EUROPEAN
COMMISSION

Brussels, 23.9.2022
SWD(2022) 297 final

COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

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

{COM(2022) 481 final}

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ANNEX 1 – BRIEF DESCRIPTION OF THE NOTIFICATION PROCEDURE

This annex gives a general overview of the notification procedure for products and indicates the specific procedural rules that apply to information society services. For a more detailed description of the procedure, please refer to the information brochure *Guide to the procedure for the provision of information in the field of technical regulations and of rules on Information Society services*, available at https://ec.europa.eu/growth/tools-databases/tris/en/the-20151535-and-you/being-informed/guidances/vademecum/.

Legal bases

Introduced in 1984 by Directive 83/189/EEC[1], the notification procedure in the field of technical regulations has gradually been extended to all industrial, agricultural and fishery products. In 1998, Directive 83/189/EEC was repealed and codified by Directive 98/34/EC[2]. Directive 98/34/EC was in turn amended by Directive 98/48/EC[3] in order to extend the notification procedure to information society services, with the adaptations needed to take account of the demands of the sector. In 2015, Directive 98/48/EC was repealed and replaced by Directive (EU) 2015/1535[4] with the aim of codifying it after the adoption of Regulation (EU) No 1025/2012[5].

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 their transparency, clarity 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 their businesses to the new rules, reducing the cost of accessing the regulations and applying them correctly.

Obligation to notify and standstill period

Article 5(1) of Directive (EU) 2015/1535 (the Single Market Transparency Directive) stipulates that the EU Member States must inform the Commission of any draft technical regulation prior to its adoption. Simple transposing an EU act does not require prior notification, unless the national authorities adopt national provisions that go beyond mere

1 Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 109, 26.4.1983, p. 8.

2 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204, 21.7.1998, p. 37.

3 Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 217, 5.8.1998, p. 18.

4 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.

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

automatic compliance with EU acts and that contain technical regulations within the meaning of the Single Market Transparency Directive (Article 7 of the Single Market Transparency Directive). It is the Member States' prerogative to decide whether or not to notify.

Starting from the date of notification of a draft technical regulation, a **three-month standstill** period – during which the notifying Member State cannot adopt the technical regulation in question – enables the Commission and the other Member States to examine the notified text and to respond appropriately. The only derogation from this rule is linked to the nature of the measure in question: for technical regulations linked to fiscal or financial measures, there is no standstill period. This also applies to technical regulations that have to be adopted urgently (see below).

The Commission observes that national measures are often misclassified as a 'fiscal or financial measure' in the meaning of the Single Market Transparency Directive when they contain any fiscal or financial measures not linked to technical regulations. In order to help Member States to correctly classify these measures, the Commission has provided them with some guidelines on the definition and notification of 'fiscal or financial measures' for the purposes of the Single Market Transparency Directive.

Possible reactions and consequences

Where it emerges that the notified drafts may create obstacles to the free movement of goods or the free provision of information society services (Articles 34-36, 49 and 56 of the Treaty on the Functioning of the European Union (TFEU)) or that they are not in line with EU secondary legislation, the Commission and the other Member States may submit a **detailed opinion** to the Member State that has notified the draft (Article 6(2) of the Single Market Transparency Directive). The detailed opinion has the effect of extending the three-month standstill period by an additional 3 months (only 1 additional month in the case of technical regulations related to information socicety services). The Commission and the Member States can also make **comments** on a notified draft (Article 5(2) of the Single Market Transparency Directive). Comments are usually sent when the notified draft text raises issues of interpretation or needs to be complemented with some arrangements for its implementation. The Commission and the Member States can also give an overall assessment of the measure, having regard to the general principles of EU law and policies, or inform the notifying Member State of its future obligations with regard to EU acts to be adopted or implemented. Unlike detailed opinions, comments do not extend the three-month standstill period. The Commission can also block a draft for 12 months (which could be extended to 18 months) if EU harmonisation work is envisaged or already underway in the same field (Article 6(3) to (5) of the Single Market Transparency Directive).

If a detailed opinion is issued, the Member State concerned shall inform the Commission of the action it intends to take in response to the detailed opinion. The Commission then comments on that action (Article 6(2) of the Single Market Transparency Directive). In the case of comments, the Single Market Transparency Directive does not lay down any legal obligation for the Member State that receives the comments to indicate what follow-up action it intends to take.

Urgency procedure

Article 6(7) of the Single Market Transparency Directive describes the urgency procedure, designed to allow the immediate adoption of a national draft, subject to a closed list of certain conditions that must be clearly indicated upon notification. The aim of the urgency procedure is to enable a notifying Member State faced with serious and unforeseeable circumstances to immediately adopt the draft technical regulation in question, without having to wait for the expiry of the three-month standstill period. The Commission decides on the justification for the urgency procedure as soon as possible. If the request to apply the urgency procedure is accepted by the Commission, the three-month stanstill period does not apply and the notified text can be adopted. Nevertheless, any examination of the substance of the text can subsequently be carried out, as part of infringement proceedings for breaching EU law.

Confidential notifications

According to Article 5(4) of the Single Market Transparency Directive information supplied upon notification shall not be confidential except at the express request of the notifying Member State[6]. Any such request shall be supported by reasons.

Although the Directive does not provide elements to interpret how the term 'confidential' in Article 5(4) should be understood, it is apparent that the ultimate objective of the Single Market Transparency Directive is to prevent barriers to the free movement of goods and the provision of information society services, namely by guaranteeing a high level of transparency in the single market. Therefore, when implementing the Single Market Transparency Directive, Member States have to interpret exceptions to the transparency principle in a restrictive manner. The Commission is committed to carefully monitoring Member States' use of confidential notifications under Article 5(4) of the Single Market Transparency Directive, and to taking the necessary measures if it suspects that provision is being abused.

The confidentiality of information supplied upon notification has to be explicitly justified by the notifying Member State with grounded arguments, in line with the proportionality principle. A clear distinction should be made between:

(i) cases in which the need for confidentiality is inherent to the substance of the draft legislation (e.g. the fight against terrorism);

(ii) other cases in which economic grounds are used to justify confidentiality, including copyright protection, frequently used as justification by Member States.

Any general argument on economic grounds put forward by the notifying Member State to substantiate the need for confidentiality is rejected by default.

Communication of final texts

[6] On this aspect see the conclusions of the European Ombudsman in the recent Case 2204/2018/TE: https://www.ombudsman.europa.eu/en/news-document/en/126600?utm_source=some_EO&utm_medium=tw_organic&utm_campaign=TRIS_database

At the end of the notification procedure, the Member States are obliged to inform the Commission when the final texts have been adopted or to indicate if the notified draft has been abandoned, in order to allow the procedure to be closed (Article 5(3) of the Single Market Transparency Directive). However, over the reference period only 2 514 final texts (i.e. 151 in 2016, 596 in 2017, 492 in 2018, 550 in 2019 and 725 in 2020) were communicated to the Commission, out of 3 553 notifications received (i.e. for 71% of the notifications received in the reference period a final text was communicated to the Commission)[7].

Technical Regulations Standing Committee

The Standing Committee mentioned in Article 2 of the Single Market Transparency Directive, comprising representatives appointed by the Member States, is chaired by a Commission representative. The Committee meets twice a year and serves as a forum for discussing all issues concerning the application of the Single Market Transparency Directive.

Application of the notification procedure to information society services

The notification procedure also applies to information society services, with the following adaptations:

a) if a detailed opinion is issued, the total extended standstill period is 4 months, instead of the 6 months stipulated for products (see above);

b) the Commission can only block the draft if the subject of the draft is already covered by a proposal presented by the Commission to the European Parliament and the Council and if the notified text contains provisions that do not comply with the Commission's proposal;

c) the urgency procedure can be invoked under specific circumstances additional to those applicable to products.

The simplified procedure

European Free Trade Association (EFTA) countries that are contracting parties to the Agreement on the European Economic Area (EEA), namely Norway, Iceland and Liechtenstein, apply the notification procedure with the necessary adaptations[8]: they notify their drafts through the EFTA Surveillance Authority and can comment on the drafts notified by EU Member States. On the other hand, EU Member States can comment on the draft technical regulations notified by the three countries that are contracting parties to the EEA Agreement.

Switzerland (which is part of the EFTA, but applies the EEA Agreement) also participates in the system. It submits its drafts to the Commission and can make or receive comments on the notified drafts on the basis of an informal agreement on the exchange of information in the field of technical regulations.

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7 Data extrapolated on 15 July 2021.

8 See point 1 of Annex II, Chapter XIX, to the EEA Agreement.

Turkey participates in the procedure in the same way as the EFTA countries that are contracting parties to the EEA Agreement. The decision to include Turkey in the notification system was taken in 1997 as part of the implementation of the final phase of the Customs Union between Turkey and the European Community.

ANNEX 2- CASE-LAW ON THE SINGLE MARKET TRANSPARENCY DIRECTIVE IN 2016-2020

In the reference period the Court of Justice of the European Union (CJEU) issued several judgments referring to the Single Market Transparency Directive that help to clarify some aspects of the Directive.

Definition of a technical regulation

As regards the definition of a technical regulation, in Case C-62/19, *Star Taxi app*[9], the CJEU argued that in order to be qualified as a 'technical regulation' under the Single Market Transparency Directive, a national measure concerning information society services should not only be considered a rule on information society services as defined in Article 1(1)(e) of the Single Market Transparency Directive, but also be binding *de jure* (by law) or *de facto* (by dint of circumstances), in particular, for the provision of the service concerned or its use, in a Member State or a significant part of it.

In Case C-275/19, *Sportingbet and Internet Opportunity Entertainment*[10], the CJEU clarified that national legislation stating that the right to operate games of chance is reserved for the State and may be exercised only by undertakings that are established as public limited companies, to which the Member State concerned awards the corresponding concession, and which lays down the conditions and zones for exercising that activity, does not amount to a 'technical regulation' within the meaning of that provision. In the same case, the CJEU also concluded that national legislation which states that the exclusive right to operate certain games of chance awarded to a public entity for the entire national territory is to include such operations on the internet constitutes a 'technical regulation' within the meaning of the first of those provisions, and the failure to communicate that regulation to the European Commission makes that legislation unenforceable against individuals.

In Case C-137/17, *Van Gennip and Others*[11], the CJEU stated that an authorisation requirement for the transport and storage of certain pyrotechnic articles, as a condition for their sale, 'does not constitute a requirement in respect of the product concerned, but for potential buyers and, indirectly, for economic operators selling pyrotechnic articles'. Therefore, it cannot be considered a technical regulation.

In Case C-613/14, *James Elliott Construction*[12], the CJEU concluded that national provisions specifying, unless the parties agree otherwise, implied contractual terms concerning the

9 Judgment of 3 December 2020, *Star Taxi app*, Case C-62/19, EU:C:2020:980.
10 Judgment of 22 October 2020, *Sportingbet and Internet Opportunity Entertainment*, Case C-275/19, EU:C:2020:856.
11 Judgment of 26 September 2018, *Van Gennip and Others*, Case C-137/17, EU:C:2018:771.
12 Judgment of 27 October 2016, *James Elliott Construction*, Case C-613/14, EU:C:2016:821.

merchantable quality and fitness for purpose of the products sold, are not 'technical regulations'.

In accordance with settled case-law[13], the CJEU restated in Case C-303/15, *M.and S.*[14] that national measures merely laying down conditions governing the establishment or provision of services by undertakings, such as national provisions requiring a license to operate a gaming casino for the organisation of roulette games, card games, dice games and gaming on machines, do not constitute technical regulations within the meaning of the Single Market Transparency Directive.

Furthermore, with respect to the notion of a technical regulation, in Case C-727/17, *ECO-WIND Construction*[15], the CJEU clarified that in order to be included in the scope of the category 'other requirements', a requirement should lay down conditions capable of significantly influencing the composition, nature or marketing of a product. On the other hand, in order to fall within the category of 'laws, regulations or administrative provisions of the Member States prohibiting the manufacture, importation, marketing or use of a product', a measure's scope should clearly go beyond a limitation to certain uses of a product and not be confined to a mere restriction of its use. That category is particularly intended to cover national measures that leave no room for any use that could reasonably be made of the product concerned other than a purely marginal one.

Fiscal measures

In Case C-711/19, *Admiral Sportwetten and Others*[16], the CJEU ruled that a national tax rule that puts in place taxation of the operation of betting terminals does not constitute a 'technical regulation' within the meaning of the Single Market Transparency Directive. On the other hand, according to the Court, tax legislation, which is not accompanied by any technical specification or any other requirement with which it is purportedly intended to ensure compliance, cannot be considered as a '*de facto* technical regulation'.

Judgments on rules on services

Regarding the definition of 'rules on services' as laid down in Article 1.1(e) of the Single Market Transparency Directive, and in particular whether or not a rule is specifically aimed at information society services, in Case C-255/16, *Falbert*[17], the CJEU concluded that a national measure that imposes sanctions in the event of advertising for unauthorised gaming, lotteries or betting, constitutes a technical regulation if it is clear from the 'preparatory works' for that provision of national law that its object and purpose was to extend a pre-existing prohibition on advertising to online gaming services, which it is for the national court to determine.

