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COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

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

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

{COM(2017) 788 final}

TABLE OF CONTENTS – ANNEXES

Annex 1 – Brief description of the notification procedure	2
Annex 2 – Application of the procedure between 2014-2015: notifications of technical regulations submitted by the Member States	4
2.1 Volume of notifications during the 2014-2015 period	6
2.2 Breakdown by country	7
2.3 Breakdown by sector	10
2.4 Commission reactions: comments and detailed opinions in 2014 and 2015 (articles 5(2) and 6(2) of the directive)	12
2.5 Commission reactions: blockages in 2014 and 2015 (articles 9(3) and 9(4) of the directive)	13
2.6 Member States reactions.....	14
2.7 Urgency Procedure (Article 9(7) of the Directive).....	16
2.8 Follow-up to Commission reactions.....	18
Annex 3 – Application of the procedure in 2011-2013: participation of efta countries signatory to the EEA Agreement, of Switzerland and of Turkey	19
Annex 4 – Internet consultations 2011-2013	21

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 characteristics 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 standards and regulations and of rules on Information Society services*, available on the following website: <http://ec.europa.eu/growth/tools-databases/tris>.

Legal bases

Introduced in 1984 by Directive 83/189/EEC¹, 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 In 1998, Directive 83/189/EEC was repealed and codified by Directive 98/34/EC², which in turn was amended by Directive 98/48/EC³ in order to extend the notification procedure to Information Society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 In 2015, Directive 98/48/EC was repealed and replaced by Directive (EU) 2015/1535⁴ with the aim of codifying it after the adoption of Regulation (EU) No 1025/2012⁵.

Obligation to notify and standstill period

Article 5(1) of Directive (EU) 2015/1535 (hereinafter "the Single Market Transparency Directive") stipulates that the Member States shall inform the Commission of any draft technical regulation prior to its adoption. The simple transposition of a European Union act does not require prior notification, unless the national authorities adopt national provisions that go beyond mere compliance with European Union acts and that contain technical regulations within the meaning of the Directive (Article 7 of the Single Market Transparency Directive).

Starting from the date of notification of the draft, 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 to this rule is linked to the nature of the measure in question: for technical specifications linked to fiscal or financial measures, there is no

¹ Directive of 28 March 1983, OJ L 109/8 of 26.4.1983

² OJ L 204/37 of 21.7.1998, p. 37-48.

³ OJ L 217/18 of 5.8.1998, p. 18-26.

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 Text with EEA relevance, OJ L 316, 14.11.2012, p. 12–33.

standstill period. This also applies to technical regulations that have to be adopted urgently (see below).

Possible reactions and consequences

Where it emerges that the notified drafts are liable to create barriers to the free movement of goods or to the free provision of Information Society services and freedom of establishment (Articles 34-36, 49 and 56 of the Treaty on the Functioning of the European Union), 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 standstill period by an additional three months. The Commission and the Member States can also make **comments** about a notified draft that appears to comply with European Union law but that requires clarification in its interpretation (Article 5(2)). The Commission can also block a draft for a period of 12 months if European Union harmonisation work is due to be undertaken or is already underway in the same field (Article 6(3) to (5)).

In the event of a detailed opinion being issued, the Member State concerned informs the Commission of the action that it intends to take in response to the detailed opinion, and the Commission comments on that reaction (Article 6(2)). With regard to the comments, the Directive does not lay down any legal obligation for the Member State receiving the comments to indicate what follow-up action it intends to take.

Urgency procedure

Article 6(7) of the Single Market Transparency Directive describes an urgency procedure, which is designed to allow the immediate adoption of a national draft, subject to a closed list of certain conditions that must be clearly indicated at the time of notification (notably "*serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants, and for rules on [Information Society] services, also for public policy*" and "*urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, in particular the protection of depositors, investors and insured persons*"). The aim of the urgency procedure is to enable a notifying Member State faced with serious or unforeseeable circumstances to adopt immediately the draft technical regulation or rule on Information Society services, 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 standstill 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, including as part of potential infringement proceedings for breach of European Union law.

