



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 21.3.2007
SEC(2007) 350

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

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

THE OPERATION OF DIRECTIVE 98/34/EC FROM 2002 TO 2005

{COM(2007) 125 final}

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ANNEX 1 – PROCEDURES FOR STANDARDISATION

1. INFORMATION PROCEDURE

1.1. Role of ESOs

The NSBs, which are members of CEN and CENELEC (including bodies from the EFTA countries), send the necessary information to the CEN Management Centre (CEN/CMC) and the Central Secretariat of CENELEC. The information gathered is sent monthly (except in the summer and over the end of year period) by CEN and quarterly by CENELEC to the Commission (DG Enterprise and Industry), all the members of CEN and CENELEC and to ETSI.

Within the Commission, DG Enterprise and Industry disseminates both the regular returns and the annual reports of CEN and CENELEC to relevant services.

ETSI takes part in the information procedure, although its role is limited to receiving and examining the information submitted by CEN and CENELEC members via the secretariats of these two bodies. As ETSI is not made up of NSBs, any initiatives at national level would be notified via the CEN or CENELEC member.

2. MANDATES

2.1. The consultation process

Mandates are a means for Member States to give political and technical endorsement to the Commission policy in a particular area. This is achieved by means of a consultation, firstly informally with the standardisation bodies, stakeholders and Member States through sectoral committees or expert groups and then formally with the Member States through the Committee. The consultation process is co-ordinated by DG Enterprise and Industry. The Committee gives its opinion on the draft mandate, an opinion that is fully respected by the Commission services and that is acted upon wherever reasonable and possible. Following this consultation – and any amendment arising from it – the mandates are forwarded to the relevant ESOs for acceptance.

2.2. Role of ESOs

The ESOs may accept the mandate as issued by the Commission services, or indeed not accept it if they so wish, a decision made at Technical Board level. In practice, as mandates are discussed with the ESOs prior to their being issued, refusal is very rare and mandates are usually only not accepted if the work is outside the scope of the ESO.

The mandates can be addressed to any one of the ESOs, or any combination of them, as the work envisaged requires.

It is common for the ESOs to request co-funding for the mandated work following acceptance – by means of action grants – although the issuance of the mandate itself does not mean

funding will necessarily be available and the request for funding must undergo a thorough evaluation process by the Commission services.

3. FORMAL OBJECTIONS

The procedure begins with the formal objection either being received by the Commission through the Permanent Representation or being launched by the Commission itself. The documents are then circulated to the Committee, and normally a Member State expert group is consulted for opinion also. Once a draft Commission Decision is ready, this is consulted with the Committee. After receiving a positive opinion, the Decision is processed further.

ANNEX 2 BREAKDOWN OF NEW NATIONAL STANDARDISATION ACTIVITIES FROM NOTIFICATIONS 2002-2005

	2002		2003		2004		2005			
	New	Including European or international initiatives	Total	Average						
CEN	1456	20	1304	18	1528	55	1770	12	6058	1515
CENELEC	25	2	16	5	14	3	33	4	88	22
Total	1481	22	1320	23	1542	58	1803	16	6146	1537
National only total	1459		1297		1484		1787		6027	1507
From EU-15	1380		1168		1227		1512		5287	1322
From EU-10	55		135		287		261		738	185
From other members	46		17		28		30		121	30

ANNEX 3 BREAKDOWN OF NEW NATIONAL STANDARDISATION ACTIVITIES FROM NOTIFICATIONS (CEN AND CENELEC) 2002-2005 BY STATE

Country	2002	2003	2004	2005	Total
AT	175	201	172	355	903
BE	3	13	7	18	41
CH	6	6	12	10	34
CY	0	0	0	0	0
CZ	54	89	42	78	263
DE	341	298	406	385	1430
DK	5	12	6	16	39
EE	0	0	33	8	41
ES	216	235	175	159	785
FI	10	9	5	4	28
FR	117	98	168	157	540
GR	1	0	2	3	6
HU	0	17	8	12	37
IE	4	4	5	14	27
IS	1	0	0	0	1
IT	115	90	58	119	382
LU	0	0	0	0	0
LT	0	0	16	20	36
LV	0	0	9	11	20
MT	1	3	0	2	6
NL	167	46	60	51	324
NO	39	11	16	20	86
PL	0	0	130	97	227
PT	12	27	19	3	61
SE	32	11	33	5	81
SI	0	0	3	8	11
SK	0	26	46	25	97
UK	182	124	111	223	640
Total (%)	1481 (24%)	1320 (21%)	1542 (25%)	1803 (29%)	6146

ANNEX 4 SECTORAL BREAKDOWN OF NOTIFICATIONS

2002		2003		2004		2005	
Food products	114	Fasteners	66	Food products	92	Structures	103
Structures	79	Food products	60	Fire protection	62	Food products	99
Steel	59	Water quality and water supply	41	Concrete	58	Building and construction	53
Fire protection	47	Structures	39	Structures	52	Fire protection	43
Water quality and water supply	46	Road building and maintenance	36	Gas distribution installation and related equipment	48	Water quality and water supply	41
Gas distribution installation and related equipment	43	Light alloys	33	Buildings	44	Nuclear energy	38
Aerospace	36	Nuclear energy	32	Air quality	34	Masonry	37
Building and construction	35	Fire protection	30	Water quality and water supply	33	Waste	34
Small tools	34	Paints and related products	25	Tram and railways engineering	32	Concrete	32
Electrotechnical	33	Thermal matters	24	Small tools	30	Metal structures	31

ANNEX 5 MANDATES 2002-2005 – TOTAL

	2002	2003	2004	2005	Total
Mandates	8	14	21	12	55
Amendments (New Approach)	0	2	5	3	10
New Approach mandates	5	4	6	5	20
Mandates under other legislation	3	9	11	4	27
Mandates under Community policy	0	1	4	3	8

ANNEX 6 MANDATES BY SUBJECT AREA

	2002	2003	2004	2005	Total
New Approach	5	4	6	5	20
Environment	1	2	9	0	12
Consumer protection	0	1	1	2	4
Transport	1	3	1	0	5
Services	0	1	0	2	3
Other	1	3	4	3	11

