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Legislation

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Contents

[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2015/1292

of 20 July 2015

on the conclusion, on behalf of the European Union and its Member States, of the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part, to take account of the accession of the Republic of Croatia to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 217, in conjunction with point (a)(i) of the second subparagraph of Article 218(6) and the second subparagraph of Article 218(8), thereof,

Having regard to the Act of Accession of Croatia, and in particular the second subparagraph of Article 6(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) In accordance with Council Decision 2014/517/EU ([1]), the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part, to take account of the accession of the Republic of Croatia to the European Union ([2]) (the 'Protocol'), has been signed, subject to its conclusion.

(2) The conclusion of the Protocol is subject to a separate procedure as regards matters falling within the competence of the European Atomic Energy Community.

(3) The Protocol should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part, to take account of the accession of the Republic of Croatia to the European Union is hereby approved on behalf of the Union and its Member States.

([1]) Council Decision 2014/517/EU of 14 April 2014 on the signing, on behalf of the European Union and its Member States, and provisional application of the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Serbia, of the other part, to take account of the accession of the Republic of Croatia to the European Union (OJ L 233, 6.8.2014, p. 1).

([2]) OJ L 233, 6.8.2014, p. 3.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to deposit, on behalf of the Union and its Member States, the instruments of approval provided for in Article 13(2) of the Protocol.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 20 July 2015.

For the Council
The President
F. MOGHERINI

COUNCIL DECISION (EU) 2015/1293

of 20 July 2015

on the conclusion, on behalf of the European Union, of the European Convention on the legal protection of services based on, or consisting of, conditional access

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), first subparagraph, in conjunction with Article 218(6)(a)(v) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) On 16 July 1999, the Council authorised the Commission to negotiate within the Council of Europe, on behalf of the European Community, a convention concerning the legal protection of services based on, or consisting of, conditional access.

(2) The European Convention on the legal protection of services based on, or consisting of, conditional access ('the Convention') was adopted by the Council of Europe on 24 January 2001 and entered into force on 1 July 2003.

(3) The Convention establishes a regulatory framework which is almost identical to that set out in Directive 98/84/EC of the European Parliament and of the Council ([1]).

(4) On 21 December 2011, the Convention was signed on behalf of the Union ([2]).

(5) The conclusion of the Convention could help to extend the application of provisions similar to those in Directive 98/84/EC beyond the borders of the Union, and establish a law on services based on conditional access which would be applicable throughout the European continent.

(6) The Convention should be approved on behalf of the Union,

HAS ADOPTED THIS DECISION:

Article 1

The European Convention on the legal protection of services based on, or consisting of, conditional access ([3]) is hereby approved on behalf of the Union.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to deposit on behalf of the Union the instrument of approval provided for in Article 12 of the Convention, in order to express the consent of the Union to be bound.

([1]) Directive 98/84/EC of the European Parliament and of the Council of 20 November 1998 on the legal protection of services based on, or consisting of, conditional access (OJ L 320, 28.11.1998, p. 54).

([2]) The Convention was signed on the basis of Council Decision 2011/853/EU of 29 November 2011 on the signing, on behalf of the Union, of the European Convention on the legal protection of services based on, or consisting of, conditional access (OJ L 336, 20.12.2011, p. 1). That Decision has since been replaced by Council Decision 2014/243/EU of 14 April 2014 on the signing, on behalf of the European Union, of the European Convention on the legal protection of services based on, or consisting of, conditional access (OJ L 128, 30.4.2014, p. 61).

([3]) The text of the Convention has been published in OJ L 336, 20.12.2011, p. 2.

Article 3

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 20 July 2015.

For the Council
The President
F. MOGHERINI

ANNEX

DECLARATION OF THE EU (*)

While fully recognising the objectives pursued by the European Convention on the legal protection of services based on, or consisting of, conditional access, the Union expresses its concern regarding the application of Article 9 and Article 10(3) of the Convention, following the accession of the Union thereto, on the basis of its exclusive competence.