Communication of final texts

At the end of the notification procedure, the Member States are bound to inform the Commission of final texts as soon as those texts have been adopted and to indicate cases in

which the notified draft has been abandoned, in order to allow the procedure to be closed (Article 5(3) of the Single Market Transparency Directive).

‘Technical regulations’ committee

The Standing Committee laid down in Article 2 of the Single Market Transparency Directive consists of representatives appointed by the Member States and is chaired by a representative of the Commission. The Committee meets regularly and constitutes a forum for discussing all issues connected with 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) in the event of a detailed opinion being issued, the total standstill period is four months from the date of the communication, instead of the six months stipulated for products; b) the Commission can only block the draft for a maximum of 12 months if the subject of the draft is already covered by an EU Council proposal and if the notified text contains provisions that do not comply with the proposal drafted by the Commission; c) the urgency procedure can be invoked not only under the circumstances stipulated for products (*‘serious and unforeseeable circumstances’*) but also *‘for urgent reasons ... relating to public safety’*.

The simplified procedure

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 adaptations⁶: they notify their drafts via the EFTA Surveillance Authority and can comment on the drafts notified by the 28 Member States. On the other hand the entire European Union can comment on drafts notified by the three countries signatory to the EEA Agreement.

Switzerland (which is part of EFTA, but which does not apply the EEA Agreement) also participates in the system.

Turkey, which transposed the Single Market Transparency Directive in 2002, participates in the procedure in the same manner as the EFTA countries. The decision to have Turkey participate 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 – APPLICATION OF THE PROCEDURE BETWEEN 2014-2015: NOTIFICATIONS OF TECHNICAL REGULATIONS SUBMITTED BY THE MEMBER STATES

Annexes 2.1, 2.2 and 2.3 give a statistical overview of the development of the number of draft technical regulations notified by the Member States between 2014 and 2015, and of their breakdown by Member State and by sector. It should be pointed out that, in accordance

⁶ Annex II, Chapter XIX, point 1 to the EEA Agreement.

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 series⁷.

The reactions to the notified drafts – in the form of comments or detailed opinions from the Commission or the Member States, or of requests to postpone the adoption of the notified draft for 12 or 18 months (Article 6(3)(4) and (5) of the Single Market Transparency Directive) on the part of the Commission – are illustrated in Annexes 2.4 to 2.6.

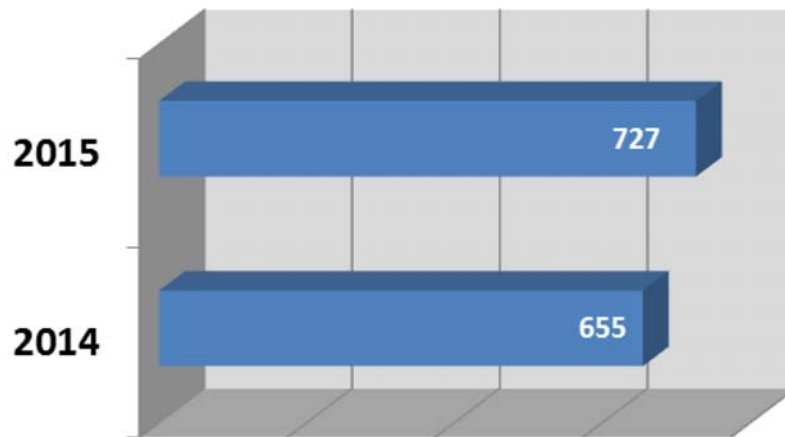
Annex 2.7 refers to the requests to apply the urgency procedure that the Member States addressed to the Commission pursuant to Article 6(7) of the Single Market Transparency Directive.

Annex 2.8 shows the action taken by the Member States in response to the Commission’s reactions.

⁷ For 2014: OJ C 174, 28.5.2015, p. 2–6.