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13 See, to that effect, *Ince* (see below, footnote 3), paragraph 76 and the case-law cited therein.
14 Judgment of 13 October 2016, *M. and S.*, Case C-303/15, EU:C:2016:771.
15 Judgment of 28 May 2020, *ECO-WIND Construction*, Case C-727/17, EU:C:2020:393.
16 Judgment of 8 October 2020, *Admiral Sportwetten and Others*, Case C-711/19, EU:C:2020:812.
17 Judgment of 20 December 2017, *Falbert and Others*, Case C-255/16, EU:C:2017:983.

Furthermore, in *Star Taxi app*[18], the CJEU stated that a service consisting of putting taxi passengers directly in contact, by means of an electronic application, with taxi drivers constitutes an 'information society service' where that service is not inextricably linked to the taxi transport service so that it does not form an integral part of that transport service.

In a similar vein, in Case C-320/16, *Uber France*[19], the CJEU ruled that a provision of national law that lays down criminal penalties for the organisation of a system putting customers in contact with persons carrying passengers by road for remuneration using vehicles with fewer than 10 seats, without being authorised to do so, concerns a 'service in the field of transport' insofar as it applies to an intermediation service that is provided by means of a smartphone application and forms an integral part of an overall service the principal element of which is the transport service. Such a service is excluded from the scope of application of the Single Market Transparency Directive.

More specifically, in Case C-390/18, *Airbnb Ireland*[20], the CJEU concluded that an intermediation service which, by means of an electronic platform, is intended to connect, for remuneration, potential guests with professional or non-professional hosts offering short-term accommodation services, while also providing a certain number of services ancillary to that intermediation service, must be classified as an 'information society service'. The CJEU clarified that, unlike the 'Uber type' intermediation services, Airbnb Ireland does not exercise such a decisive influence over the conditions for the provision of the accommodation services to which its intermediation service relates, particularly since Airbnb Ireland does not determine, directly or indirectly, the rental price charged, still less does it select the hosts or the accommodation put up for rent on its platform. Uber, however, exercises decisive influence over the conditions under which transport services are provided by the non-professional drivers using the application made available to them by that company.

Additionally, in relation to the interpretation of the notion of 'rules on services', the CJEU concluded that a measure that prohibits only commercial operators of search engines and commercial service providers that similarly publish content from making newspapers or magazines or parts thereof (excluding individual words and very short text excerpts) available to the public, constitutes a 'technical regulation' within the meaning of the Single Market Transparency Directive, notably a rule on information society services, the draft of which is subject to prior notification to the Commission[21].

Obligation to notify regional measures

In Case C-336/14, *Ince*[22], the CJEU clarified that the draft version of regional legislation which maintains in force, throughout the region concerned, the provisions of legislation common to the various regions of a Member State that has expired, is subject to the notification obligation, insofar as that regional draft version contains technical regulations. As a result, failure to comply with that obligation renders those regulations unenforceable

18 See *Star taxi app* (see above, footnote 9).
19 Judgment of 10 April 2018, *Uber France*, Case C-320/16, EU:C:2018:221.
20 Judgment of 19 December 2019, *Airbnb Ireland*, Case C-390/18, EU:C:2019:1112.
21 Judgment of 12 September 2019, *VG Media*, Case C-299/17, EU:C:2019:716.
22 Judgment of 4 February 2016, *Ince*, Case C-336/14, EU:C:2016:72.

against individuals. Such an obligation is not called into question by the fact that the common legislation had previously been notified to the Commission at a draft stage because the temporal and territorial scope of the regional draft differs from the common legislation.

Sanction of unenforceability

In Case C-144/16, *Município de Palmela*[23], the CJEU ruled that the sanction of unenforceability of a technical regulation that has not been notified applies only to that technical regulation and not to the entire legislative text containing it.

Failure of a Member State to fulfill its obligations

In Case C-514/19, *Union des industries de la protection des plantes*[24], the CJEU clarified that the communication, under Article 5 of Directive (EU) 2015/1535, of a national measure prohibiting the use of certain active substances falling within the scope of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market[25] must be regarded as the official provision of information on the need to take emergency measures within the meaning of Article 71(1) of that regulation, where: that communication contains a clear presentation of the evidence showing, first, that those active substances are likely to constitute a serious risk to human or animal health or to the environment and, second, that that risk cannot be satisfactorily controlled without the adoption, as a matter of urgency, of the measures taken by the Member State concerned, and where the European Commission failed to ask that Member State whether that communication must be treated as the official provision of information under Article 71(1) of that Regulation.

Access to documents in relation to the Single Market Transparency Directive procedure

As regards the requests for access to documents concerning the detailed opinions issued in the framework of the Single Market Transparency Directive, thanks to the CJEU judgment in Case C-331/15 P, *France v Schlyter*[26], access to such documents has been facilitated.

On 29 December 2011, the French authorities notified to the Commission, in the context of the Single Market Transparency Directive, a draft Order relating to the content and submission conditions of the annual declaration of nanoparticle substances (notification 2011/673/F). On 30 March 2012, the Commission delivered a detailed opinion, extending the initial standstill period by 3 additional months. On 16 April 2012, during the standstill period, Mr Carl Schlyter requested access to the detailed opinion in question. The Commission rejected that request by letter dated 7 May 2012. Mr Schlyter then submitted a confirmatory application asking the Commission to reconsider its position. On 27 June 2012, the Commission rejected Mr Schlyter's confirmatory application. On 6 September 2012, Mr Schlyter sought an annulment, before the General Court of the European Union, of the decision of the Commission of 27 June 2012 refusing access to its detailed opinion.

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23 Judgment of 1 February 2017, *Município de Palmela*, Case C-144/16, EU:C:2017:76.

24 Judgment of 8 October 2020, *Union des industries de la protection des plantes*, Case C-514/19, EU:C:2020:803.

25 See footnote 36.

26 Judgment of 7 September 2017, *France v Schlyter*, Case C-331/15 P, EU:C:2017:639.

In its judgment of 16 April 2015, *Schlyter v Commission*[27], the General Court held, principally, that a detailed opinion delivered by the Commission in the context of the procedure laid down in the Single Market Transparency Directive does not fall within the scope of an investigation for the purposes of the third indent of Article 4(2) of Regulation No 1049/2001 regarding public access to European Parliament, Council and Commission documents[28], and that disclosing such a detailed opinion during the standstill period would not necessarily adversely affect the purpose of that procedure. The General Court therefore annulled the decision of the European Commission not to give access to the detailed opinion to Mr Schlyter during the standstill period.

France appealed the decision of the General Court in order to have its judgment set aside, in which it had annulled the decision of the European Commission refusing, during the standstill period, access to its detailed opinion concerning the draft Order relating to the content and submission conditions of the annual declaration of nanoparticle substances.

In its judgment, the CJEU stressed that the general requirement underlying the Single Market Transparency Directive is transparency. However, the requirement of transparency does not prevent the Commission, in light of the circumstances of a particular case, from relying on the third indent of Article 4(2) of Regulation 1049/2001, 'in order to deny access to a detailed opinion delivered by itself or a Member State when it is able to demonstrate that access to the detailed opinion in question would specifically and actually undermine the objective of preventing a technical regulation that is incompatible with EU law from being adopted'.

ANNEX 3 – APPLICATION OF THE PROCEDURE BETWEEN 2016-2020: NOTIFICATIONS SUBMITTED BY THE MEMBER STATES

Annexes 3.1, 3.2 and 3.3 give a statistical overview of the development of the number of draft technical regulations notified by the Member States from 2016 to 2020, and of their breakdown by Member State and by sector. In accordance with Article 8 of the Single Market Transparency Directive, 'statistics concerning communications received' as part of the notification procedure are published once a year in the Official Journal C series[29].

Reactions to the notified drafts – in the form of comments or detailed opinions from the Commission or a Member State, or of blockages on the part of the Commission – are set out in Annexes 3.4, 3.5 and 3.6.

Annex 3.7 presents the requests to apply the urgency procedure that the Member States addressed to the Commission pursuant to Article 6(7) of the Single Market Transparency Directive.

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27 T-402/12, EU:T:2015:209.

28 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.

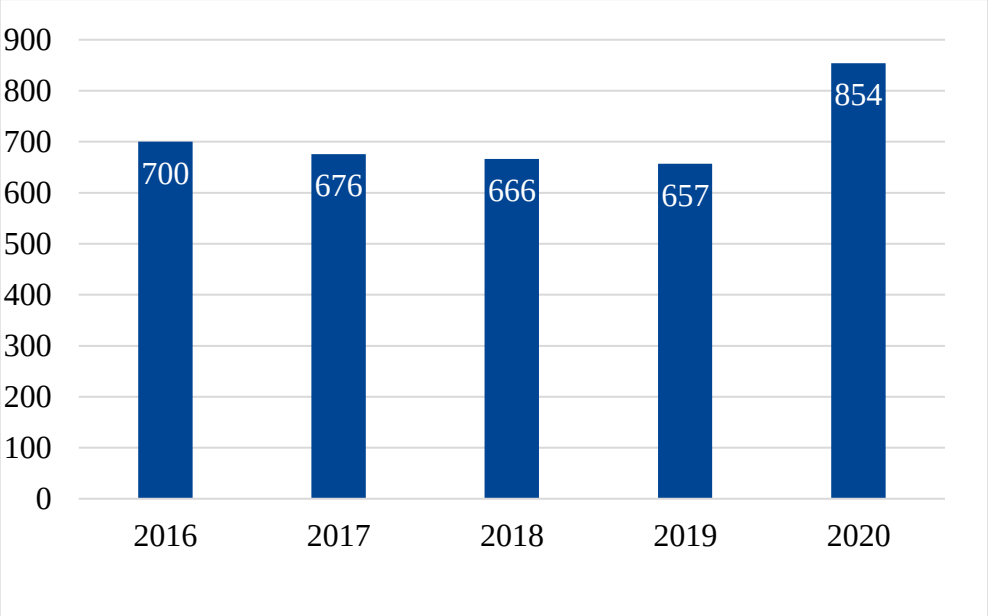
29 For 2016: OJ C 162, 23.5.2017, p. 4.
For 2017: OJ C 372, 15.10.2018, p. 3.
For 2018: OJ C 402, 28.11.2019, p. 1.
For 2019: OJ C 343, 15.10.2020, p. 1.
For 2020: OJ C 334, 20.08.2021, p.1.

Annex 3.8 shows the action taken by Member States in response to the Commission's reactions.

3.1 Volume of notifications during 2016-2020

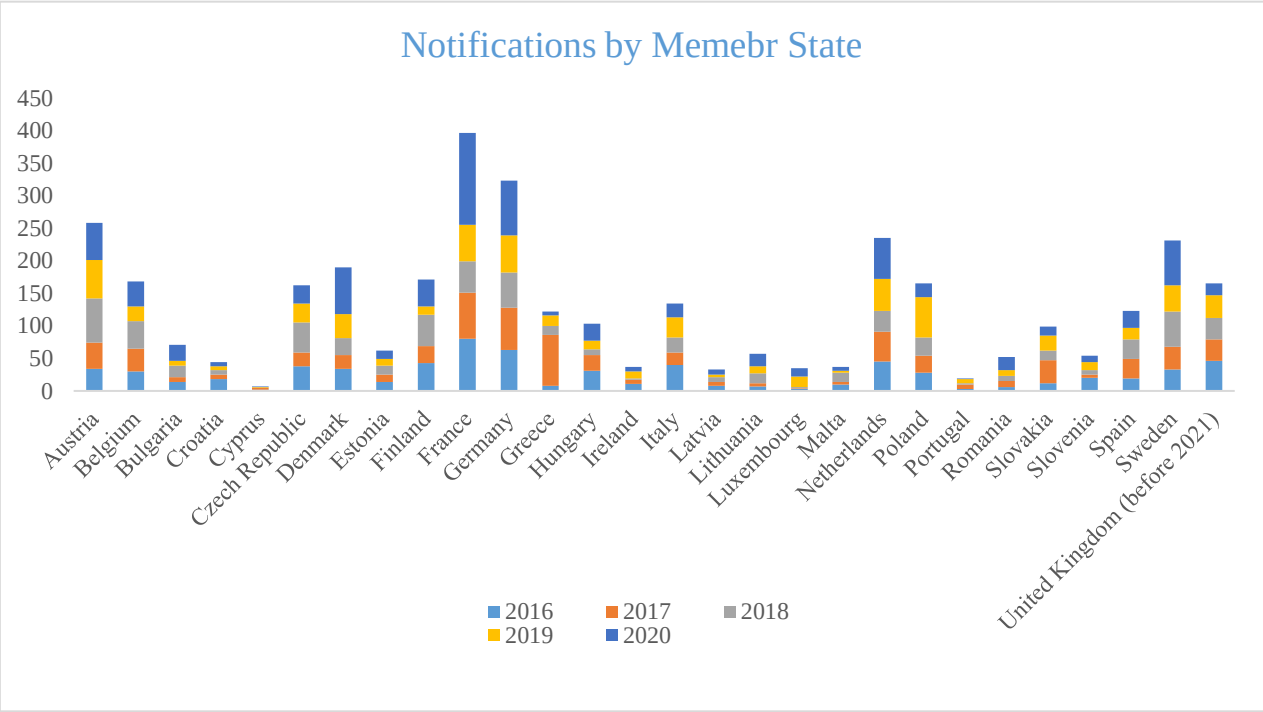
Figure 1: Number of Notifications

Figure 1 shows that the Member States notified 700 draft regulations in 2016, 676 in 2017, 666 in 2018, 657 in 2019 and 854 in 2020 to the Commission.