This Declaration is without prejudice to the voting procedures within the Committee of Ministers of the Council of Europe.

(*) To be communicated to the Secretary-General of the Council of Europe at the time of deposition of the instrument of approval of the Convention.

COUNCIL DECISION (EU) 2015/1294

of 20 July 2015

on the conclusion, on behalf of the European Union and its Member States, of the Additional Protocol to the Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part, to take account of the accession of the Republic of Croatia to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 217, in conjunction with Article 218(6) thereof,

Having regard to the Act of Accession of Croatia, and in particular the second subparagraph of Article 6(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) In accordance with Council Decision (EU) 2015/733 ([1]), the Additional Protocol to the Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part ([2]), to take account of the accession of the Republic of Croatia to the European Union ('the Protocol') has been signed, subject to its conclusion.

(2) The Protocol should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Additional Protocol to the Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part, to take account of the accession of the Republic of Croatia to the European Union ([3]) is hereby approved on behalf of the Union and its Member States.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to give, on behalf of the Union and its Member States, the notification provided for in Article 6(2) of the Protocol ([4]).

([1]) Council Decision (EU) 2015/733 of 9 October 2014 on the signing, on behalf of the European Union and its Member States, and provisional application of the Additional Protocol to the Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part, to take account of the accession of the Republic of Croatia to the European Union (OJ L 117, 8.5.2015, p. 1).
([2]) The text of the Agreement is published in OJ L 311, 4.12.1999, p. 3.
([3]) The text of the Protocol has been published in OJ L 117, 8.5.2015, p. 3, together with the decision on its signing.
([4]) The date of entry into force of the Protocol will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 20 July 2015.

For the Council
The President
F. MOGHERINI

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1295

of 27 July 2015

approving the active substance sulfoxaflor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 Ireland received on 1 September 2011 an application from Dow AgroSciences for the approval of the active substance sulfoxaflor. In accordance with Article 9(3) of that Regulation, Ireland, as rapporteur Member State, notified the Commission on 30 September 2011 of the admissibility of the application.

(2) On 23 November 2012 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the European Food Safety Authority ('the Authority'), assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(3) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report in January 2014.

(4) On 12 May 2014 the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance sulfoxaflor can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 ([2]). The Authority made its conclusion available to the public.

(5) On 11 December 2014 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for sulfoxaflor and a draft Regulation providing that sulfoxaflor is approved.

(6) The applicant was given the possibility to submit comments on the review report.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied. It is therefore appropriate to approve sulfoxaflor.

(8) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) *EFSA Journal* 2014;12(5):3692. Available online: www.efsa.europa.eu

(9) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [1] should be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance sulfoxaflor, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Sulfoxaflor CAS No: 946578-00-3 CIPAC No: 820	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ⁶-sulfanylidene]cyanamide	≥ 950 g/kg	18 August 2015	18 August 2025	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfoxaflor, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to bees and other non-target arthropods; (b) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust; (b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds; (c) the risk to pollinators other than honey bees; (d) the risk to bee brood. The applicant shall submit that information to the Commission, the Member States and the Authority by 18 August 2017.

(1) Further details on identity and specification of active substance are provided in the review report.

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'88	Sulfoxaflor CAS No: 946578-00-3 CIPAC No: 820	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ⁶-sulfanylidene]cyanamide	≥ 950 g/kg	18 August 2015	18 August 2025	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfoxaflor, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to bees and other non-target arthropods; (b) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust; (b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds; (c) the risk to pollinators other than honey bees; (d) the risk to bee brood. The applicant shall submit that information to the Commission, the Member States and the Authority by 18 August 2017.'

(*) Further details on identity and specification of active substance are provided in the review report.