2.1 Volume of notifications during the 2014-2015 period

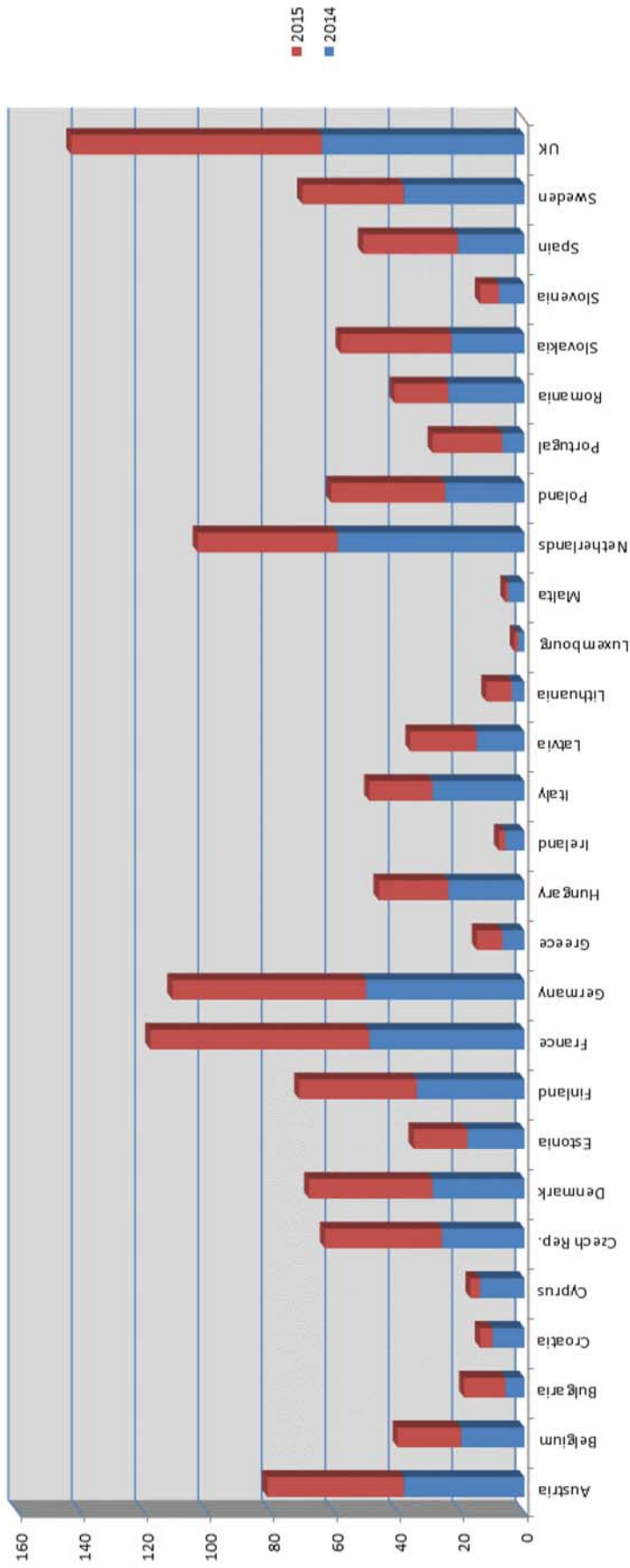
Figure 1: Number of Notifications



The statistics in Figure 1 show that the Member States notified 655 draft regulations in 2014, and 727 draft regulations in 2015 to the Commission.

2.2 Breakdown by country

Figure 2: Notifications by Member States



During the 2014-2015 period, three Member States which notified the highest number of draft technical regulations were United Kingdom (143), France (118) and Germany (111). A group of six other countries (Netherlands, Austria, Finland, Sweden, Denmark and the Czech Republic) come next with a total number of notifications of between 63 and 103.