3.2 Breakdown by country

Figure 2: Notifications by Member State



During the 2016-2020 period, the three Member States that notified the highest number of draft technical regulations were France (396), Germany (323) and Austria (258). They are followed by eight other Member States (The Netherlands, Sweden, Denmark, Finland, Belgium, the United Kingdom, Poland, the Czech Republic), with a total number of notifications between 162 and 235. At the other end of the spectrum, the three Member States that notified the lowest number of draft technical regulations were Cyprus (7), Portugal (19) and Luxembourg (35).

Table 1 – Number of notifications of technical regulations submitted by the Member States from 2016 to 2020

Member States	2016	2017	2018	2019	2020	Total
Austria	34	40	68	59	57	**258**
Belgium	30	35	42	23	38	**168**
Bulgaria	14	7	18	7	25	**71**
Croatia	18	7	7	6	6	**44**
Cyprus	2	3	0	1	1	**7**
Czech Republic	38	21	46	29	28	**162**
Denmark	34	21	26	37	72	**190**
Estonia	14	11	14	10	13	**62**
Finland	43	26	48	13	41	**171**
France	80	71	48	56	141	**396**
Germany	63	65	54	57	84	**323**
Greece	8	78	14	16	6	**122**
Hungary	31	24	9	13	26	**103**
Ireland	11	6	2	11	7	**37**
Italy	40	19	23	31	21	**134**
Latvia	8	6	7	4	8	**33**
Lithuania	7	5	15	11	19	**57**
Luxembourg	3	1	2	16	13	**35**
Malta	10	4	14	3	6	**37**
Netherlands	45	46	32	49	63	**235**
Poland	28	26	28	62	21	**165**
Portugal	3	7	2	6	1	**19**
Romania	6	9	8	9	20	**52**
Slovakia	12	35	15	23	14	**99**
Slovenia	20	5	7	12	10	**54**
Spain	19	30	30	18	26	**123**
Sweden	33	35	54	40	69	**231**
United Kingdom	46	33	33	35	18	**165**
Total	**700**	**676**	**666**	**657**	**854**	**3553**

Table 2 – Percentage of notifications submitted by the Member States from 2016 to 2020

Member States	2016	2017	2018	2019	2020	2016-2020
Austria	4.9%	5.9%	10.2%	9.0%	6.7%	7.26%
Belgium	4.3%	5.2%	6.3%	3.5%	4.4%	4.73%
Bulgaria	2.0%	1.0%	2.7%	1.1%	2.9%	2.00%
Croatia	2.6%	1.0%	1.1%	0.9%	0.7%	1.24%
Cyprus	0.3%	0.4%	0.0%	0.2%	0,1%	0.20%
Czech Republic	5.4%	3.1%	6.9%	4.4%	3.3%	4.56%
Denmark	4.9%	3.1%	3.9%	5.6%	8.4%	5.35%
Estonia	2.0%	1.6%	2.1%	1.5%	1.5%	1.75%
Finland	6.1%	3.8%	7.2%	2.0%	4.8%	4.81%
France	11.4%	10.5%	7.2%	8.5%	16.5%	11.15%
Germany	9.0%	9.6%	8.1%	8.7%	9.8%	9.09%
Greece	1.1%	11.5%	2.1%	2.4%	0.7%	3.43%
Hungary	4.4%	3.6%	1.4%	2.0%	3.0%	2.90%
Ireland	1.6%	0.9%	0.3%	1.7%	0.8%	1.04%
Italy	5.7%	2.8%	3.5%	4.7%	2.5%	3.77%
Latvia	1.1%	0.9%	1.1%	0.6%	0.9%	0.93%
Lithuania	1.0%	0.7%	2.3%	1.7%	2.2%	1.60%
Luxembourg	0.4%	0.1%	0.3%	2.4%	1.5%	0.99%
Malta	1.4%	0.6%	2.1%	0.5%	0,7%	1.04%
Netherlands	6.4%	6.8%	4.8%	7.5%	7,4%	6.61%
Poland	4.0%	3.8%	4.2%	9.4%	2,5%	4.64%
Portugal	0.4%	1.0%	0.3%	0.9%	0,1%	0.53%
Romania	0.9%	1.3%	1.2%	1.4%	2,3%	1.46%
Slovakia	1.7%	5.2%	2.3%	3.5%	1,6%	2.79%
Slovenia	2.9%	0.7%	1.1%	1.8%	1,2%	1.52%
Spain	2.7%	4.4%	4.5%	2.7%	3,0%	3.46%
Sweden	4.7%	5.2%	8.1%	6.1%	8,1%	6.50%
United Kingdom	6.6%	4.9%	5.0%	5.3%	2,1%	4.64%

3.3 Breakdown by sector

Figure 3: Breakdown by sector of the drafts notified by Member States of the EU from 2016 to 2020

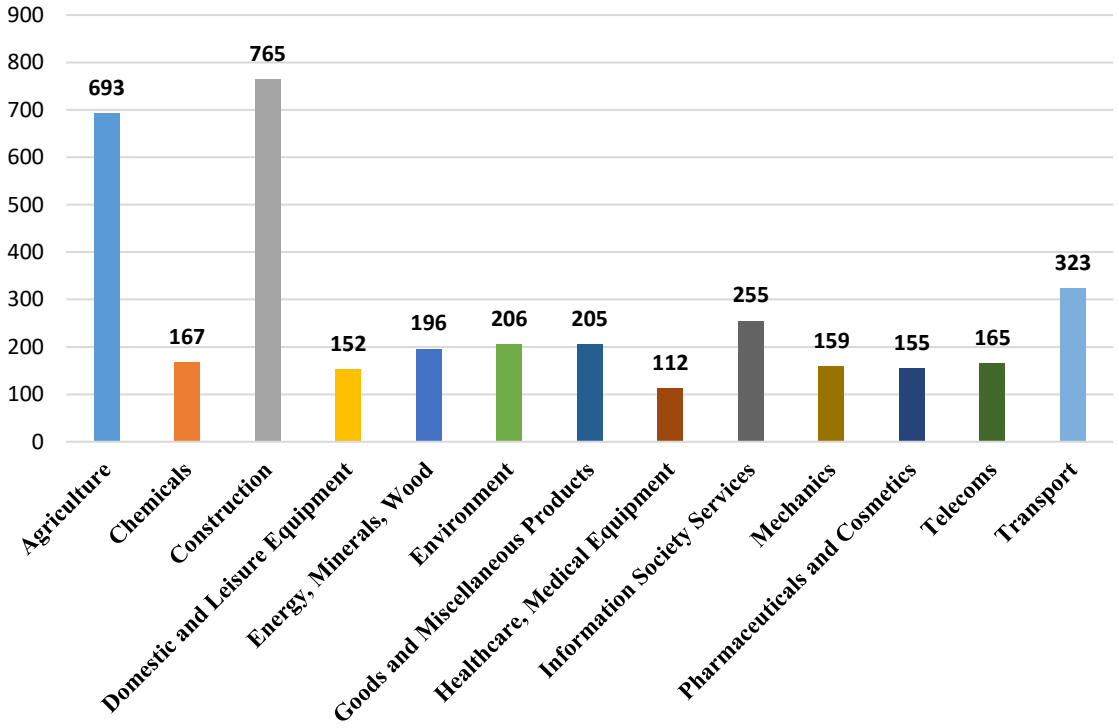


Figure 4: Breakdown by sector in 2016

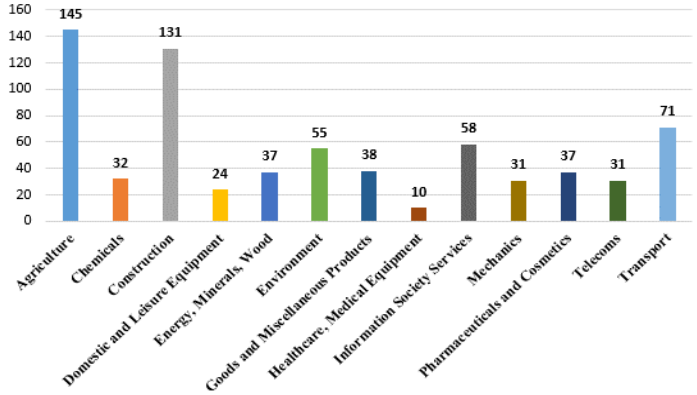


Figure 5: Breakdown by sector in 2017

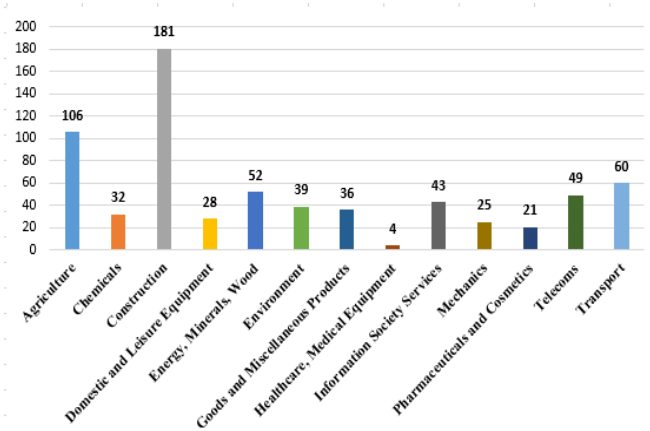


Figure 6: Breakdown by sector in 2018

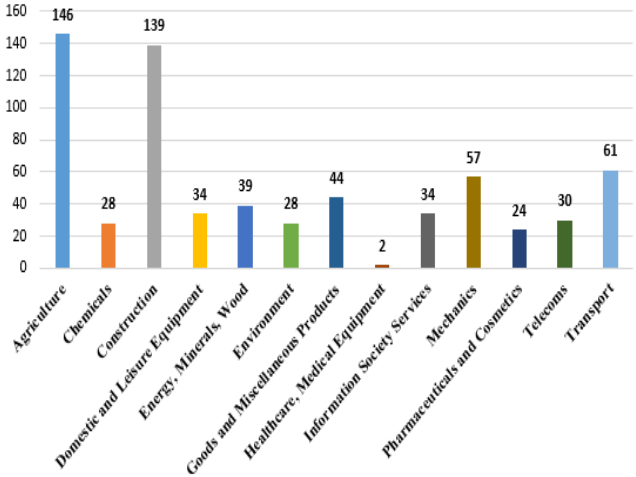


Figure 7: Breakdown by sector in 2019

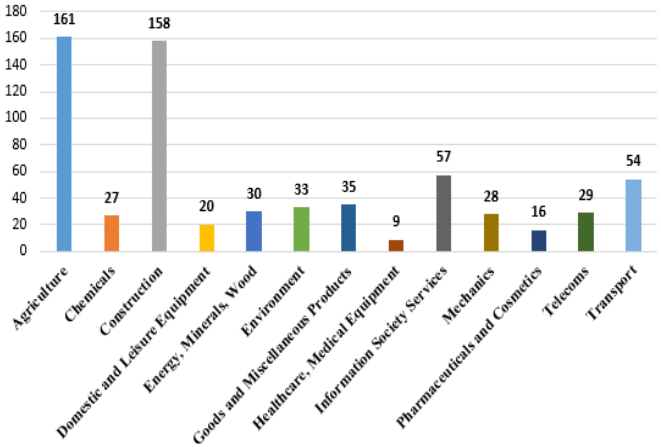


Figure 8: Breakdown by sector in 2020

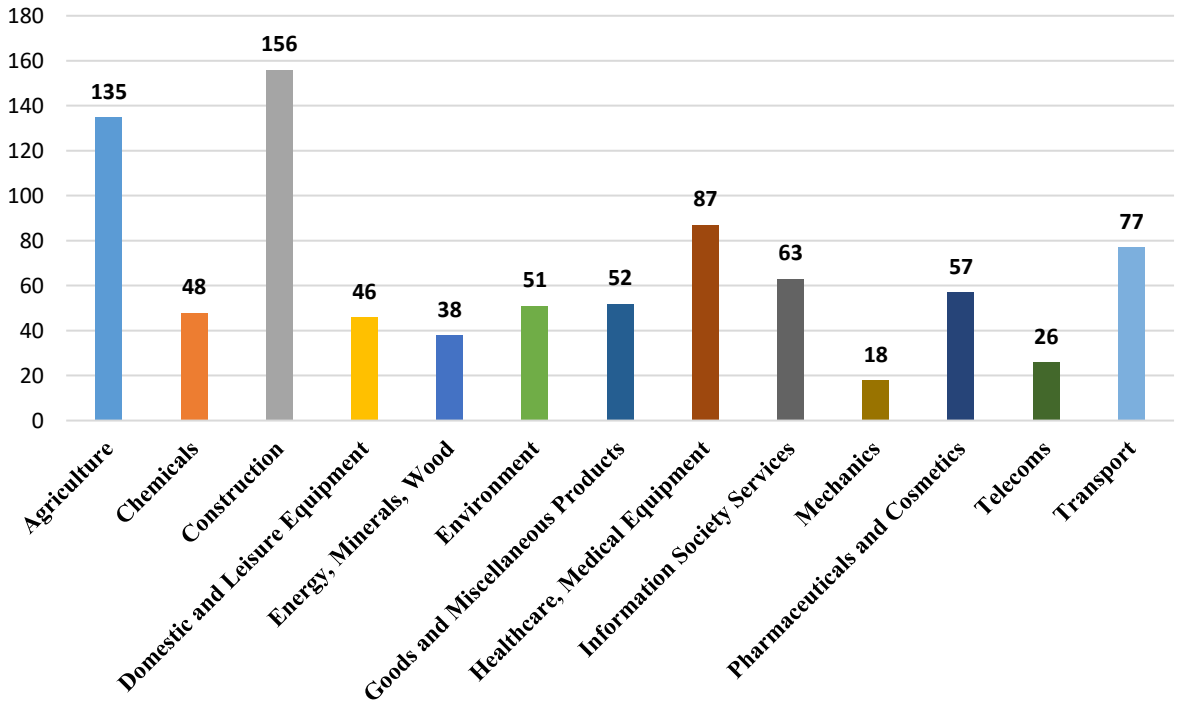


Figure 9: Percentage per sector of the drafts notified by the Member States of the EU from 2016 to 2020