ANNEX 7 COMMISSION DECISIONS ON FORMAL OBJECTIONS 2002-2005

	Standard	Directive	Decision	Date	Decision number	O.J. Reference
1	EN 848-3 "Safety of woodworking machines — One-side moulding machines with rotating tool — Part 3: Numerical control boring machines and routing machines	98/37/EC machinery	Presumption of conformity not withdrawn	17/12/2002	2002/1002/EC	L 349/103 24/12/2002
2	EN 613:2000 'Independent gas-fired convection heaters'	90/396/EEC appliances burning gaseous fuels	Presumption of conformity not withdrawn	18/03/2003	2003/189/EC	L 74/26 20/03/2003
3	EN 521:1998 'Specifications for dedicated liquefied petroleum gas appliances — Portable vapour pressure liquefied petroleum gas appliances',	90/396/EEC appliances burning gaseous fuels	Presumption of conformity not withdrawn	18/03/2003	2003/190/EC	L 74/28 20/03/2003
4	EN 1495:1997 'Lifting platforms — mast climbing work platforms'	98/37/EC machinery	Partial withdrawal of presumption of conformity	21/03/2003	2003/224/EC	L 83/70 01/04/2003
5	30 standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks	89/106/EEC construction products	Presumption of conformity not withdrawn	9/04/2003	2003/312/EC	L 114/50 08/05/2003
6	EN 1970:2000 'Adjustable beds for disabled persons — Requirements and test methods'	93/42/EEC medical devices	Presumption of conformity not withdrawn	20/04/2004	2004/376/EC	L 118/76 23/04/2004
7	EN 12180:2000 'Non-active surgical implants — Body contouring implants — Specific requirements for mammary implants'	93/42/EEC medical devices	Presumption of conformity withdrawn	20/04/2004	2004/389/EC	L 120/48 24/4/2004
8	EN 71-1:1998 "Safety of Toys – Part 1: mechanical and physical properties	88/378/EEC toys	Partial withdrawal of presumption of conformity	9/03/2005	2005/195/EC	L 63/27 10/03/2005

ANNEX 8 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/enterprise/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.

Obligation to notify and the standstill period

Article 8(1) of the Directive stipulates that the Member States shall inform the Commission of any draft technical regulation prior to its adoption. The simple transposition of a Community act does not require prior notification, unless the national authorities adopt national provisions that go beyond mere compliance with Community acts and that contain technical regulations within the meaning of the Directive (Article 10).

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 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 (Articles 28-30, 43 and 49 of the EC Treaty) or to secondary legislation, the Commission and the other Member States submit a **detailed opinion** to the Member State that has prepared the draft (Article 9(2) of the 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 Community law but that requires clarifications in its interpretation (Article 8(2)). The Commission can also block a draft for a

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

² O L 204/37 of 21.7.1998.

³ O L 217/18 of 5.8.1998.

period of 12 months if Community harmonisation work is due to be undertaken or is already underway in the same field (Article 9(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 9(2)). With regard to the comments, even though 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, the Member States are inclined to respond, thus making the procedure a genuine instrument of dialogue.

Urgency procedure

Article 9(7) of the 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 (*'serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants'*). The aim of the urgency procedure is to enable a notifying Member State faced with serious or unforeseeable circumstances immediately to adopt the draft technical regulation, without having to wait for the three-month standstill. 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 time limit for the 98/34 procedure 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 breach of Community law.

Communication of final texts

At the end of the 98/34 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 98/34 procedure to be closed (Article 8(3) of the Directive).

The 'Standards and technical regulations' Committee

The Committee laid down in Article 5 of the Directive consists of representatives appointed by the Member States and is chaired by a representative of the Commission. In its 'Standards and technical regulations' configuration, the Committee meets regularly and constitutes a forum for discussing all issues connected with the application of the directive.

Application of the 98/34 procedure to Information Society services

Since 5 August 1999, the 98/34 procedure has also applied 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 98/34 procedure with the necessary adaptations⁴: they notify their drafts via the EFTA Surveillance Authority and can comment on the drafts notified by the 25 Member States. The same kind of reaction is provided for, for the entire European Community, in respect of drafts notified by the three countries signatory to the EEA Agreement.

Switzerland (which is part of EFTA, but which does apply the EEA Agreement) also participates in the system. This country applies the 98/34 procedure on a voluntary basis following an informal agreement to exchange information in the field of technical regulations: it submits its drafts to the Commission and can make and receive comments on the notified drafts.

Turkey, which transposed the 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.

⁴ Annex II, Chapter XIX, point 1 to the EEA Agreement, which includes Article 8(2) of the Directive

ANNEX 9 DEVELOPMENTS IN COURT OF JUSTICE CASE-LAW ON THE MATTER 2002-2005

The eight Court of Justice judgments delivered on the Directive during the 2002-2005 period are presented below in chronological order: Six of them were delivered under the preliminary ruling procedure (Article 234 of the EC Treaty) and two following proceedings for failure to fulfil an obligation launched by the Commission against a Member State (Article 226 of the EC Treaty). The common features of these judgments: they clarify the notion of technical regulation and the obligation to notify, and confirm the Court's previous case-law regarding the unenforceability of technical regulations not notified prior to their adoption.

It should be pointed out that, like the other Court judgments on the notification procedure, these judgments can be consulted on the following website: <http://ec.europa.eu/enterprise/tris>.

Judgment of 22 January 2002, C-390/99, Canal Satélite Digital SL

(OJ C 84 of 6 April 2002, page 10; Rec. 2002, p. I-607)

In this judgment delivered under the preliminary ruling procedure, the Court, having confirmed that a national regulation is notifiable unless it transposes a Community provision, as stipulated by Article 10 of the Directive, subsequently indicated that the obligation for businesses to list apparatus, equipment and decoders in a register and to obtain prior type-approval for these products cannot be described as a measure by which the Member State conforms to a binding Community act. Such measures must therefore be notified as part of the 98/34 procedure. In the case in point, the subject in question was Directive 95/47/EC on the use of standards for the transmission of television signals, which contains provisions relating to both the obligations of conditional access service providers and the characteristics of hired or purchased equipment but which leaves it to the Member States to choose the appropriate administrative procedures.