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1296

of 28 July 2015

amending Regulation (EU) No 468/2010 establishing the EU list of vessels engaged in illegal, unreported and unregulated fishing

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 ([1]), and in particular Article 30 thereof,

Whereas:

(1) Chapter V of Regulation (EC) No 1005/2008 lays down procedures for the identification of fishing vessels engaged in illegal, unreported and unregulated fishing ('IUU') as well as procedures for establishing a Union list of such vessels ('the Union list'). Article 37 of that Regulation provides for actions to be taken against fishing vessels included in that list.

(2) The Union list was established by Commission Regulation (EU) No 468/2010 ([2]) and subsequently amended by Implementing Regulations (EU) No 724/2011 ([3]), (EU) No 1234/2012 ([4]), (EU) No 672/2013 ([5]) and (EU) No 137/2014 ([6]).

(3) According to Article 30(1) of Regulation (EC) No 1005/2008, vessels included in the IUU vessel lists adopted by regional fisheries management organisations are to be included in the Union list.

(4) All regional fishery management organisations provide for the establishment and regular up-date of IUU vessel lists in accordance with their respective rules ([7]).

(5) According to Article 30 of Regulation (EC) No 1005/2008, upon the receipt from regional fisheries management organisations of the lists of fishing vessels presumed or confirmed to be involved in illegal, unreported and unregulated fishing, the Commission is to update the Union list. Since the Commission has received new lists from the regional fisheries management organisations, the Union list should now be updated.

(6) Considering that the same vessel might be listed under different names and/or flags depending on the time of its inclusion on the regional fisheries management organisations lists, the updated Union list should include the different names and/or flags as established by the relevant regional fisheries management organisations.

(7) The vessel 'Dolphin', which is currently included in the Union list, has been removed from the lists established by the North East Atlantic Fisheries Commission (NEAFC), the Northwest Atlantic Fisheries Organization (NAFO) and the South East Atlantic Fisheries Organisation (SEAFO), since it had been scrapped. That vessel should thus be removed from the Union list despite the fact that it has not yet been deleted from the list established by the General Fisheries Commission for the Mediterranean (GFCM). This vessel should be considered as removed from the Union list as of 14 November 2014.

([1]) OJ L 286, 29.10.2008, p. 1.
([2]) OJ L 131, 29.5.2010, p. 22.
([3]) OJ L 194, 26.7.2011, p. 14.
([4]) OJ L 350, 20.12.2012, p. 38.
([5]) OJ L 193, 16.7.2013, p. 6.
([6]) OJ L 43, 13.2.2014, p. 47.
([7]) Last updates: CCAMLR: 2014/2015 IUU list as adopted at annual meeting CCAMLR-XXXIII 20 October-31 October 2014; SEAFO: SEAFO includes in its IUU list CCAMLR, NEAFC-B and NAFO lists (as adopted at its Compliance Committee in December 2014); ICCAT: 2014 IUU list as adopted at 19th Special Meeting of the Commission in November 2014 (Recommendation 11-18); IATTC: 2014 list as adopted in 87th meeting of IATTC in July 2014; NEAFC: IUU B list AM 2014 as adopted at 33nd annual meeting November 2014; NAFO: 2014 list as adopted at 36th annual meeting September 2014; WCPFC: WCPFC IUU vessel list for 2015, effective from 3 February 2015; IOTC: IOTC IUU Vessels List, approved at the 18th Session of the IOTC in June 2014; GFCM: 2014 IUU List as adopted at annual session in May 2014; SPRFMO: IUU vessel list as adopted at 3rd Commission Meeting in February 2015.

(8) The vessel 'Tiantai', which is currently included in the Union list, has been removed from the list established by the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR), since it had sunk within the CCAMLR area. That vessel should thus be removed from the Union list despite the fact that it has not yet been deleted from the lists established by the South East Atlantic Fisheries Organisation (SEAFO) and the General Fisheries Commission for the Mediterranean (GFCM). This vessel should be considered as removed from the Union list as of 20 October 2014.

