of awareness or by a higher/lower degree of regulatory activity, this wide discrepancy raised doubts as to whether there has been full compliance with the notification obligations. Analysis showed that in 2017, 2018 and 2019 almost all Member States did not notify nor re-notify draft technical regulations. However, the vast majority of Member States had relatively low numbers of non-notified drafts, equal to or below 10 per year.

A correlation between the size of the Member States and the number of notifications can be observed in Annex 3.2 (Table 1), with the biggest Member States notifying in general more than the medium-sized and small ones. This can be partly explained by a higher number of regional and local authorities that 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 certain bigger Member States and bigger Member States with a centralised structure notified more than Member States with a decentralised structure.

As in the previous reporting period, the highest number of notifications over 2016-2020 concerned **the construction sector, followed by** the notifications in the area of **agricultural products, fishery, aquaculture and other foodstuffs**.

Numerous notifications were also made in the area of **information society services**, in the **environmental and chemical sectors** (mainly on packaging and packaging waste, plastic products, fertilisers, plant protection products containing glyphosate or neonicotinoids, emission standards, cosmetic products containing microplastics) and **transport** (e.g. on electric vehicles, special equipment for passenger vehicles and taxis, snow mobiles, e-scooters, ships and recreational craft, drones) (see Annex 3.3).

► **Issues addressed by the Commission in its reactions**

In the **non-harmonised areas**, i.e. those in which national measures in the 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 connected to the information society) TFEU, the Commission's reactions were intended to draw the Member States' attention to potential non-justified obstacles to trade after assessing the necessity and the proportionality of the measure in line with the case-law of the Court of Justice of the European Union.

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

- In 2016-2020, Member States notified 765 draft technical regulations in the field of **construction** (131 in 2016, 181 in 2017, 139 in 2018, 158 in 2019 and 156 in 2020¹⁷). These drafts concerned all types of construction products, including 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, and 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

¹⁷ See Annex 3.3.

mainly under Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products¹⁸.

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)¹⁹ and Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels²⁰.

Technical regulations relating to buildings' energy efficiency were assessed under Directive 2012/27/EU on energy efficiency²¹, Directive 2010/31/EU on the energy performance of buildings²² and Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products²³.

The Commission also assessed draft legislation concerning requirements for motorway communications equipment. The draft notified was examined under Directives 1999/5/EC²⁴, 2006/95/EC²⁵ and 2004/108/EC²⁶.

- On **agricultural products, fishery, aquaculture and other foodstuffs**, from 2016 to 2020 Member States notified 693 draft technical regulations (145 in 2016, 106 in 2017, 146 in 2018, 161 in 2019 and 135 in 2020²⁷). The areas covered by these drafts included, for instance, 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 were examined under the TFEU provisions on the free movement of goods and Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs²⁸.

¹⁸ 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.

¹⁹ 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.

²⁰ 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.

²¹ 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.

²² 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.

²³ 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.

²⁴ 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, 7.4.1999, p. 10.

²⁵ 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, 27.12.2006, p. 10.

²⁶ 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, 31.12.2004, p. 24.

²⁷ See Annex 3.3.

²⁸ 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.

During the relevant period, the Commission examined 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 foodstuffs²⁹, Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin³⁰ and Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption³¹.

Other notifications concerned the labelling of foodstuffs. The Commission assessed their compatibility with Regulation (EU) No 1169/2011 on the provision of food information to consumers³², in particular with the provisions on nutritional declarations, or other sector-specific provisions on consumer information³³.

- In the **information society services sector**, Member States notified 255 measures (58 in 2016, 43 in 2017, 34 in 2018, 57 in 2019 and 63 in 2020³⁴), with the bulk of notifications concerning draft legislation affecting electronic commerce, social media and online platform operators, net neutrality and media pluralism, fake news and online hate speech, as well as other rules on information society services falling within the scope of Directive 2000/31/EC ('the e-Commerce Directive')³⁵ and rules related to audiovisual media services falling within the scope of Directive (EU) 2018/1808 (the revised Audiovisual Media Services Directive)³⁶.

²⁹ 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.

³⁰ 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.

³¹ 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. Regulation (EC) No 854/2004 was repealed by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1.

³² 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.

³³ 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.