The Court also explained that national provisions that merely lay down conditions governing the establishment of undertakings, such as provisions making the exercise of an activity subject to prior authorisation, do not constitute technical regulations (see paragraph 45). However, national provisions that require undertakings to apply for prior approval of their equipment do constitute technical regulations.

Judgment of 6 June 2002, C-159/00, Sapod Audic/Eco-Emballages SA

(OJ C 180 of 27 July 2002, p. 4; Rec. 2002, p. I-5031)

This is a judgment delivered under the preliminary ruling procedure that is mainly focused on the notion of technical specification. Thus, the requirement to identify packaging, as stipulated in national legislation, insofar as it does not require the said packaging to be marked or labelled and does not appear necessarily to refer to the product or the packaging as such, does not constitute a technical specification because it does not stipulate the characteristics required of a product within the meaning of Article 1(1) of the Directive. Consequently, there is no requirement for prior notification within the meaning of Article 8. If, however, a national provision includes a marking or labelling requirement and must

therefore be notified, individuals may invoke a possible failure to notify; as the Court stated in the 1996 CIA International judgment, it is the responsibility of the national judge to refuse to apply this provision; the extent of the applicable penalty, such as the nullity or unenforceability of a contract, is governed by national law. *‘That conclusion is, however, subject to the condition that the applicable rules of national law are not less favourable than those governing similar domestic actions and are not framed in such a way as to render impossible in practice the exercise of rights conferred by Community law’.*

Judgment of 21 April 2005, C-267/03, Lars Erik Staffan Lindbergh

(OJ C 143 of 11 June 2005, p. 9; Rec. 2005, p. I-3247)

This judgment, which was delivered under the preliminary ruling procedure, confirms that the possible effects of a technical regulation on intra-Community trade do not constitute a criterion for defining the scope of the Directive. It also contains some useful clarifications regarding the notions of *‘technical specification’*, *‘other requirements’* and *‘provisions ... banning the manufacture, import, sale and use of a product’* referred to in Article 8 of the Directive. Thus, national provisions banning the organisation of games of chance through the use of certain automated gaming machines are liable to constitute a technical regulation, if the scope of the ban permits only marginal use of the product or may significantly affect the composition, nature or sale of the product.

Judgment of 2 June 2005, C-89/04, Mediakabel BV/Commissariaat voor de Media

(OJ C 182 of 23 July 2005, p. 16; Rec. 2005, p. I-4891)

The Court was bound to deliver a preliminary ruling on the definition of the notions of *‘television broadcasting services’* within the meaning of Directive 89/552/EEC on the pursuit of television broadcasting activities, and of *‘Information Society service’* of Directive 98/34/EC. The Community judges concluded that a *‘pay per view’* service, which consists in broadcasting television programmes to the public and which is not supplied upon individual request, is a television broadcasting service that does not fall within the scope of the Directive and that is therefore not subject to the requirement for prior notification.

Judgment of 8 September 2005, C-57/05, Commission/France

(OJ C 271 of 29 October 2005, p. 11; not published in the Rec.)

In this matter, which concerns a failure to fulfil obligations, the Court stressed that the fact that a Member State had chosen to integrate transposing measures (in this case, it was Directive 2002/46/EC on food supplements that was being transposed) within a more general text, several provisions of which constitute technical regulations that require notification prior to their adoption, did not justify the failure to transpose the directive in question within the time limit set by the Court. In other words, the Member State cannot take advantage of the obligation to notify and of the resulting three-month standstill period in order to justify a delay in transposition.

Judgment of 8 September 2005, *Lidl Italia Srl/Comune di Stradella*, C-303/04

(OJ C 281 of 12 November 2005, p. 4; Rec. 2005, p. I-7865)

In returning to the notion of technical regulation in this matter, which was opened following a reference for a preliminary ruling, the Court confirmed that a national provision requiring cotton buds intended for cleaning out ears to be manufactured exclusively from biodegradable materials constitutes a technical regulation requiring prior notification within the meaning of Article 8 of the Directive. The established case-law from the *CIA International* judgment, whereby a national judge must rule out the application of a national provision if it has not been notified, was also referred to.

Judgment of 8 September 2005, C-500/03, *Commission/Portugal*

(OJ C 271 of 29 October 2005, p. 6; not published in the Rec.)

Following a failure to fulfil obligations, the Court condemned Portugal for not having notified as a draft the provisions of a regulation on lagoon navigation, which contained technical specifications for pleasure craft capable of navigating lagoons, particularly in relation to maximum length and height and to propulsion power limits.

ANNEX 10 NEGOTIATION OF BILATERAL AGREEMENTS WITH A VIEW TO THE ENLARGEMENT OF 1 MAY 2004

On 21 October 2002, the Commission received a mandate from the EU Council to negotiate the conclusion of bilateral agreements with the candidate countries that had already finished negotiating on Chapter 1 of the *acquis communautaire* ('Free movement of goods').

The aim of these agreements was to familiarise the candidate countries with the notification procedure and to implement the necessary human and computer infrastructure, in order to allow them to participate in the system even before they joined the EU, if they so desired.

The text of the agreements provided for the establishment of a simplified procedure characterised, *inter alia*, by the option to notify draft technical regulations in one of the Community languages and by a single three-month standstill period.

During this period, the candidate countries had the opportunity to comment on the drafts notified by the Member States and, equally, the Member States and the Commission could comment on any drafts notified by the candidate countries.

Following the negotiations, in April 2003 the Commission invited the Council to sign the bilateral agreements on the extension of the notification procedure with Estonia, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia and the Czech Republic⁵. Three months later, in July 2003, the Commission invited the Council to sign the agreements with Cyprus and Hungary⁶.

⁵ Commission proposal of 24 April 2003, COM(2003) 203 final, approved by the Council on 22 September 2003 by Decision 2004/330/EC on the conclusion of bilateral agreements between the European Community and the Czech Republic, the Republic of Estonia, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta, the Republic of Poland, the Slovak Republic and the Republic of Slovenia, respectively, laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L117/1 of 22.4.2004).