(9) Regulation (EU) No 468/2010 should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

Part B of the Annex to Regulation (EU) No 468/2010 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the seventh day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

IMO (1) ship identification number/RFMO Reference	Vessel's name (previous name) (2)	Flag State or Flag Territory [according to a RFMO] (2)	Listed in RFMO (2)
20060010 [ICCAT]	ACROS No 2	Unknown (latest known flag: Honduras)	ICCAT, GFCM
20060009 [ICCAT]	ACROS No 3	Unknown (latest known flag: Honduras)	ICCAT, GFCM
7306570	ALBORAN II (WHITE ENTERPRISE [NAFO, NEAFC]/WHITE, ENTERPRISE, ENXEMBRE, ATALAYA, REDA IV, ATALAYA DEL SUR [SEAFO])	Unknown (latest known flags: Panama, Saint Kitts and Nevis) [NAFO, NEAFC, SEAFO]/Panama [GFCM]	NEAFC, NAFO, SEAFO, GFCM
7424891	ALDABRA (OMOA I [CCAMLR, GFCM]/ OMOA 1 [SEAFO])	Unknown (latest known flags: Tanzania, Honduras) [CCAMLR]/ Tanzania (previous flags: Honduras, Togo) [SEAFO]	CCAMLR, SEAFO, GFCM
7036345	AMORINN (ICEBERG II, LOME, NOEMI [CCAMLR, GFCM])	Unknown (latest known flags: Togo, Belize)	CCAMLR, SEAFO, GFCM
Unknown	ANEKA 228	Unknown	IOTC
Unknown	ANEKA 228; KM.	Unknown	IOTC
9179359	AURORA (PACIFIC CONQUEROR)	Russia (latest known flag: Peru)	SPRFMO
9037537	BAROON (LANA, ZEUS, TRITON I [CCAMLR])/LANA [SEAFO]/LANA (ZEUS, TRITON-1, KINSHO MARU No 18 [GFCM])	Tanzania (previous flags: Nigeria, Mongolia, Togo, Sierra Leone [CCAMLR])/Unknown [GFCM]	CCAMLR, SEAFO, GFCM
12290 [IATTC]/20110011 [ICCAT]	BHASKARA No. 10	Unknown (latest known flag: Indonesia)	IATTC, ICCAT, GFCM
12291 [IATTC]/20110012 [ICCAT]	BHASKARA No. 9	Unknown (latest known flag: Indonesia)	IATTC, ICCAT, GFCM
20060001 [ICCAT]	BIGEYE	Unknown	ICCAT, GFCM
20040005 [ICCAT]	BRAVO	Unknown	ICCAT, GFCM
9407 [IATTC]/20110013 [ICCAT]	CAMELOT	Unknown	IATTC, ICCAT, GFCM
6622642	CHALLENGE (PERSEVERANCE, MILA [CCAMLR]/MILA, ISLA, MONTANA CLARA, PERSEVERANCE [GFCM])	Unknown (latest known flags: Panama, Equatorial Guinea, United Kingdom) [CCAMLR]/Panama [GFCM]	CCAMLR, SEAFO, GFCM
125, 280020064 [IATTC]/ 20110014 [ICCAT]	CHIA HAO No 66	Unknown (latest known flag: Belize, Equatorial Guinea)	IATTC, ICCAT, GFCM