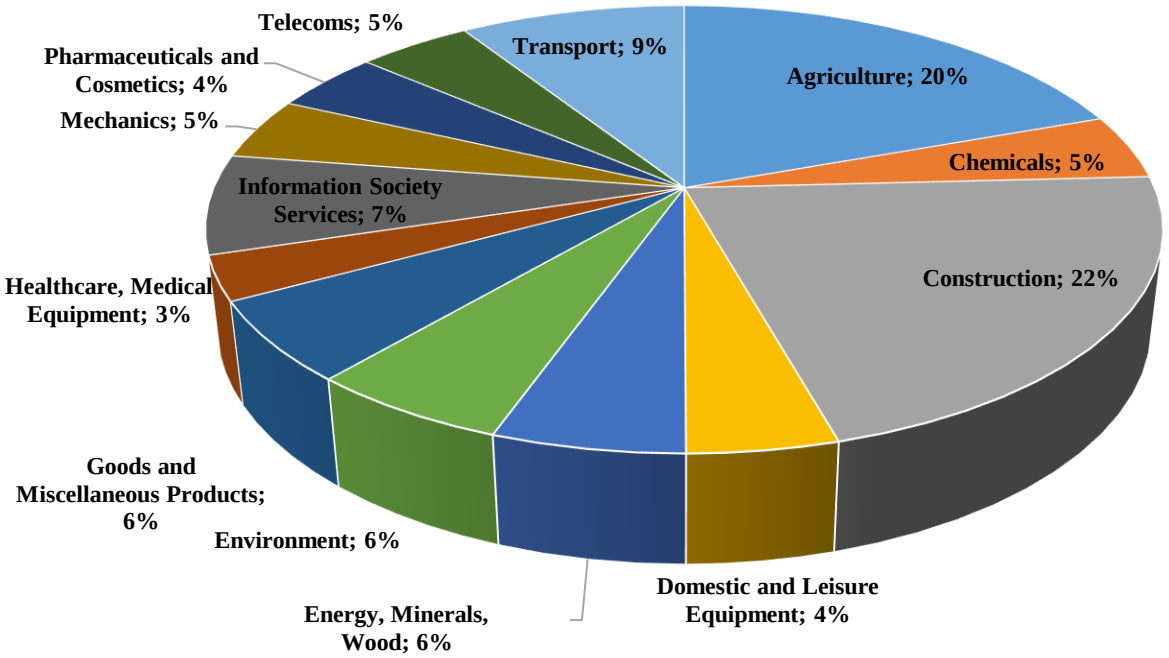


Figure 10: Breakdown by sector in 2016

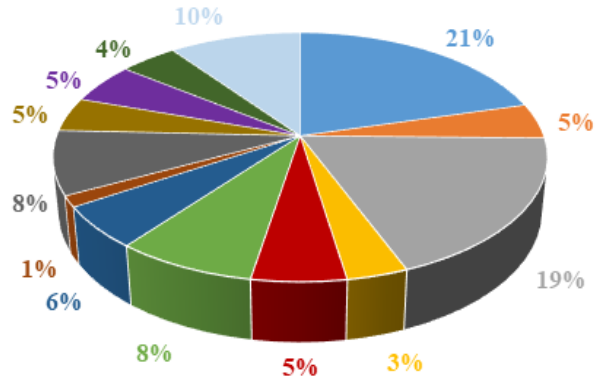


Figure 11: Breakdown by sector in 2017

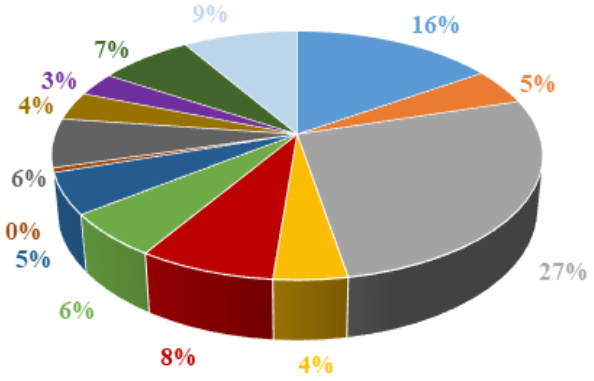


Figure 12: Breakdown by sector in 2018

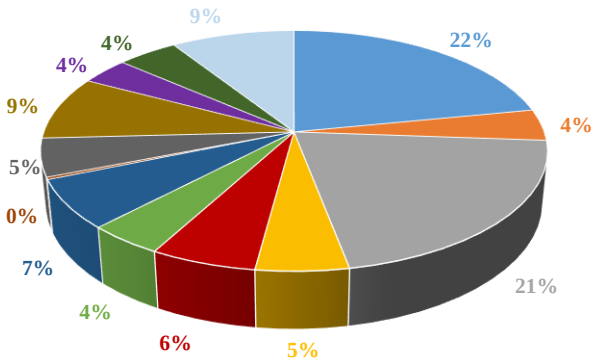


Figure 13: Breakdown by sector in 2019

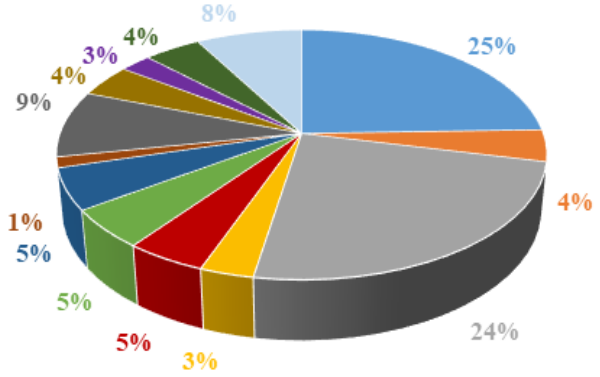
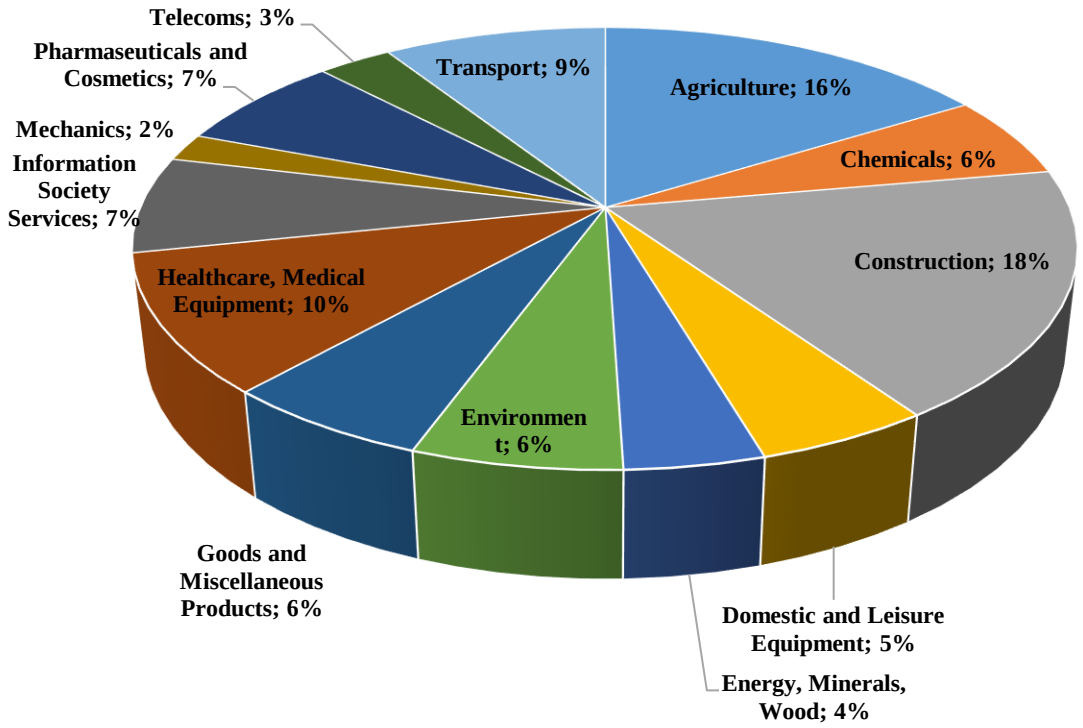
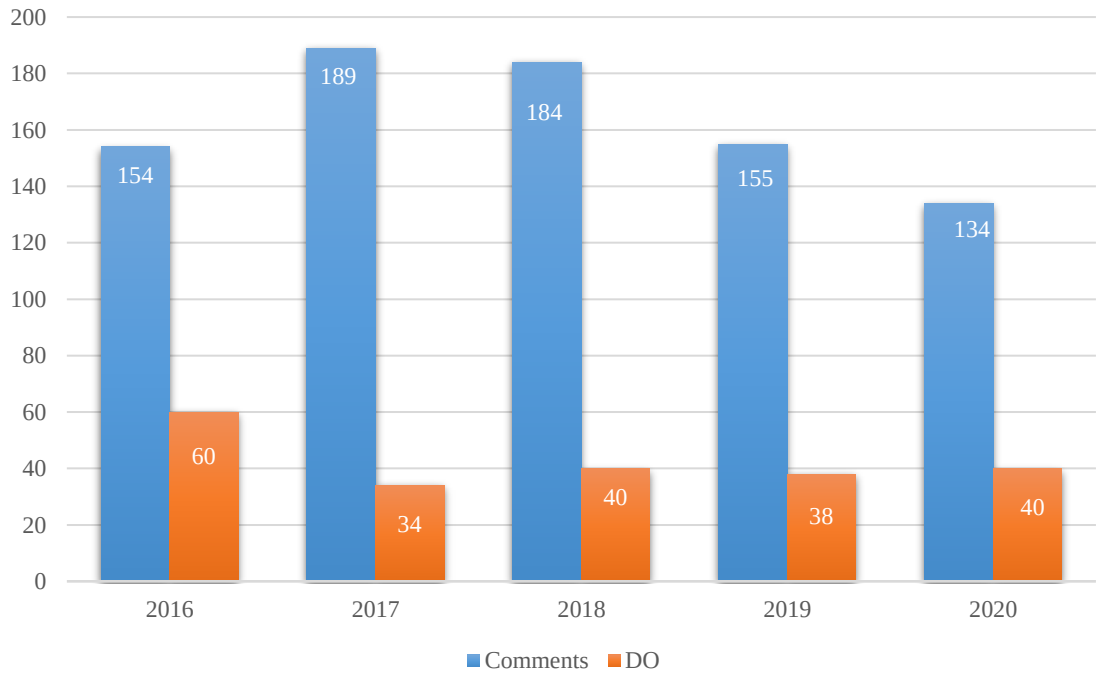


Figure 14: Breakdown by sector in 2020



3.4 Commission reactions: comments and detailed opinions (DO) issued on notifications from 2016 to 2020 (Articles 5(2) and 6(2) of the Single Market Transparency Directive)

Figure 15: Commission reactions to notifications from 2016 to 2020



The number of **comments** made by the Commission decreased from 154 in 2016 to 134 in 2020.

The number of **detailed opinions** issued by the Commission from 2016-2020 decreased. In 2016, the Commission issued 60 detailed opinions on the total of 700 notifications (8.5%). In 2017 it issued 34 on the total of 676 (5.0%). In 2018 it issued 40 on the total of 666 (6%). In 2019 it issued 38 on the total of 657 (5.7%). In 2020 it issued 40 on the total of 854 (4.6%).