⁶ Commission proposal of 9 July 2003, COM (2003) 404 final, approved by the Council on 24 November 2003 by Decision 2004/299/EC on the conclusion of bilateral agreements between the European Community and the Republic of Cyprus and the Government of the Republic of Hungary, laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 98/30 of 2.4.2004).

ANNEX 11 APPLICATION OF THE PROCEDURE 2002-2005: NOTIFICATIONS OF TECHNICAL REGULATIONS SUBMITTED BY THE MEMBER STATES

Annexes 11.1, 11.2 and 11.3 give a statistical overview of the development of the number of draft technical regulations notified by the Member States between 2002 and 2005, and of their breakdown by Member State and by sector. It should be pointed out that, in accordance with Article 11 of the Directive, ‘statistics concerning communications received’ as part of the notification procedure are published once a year in the Official Journal, C series⁷.

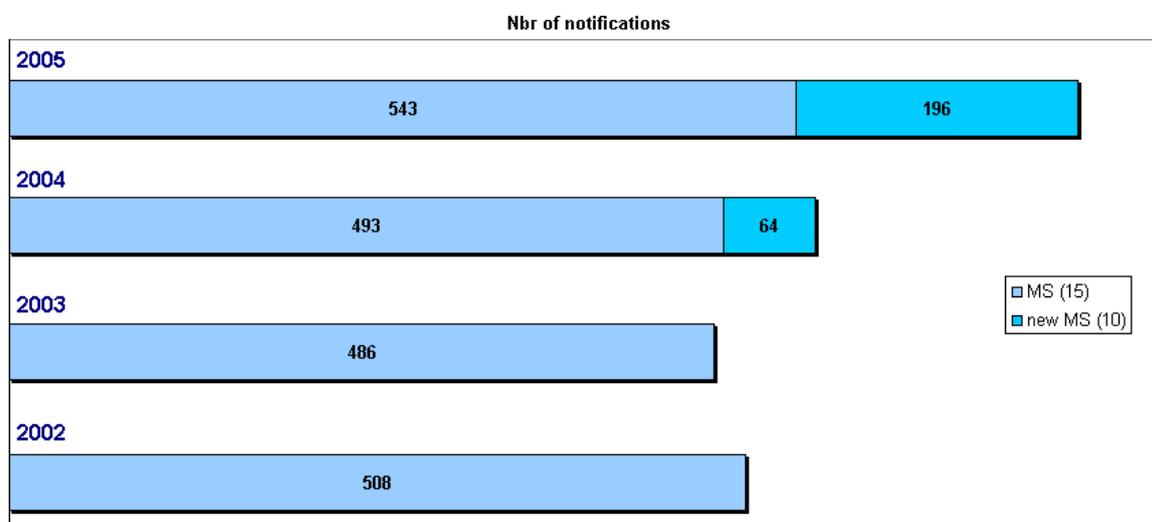
The reactions to the notified drafts – in the form of comments or detailed opinions from the Commission or the Member States, or of blocks on the part of the Commission – are illustrated in Annexes 11.4 to 11.6.

Annex 11.7 refers to the requests to apply the emergency procedure that the Member States addressed to the Commission pursuant to Article 9(7) of the Directive.

Annex 11.8 shows the action taken by the Member States in response to the Commission’s reactions.

11.1 VOLUME OF NOTIFICATIONS DURING THE 2002-2005 PERIOD

Figure 1



The statistics in figure 1 show that the Member States notified to the Commission 508 draft regulations in 2002, 486 in 2003, 557 in 2004 and 739 in 2005.

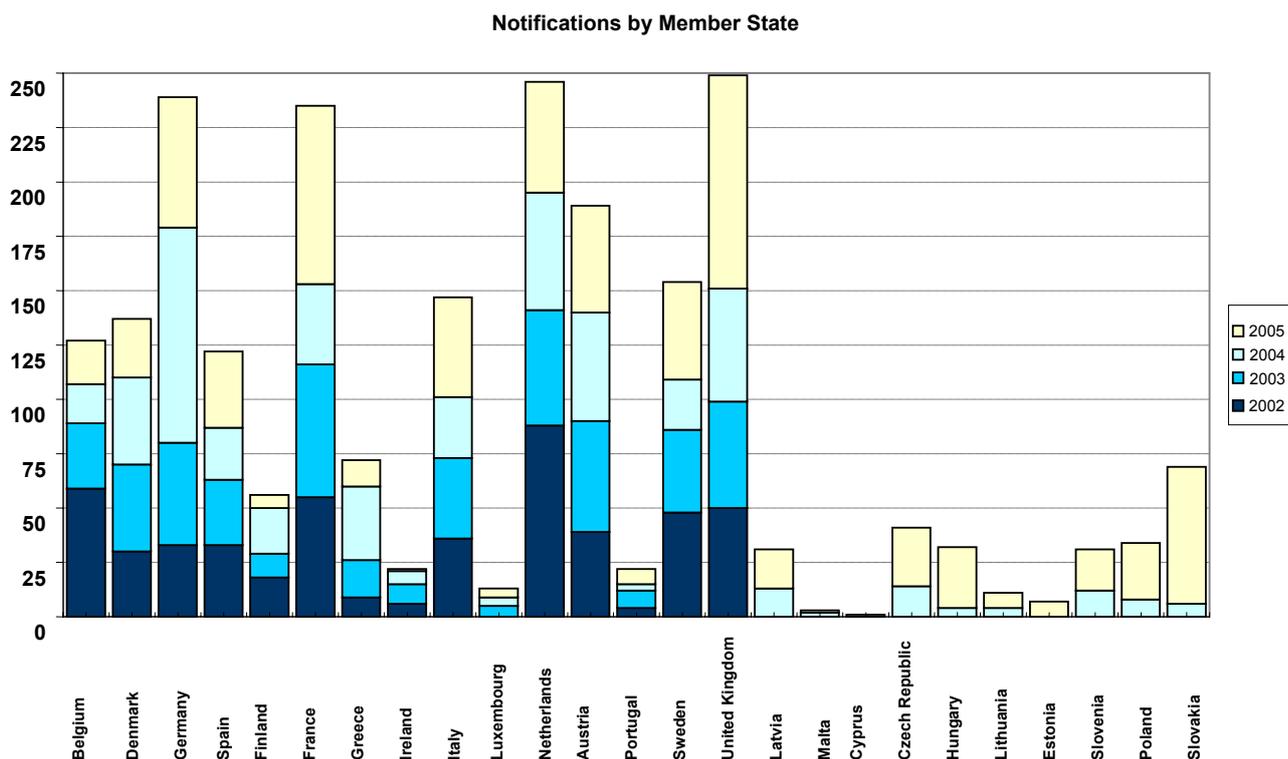
Starting with **the 15 old Member States**, between 2002 and 2004 the number of notified drafts remained steady at around 500 notifications per year, which was a reduction compared with the previous period (from 1991 to 2001 there were respectively 591-751-530