³⁴ See Annex 3.3.

³⁵ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'), OJ L 178, 17.7.2000, p. 1.

³⁶ Directive (EU) 2018/1808 of the European Parliament and of the Council of 14 November 2018 amending Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) in view of changing market realities, OJ L 303, 28.11.2018, p. 69.

Other Commission reactions were issued in relation to notified draft measures concerning rules on information society services focusing on electronic identification and trust services falling under the scope of Regulation (EU) 910/2014 (the ‘eIDAS Regulation’)³⁷ and the free flow of non-personal data as regulated under Regulation (EU) 2018/1807³⁸. There were also notifications on digital data privacy, cybersecurity, data retention, electronic invoicing, copyright, telecom and electronic communications (including 5 G), safer internet for kids, e-books, online gambling and in several cases linked, in explicit or in ancillary terms, to the free movement of services and freedom of establishment (Articles 49 and 56 TFEU, as well as the Services Directive³⁹), to consumer rights under Directive 2011/83/EU⁴⁰, to the protection of personal data under the General Data Protection Regulation (EU) 2016/679⁴¹, and to the freedom of expression and the freedom to conduct a business as enshrined in the Charter of Fundamental Rights of the European Union.

- In the **chemicals** sector, the Commission received 167 notifications (32 in 2016, 32 in 2017, 28 in 2018, 27 in 2019 and 48 in 2020⁴²), regarding areas such as biocidal products, plant protection products and products falling within the scope of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (‘REACH’)⁴³, which were mainly examined under the Biocidal Products Regulation⁴⁴, Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market⁴⁵ and under REACH.
- In the **environmental sector**, the Commission examined 206 draft measures (55 in 2016, 39 in 2017, 28 in 2018, 33 in 2019 and 51 in 2020⁴⁶). Some notified drafts concerned packaging waste and disposable plastic products and raised problems of compatibility with Directive 94/62/EC on packaging and packaging waste⁴⁷ (for

³⁷ Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, OJ L 257, 28.8.2014, p. 73.

³⁸ Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union, OJ L 303, 28.11.2018, p. 59.

³⁹ 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.

⁴⁰ Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council, OJ L 304, 22.11.2011, p. 64.

⁴¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1.

⁴² See Annex 3.3.

⁴³ 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.

⁴⁴ 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.

⁴⁵ 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, OJ L 309, 24.11.2009, p. 1.

⁴⁶ See Annex 3.3.

⁴⁷ 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.

example with regard to the requirements for banning lightweight plastic carrier bags) and Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment⁴⁸ (for example as regards the definitions of ‘plastic’).

The notification procedure also allowed the Commission to intervene in sectors where harmonisation was envisaged or under way at EU level and thus prevented Member States from introducing divergent national measures. Pursuant to Articles 6(3) and 6(4) of the Single Market Transparency Directive, the Commission requested the notifying Member States to postpone the adoption of notified draft technical regulations for 12 months from the date of notification in the fields of organic production of plants, animals and aquaculture products and foodstuffs (notification 2018/190/BG), organic production of rabbit meat (notification 2018/219/E), organic broiler quails (notification 2018/666/F) and disposable plastic products (notifications 2018/665/B and 2019/9/UK).

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

During the reporting period, the Single Market Transparency Directive proved to be effective in numerous cases as the national authorities redrafted the notified drafts according to the Commission’s recommendations or withdrew them. A case in point was the notification concerning a draft decree obliging car drivers residing in Italy and transporting with them children under 4 years of age to use specific car seat reminder alarm devices that prevent minors from being left behind in the vehicle. In its detailed opinion, the Commission pointed out that several requirements of the notified draft were in conflict with EU harmonisation rules and with the free movement of goods (Articles 34-36 TFEU). This was due to the lack of evidence for: (i) the proportionality of the requirement concerning the prior approval procedure for car seat reminder alarm devices lawfully manufactured in other Member States; and (ii) the obligation to equip those devices with an automatic communication system for sending messages or calls via mobile wireless communication networks to at least three different phone numbers. The Commission highlighted that the ‘prior authorisation procedure’ obliging ‘accredited bodies’ to apply for recognition to the Italian Directorate-General for Motor Vehicles could be in conflict with the principle of free provision of services within the Union (Article 56 TFEU). The Italian authorities redrafted the proposed decree according to the Commission’s remarks, while ensuring that the notified draft measure could attain the objective of children’s safety.