Table 1 – Number of notifications of technical regulations submitted by the Member States in 2014 and 2015

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

Table 2 – Percentage of notifications submitted by the Member States in 2014 and 2015

Member States	2014	2015
Austria	5.8%	5.9%
Belgium	3.1%	2.8%
Bulgaria	0.9%	1.8%
Croatia	1.5%	0.6%
Cyprus	2.1%	0.4%
Czech Republic	4.0%	5.1%
Denmark	4.4%	5.4%
Estonia	2.7%	2.3%
Finland	5.2%	5.1%
France	7.5%	9.5%
Germany	7.6%	8.4%
Greece	1.1%	1.1%
Hungary	3.7%	3.0%
Ireland	0.9%	0.3%
Italy	4.4%	2.8%
Latvia	2.3%	2.9%
Lithuania	0.6%	1.1%
Luxembourg	0.3%	0.1%
Malta	0.8%	0.1%
Netherlands	9.0%	6.1%
Poland	3.8%	5.0%
Portugal	1.1%	3.0%
Romania	3.7%	2.3%
Slovakia	3.5%	4.8%
Slovenia	1.2%	0.8%
Spain	3.2%	4.1%
Sweden	5.8%	4.4%
United Kingdom	9.8%	10.9%

2.3 Breakdown by sector

Table 3: Breakdown by sector of the drafts notified by the Member States of the European Union in 2014

Sectors	2014
Construction	143
Agriculture, Fisheries and Foodstuffs	127
Telecoms	52
Transport	48
Mechanics	47
Environment	41
Energy, Minerals, Wood	38
Goods and Miscellaneous Products	37
Domestic and Leisure Equipment	36
Chemicals	31
98/48/EC Information Society Services	25
Pharmaceuticals and Cosmetics	23
Health, Medical Equipment	7
Total	655