⁷ For 2002: OJ C 131/18 of 5.6.2003; for 2003: OJ C 216/2 of 28.8.04; for 2004: OJ C 158/20 of 29.6.2005; for 2005: OJ C 166/2 of 18.7.2006.

notifications⁸). In 2005, the notifications greatly exceeded the threshold of 500 notifications. With regard to the **new Member States**, between 1 May 2004, the date of their accession to the EU, and 31 December of the same year, they notified 64 draft technical regulations. In 2005, the number of notifications from the new countries more than trebled: 196 notifications, which represent 25.6% of the total number of notifications from the 25 Member States for the year in question.

11.2 BREAKDOWN BY COUNTRY

Figure 2



During the 2002-2005 period, four Member States each notified more than 230 draft technical regulations: they were the United Kingdom (249), the Netherlands (246), Germany (239) and France (235). For at least two of those countries, this would seem due to very sharp peaks in one year or another: the United Kingdom, for example, almost doubled the number of notified drafts in 2005 compared with previous years (99 notifications). The same is true of Germany, which notified 99 drafts in 2004. A group of six other countries (Austria, Sweden, Italy, Denmark, Belgium and Spain) come next with a total number of notifications of between 120 and 190. Of the new Member States, the Czech Republic, Latvia and Slovenia (39 notifications in total) alone account for 60.9% of the notifications sent to the Commission by the new Member States in 2004. Of the 196 drafts submitted in 2005, 63 were notified by the new Member States in 2004. Of the 196 drafts submitted in 2005, 63 were notified by the Slovakian authorities (32% of the total number). Hungary, the Czech Republic and Poland come next, with 28, 27 and 26 notifications respectively.

⁸ Report on the functioning of Directive 98/34/EC from 1999 to 2001, COM(2003) 200 final, available on the following website: <http://ec.europa.eu/enterprise/tris>.

Table 1 – Number of notifications of technical regulations submitted by the Member States from 2002 to 2005

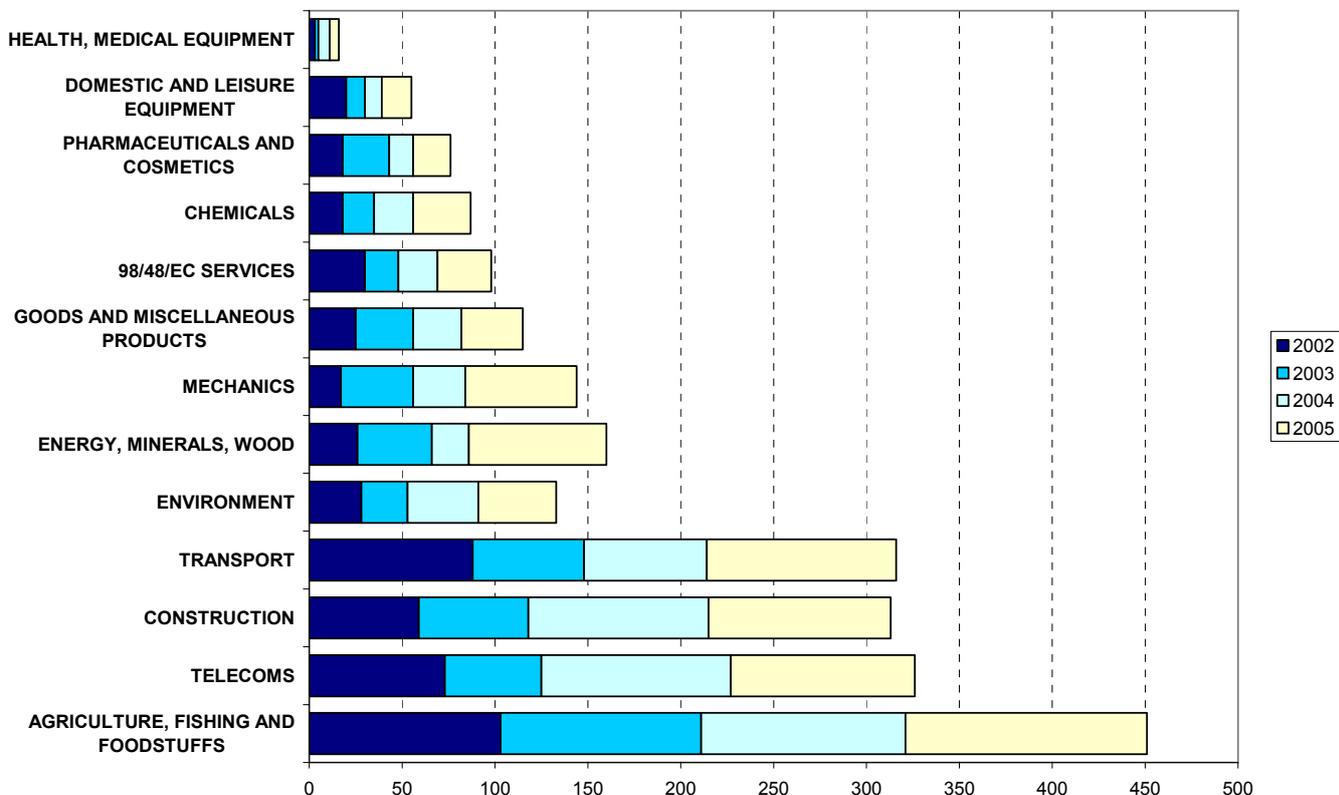
Member States	2002	2003	2004	2005
Belgium	59	30	18	20
Denmark	30	40	40	27
Germany	33	47	99	60
Spain	33	30	24	35
Finland	18	11	21	6
France	55	61	37	82
Greece	9	17	34	12
Ireland	6	9	6	1
Italy	36	37	28	46
Luxembourg	0	5	4	4
Netherlands	88	53	54	51
Austria	39	51	50	49
Portugal	4	8	3	7
Sweden	48	38	23	45
United Kingdom	50	49	52	98
Latvia	-	-	13	18
Malta	-	-	2	1
Cyprus	-	-	1	0
Czech Rep.	-	-	14	27
Hungary	-	-	4	28
Lithuania	-	-	4	7
Estonia	-	-	0	7
Slovenia	-	-	12	19
Poland	-	-	8	26
Slovakia	-	-	6	63
Total EC	508	486	557	739