Similarly, in 2016, 2017 and 2018, the Commission received several notifications concerning the characteristics and specific equipment of unmanned aircraft (drones). In its reactions, the Commission recalled the ongoing harmonisation process at EU level and invited the Member States concerned to cooperate to establish an EU regulatory framework applicable to unmanned aircraft which would ensure a high level of safety with regard to the operation of such aircraft and make it possible to manage the associated risks relating to safety, the protection of privacy and of personal data. The Member States concerned complied with the Commission’s recommendations, as expressed in the comments and detailed opinions, or withdrew the notified drafts⁴⁹.

In 2020, at the outset of the COVID-19 pandemic, some Member States adopted or prepared national measures affecting the free movement of personal protective equipment such as protective glasses, facemasks, gloves, surgical overalls and gowns, and the free movement of medicines. These measures risked preventing such essential goods from

⁴⁸ Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment, OJ L 155, 12.6.2019, p. 1.

⁴⁹ See Annex 3.9 for additional examples.

reaching those who needed them most, notably healthcare workers, field intervention teams and patients in affected areas all across Europe. They created domino effects, with Member States taking measures to mitigate the impact of measures taken by other Member States. In a short time span, restrictions spread to an increasing range of products, starting with personal protective equipment and extending to medicines. Such measures disrupted logistics and distribution chains and encouraged stockpiling responses in the supply chain. Ultimately, such measures reintroduced internal borders at a time where solidarity between Member States was the most needed. The Commission urged Member States to notify such measures via the Single Market Transparency Directive mechanism and provided guidance on how to do this. The measures notified to the Commission were assessed as a matter of high priority and the Commission supported Member States in correcting those measures that could have hindered the free movement of essential goods in the single market⁵⁰. The experience of the COVID-19 pandemic demonstrated the relevance of the Single Market Transparency Directive procedures, including the urgency procedure (see paragraph 2.2), while it also offered useful lessons for future tackling of adverse single market effects caused by emergency situations. Where the measures were notified after their adoption, as was the case for approximately 150 COVID-19-related notifications in 2020, the notification mechanism offered by the Directive meant that the information and peer-review benefits could still be harnessed during the crisis thanks to the TRIS communication platform, where Member States could get acquainted with the COVID measures adopted by other Member States.

► **Most commonly tackled barriers**

One of the purposes of the Single Market Transparency Directive is to detect areas where recurrent obstacles to the free movement of goods and the freedom to provide information society services arise and, as a result, to identify the need to intervene with harmonisation measures aimed at ensuring a smoother functioning of the single market⁵¹. In the period under analysis, the Commission identified several recurrent barriers in the notified draft measures. These included the lack of the single market clause, misleading and unclear provisions that could have been interpreted and applied as market restrictions or repetition of provisions of EU regulations, the issue of mandatory standards, and additional test methods⁵².

► **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, when assessing notified drafts. The intensity of this exchange of information is proven 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 subsequent exchange of messages (see Annexes 3.4, 3.5, 3.6 and 3.8). This exchange of information provides the Member States with the possibility to ascertain the degree of compatibility of the notified drafts with EU legislation. The Commission met regularly at expert level during the reporting period with representatives of the Member States to clarify outstanding issues, when necessary, and requested supplementary information from Member States to clarify the scope of notified technical regulations.

In the period considered, the Commission issued 212 detailed opinions (60 in 2016, 34 in 2017, 40 in 2018, 38 in 2019 and 40 in 2020), which represent 5.9% of the total number of

⁵⁰ Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup – *Coordinated economic response to the COVID-19 Outbreak*, COM(2020) 112.

⁵¹ See Recital 15 of the Single Market Transparency Directive.