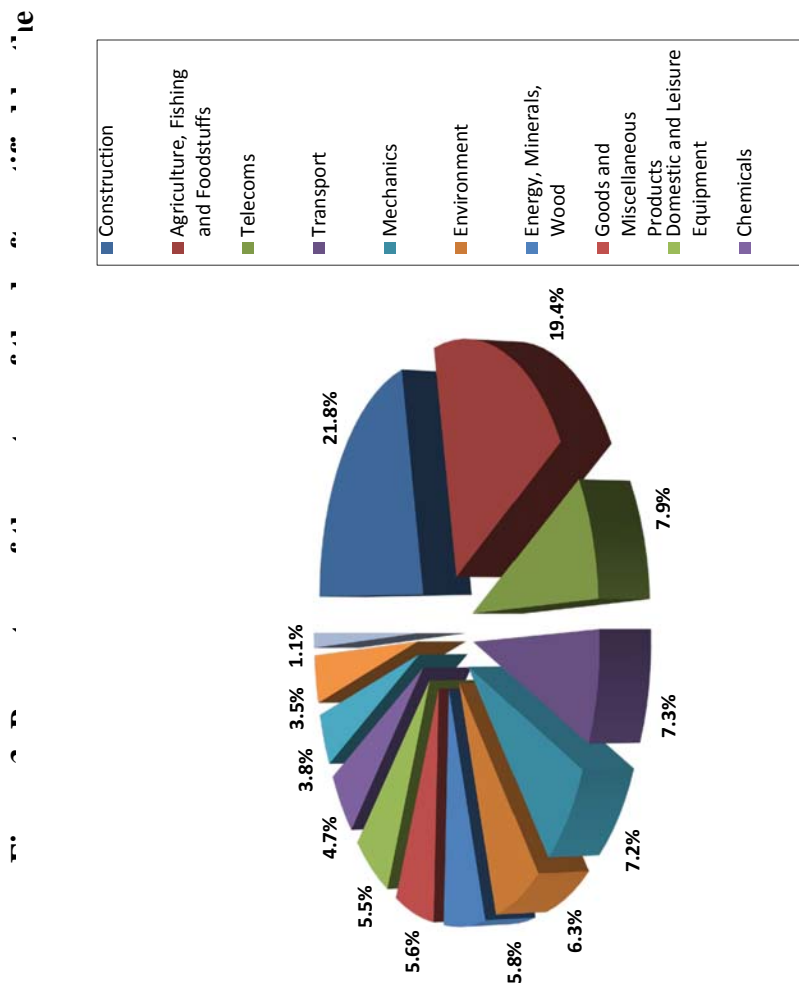
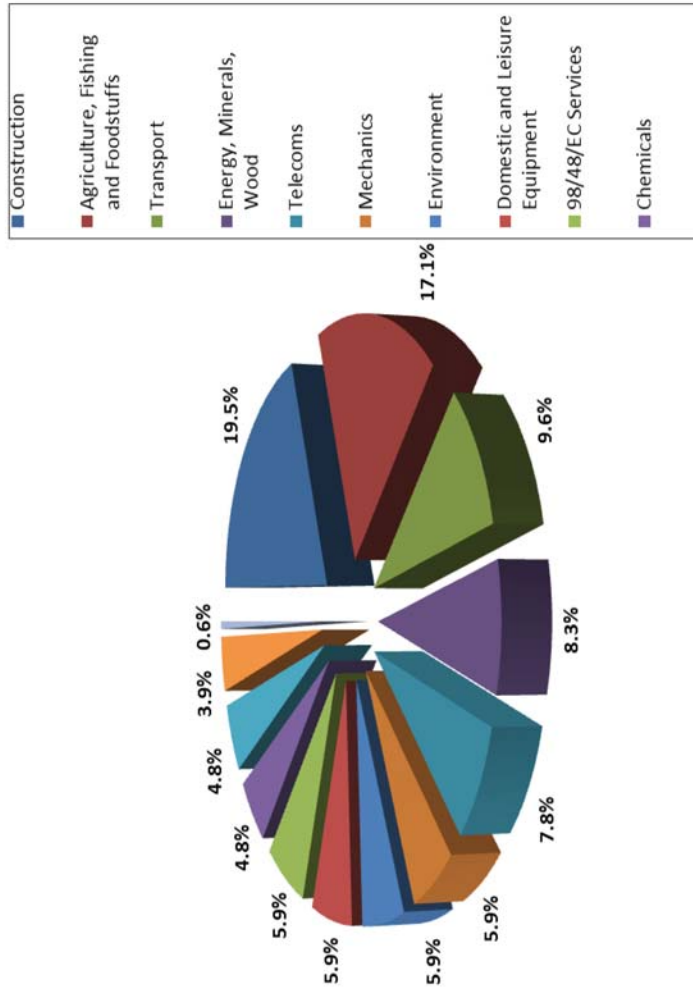


Table 4: Breakdown by sector of the drafts notified by the Member States of the European Union in 2015