Table 3 – Number of comments and detailed opinions issued by the Commission on Member States' notifications for the period 2016-2020[30]

	2016		2017		2018		2019		2020	
	Comments	Detailed Opinion	Comments	Detailed Opinion	Comments	Detailed Opinion	Comments	Detailed Opinion	Comments	Detailed Opinion
Austria	13	1	9	0	25	0	20	1	9	0
Belgium	6	2	6	1	13	1	5	0	7	0
Bulgaria	4	2	0	0	1	4	1	1	2	8
Croatia	7	2	1	1	2	1	1	1	2	0
Cyprus	0	1	1	0	0	0	0	0	0	0
Czech Republic	7	5	6	2	23	1	4	3	1	0
Denmark	7	2	6	1	2	0	8	0	13	2
Estonia	3	0	1	1	5	1	0	2	1	0
Finland	4	5	3	1	25	2	3	0	3	0
France	16	7	19	2	12	2	11	1	21	13
Germany	22	5	14	2	7	0	8	3	23	4
Greece	3	0	70	2	3	10	4	0	0	0
Hungary	2	2	5	2	1	1	3	0	2	2
Ireland	1	1	0	0	1	0	7	0	3	0
Italy	12	4	5	5	6	2	10	5	4	0
Latvia	0	2	0	2	1	0	1	1	3	0
Lithuania	0	0	0	0	3	2	3	4	4	3
Luxembourg	1	0	0	0	1	0	0	0	3	0
Malta	4	3	1	1	10	1	1	0	1	1
Netherlands	8	3	5	1	2	0	3	2	4	1
Poland	6	0	3	0	7	0	35	4	6	0
Portugal	0	1	2	0	1	1	1	2	0	1
Romania	0	0	2	2	1	1	0	0	4	0
Slovakia	6	1	17	1	3	1	3	1	2	0
Slovenia	9	3	1	0	2	2	5	0	1	0
Spain	4	2	6	7	7	6	3	5	6	4
Sweden	3	1	5	0	13	1	5	2	7	1
United Kingdom (before 2021)	6	5	1	0	7	0	10	0	2	0
Totals per reaction type	**154**	**60**	**189**	**34**	**184**	**40**	**155**	**38**	**134**	**40**
Totals per year	**214**		**223**		**224**		**193**		**174**	
Total number of reactions	**1028**									

[30] This table refers to comments and detailed opinions issued by the Commission on Member States' notifications during the period 2016-2020. The table therefore includes reactions in the first 3 months of 2021, as those reactions relate to notifications from 2020.

3.5 Commission reactions: postponement of the adoption of a notified draft in 2016-2020 (Articles 6(3) and 6(4) of the Single Market Transparency Directive)

For notifications from the period 2016-2020, the Commission requested a twelve-month postponement of the adoption of five draft technical regulations notified by the Member States, because they concerned a matter on which EU harmonisation work had already been announced or was underway.

Table 4 – Postponements of notifications from 2016 to 2020

2016	**2017**	**2018**	**2019**	**2020**
0	0	Article 6(3)* **3**	0	0
0	0	Article 6(4)** **1**	Article 6(4)** **1**	0

***** Article 6(3): postponement when the Commission announces its intention to propose or adopt a directive, regulation or decision on the matter covered by a notified technical regulation.
****** Article 6(4): postponement when the Commission announces its finding that the draft technical regulation concerns a matter covered by a proposal for a directive, regulation or decision presented to the European Parliament and the Council.

3.6 Member States' reactions

Table 5 – Comments and detailed opinions issued by the Member States on noifications from 2016 to 2020 (Articles 5(2) and 6(2) of the Single Market Transparency Directive)

	2016		2017		2018		2019		2020		TOTALS	
	COM	DO	COM	DO	COM	DO	COM	DO	COM	DO	COM	DO
Austria	9	5	14	4	6	4	7	2	24	1	**60**	**16**
Belgium	0	0	0	0	0	1	0	1	3	1	**3**	**3**
Bulgaria	0	2	1	1	0	4	0	2	0	2	**1**	**11**
Croatia	2	0	0	0	0	1	0	0	0	0	**2**	**1**
Cyprus	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Czech Republic	3	3	2	1	1	6	0	3	5	5	**11**	**18**
Denmark	4	1	5	0	2	0	0	0	5	3	**16**	**4**
Estonia	0	0	2	0	0	1	0	0	3	1	**5**	**2**
Finland	2	2	0	0	1	1	1	0	4	0	**8**	**3**
France	3	7	2	5	3	2	1	2	5	1	**14**	**17**
Germany	16	8	8	3	6	1	6	1	10	1	**46**	**14**
Greece	0	2	0	0	2	2	1	1	0	2	**3**	**7**
Hungary	6	1	4	7	1	4	2	0	3	0	**16**	**12**
Ireland	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Italy	16	4	9	6	12	5	10	1	19	15	**66**	**31**
Latvia	0	0	1	2	0	0	0	0	1	0	**2**	**2**
Lithuania	0	0	0	0	0	0	1	0	0	2	**1**	**2**
Luxembourg	0	0	0	0	0	0	0	0	0	0	**0**	**0**
Malta	2	3	1	0	1	0	1	2	0	1	**5**	**6**
Netherlands	1	4	1	1	0	0	1	1	0	4	**3**	**10**
Poland	13	6	6	5	17	1	8	2	16	1	**60**	**15**
Portugal	1	3	1	1	0	2	0	5	1	5	**3**	**16**
Romania	0	2	1	0	2	2	3	1	0	2	**6**	**7**
Slovakia	3	7	1	1	1	1	4	1	1	0	**10**	**10**
Slovenia	4	1	3	0	1	0	2	0	4	0	**14**	**1**
Spain	18	14	6	5	9	0	13	3	16	6	**62**	**28**
Sweden	10	1	3	0	6	0	3	0	22	0	**44**	**1**
United Kingdom	5	2	3	2	6	0	0	2	0	0	**14**	**6**
TOTALS	**118**	**78**	**74**	**44**	**77**	**38**	**64**	**30**	**142**	**53**	**475**	**243**

Figure 16 – Comments and detailed opinions issued by each Member State on notifications from 2016 to 2020 (Articles 5(2) and 6(2) of the Single Market Transparency Directive)

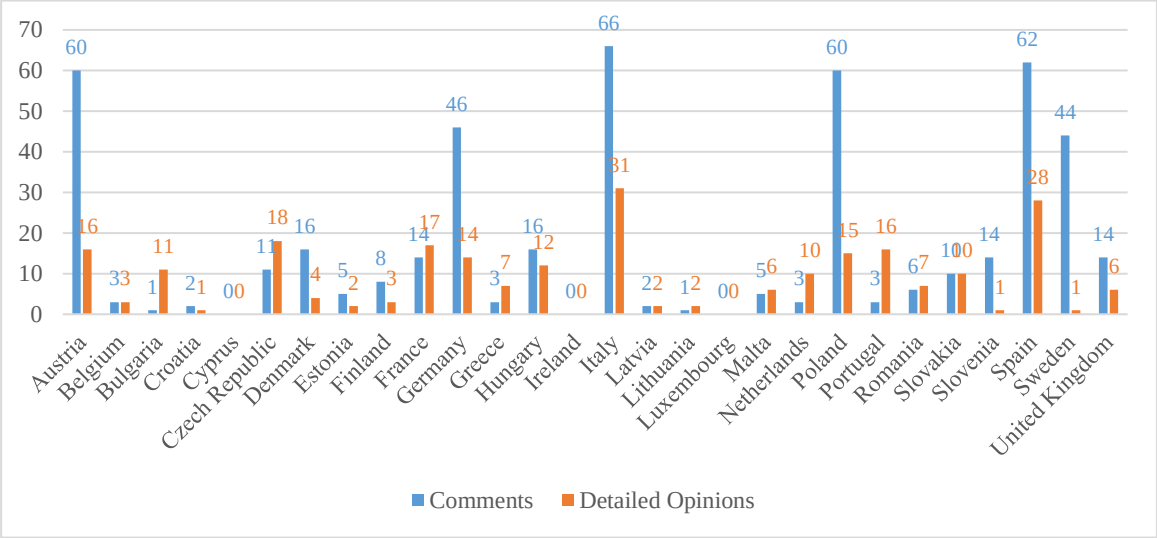


Figure 17 – Comments and detailed opinions issued by Member States on notifications from 2016 to 2020 (Articles 5(2) and 6(2) of the Single Market Transparency Directive)

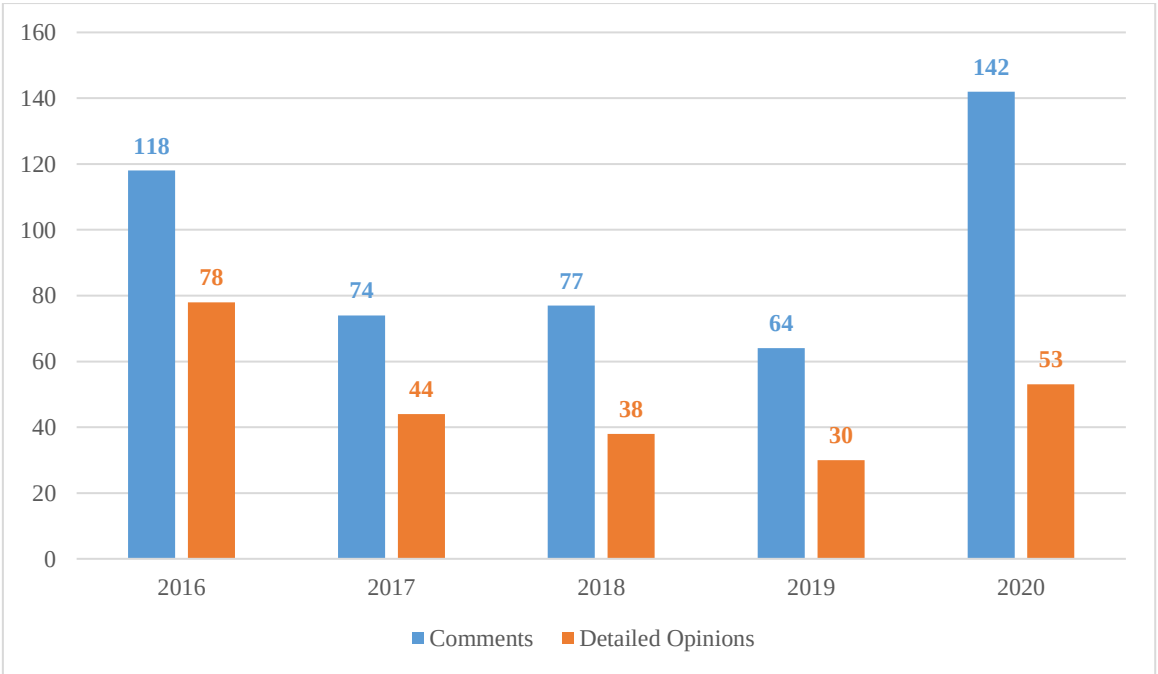


Table 6 – Number of reactions (comments, detailed opinions and decisions to postpone the adoption of a draft[31]) issued by Member States and the Commission to notifications from 2016 to 2020 by sector

	Agriculture	Chemicals	Construction	Domestic and Leisure Equipment	Energy, Minerals, Wood	Environment	Goods and Miscellaneous Products	Healthcare, Medical Equipment	Information Society Services	Mechanics	Pharmaceuticals and Cosmetics	Telecoms	Transport	Total per MS
Austria	33	2	7	12	3	0	3	0	2	8	1	1	4	**76**
Belgium	2	0	4	0	0	0	0	0	0	0	0	0	0	**6**
Bulgaria	5	0	0	0	0	0	6	1	0	0	0	0	0	**12**
Croatia	1	0	0	0	1	0	1	0	0	0	0	0	0	**3**
Cyprus	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Czech Republic	10	1	3	0	1	1	5	1	1	5	0	1	0	**29**
Denmark	14	0	3	1	0	1	1	0	0	0	0	0	0	**20**
Estonia	5	0	1	0	1	0	0	0	0	0	0	0	0	**7**
Finland	6	0	3	1	1	0	0	0	0	0	0	0	0	**11**
France	15	0	3	1	0	4	7	0	0	0	0	0	1	**31**
Germany	28	2	7	2	0	0	3	0	0	0	5	12	1	**60**
Greece	4	0	0	0	0	0	5	1	0	0	0	0	0	**10**
Hungary	20	1	2	0	2	0	2	0	0	0	1	0	0	**28**
Italy	53	2	7	2	2	7	8	1	5	1	4	2	3	**97**
Ireland	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Latvia	2	0	0	2	0	0	0	0	0	0	0	0	0	**4**
Lithuania	1	0	0	0	1	0	1	0	0	0	0	0	0	**3**
Luxembourg	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Malta	0	0	0	8	0	0	0	0	3	0	0	0	0	**11**
Netherlands	9	0	0	0	0	0	2	0	1	0	1	0	0	**13**
Poland	26	1	17	4	1	2	2	0	1	11	1	1	8	**75**
Portugal	6	0	4	0	0	0	6	3	0	0	0	0	0	**19**
Romania	3	1	1	0	0	0	7	1	0	0	0	0	0	**13**
Slovakia	16	0	0	0	0	0	3	0	0	1	0	0	0	**20**
Slovenia	15	0	0	0	0	0	0	0	0	0	0	0	0	**15**
Spain	74	0	5	3	0	5	1	1	0	0	0	1	0	**90**
Sweden	20	0	0	2	0	2	3	6	4	0	8	0	0	**45**
United Kingdom (before 2021)	10	0	2	2	0	1	4	0	0	0	1	0	0	**20**
Commission	333	35	246	54	30	55	49	14	59	42	17	26	68	**1028**
Totals per sector	**711**	**45**	**315**	**94**	**43**	**78**	**119**	**29**	**76**	**68**	**39**	**44**	**85**	**1746**

[31] Detailed opinions with comments were counted as one reaction, that is, as a detailed opinion. If the same reaction concerned more than one notification, it was counted as multiple reactions.