⁵² See Annex 3.11 for additional details on the most common barriers removed.

drafts notified by the Member States over the reporting period. For their part, the Member States issued 243 detailed opinions (78 in 2016, 44 in 2017, 38 in 2018, 30 in 2019 and 53 in 2020). Out of the 1 291 comments issued during the reporting period, 816 were made by the Commission (154 in 2016, 189 in 2017, 184 in 2018, 155 in 2019 and 134 in 2020) and 475 by the Member States (118 in 2016, 74 in 2017, 77 in 2018, 64 in 2019 and 142 in 2020) (see Annexes 3.4 and 3.6). In five cases, the Commission invited the Member States concerned to postpone adoption of the notified technical regulations for 1 year from the date of their receipt, because there was EU harmonisation work announced or under way in the area covered by the notified drafts (see Annex 3.5).

Looking by sector at the number of reactions (comments, detailed opinions and Commission decisions to postpone adoption of a draft) issued by each Member State and the Commission in the reporting period, we can gain further insight into the Member States' participation in the dialogue triggered by the notifications and on the specific interests of certain Member States whose reactions are more concentrated in specific sectors (see Annex 3.6, Table 6). Italy, Spain, Austria and Poland are among the most active Member States. Analysis of the reactions per Member State and by sector shows that Austria, Spain and Italy take a particular interest in the agriculture, fishery and foodstuffs sector. Most of the reactions issued by the Commission concern the construction and agricultural sectors.

Thanks to the access to all notifications and to the messages exchanged within the dialogues, Member States can use the Single Market Transparency Directive to draw on the ideas of their partners. These can be used to solve common problems regarding technical regulations and to understand when a draft technical regulation could be in breach of EU law.

2.2 *Use of the urgency procedure*

Member States may request the Commission to assess their proposal to invoke the urgency procedure provided for in Article 6(7) of the Single Market Transparency Directive if, in order to respond to an urgent and unforeseeable situation they are obliged to adopt technical regulations immediately and do not have time to wait for the 3-month standstill period to consult the Commission and the other Member States beforehand. If the Commission, after reviewing the reasons brought forward by the Member State concerned, accepts the urgency procedure, the standstill period of 3 months does not apply and the measure can be adopted immediately⁵³. It typically takes the Commission several working days after the notification to decide whether it accepts the reasons brought forward by the Member State concerned and allows it to adopt the technical regulations immediately.

Out of a total of 3 553 notifications, Member States made 346 requests to apply the urgency procedure to notified drafts (51 in 2016, 34 in 2017, 35 in 2018, 39 in 2019 and 187 in 2020)⁵⁴. The 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 delays, as well as in cases for which no unforeseeable circumstances were demonstrated. The urgency procedure was deemed justified in 283 cases (41 in 2016, 28 in 2017, 21 in 2018, 29 in 2019 and 164 in 2020). These cases concerned in particular psychotropic substances, control of narcotics, the fight against terrorism, firearms, infection of bees, biocidal products, prohibition of products that are harmful to health, pyrotechnic articles, medicines (critical medicines/substances necessary for the treatment of COVID-19 patients), protective equipment, masks, medical devices and in vitro medical devices, disinfectants and alcohols needed for their production (see Annex 3.7).

⁵³ See Annex 1 for further details on the urgency procedure.

⁵⁴ See Annex 3.7.

2.3 Notification of ‘fiscal or financial measures’

Under the Single Market Transparency Directive, Member States have to provide notification of ‘fiscal and financial measures’, i.e. technical regulations linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical regulations. The peculiarity of such measures is that the standstill period does not apply (Article 7(4) of the Single Market Transparency Directive).

During the period 2016-2020, Member States notified 149 draft measures as ‘fiscal or financial measures’ (44 in 2016, 48 in 2017, 26 in 2018, 31 in 2019 and 45 in 2020)⁵⁵.

2.4 Follow-up to Commission reactions

Under 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 2016 to 2020, the ratio between the number of responses by the Member States to Commission detailed opinions and the volume of detailed opinions issued by the Commission was satisfactory, but could be further improved (an average of 87% over the period). Satisfactory responses by Member States accounted on average for 45% of the replies (see Annex 3.8).

In the period considered, the Member States withdrew 217⁵⁶ draft technical regulations. In 30 cases (4 in 2016, 13 in 2017, 9 in 2018, 2 in 2019 and 2 in 2020) the withdrawal followed the adoption of a detailed opinion issued by the Commission. Reasons for these withdrawals include: (i) the notifying Member State’s introduction of substantial changes to the draft technical regulation, which required a new notification (Article 5(1) of the Directive); and (ii) the national authorities’ simple decision not to go ahead with adopting the draft technical regulation. For other notified draft technical regulations the dialogue is still ongoing.