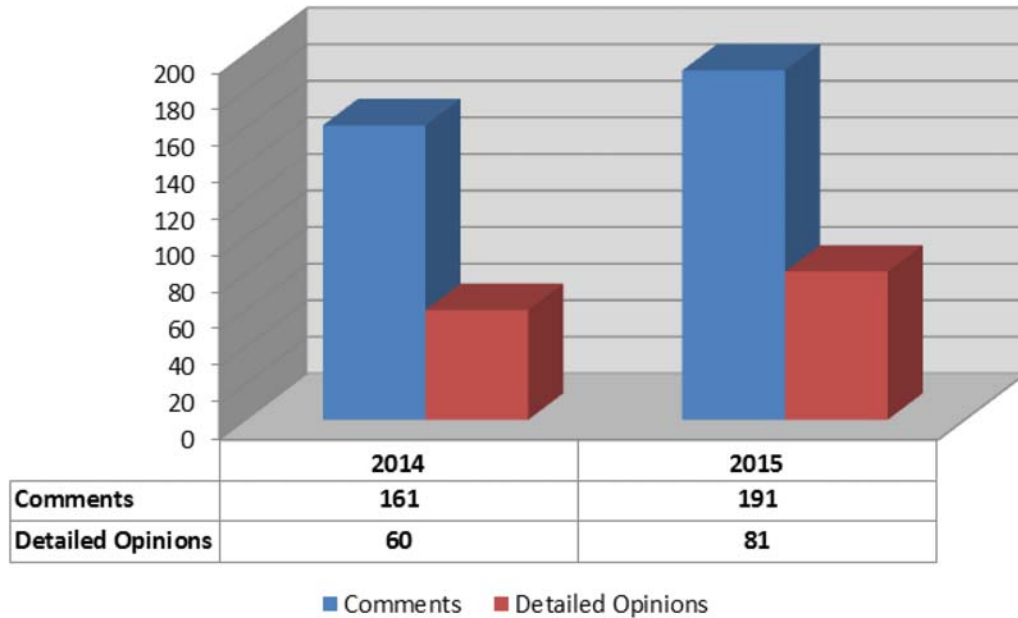
Sectors	2015
Construction	142
Agriculture, Fisheries and Foodstuffs	124
Transport	70
Energy, Minerals, Wood	60
Telecoms	57
Mechanics	43
Environment	43
Domestic and Leisure Equipment	43
98/48/EC Information Society Services	43
Chemicals	35
Pharmaceuticals and Cosmetics	35
Goods and Miscellaneous Products	28
Health, Medical Equipment	4
Total	727

Figure 4: Percentage of the sectors of the drafts notified by the Member States of the European Union in 2015



2.4 Commission reactions: comments and detailed opinions in 2014 and 2015 (Articles 5(2) and 6(2) of Directive (EU) 2015/1535)

Figure 5: Commission Reactions to Notifications in 2014 and 2015



The number of **comments** made by the Commission increased from 161 in 2014 to 191 in 2015.

The number of **detailed opinions** issued by the Commission increased between 2014 and 2015: 60 detailed opinions in 2014 on the total number of 655 notifications (9.1%) and 81 in 2015 on the total number of 725 notifications (11.2%).

2.5 Commission reactions: requests to postpone the adoption of the notified draft for 12 months in 2014 and 2015 (articles 6(3) and 6(4) of Directive (EU) 2015/1535)

During the 2014-2015 period, the Commission requested a 12-month postponement of the adoption of 12 draft regulations notified by the Member States, because they concerned a subject on which Union harmonisation work had already been announced or was underway.

Table 5

Year	Standstills (Blockages)		Total
	Announcement of a Community text (Article 9(3))	Presentation to the Council of a Community text (Article 9(4))	
2014	0	2	2
2015	0	1	1

2.6 Member States reactions

Table 6 - Comments and detailed opinions issued by the Member States in 2014 and 2015 (Articles 5(2) and 6(2) of Directive (EU) 2015/1535)

	2014		2015	
	Comments	Detailed Opinions	Comments	Detailed Opinions
Austria	8	9	9	5
Belgium	0	1	1	1
Bulgaria	1	2	3	3
Croatia	4	0	1	0
Cyprus	0	0	0	0
Czech Republic	0	6	5	4
Denmark	1	1	4	0
Estonia	1	0	2	1
Finland	3	0	2	1
France	10	5	8	2
Germany	17	0	33	6
Greece	0	2	0	3
Hungary	2	2	5	3
Ireland	1	1	2	0
Italy	8	4	7	6
Latvia	0	0	0	0
Lithuania	0	1	0	2
Luxembourg	0	0	0	0
Malta	3	5	1	2
Netherlands	3	1	0	0
Poland	15	6	12	2
Portugal	0	2	0	5
Romania	3	2	1	2
Slovakia	2	6	6	6
Slovenia	6	0	2	0
Spain	9	8	9	11
Sweden	3	0	5	0
UK	12	0	7	2
Total	112	64	125	67