3.7 Urgency procedure (Article 6(7) of the Single Market Transparency Directive)

Table 7 – Requests to apply the urgency procedure received from 2016 to 2020

	2016		2017		2018		2019		2020		Totals	
	Requests	Acceptance	Requests	Acceptance	Requests	Acceptance	Requests	Acceptance	Requests	Acceptance	Requests	Acceptance
Austria	1	**1**	0	**0**	0	**0**	0	**0**	2	**2**	3	3
Belgium	2	**0**	3	**2**	1	**0**	1	**0**	12	**9**	19	11
Bulgaria	1	**1**	1	**0**	1	**1**	0	**0**	3	**3**	6	5
Croatia	0	**0**	0	**0**	0	**0**	0	**0**	0	**0**	0	0
Cyprus	0	**0**	1	**0**	0	**0**	0	**0**	0	**0**	1	0
Czech Republic	2	**0**	0	**0**	1	**1**	0	**0**	8	**5**	11	6
Denmark	0	**0**	0	**0**	0	**0**	2	**0**	12	**12**	14	12
Estonia	5	**5**	2	**2**	0	**0**	1	**1**	4	**3**	12	11
Finland	5	**5**	4	**4**	2	**2**	3	**3**	7	**7**	21	21
France	5	**5**	0	**0**	0	**0**	5	**4**	71	**68**	81	77
Germany	3	**2**	3	**2**	1	**1**	4	**3**	10	**7**	21	15
Greece	0	**0**	3	**2**	11	**0**	1	**0**	1	**1**	16	3
Hungary	10	**10**	2	**2**	1	**1**	2	**1**	11	**9**	26	23
Ireland	1	**0**	1	**1**	0	**0**	3	**3**	1	**0**	6	4
Italy	1	**1**	0	**0**	0	**0**	1	**1**	3	**3**	5	5
Latvia	1	**1**	1	**1**	1	**1**	1	**1**	3	**3**	7	7
Lithuania	0	**0**	0	**0**	0	**0**	0	**0**	0	**0**	0	0
Luxembourg	0	**0**	0	**0**	0	**0**	0	**0**	0	**0**	0	0
Malta	0	**0**	0	**0**	0	**0**	0	**0**	0	**0**	0	0
Netherlands	2	**0**	1	**1**	0	**0**	0	**0**	3	**3**	6	4
Poland	0	**0**	1	**1**	1	**1**	3	**2**	3	**3**	8	7
Portugal	1	**0**	0	**0**	0	**0**	0	**0**	0	**0**	1	0
Romania	1	**1**	2	**2**	0	**0**	1	**1**	11	**7**	15	11
Slovakia	1	**1**	0	**0**	0	**0**	1	**1**	3	**3**	5	5
Slovenia	0	**0**	0	**0**	0	**0**	0	**0**	2	**2**	2	2
Spain	1	**0**	1	**0**	2	**1**	1	**0**	5	**2**	10	3
Sweden	7	**7**	7	**7**	11	**10**	9	**8**	12	**12**	46	44
United Kingdom (before 2021)	1	**1**	1	**1**	2	**2**	0	**0**	0	**0**	4	4
TOTALS	**51**	**41**	**34**	**28**	**35**	**21**	**39**	**29**	**187**	**164**	**346**	**283**

Table 7 provides an overview of the number of requests to apply the urgency procedure, by Member State and by year. It also shows the number of requests on which the Commission gave a favourable opinion.

Figure 18 – Member States' requests to apply the urgency procedure and percentage of favorable opinions given by the Commission between 2016 and 2020

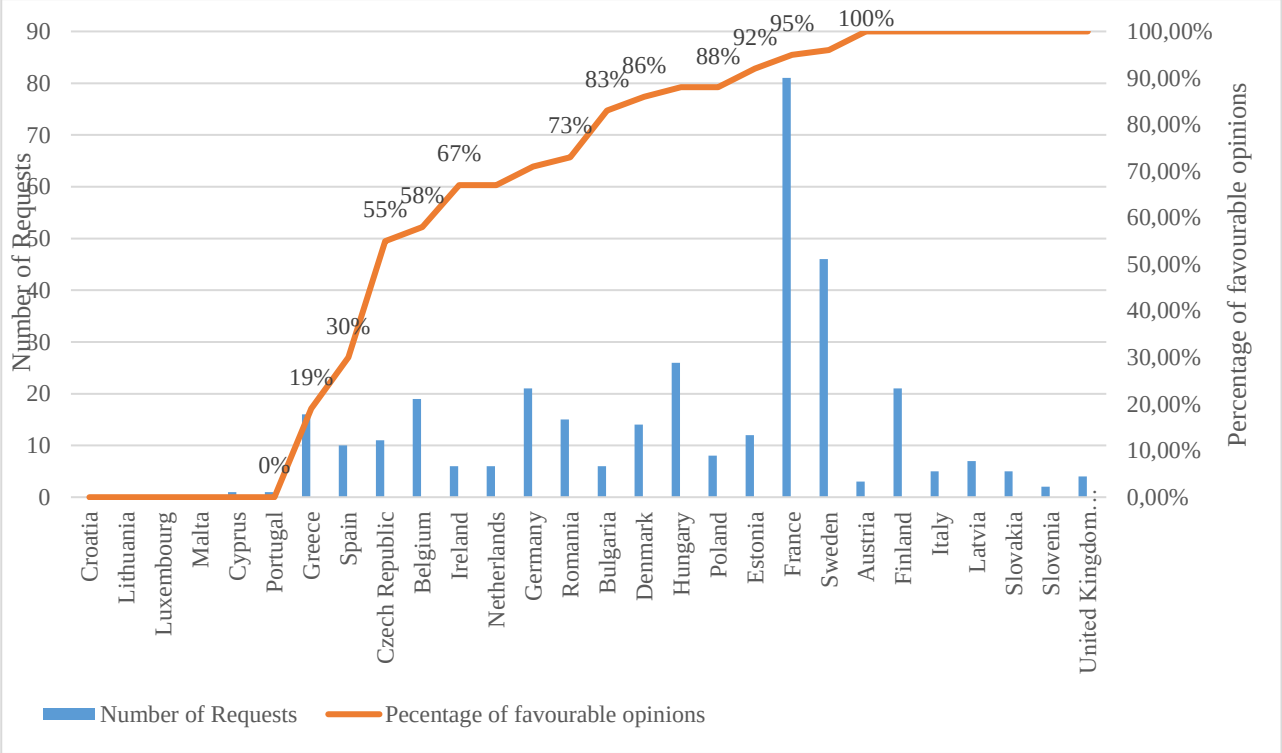


Table 8 – Breakdown by sector of requests to apply the urgency procedure from 2016 to 2020

	Agriculture	Chemicals	Construction	Domestic and Leisure Equipment	Energy, Minerals, Wood	Environment	Goods and Miscellaneous Products	Healthcare, Medical Equipment	Information Society Services	Mechanics	Pharmaceuticals and Cosmetics	Telecoms	Transport	Totals per MS
Austria	0	1	0	0	0	0	0	0	2	0	0	0	0	**3**
Belgium	1	2	4	0	0	0	2	5	2	0	2	0	1	**19**
Bulgaria	0	0	0	0	1	0	0	1	0	0	4	0	0	**6**
Cyprus	0	0	0	1	0	0	0	0	0	0	0	0	0	**1**
Czech Republic	2	1	0	0	0	0	0	3	0	0	5	0	0	**11**
Denmark	1	3	0	0	0	0	0	4	0	0	4	0	2	**14**
Estonia	0	5	0	0	0	0	0	0	0	0	6	1	0	**12**
Finland	0	16	0	0	0	0	0	0	0	0	4	1	0	**21**
France	2	0	0	0	0	1	6	45	1	0	22	3	1	**81**
Germany	1	5	3	0	0	0	0	3	0	0	7	0	2	**21**
Greece	11	0	3	0	1	0	1	0	0	0	0	0	0	**16**
Hungary	0	1	2	0	0	0	2	3	4	0	13	1	0	**26**
Ireland	2	0	0	0	0	0	0	0	0	0	4	0	0	**6**
Italy	2	0	0	0	0	0	1	2	0	0	0	0	0	**5**
Latvia	1	4	0	0	0	0	1	0	0	0	1	0	0	**7**
Netherlands	3	0	0	0	0	1	1	0	0	0	0	0	1	**6**
Poland	1	0	0	0	1	0	0	2	1	0	3	0	0	**8**
Portugal	0	0	0	0	0	0	0	0	0	0	1	0	0	**1**
Romania	0	5	1	0	0	0	1	1	0	0	7	0	0	**15**
Slovakia	0	0	0	0	0	0	2	0	0	0	3	0	0	**5**
Slovenia	1	0	0	0	0	0	0	1	0	0	0	0	0	**2**
Spain	1	0	1	2	0	0	1	0	2	0	0	1	2	**10**
Sweden	3	40	1	2	0	0	0	0	0	0	0	0	0	**46**
United Kingdom (before 2021)	0	0	1	0	0	1	1	0	0	0	0	1	0	**4**
Totals per sector	**32**	**83**	**16**	**5**	**3**	**3**	**19**	**70**	**12**	**0**	**86**	**8**	**9**	**346**

Table 8, which gives a sectoral breakdown of the requests to apply the urgency procedure received by the Commission during the 2016-2020 period, shows that the application of this exceptional procedure was invoked largely in the chemical sector (83 requests), but also in the healthcare and medical equipment sector (70), the pharmaceutical and cosmetics sectors (86) and the agricultural sector (30).

3.8 Follow-up to Commission reactions

Table 9 shows that, in **2016**, the recipient Member States responded to 57 of the 60 detailed opinions issued by the Commission (95%) and that the Commission deemed 41 (72%) of those responses satisfactory.

In **2017**, they responded to 27 of the 34 detailed opinions (79%); 17 responses were satisfactory (63%).

In **2018**, they responded to 33 of the 40 detailed opinions (83%); 12 replies were satisfactory (36%).

In **2019**, they responded to 36 of the 38 detailed opinions (95%); 20 replies were satisfactory (44%).

In **2020,** they responded to 34 of the 40 detailed opinions (85%); 3 replies were satisfactory (9%).

Table 9 – Responses from the Member States to detailed opinions issued by the Commission each year

	2016	2017	2018	2019	2020
Number of Commission DO	60	34	40	38	40
Replies from MS	57	27	33	36	34
% of Replies from MS	95%	79%	83%	95%	85%
Satisfactory replies	41	17	12	16	3
% of satisfactory replies	72%	63%	36%	44%	9%

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

- In 2018 and 2019 the Finnish authorities notified several measures on a new category of vehicles, converted from an existing passenger car to a ‘car tractor’, with their speed limited to 45 km/h and that could be driven with a ‘moped’ driving licence. The Commission issued comments on vehicle classification rules and the compatibility of the notified measures with the rules on driving licence categories and the minimum

driving age laid down in Directive 2006/126/EC on driving licences[32]. Finland deemed it appropriate to withdraw the notified measures at issue.

- In 2019 Spain notified a draft royal decree introducing a voluntary quality mark for agricultural machinery and providing for market access-related advantages to products bearing the quality mark. The Commission issued a detailed opinion because the notified draft was in breach of Article 34 TFEU. By supporting the products bearing the Spanish quality mark, the notified draft created an advantage for domestic products, compared to products that satisfied the applicable mandatory requirements in Spain, or equivalent requirements applicable in another Member State of the EU, but not bearing the Spanish quality mark. Following a dialogue between the Commission and Spain in the context of the Single Market Transparency Directive, Spain amended the draft in question in line with the Commission's remarks.

- In 2019 France notified a draft decree aimed at enhancing consumer information on the origin of honeys and laying down the obligation for blends of honeys packaged in France to indicate the names of the countries of origin in descending order by weight. This name had to be highlighted when the corresponding quantity of honey constituted more than 20% of the weight of the product. The Commission issued a detailed opinion to point out that imposing on operators packaging honey in France an additional mandatory labelling requirement to indicate in descending order of weight the countries of origin and to highlight the name of the country from which the honey constituting more than 20% of the weight comes and to indicate 'More than 20%' or '>20%', is contrary to Directive 2001/110/EC on honey[33]. France agreed to amend the notified draft to meet the requirements of Directive 2001/110/EC in the context of this notification.