2.5 Follow-up to the notification procedure

For those cases in which the potential breaches of the EU internal market law were not entirely removed via the notification procedure, the Commission conducted further investigations (e.g. on plant protection products, electronic cigarettes, tobacco). The Commission also conducted investigations on Member States’ alleged breaches of the notification obligation, for example, in relation to rules on taximeters, glass bottles for wine and spirits, advertising equipment, waste, gambling, gaming machines, fluorinated greenhouse gas emissions, plastic products, furniture, collaborative economy, etc. In such cases, the Commission informed the concerned national contact point for the Single Market Transparency Directive of the consequences of breaching the notification obligation and recalled the obligation to notify.

2.6 Structured exchanges with the Member States, EEA-EFTA countries, Switzerland and Turkey

The regular meetings of the Technical Regulations Standing Committee fostered a fruitful exchange of views on points of general interest and also on specific aspects of the notification procedure.

As regards the notification procedure, the discussions in the context of the Technical Regulations Standing Committee meetings particularly concerned:

⁵⁵ See Annex 1 for further details on the ‘fiscal and financial measures’.

⁵⁶ Data extrapolated on 14 July 2021.

- the urgency procedure under the Single Market Transparency Directive;
- access to documents of the Commission and confidential notifications;
- the notification procedure for the Swiss and EEA notifications;
- the obligation for Member States to communicate to the Commission the final text of a notified technical regulation;
- developments on CJEU jurisprudence concerning the Single Market Transparency Directive; and
- the functioning of the one-stop shop mechanism.

Based on requests from the Member States or on the initiative of the Commission, the Commission gave presentations in the Technical Regulations Standing Committee to provide clarification on some recurrent barriers or on new pieces of EU legislation. The presentations concerned:

- Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment;
- the notification procedure under the Services Directive 2006/123/EC Regulation (EU) 2018/1807 on the free flow of non-personal data in the EU;
- the General Data Protection Regulation (EU) 2016/679;
- the Road Safety Directives 2014/45/EU⁵⁷, 2014/46/EU⁵⁸ and 2014/47/EU⁵⁹;
- restrictions on microbeads at EU level;
- Directive 94/62/EC on packaging and packaging waste;
- the single market clause and Articles 34-36 TFEU.

Several Member States shared their best practices for notifications under the Single Market Transparency Directive with the Standing Committee.

Bilateral meetings were also held in many Member States as part of the ‘country knowledge’ missions. These meetings aimed to target specific single market needs of each Member State by means of a direct dialogue between the Commission and the national authorities, as well as through meetings with national stakeholders. In this context, the Commission visited several EU capitals⁶⁰ and attended meetings with Member State authorities and national stakeholders. The main problems concerning implementation of the Single Market Transparency Directive at national level as identified through these missions concern the low level of notifications (e.g. in Romania, Lithuania and Portugal), administrative capacity (e.g. in Bulgaria) or coordination issues (e.g. in Italy, Spain and Germany) and limited knowledge of the Single Market Transparency Directive by national administrations.

Throughout the reference period, the Commission also discussed the application of the Directive in the compliance dialogue meetings with Member States, which are carried out following the commitment on the single market strategy. The Commission also regularly gave ad hoc technical seminars to the national authorities involved in the notification procedure.

⁵⁷ Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC, OJ L 127, 29.4.2014, p. 51.

⁵⁸ Directive 2014/46/EU of the European Parliament and of the Council of 3 April 2014 amending Council Directive 1999/37/EC on the registration documents for vehicles, OJ L 127, 29.4.2014, p. 129.

⁵⁹ Directive 2014/47/EU of the European Parliament and of the Council of 3 April 2014 on the technical roadside inspection of the roadworthiness of commercial vehicles circulating in the Union and repealing Directive 2000/30/EC, OJ L 127, 29.4.2014, p. 134.

⁶⁰ The Commission visited Bulgaria, Spain, Poland, Romania, Italy, France, Germany, Portugal, Ireland and Lithuania.

Turkey improved its participation in the notification procedure over the reference period.