IMO (1) ship identification number/RFMO Reference	Vessel's name (previous name) (2)	Flag State or Flag Territory [according to a RFMO] (2)	Listed in RFMO (2)
Unknown	CHI TONG	Unknown	IOTC
7913622	DAMANZAIHAO (LAFAYETTE)	Peru (latest known flag: Russia)	SPRFMO
20080001 and previously AT000GUI000002 [ICCAT]	DANIAA (CARLOS)	Unknown (latest known flag: Guinea) [ICCAT]/Guinea [GFCM]	ICCAT, GFCM
6163 [IATTC]/20130005 [ICCAT]	DRAGON III	Unknown	IATTC, ICCAT, GFCM
8604668	EROS DOS (FURABOLOS)	Unknown (latest known flags: Panama, Seychelles) [NAFO, NEAFC, SEAFO]/Panama [GFCM]	NEAFC, NAFO, SEAFO, GFCM
Unknown	FU HSIANG FA 18	Unknown	IOTC
Unknown	FU HSIANG FA No. 01	Unknown	IOTC
Unknown	FU HSIANG FA No. 02	Unknown	IOTC
Unknown	FU HSIANG FA No. 06	Unknown	IOTC
Unknown	FU HSIANG FA No. 08	Unknown	IOTC
Unknown	FU HSIANG FA No. 09	Unknown	IOTC
Unknown	FU HSIANG FA No. 11	Unknown	IOTC
Unknown	FU HSIANG FA No. 13	Unknown	IOTC
Unknown	FU HSIANG FA No. 17	Unknown	IOTC
Unknown	FU HSIANG FA No. 20	Unknown	IOTC
Unknown	FU HSIANG FA No. 21	Unknown	IOTC
20130003 [ICCAT]	FU HSIANG FA No. 21 [ICCAT]/ FU HSIANG FA [GFCM]	Unknown	IOTC, ICCAT, GFCM
Unknown	FU HSIANG FA No. 23	Unknown	IOTC
Unknown	FU HSIANG FA No. 26	Unknown	IOTC
Unknown	FU HSIANG FA No. 30	Unknown	IOTC
7355662/20130001 [ICCAT]	FU LIEN No 1	Georgia	WCPFC, ICCAT, GFCM
20130004 [ICCAT]	FULL RICH	Unknown (latest known flag: Belize [IOTC])	IOTC, ICCAT, GFCM

IMO (1) ship identification number/RFMO Reference	Vessel's name (previous name) (2)	Flag State or Flag Territory [according to a RFMO] (2)	Listed in RFMO (2)
200800005 previously AT000LIB00041 [ICCAT]	GALA I (MANARA II, ROAGAN)	Unknown (latest known flags: Libya)	ICCAT, GFCM
6591 [IATTC]/20130006 [ICCAT]	GOIDAU RUEY No 1	Unknown (latest known flag: Panama)	IATTC, ICCAT, GFCM
7020126	GOOD HOPE (TOTO [CCAMLR, SEAFO]/SEA RANGER V, TOTO [GFCM])	Nigeria (previous flag: Belize [SEAFO])	CCAMLR, SEAFO, GFCM
6719419 [NEAFC, SEAFO]/ 6714919 [NAFO]	GORILERO (GRAN SOL)	Unknown (latest known flags: Sierra Leone, Panama [NAFO, NEAFC, GFCM])	NEAFC, NAFO, SEAFO, GFCM
2009003 [ICCAT]	GUNUAR MELYAN 21	Unknown	IOTC, ICCAT, GFCM
7322926	HEAVY SEA (DUERO, JULIUS, KETA, SHERPA UNO [CCAMLR])	Unknown (latest known flags: Panama, Saint Kitts and Nevis, Belize) [CCAMLR]/Panama [GFCM]	CCAMLR, SEAFO, GFCM
201000004 [ICCAT]	HOOM XIANG 11 [ICCAT, GFCM]/ HOOM XIANG II [IOTC]	Unknown (latest known flag: Malaysia)	IOTC, ICCAT, GFCM
Unknown	HOOM XIANG 101	Unknown (latest known flag: Malaysia)	IOTC
Unknown	HOOM XIANG 103	Unknown (latest known flag: Malaysia)	IOTC
Unknown	HOOM XIANG 105	Unknown (latest known flag: Malaysia)	IOTC
7332218	IANNIS 1 [NEAFC]/IANNIS I [NAFO, SEAFO, GFCM] (MOANA MAR, CANOS DE MECA [GFCM])	Unknown (latest known flag: Panama [NEAFC, NAFO, SEAFO])	NEAFC, NAFO, SEAFO, GFCM
6803961	ITZIAR II (SEABULL 22, CARMELA, GOLD DRAGON, GOLDEN SUN, NOTRE DAME, MARE [CCAMLR, GFCM])	Nigeria (previous flags: Mali, Nigeria, Togo, Equatorial Guinea, Bolivia, Namibia [CCAMLR]) [CCAMLR]/Mali [GFCM]	CCAMLR, SEAFO, GFCM
9505 [IATTC]/20130007 [ICCAT]	JYI LIH 88	Unknown	IATTC, ICCAT, GFCM
Unknown	KIM SENG DENG 3	Bolivia	IOTC
7905443	KOOSHA 4 (EGUZKIA [GFCM])	Iran	CCAMLR, SEAFO, GFCM
Unknown	KUANG HSING 127	Unknown	IOTC
Unknown	KUANG HSING 196	Unknown	IOTC