Table 7 – Number of reactions (comments and detailed opinions) issued by Member States between 2014 and 2015 by sector

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

2.7 Urgency Procedure (Article 6(7) of Directive (EU) 2015/1535)

Table 8 - Requests to apply the urgency procedure received in 2014 and 2015

	2014		2015	
	Requests	Favourable opinion	Requests	Favourable opinion
Austria	0	0	0	0
Belgium	4	1	1	1
Bulgaria	0	0	1	1
Croatia	1	0	0	0
Cyprus	0	0	0	0
Czech R.	0	0	1	0
Denmark	0	0	0	0
Estonia	3	3	4	4
Finland	10	10	4	4
France	1	1	2	2
Germany	1	1	3	3
Greece	0	0	0	0
Hungary	5	5	5	5
Ireland	0	0	0	0
Italy	1	0	0	0
Latvia	0	0	3	2
Lithuania	0	0	3	0
Luxembourg	0	0	0	0
Malta	0	0	0	0
Netherlands	1	1	0	0
Poland	3	1	1	1
Portugal	0	0	0	0
Romania	1	0	1	1
Slovakia	0	0	1	1
Slovenia	1	0	0	0
Spain	1	0	0	0
Sweden	6	6	6	6
UK	1	0	0	0
Total	40	29	36	31

Table 8 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 to which the Commission gave a favourable opinion.

Table 9 - Breakdown by sector of the requests to apply the urgency procedure in 2014 and 2015

	BE		BG		CZ		EE		FI		FR		DE		HR		HU		IT		LT		LV		NL		PL		RO		SI		SK		ES		SE		UK			
	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F	R	F				
98/48/EC Information Society Services	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Agr. Fisheries and Foodstuffs	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0			
Chemical	1	1	0	0	0	0	6	6	14	14	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	5	0	0	0		
Construction	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	
Domestic and Leisure Equip.	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Environment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	3	3	0	0	0	
Goods & Misc. Products	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Mechanics	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pharmac. and Cosmetics	0	0	1	1	0	0	1	0	0	0	0	3	0	0	0	0	0	10	10	0	0	1	0	2	2	0	2	2	1	0	0	0	0	0	0	0	2	2	0	0	0	0
Telecoms	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Transport	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	5	2	1	1	1	0	7	14	14	3	3	4	4	1	0	10	10	1	0	3	0	3	2	3	2	1	4	2	2	1	1	1	0	12	12	1	1	0	0	0	0	

R: Requests F: Favorable Opinions

Table 9, which gives a sectoral breakdown of the requests to apply the urgency procedure received by the Commission during the 2014-2015 period, shows that the application of this exceptional procedure was invoked mainly in the pharmaceutical and cosmetics sector (29 requests) and in the chemicals sector (23).

2.8 Follow-up to Commission reactions

Table 10 shows the number of detailed opinions issued by the Commission in 2014-2015, the number of replies to detailed opinions by Member States and the number of replies that were deemed satisfactory. The table also shows the number of notifications that were closed.⁸

Table 10

Year	Detailed Opinions	Responses from the MS	Satisfactory	Closures
2014	60	62	28	3
2015	81	69	35	6

Table 11

Year	Comments	Responses from MS
2014	161	101
2015	191	132

Table 11 shows the number of comments issued by the Commission in 2014-2015 and the number of replies to comments by Member States.

⁸ The number of replies by Member States to detailed opinions and comments refers to the replies sent during each of the two years considered. These replies do not necessarily refer to the detailed opinions issued in the same year (for instance, some of the replies sent in 2014 concern detailed opinions issued in 2013). This explains why the number of replies to detailed opinions by Member States in 2014 is higher than the number of detailed opinions issued in the same year.