Table 2 – Percentages of notifications submitted by the Member States from 2002 to 2005

Member States	2002	2003	2004	2005
Belgium	11.6%	6.2%	3.2%	2.7%
Denmark	5.9%	8.2%	7.2%	3.7%
Germany	6.5%	9.7%	17.8%	8.1%
Spain	6.5%	6.2%	4.3%	4.7%
Finland	3.5%	2.3%	3.8%	0.8%
France	10.8%	12.6%	6.6%	11.1%
Greece	1.8%	3.5%	6.1%	1.6%
Ireland	1.2%	1.9%	1.1%	0.1%
Italy	7.1%	7.6%	5.0%	6.2%
Luxembourg	0.0%	1.0%	0.7%	0.5%
Netherlands	17.3%	10.9%	9.7%	6.9%
Austria	7.7%	10.5%	9.0%	6.6%
Portugal	0.8%	1.6%	0.5%	0.9%
Sweden	9.4%	7.8%	4.1%	6.1%
United Kingdom	9.8%	10.1%	9.3%	13.3%
Latvia	-	-	2.3%	2.4%
Malta	-	-	0.4%	0.1%
Cyprus	-	-	0.2%	0.0%
Czech Rep.	-	-	2.5%	3.7%
Hungary	-	-	0.7%	3.8%
Lithuania	-	-	0.7%	0.9%
Estonia	-	-	0.0%	0.9%
Slovenia	-	-	2.2%	2.6%
Poland	-	-	1.4%	3.5%
Slovakia	-	-	1.1%	8.5%

11.3 BREAKDOWN BY SECTOR 2002-2005

Figure 3



As in the past, the number of notifications relating to **agricultural products and foodstuffs** is constantly increasing and these are the sector with the highest number of notifications during the period in question (an average 20% of the total number, with a slight decrease from 2005). They are followed by the **telecommunications, transport** and **construction** sectors, which recorded strong growth between 2004 and 2005. In 2005, two other sectors grew significantly: the **energy** and **mechanical engineering** sectors. **Information Society** services represent 4-6% of the total number of notifications.

Tables 3 and 4 – Breakdown by sector of the drafts notified by the Member States of the European Union in 2002 and 2003

Sectors	2002	
Foodstuffs and agricultural products	103	20.3%
Transport	88	17.3%
Telecommunications	73	14.4%
Building and construction	59	11.6%
Information Society services	30	5.9%
Environment, packaging	28	5.5%
Energy, ores, wood	26	5.1%
Miscellaneous products	25	4.9%
Domestic and leisure equipment	20	3.9%
Chemicals	18	3.5%
Pharmaceuticals	18	3.5%
Mechanical engineering	17	3.3%
Health, medical equipment	3	0.6%

Sectors	2003	
Foodstuffs and agricultural products	108	22.2%
Transport	60	12.3%
Building and construction	59	12.1%
Telecommunications	52	10.7%
Energy, ores, wood	40	8.2%
Mechanical engineering	39	8.0%
Miscellaneous products	31	6.4%
Pharmaceuticals	25	5.1%
Environment, packaging	25	5.1%
Information Society services	18	3.7%
Chemicals	17	3.5%
Domestic and leisure equipment	10	2.1%
Health, medical equipment	2	0.4%

Tables 5 and 6 – Breakdown by sector of the drafts notified by the Member States of the European Union in 2004 and 2005

Sectors	2004	
Foodstuffs and agricultural products	110	19.7%
Telecommunications	102	18.3%
Building and construction	97	17.4%
Transport	66	11.8%
Environment, packaging	38	6.8%
Mechanical engineering	28	5.0%
Miscellaneous products	26	4.7%
Chemicals	21	3.8%
Information Society services	21	3.8%
Energy, ores, wood	20	3.6%
Pharmaceuticals	13	2.3%
Domestic and leisure equipment	9	1.6%
Health, medical equipment	6	1.1%

Sectors	2005	
Foodstuffs and agricultural products	130	17.6%
Transport	102	13.8%
Telecommunications	99	13.4%
Building and construction	98	13.3%
Energy, ores, wood	74	10.0%
Mechanical engineering	60	8.1%
Environment, packaging	42	5.7%
Miscellaneous products	33	4.5%
Chemicals	31	4.2%
Information Society services	29	3.9%
Pharmaceuticals	20	2.7%
Domestic and leisure equipment	16	2.2%
Health, medical equipment	5	0.7%