IMO (1) ship identification number/RFMO Reference	Vessel's name (previous name) (2)	Flag State or Flag Territory [according to a RFMO] (2)	Listed in RFMO (2)
7322897	KUNLUN (TAISHAN, CHANG BAI, HOUGSHUI, HUANG HE 22, SIMA QIAN BARU 22, CORVUS, GALAXY, INA MAKA, BLACK MOON, RED MOON, EOLO, THULE, MAGNUS, DORITA [CCAMLR])/CHANG BAI [SEAFO]/HUANG HE 22 (SIMA QIAN BARU 22, DORITA, MAGNUS, THULE, EOLO, RED MOON, BLACK MOON, INA MAKA, GALAXY, CORVUS [GFCM])	Equatorial Guinea (latest known flags: Indonesia, Tanzania, North Korea (DPRK), Panama, Sierra Leone, Equatorial Guinea, Saint Vincent and the Grenadines, Uruguay) [CCAMLR]/ Tanzania, Unknown [GFCM]	CCAMLR, SEAFO, GFCM, IOTC
20060007 (ICCAT)	LILA No 10	Unknown (latest known flag: Panama)	ICCAT, GFCM
7388267	LIMPOPO (ROSS, ALOS, LENA, CAP GEORGE [CCAMLR])	Unknown (latest known flags: Togo, Ghana, Seychelles, France [CCAMLR]/ Togo, Ghana, Seychelles [GFCM])	CCAMLR, SEAFO, GFCM
Unknown	MAAN YIH HSING	Unknown	IOTC
20040007 [ICCAT]	MADURA 2	Unknown	ICCAT, GFCM
20040008 [ICCAT]	MADURA 3	Unknown	ICCAT, GFCM
7325746	MAINE (GUINESPA I, MAPOSA NOVENO [SEAFO])	Guinea	NEAFC, NAFO, SEAFO, GFCM
20060002 [ICCAT]	MARIA	Unknown	ICCAT, GFCM
20060005 [ICCAT]	MELILLA No 101	Unknown (latest known flag: Panama)	ICCAT, GFCM
20060004 [ICCAT]	MELILLA No 103	Unknown (latest known flag: Panama)	ICCAT, GFCM
7385174	MURTOSA	Unknown (latest known flag: Togo [NAFO, NEAFC, SEAFO])	NEAFC, NAFO, SEAFO, GFCM
C-00545 [WCPFC, ICCAT]/ 14613 [IATTC]/20110003 [ICCAT]	NEPTUNE	Georgia	IATTC, ICCAT, WCPFC, GFCM
20060003 [ICCAT]	No 101 GLORIA (GOLDEN LAKE)	Unknown (latest known flag: Panama)	ICCAT, GFCM
20060008 [ICCAT]	No 2 CHOYU	Unknown (latest known flag: Honduras)	ICCAT, GFCM
20060011 [ICCAT]	No 3 CHOYU	Unknown (latest known flag: Honduras)	ICCAT, GFCM