ANNEX 3 – APPLICATION OF THE PROCEDURE IN 2014-2015: PARTICIPATION OF EFTA COUNTRIES SIGNATORY TO THE EEA AGREEMENT, OF SWITZERLAND AND OF TURKEY

Table 12 – Number of notifications from EFTA countries and comments issued to them by the European Union

	2014		2015	
	Notifications	Comments	Notifications	Comments
EFTA	Iceland	2	2	0
	Liechtenstein	0	3	2
	Norway	17	5	18

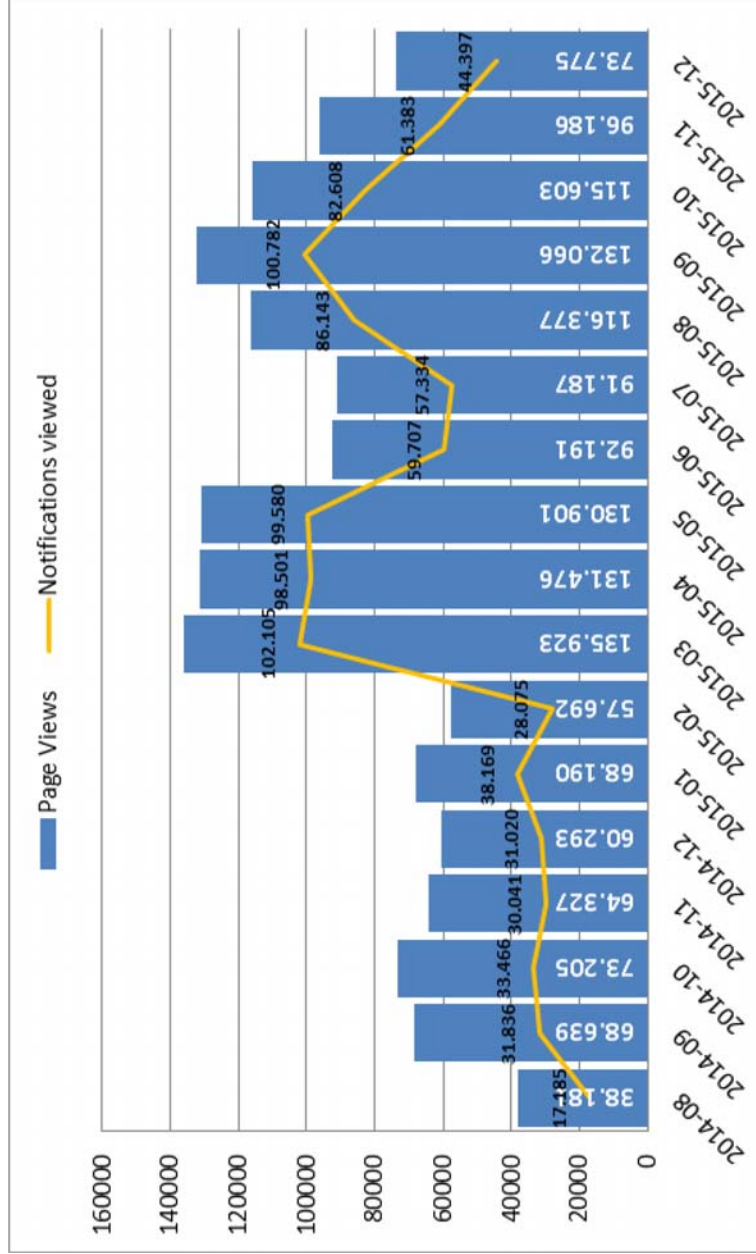
Table 13 – Number of notifications submitted by Switzerland and Turkey and comments issued to them by the Commission or the Member States

	2014		2015	
	Notifications	Comments	Notifications	Comments
Switzerland	9	3	10	5
Turkey	6	2	16	2

Table 14 – Number of comments from EFTA, Switzerland and Turkey regarding the notifications from the Member States

	2014	2015
EFTA	0	0
Switzerland	0	0
Turkey	0	0

ANNEX 4 – INTERNET CONSULTATIONS 2014-2015



Note: Internet consultations available only after August 2014 due to the roll-out of the new website and new statistical analysis algorithm.