2.7 Transparency

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

From 2016 to 2020 the Commission received 531⁶¹ requests for access to documents issued in the context of the Single Market Transparency Directive. Most requests concerned detailed opinions and comments delivered by the Commission. In line with the latest developments in CJEU case-law (see Annex 2, Case C-331/15 P, *France v Schlyter*), most of the documents were disclosed.

2.7.2 Participation of stakeholders

Transparency is a fundamental feature of the notification procedure. The TRIS website, which is publicly available, ensures that stakeholders are constantly informed about all draft technical regulations under preparation by Member States and that a dialogue between stakeholders and the Commission takes place, thanks to the function enabling stakeholders to submit contributions on draft technical regulations. As already mentioned, between 2016 and 2020, the Commission received 1 618 contributions via this functionality. Over the reference period, the Commission also started translating the final texts of the notified measures into all EU languages. The translations of the final texts are available on the TRIS website and provide additional transparency.

The success of the TRIS website is confirmed by numbers:

- At the end of 2020 there were 6 467 active subscribers to the TRIS mailing list, compared to 5 196 at the end of 2015, marking a 25% increase over the 5-year reporting period.
- In the period considered, 871 744 searches were carried out through the TRIS website (151 202 in 2016, 134 737 in 2017, 152 158 in 2018, 197 341 in 2019 and 236 306 in 2020), with an average of 174 349 searches per year⁶².
- Access to notifications by users also increased, from 1 203 299 occurrences by the end of 2015 to 7 394 991 by the end of 2020, amounting to a specific increase of 514.6% over the whole reference period 2016-2020 compared with the end of 2015.

3. CONCLUSION

During the period 2016-2020, the effectiveness of the Single Market Transparency Directive procedure was confirmed again in terms of transparency, administrative cooperation and prevention of technical barriers in the single market. The notification procedure's preventive and networking approach reduced the risk that national regulatory activities could create technical barriers to the free movement of goods and information society services. In that respect, boosting the Member States' participation in the Single Market Transparency Directive procedure, both in terms of notifications sent and of reactions to drafts notified by other Member States, demonstrates the joint ownership of the single market, which is a key objective for the Commission. In 2020, during the COVID-19 pandemic, the Single Market

⁶¹ As there was no possibility to encode the lead Unit for access to document requests in the Commission databases during the period from 1.1.2018 to 1.10.2018, the figures concerning this period are based on a simulation using the average percentage of requests for access to documents assigned to the Unit in charge of the management of the Single Market Transparency Directive for the years 2016, 2017 and 2019.

⁶² See Annex 5.

Transparency Directive procedure ensured that that the primary objective of protecting health and human life was pursued by national measures in compliance with the single market rules. The Directive and its notification system supported Member States in this respect by ensuring transparency, synergies and, ultimately, European solidarity.

The Directive's importance is proven by stakeholders' growing interest in the notification procedure and the number of contributions by them via the TRIS website in the reference period. This growing interest mirrors the effort to improve the transparency and the efficiency of the TRIS website.

The notification procedure has also confirmed its usefulness in providing the possibility to identify areas where further harmonisation at EU level is necessary, such as harmonisation of packaging labelling for disposal of waste. Efforts will continue to ensure a clear legal framework for economic operators, aiming to enhance the competitiveness of European enterprises in the EU and abroad, while taking into account the links between the notification procedure and the procedure established by the Agreement on Technical Barriers to Trade in the context of the World Trade Organization (WTO)⁶³.

The experience gained in these recent years is essential to build up this improved landscape for the implementation of the Single Market Transparency Directive. To achieve the Directive's full potential, the Commission will continue to incentivise Member States' participation, both in notifying national draft technical regulations and in reacting to drafts notified by other Member States. In its reactions, the Commission will put special emphasis on matters of significant importance to the single market and on those that serve in particular to efficiently address bottlenecks identified in the context of the recovery and green and digital transitions. This greater focus will also lead to the appropriate follow-up to the Commission reactions so that effective action is taken to prevent potential barriers from being put in place.

⁶³ In the period concerned, the EU Member States, the EFTA Member States that are signatories to the EEA Agreement, Switzerland and Turkey flagged 363 notifications in the TRIS database as being subject to notification to the WTO under the Agreement on Technical Barriers to Trade.