- In 2018 the Czech Republic notified a draft measure on the introduction to, and supply of construction products on, the market and the use of construction products in buildings. The Commission issued a detailed opinion because the notified draft was in breach of Regulation (EU) No 305/2011 on construction products[34] and Article 34 TFEU. Following a dialogue, the Czech Republic amended the draft in question in line with the Commission's recommendations.

- In 2018 Spain notified a draft royal decree laying down zootechnical standards on the rearing, trade and entry into the EU of pure-bred breeding animals, hybrid breeding pigs and their reproductive material, and updating the national programme for the conservation, improvement and promotion of livestock breeds. The Commission issued a detailed opinion because the notified draft was in breach of the EU provisions harmonised by the Animal Breeding Regulation (Regulation (EU) 2016/1012[35]). Following a dialogue, Spain amended the draft in line with the Commission's remarks.

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32 Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licences, OJ L 403, 30.12.2006, p. 18.

33 Council Directive 2001/110/EC of 20 December 2001 relating to honey, OJ L 10, 12.1.2002, p. 47.

34 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.

35 Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and

- In 2018 Spain notified a draft decree regulating and promoting artisan food. The Commission issued a detailed opinion because the notified draft was in breach of Article 34 TFEU. Following a dialogue, Spain amended the draft in line with the Commission's remarks.

- In 2018 the Finnish authorities notified a draft on the cross-border distance sales of alcoholic beverages aimed at clarifying the provisions applicable to retail sales of alcoholic beverages subject to approval. The Commission issued a detailed opinion pointing out that the measures in question were considered a quantitative restriction on the free movement of goods under Article 34 TFEU because they favoured distance sales from retailers in Finland over those from other Member States. Such measures were not justified in the light of Article 36 TFEU. The Finnish authorities decided to withdraw the draft.

- In 2018 Spain notified a draft technical regulation aimed at ensuring that farmers produced high-quality and healthy agricultural products for consumers by using environmentally friendly farming practices. The Commission issued comments on this notification, reminding Spain of the conditions for obtaining support from the EAFRD (European Agricultural Fund for Rural Development). The Spanish authorities took the Commission's comments into account.

- In 2017 Austria notified a total ban on the use, for professional and non-professional purposes, of plant protection products containing the active substance glyphosate in Carinthia. The Commission issued comments because the draft appeared to raise concerns in relation to the provisions on the authorisation of plant protection products contained in Regulation (EC) No 1107/2009 on the placing of plant protection products on the market[36]. The draft measure was not adopted. Instead, in 2018 Austria notified an amendment to the draft that no longer targeted a specific substance and limited non-professional users' access to low-risk products, authorised for minor gardening purposes. The revised measure was aligned with other similar measures notified by other Member States to which the Commission had not reacted.

- In 2017 Hungary notified a measure on a labelling obligation for dual use food chain products, i.e. products placed on the market in Hungary with different ingredients or with a different ratio of ingredients than in countries outside Hungary, but with the same name and appearance. The Commission issued a detailed opinion because it considered the notified draft was in breach of the free movement of goods principle as set out in Article 34 TFEU. Hungary decided to withdraw the measure in question.

- In 2017 Germany notifed a complete ban on the importation, placement on the market and sowing of certain types of seeds treated with particular plant protection products. The Commission issued a detailed opinion because the proposed ban was in breach of applicable EU legislation on plant protection products, pursuant to which Member States may not prohibit the placement on the market or use of seeds treated with plant

90/425/EEC and repealing certain acts in the area of animal breeding (Animal Breeding Regulation), OJ L 171, 29.6.2016, p. 66.

36 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 of 24.11.2009, p. 1.

protection products authorised for such use in at least one Member State. Germany agreed to address the concerns the Commission had raised.

3.10 Impact assessments

In line with the Commission's action plan to simplify and improve the regulatory environment[37], the Member States of the EU have been invited to submit impact assessments (or their conclusions) together with notified draft technical regulations under the Single Market Transparency Directive, where such studies have been carried out internally. By carrying out these impact assessments, Member States are encouraged to reflect in advance on the most appropriate instrument to be used, and the Commission can in turn better assess the necessity and proportionality of the measures proposed.

In the reporting period, Member States submitted impact assessments for 898 notifications (25% of the total number of notifications).

3.11 Most common barriers removed

Mutual recognition clause

The Commission frequently reacted to notifications of draft technical regulations in which the mutual recognition clause was not included when needed, or was not drafted in line with the single market clause, as set out in Commission Communication *The Goods Package: Reinforcing trust in the single market* (COM(2017) 787 of 19 December 2017).

This preventive mechanism could be complemented by a corrective mechanism applicable if the national authorities, in taking decisions based on national rules in individual cases, misapply the principle of mutual recognition. Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member State aims to give a major boost to mutual recognition in the area of goods[38]. 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 trade barriers[39].

Improper legal drafting technique – Repetition of provisions of EU regulations

One of the most frequent issues addressed by the Commission in the detailed opinions they issued, for example, on the basis of EU regulations applicable in the area of food hygiene and to plant protection products, was a practice whereby the notified draft technical regulations repeated, often partially and in an incomplete or even diverging way, the provisions of applicable EU regulations. According to Article 288 TFEU, a regulation has general application, is binding in its entirety and is directly applicable in all Member States. This means that Member States may not lay down rules in the area governed by directly applicable EU legislation, even if

37 Action plan for improving the regulatory environment, COM(2002) 278.

38 Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, OJ L 91, 29.3.2019, p. 1.

39 https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition_en

identical to EU rules, as they would interfere with the correct application of EU legislation and give rise to uncertainty about the complete application of the relevant EU law.

Incorrect implementation of food hygiene regulation exemptions

Several potential breaches have also been identified in the implementation by the notifying Member States of the exceptions and flexibility clauses in three food hygiene regulations:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Member States wrongly implemented or went beyond what these exemptions allow.

Unjustified barriers to information society services

In the area of information society services, the Commission identified recurrent problems, mainly concerning unjustified or disproportionate restrictions on the free provision of services in relation to the e-Commerce Directive[40], the revised Audiovisual Media Services Directive, the free flow of non-personal data Regulation[41] and the eIDAS Regulation (EU) 910/2014[42]. Unjustified restrictions were also addressed explicitly or in ancillary terms regarding the free movement of services and the freedom of establishment in the area of information society activities (Articles 49 and 56 TFEU, as well as Directive 2006/123/EC on services[43]) and regarding the General Data Protection Regulation[44], the Consumer Rights Directive[45], the electronic invoicing Directive[46], as well as the freedom of expression and the freedom to conduct a business.

Standards – making them mandatory, requring additional test methods

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

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40 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.

41 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.

42 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.

43 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.

44 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.

45 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.

46 Directive 2014/55/EU of the European Parliament and of the Council of 16 April 2014 on electronic invoicing in public procurement, OJ L 133, 6.5.2014, p. 1.

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 mandatory essential requirements. They should therefore remain voluntary.

The practice, mentioned above, followed by some Member States, of making voluntary European harmonised standards compulsory, could create trade barriers in the single market. This is because products complying with the essential requirements of the New Approach Directives, but not with European harmonised standards, could not freely circulate in the Member State in question.

All the recurrent practices mentioned above were discussed with the Member States in the Technical Regulations Standing Committee, set up in accordance with Article 2 of the Single Market Transparency Directive. The Technical Regulations Standing Committee meets twice a year, as stated in Article 3 of the Single Market Transparency Directive. The recurrent practices were also discussed in 'Country knowledge' meetings with the Member States.

ANNEX 4 – APPLICATION OF THE PROCEDURE IN 2016-2020: PARTICIPATION OF EFTA COUNTRIES SIGNATORY TO THE EEA AGREEMENT, OF SWITZERLAND AND OF TURKEY

Table 10 – Number of notifications from EEA-EFTA countries and comments issued on those notifications by the EU

	2016		2017		2018		2019		2020		Total	
	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.
Iceland	6	1	6	3	1	1	2	1	8	2	**23**	**8**
Liechtenstein	1	2	1	0	3	1	0	0	3	0	**8**	**3**
Norway	34	6	11	4	13	5	18	0	17	3	**93**	**20**
Total	**41**	**9**	**18**	**7**	**17**	**7**	**20**	**1**	**28**	**5**	**124**	**31**

Table 11 – Number of notifications from Switzerland and comments issued on notifications from Switzerland by the EU

	2016		2017		2018		2019		2020		Total	
	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.
Switzerland	1	5	15	4	4	2	8	1	6	0	**34**	**12**

Table 12 – Number of notifications from Turkey and comments issued on notifications from Turkey by the EU

2016		2017		2018		2019		2020		Total	
Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.	Not.	Com.

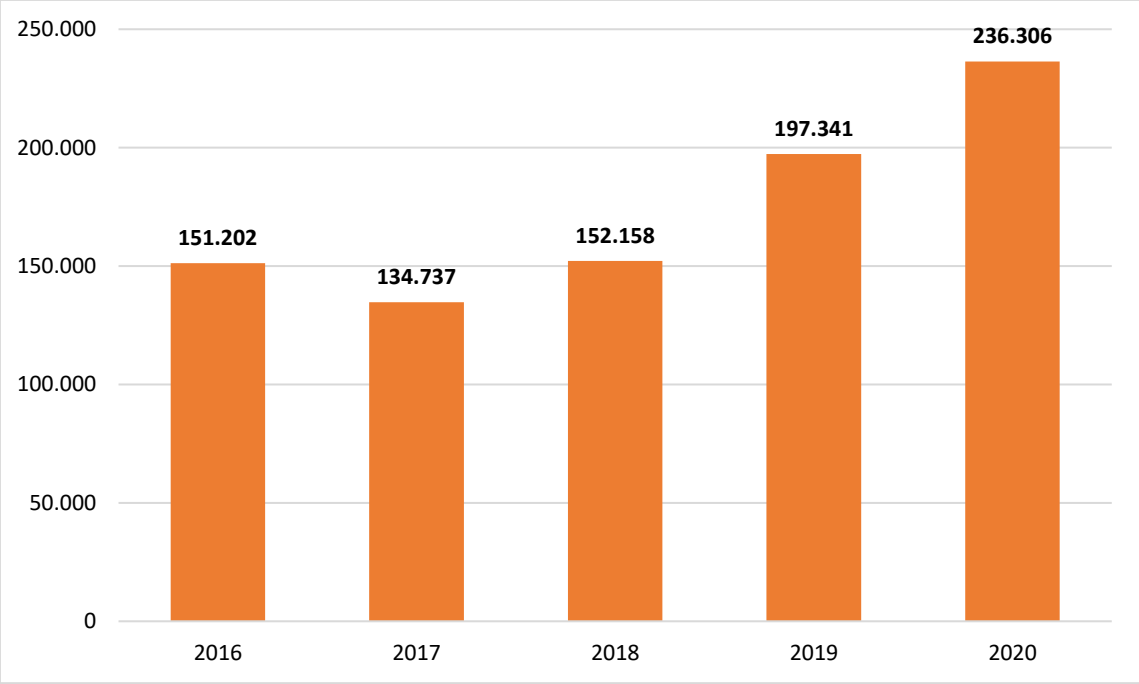
Turkey	15	3	17	0	26	1	9	4	7	0	**74**	**8**

Table 13 – Comments by EEA-EFTA countries, Switzerland and Turkey on Member States' notifications

	2016	**2017**	**2018**	**2019**	**2020**	**Total**
EEA-EFTA	0	2	0	0	0	**2**
Switzerland	1	0	0	1	0	**2**
Turkey	0	0	0	0	0	**0**

ANNEX 5 – ONLINE CONSULTATIONS 2016-2020

Figure 17 – Online consultations between 2016 and 2020



In the period in question, 871 744 searches were carried out using the Technical Regulation Information System (TRIS) website (151 202 in 2016, 134 737 in 2017, 152 158 in 2018, 197 341 in 2019 and 236 306 in 2020).