11.4 COMMISSION REACTIONS: COMMENTS AND DETAILED OPINIONS 2002-2005 (ARTICLES 8(2) AND 9(2) OF THE DIRECTIVE)

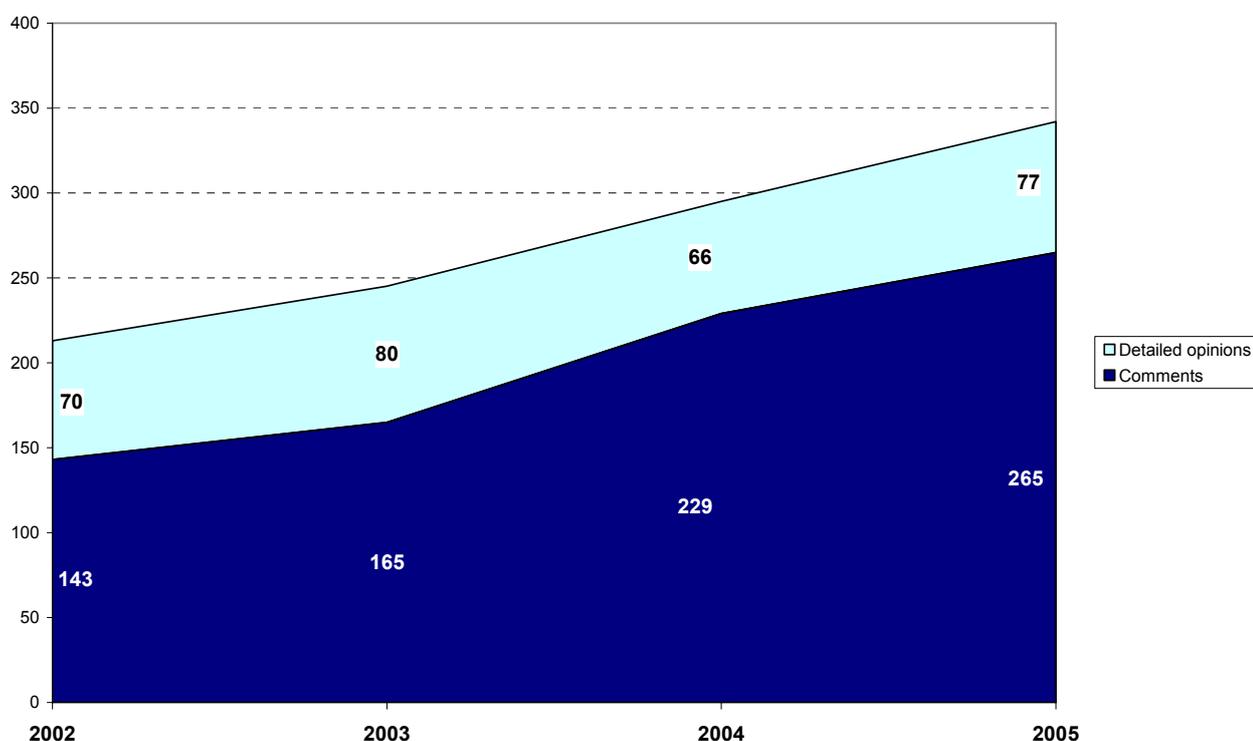
Table 7

Year	Comments	Detailed opinions
2002	143	70
2003	165	80
2004	229	66
2005	265	77

The number of **detailed opinions** issued by the Commission during the period in question did not vary significantly: 70 detailed opinions in 2002 on the total number of 508 notifications (13.7%); in 2003, 80 detailed opinions on the total number of 486 notifications (16.4%). On the 557 notifications of 2004 (64 of which came from the new Member States) the Commission issued 66 detailed opinions (12 of which were addressed to the new Member States), corresponding to 11.8% of the total number. The 77 opinions on the 739 notifications of 2005 (196 of which came from the new Member States) correspond to 10.4%: this is the lowest response rate of the entire 2002-2005 period, particularly given the substantial increase in the number of drafts notified by the Member States.

On the other hand, the number of **comments** adopted by the Commission increased at a constant rate and rose from 143 in 2002 to 265 in 2005.

Figure 4



11.5 COMMISSION REACTIONS: BLOCKS 2002-2005 (ARTICLES 9(3) AND 9(4) OF THE DIRECTIVE)

During the 2002-2005 period, the Commission requested a 12-month postponement of the adoption of 22 draft regulations notified by the Member States, because they concerned a subject on which Community harmonisation work had already been announced or was underway.

Table 8

Year	Standstills		Total
	Announcement of a Community text (Article 9.3)	Presentation to the Council of a Community text (Article 9.4)	
2002	8	3	11
2003	4	1	5
2004	1	0	1
2005	3	1	4

11.6 MEMBER STATE REACTIONS

Table 9 Comments and detailed opinions issued by the Member States 2002-2005 (Articles 8(2) and 9(2))

	2002		2003		2004		2005	
	Com.	D.O.	Com.	D.O.	Com.	D.O.	Com.	D.O.
Belgium	3	6	1	4	0	5	0	6
Denmark	3	2	3	0	1	3	0	3
Germany	27	21	25	7	21	10	56	6
Spain	25	16	27	13	29	7	19	5
Finland	6	3	3	0	7	1	2	0
France	14	14	29	15	22	6	27	10
Greece	0	0	0	0	0	0	0	0
Ireland	1	1	1	0	0	1	0	1
Italy	75	5	35	3	39	9	30	1
Luxembourg	0	1	0	1	0	1	0	1
Netherlands	8	13	3	7	5	3	11	3
Austria	10	7	13	3	7	4	15	2
Portugal	1	4	1	1	0	0	2	0
Sweden	11	16	15	5	22	3	16	4
United Kingdom	14	2	1	0	6	1	7	0
Latvia	0	0	0	0	9	0	5	0
Malta	0	0	0	0	0	0	0	0
Cyprus	0	0	0	0	0	0	1	0
Czech Rep.	0	0	0	0	2	0	9	2
Hungary	0	0	0	0	2	1	6	0
Lithuania	0	0	0	0	0	0	1	0
Estonia	0	0	0	0	0	0	1	0
Slovenia	0	0	0	0	3	3	10	1
Poland	0	0	0	0	2	0	8	0
Slovakia	0	0	0	0	1	2	4	0
Total	198	111	157	59	178	60	228	45

11.7 URGENCIES (ARTICLE 9(7) OF THE DIRECTIVE)

Table 10 Requests to apply the urgency procedure received 2002-2005

YEAR	2002		2003		2004		2005	
	Requests	Favourable opinion						
Belgium	7	2	4	2	0	0	3	2
Denmark	0	0	0	0	4	1	1	1
Germany	4	3	0	0	3	1	4	0
Spain	1	0	1	0	3	1	0	0
Finland	0	0	0	0	0	0	0	0
France	4	2	7	5	5	2	7	6
Greece	0	0	0	0	0	0	0	0
Ireland	0	0	0	0	0	0	0	0
Italy	1	0	1	0	1	1	2	0
Luxembourg	0	0	0	0	0	0	0	0
Netherlands	5	5	2	0	0	0	1	0
Austria	1	0	1	0	1	1	0	0
Portugal	3	2	2	2	1	0	3	1
United K	0	0	1	1	0	0	0	0
Sweden	1	1	3	3	1	1	2	2
Latvia	0	0	0	0	0	0	1	0
Malta	0	0	0	0	0	0	0	0
Cyprus	0	0	0	0	0	0	0	0
Czech Rep.	0	0	0	0	1	1	0	0
Hungary	0	0	0	0	0	0	6	0
Lithuania	0	0	0	0	0	0	0	0
Estonia	0	0	0	0	0	0	0	0
Slovenia	0	0	0	0	0	0	0	0
Poland	0	0	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0	0	0
Total	27	15	22	13	20	9	30	13

Table 10 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 (50 out of the 99 made during the entire 2002-2005 period). Of the 25 Member States, 11 countries never resorted to using the urgency procedure during the period in question (Finland, Greece, Ireland, Malta, Cyprus, Hungary, Lithuania, Estonia, Slovenia, Poland, Slovakia).

Table 11, which gives a sectoral breakdown of the requests to apply the urgency procedure received by the Commission during the 2002-2005 period, shows that the application of this exceptional procedure was invoked mainly in the foodstuffs and agricultural products sector (40 requests) and in the transport sector (14). These two fields alone account for more than half of the total number of urgencies (54 requests out of the sum total of 99).

Table 11 – Breakdown by sector of the requests to apply the urgency procedure 2002-2005.

DESCRIPTION	Belgium		Denmark		Germany		Spain		France		Italy		Netherlands		Austria		Portugal		Sweden		UK		Latvia		Czech R.		Hungary		Total D	Total AF
	R	A	R	A	R	A	R	A	R	A	R	A	R	A	R	A	R	A	R	A	R	A	R	A	R	A	R	A		
AGRICULTURE, FISHING AND FOODSTUFFS	3	0	0	0	4	0	2	0	12	8	3	0	3	2	1	0	1	0	5	5	1	1	0	0	0	0	5	0	40	16
TRANSPORT	6	4	2	0	2	0	0	0	0	0	0	0	2	2	0	0	1	0	1	1	0	0	0	0	0	0	0	0	14	7
GOODS AND MISCELLANEOUS PRODUCTS	0	0	0	0	1	1	1	0	0	0	0	0	1	1	1	1	3	2	0	0	0	0	1	0	0	0	1	0	9	5
MECHANICS	0	0	0	0	0	0	1	0	6	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	5
CONSTRUCTION	0	0	0	0	0	0	0	0	4	1	0	0	0	0	1	0	1	1	0	0	0	0	0	0	1	1	0	0	7	3
CHEMICALS	0	0	3	2	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6	4
98/48/EC SERVICES	1	0	0	0	2	2	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	4	2
PHARMACEUTICALS AND COSMETICS	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	4	4
ENERGY, MINERALS, WOOD	2	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	0	0	3	0
ENVIRONMENT	1	1	0	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	2	1
DOMESTIC AND LEISURE EQUIPMENT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	2	2
TELECOMS	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
TOTAL	14	6	5	2	11	4	5	1	23	15	5	1	8	5	3	1	9	5	7	7	1	1	1	0	1	1	6	0	99	49

R : request A : accepted

11.8 FOLLOW-UP TO COMMISSION REACTIONS

Table 12 shows that, in **2002**, the recipient Member States responded to 55 of the 70 detailed opinions issued by the Commission (78.5%) and that 31 responses were deemed satisfactory by the Commission (56,36%). In **2003**, they responded to 72 of the 80 detailed opinions (90%); 54 were satisfactory (75%). In **2004**, 66 detailed opinions were issued by the Commission, 12 of which were addressed to the new Member States. Of the 55 responses from the Member States (83.3%), 35 were deemed favourable by the Commission (63,6%). With regard to the drafts notified in **2005**, the Commission issued 77 detailed opinions and there were 67 responses (87%), 32 of which were favourable (47.7%).

Table 12*

Year	Detailed opinions	Responses from the Member States	Satisfactory	closures
2002	70	55	31	13
2003	80	72	54	10
2004	66	55	35	11
2005	77	67	32	5

*Data at 30/10/2006

ANNEX 12 APPLICATION OF THE PROCEDURE 2002-2005: PARTICIPATION OF EFTA COUNTRIES SIGNATORY TO THE EEA AGREEMENT, OF SWITZERLAND AND OF TURKEY

Table 13 – Number of notifications from EFTA countries and comments issued to them by the European Community

		2002		2003		2004		2005	
		Notificati ons	Com. EC	Notifications	Com. EC	Notifications	Com. EC	Notifications	Com . EC
EFTA	Norway	38	7	25	17	23	13	34	17
	Liechtenstein	7	1	1	0	3	2	4	2
	Iceland	4	4	3	1	11	4	17	10

Table 14 – Number of notifications submitted by Switzerland and Turkey and comments issued to them by the European Community

	2002		2003		2004		2005	
	Notifications	Com.	Notifications	Com.	Notifications	Com.	Notifications	Com .
Switzerland	6	2	5	1	15	9	6	2
Turkey	0	0	0	0	3	3	0	0

Table 15 – Number of comments from EFTA regarding the notifications from the Member States

	2002	2003	2004	2005
EFTA	0	0	1	0

ANNEX 13 – INTERNET CONSULTATIONS 2003-2005

Figure 5