Figure 18 – Online consultations in 2016

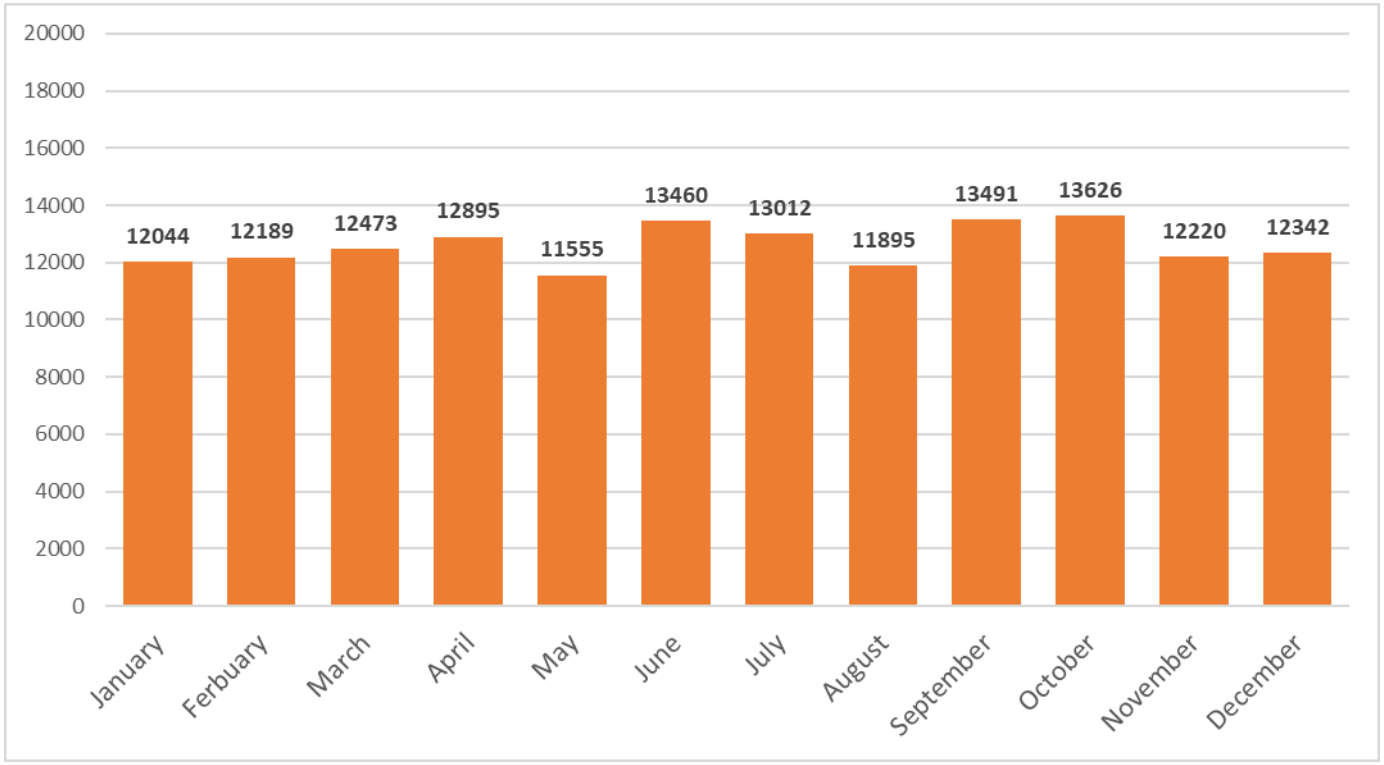


Figure 19 – Online consultations in 2017

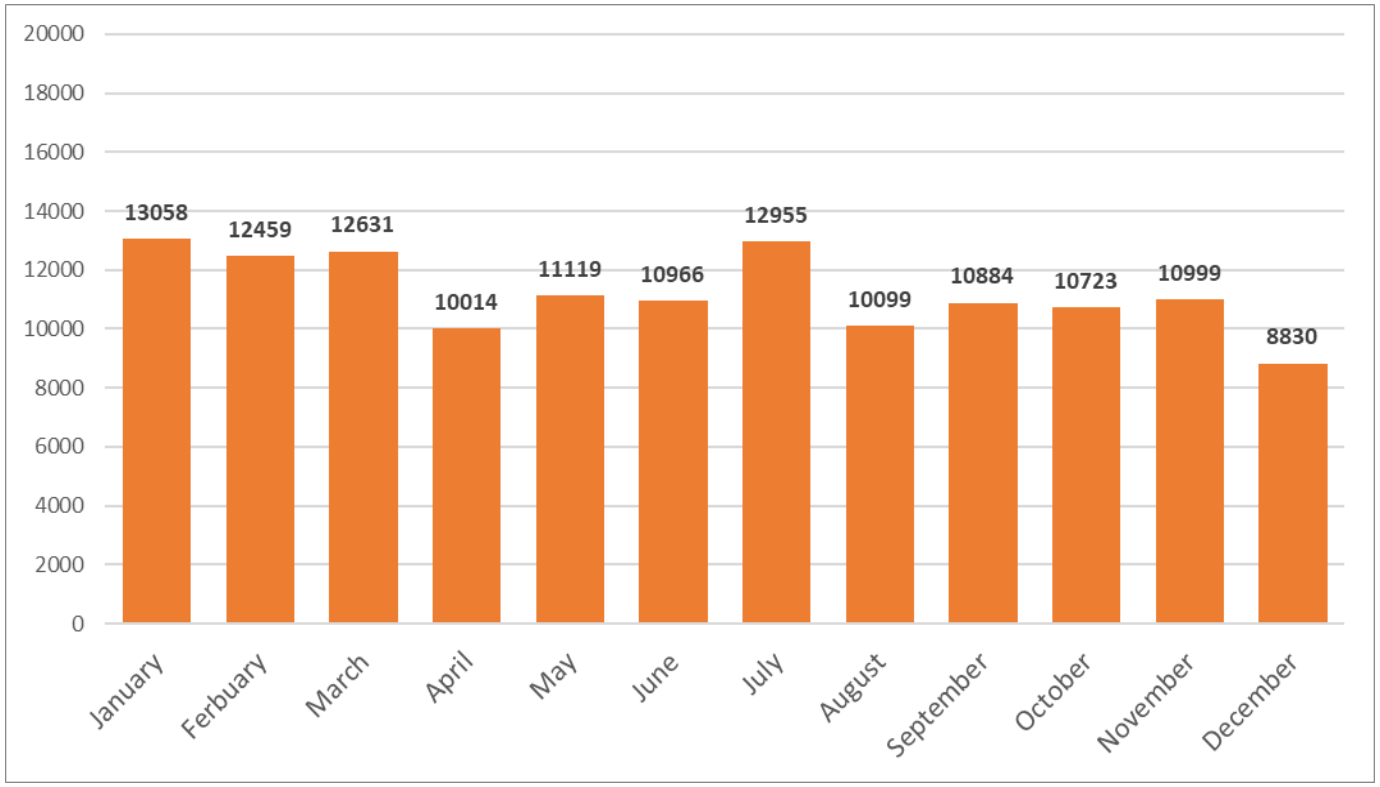


Figure 20 – Online consultations in 2018

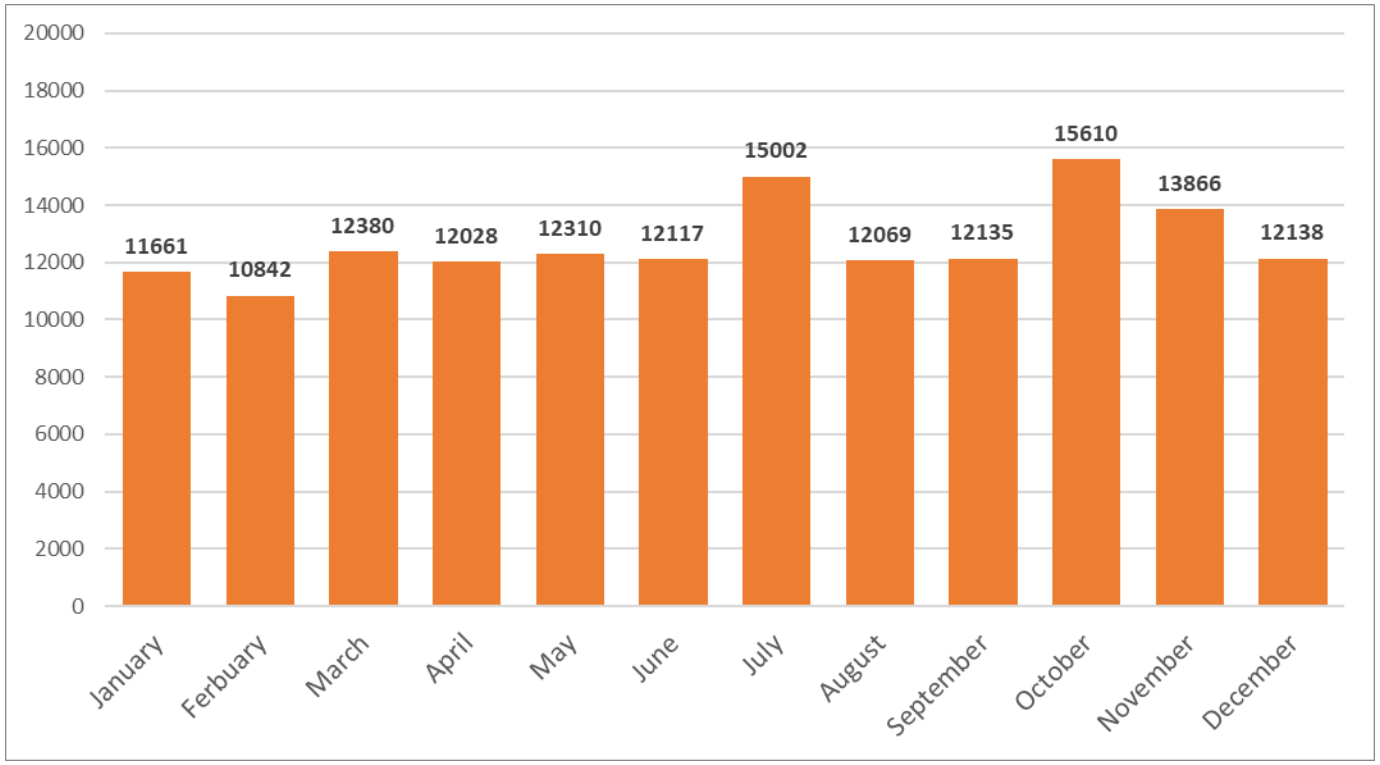


Figure 21 – Online consultations in 2019

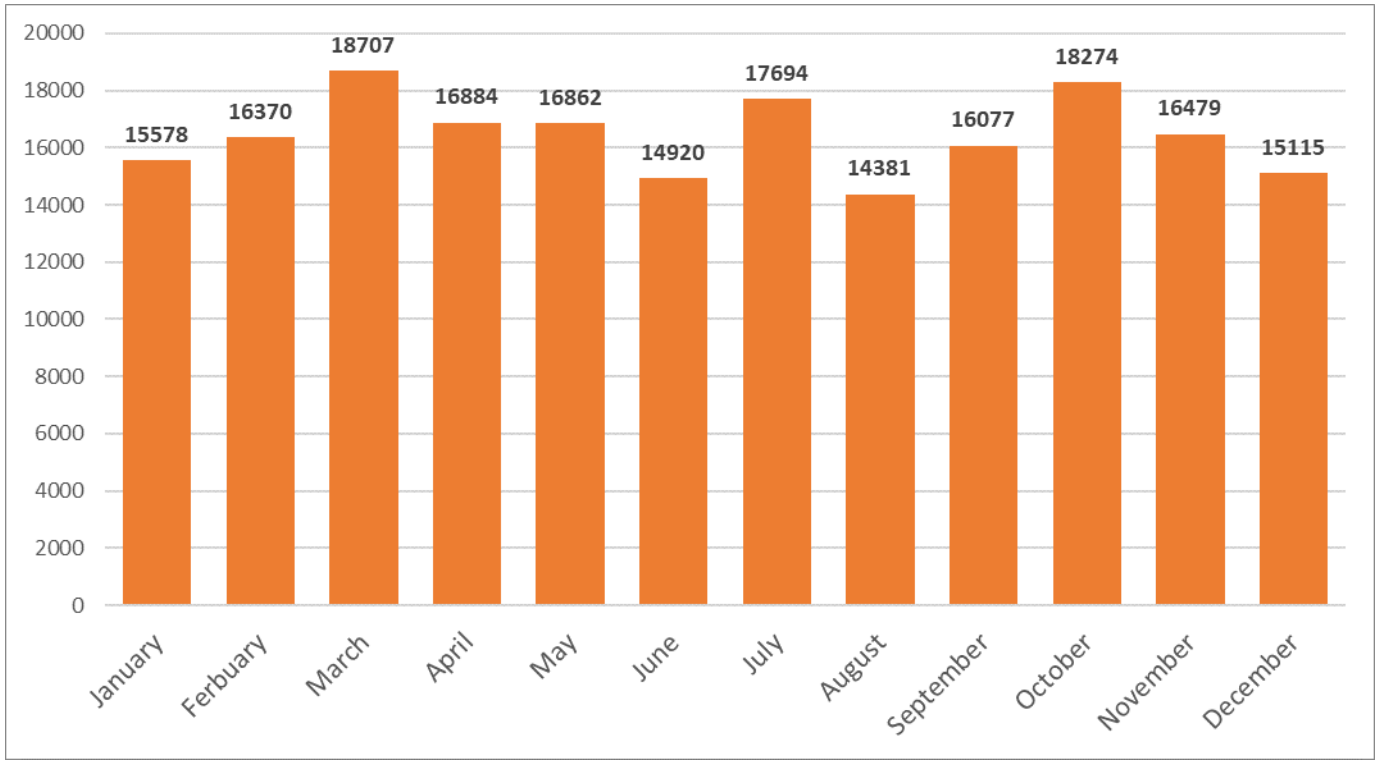


Figure 22 – Online consultations in 2020