IMO (1) ship identification number/RFMO Reference	Vessel's name (previous name) (2)	Flag State or Flag Territory [according to a RFMO] (2)	Listed in RFMO (2)
20040006 [ICCAT]	OCEAN DIAMOND	Unknown	ICCAT, GFCM
7826233/20090001 [ICCAT]	OCEAN LION	Unknown (latest known flag: Equatorial Guinea)	IOTC, ICCAT, GFCM
11369 [IATTC]/20130008 [ICCAT]	ORCA	Unknown (latest known flag: Belize)	IATTC, ICCAT, GFCM
20060012 [ICCAT]	ORIENTE No 7	Unknown (latest known flag: Honduras)	ICCAT, GFCM
5062479	PERLON (CHERNE, BIGARO, HOKING, SARGO, LUGALPESCA [CCAMLR, GFCM])	Nigeria (latest known flags: Mongolia, Togo, Uruguay [CCAMLR]) [CCAMLR, SEAFO]/Unknown (latest known flags: Uruguay, Mongolia, Togo [GFCM])	CCAMLR, SEAFO, GFCM
6607666	RAY (KILY, CONSTANT, TROPIC, ISLA GRACIOSA [CCAMLR]/KILLY, CONSTANT, TROPIC, ISLA GRACIOSA [NEAFC, SEAFO, GFCM])	Unknown (latest known flags: Belize, Equatorial Guinea, South Africa) [CCAMLR]/Belize (previous flags: South Africa, Equatorial Guinea, Mongolia) [SEAFO, NEAFC]	CCAMLR, NEAFC, SEAFO, GFCM
95 [IATTC]/20130009 [ICCAT]	REYMAR 6	Unknown (latest known flag: Belize)	IATTC, ICCAT, GFCM
20130013 [ICCAT]	SAMUDERA PASIFIK No 18 (KAWIL No 03, LADY VI-TI-III [ICCAT])	Indonesia	ICCAT, GFCM
Unknown	SAMUDERA PERKASA 11	Unknown	IOTC
Unknown	SAMUDRA PERKASA 12	Unknown	IOTC
200800004 previously AT000LIB00039 [ICCAT]	SHARON 1 (MANARA 1, POSEIDON)	Unknown (latest known flags: Libya)	ICCAT, GFCM
Unknown	SHUEN SIANG	Unknown	IOTC
Unknown	SIN SHUN FA 6	Unknown	IOTC
Unknown	SIN SHUN FA 67	Unknown	IOTC
Unknown	SIN SHUN FA 8	Unknown	IOTC
Unknown	SIN SHUN FA 9	Unknown	IOTC
9319856	SONGHUA (YUNNAN, NIHEWAN, HUIQUAN, WUTAISHAN ANHUI 44, YANGZI HUA 44, TROSKY, PALOMA V [CCAMLR])/NIHEWAN [SEAFO]/ HUIQUAN [GFCM]	Equatorial Guinea (latest known flags: Tanzania, Mongolia, Namibia, Uruguay)/Unknown (latest known flag: Equatorial Guinea) [IOTC]/ Tanzania [GFCM]	CCAMLR, SEAFO, GFCM, IOTC

IMO (1) ship identification number/RFMO Reference	Vessel's name (previous name) (2)	Flag State or Flag Territory [according to a RFMO] (2)	Listed in RFMO (2)
20050001 [ICCAT]	SOUTHERN STAR 136 (HSIANG CHANG)	Unknown (latest known flag: Saint Vincent and the Grenadines)	ICCAT, GFCM
Unknown	SRI FU FA 168	Unknown	IOTC
Unknown	SRI FU FA 18	Unknown	IOTC
Unknown	SRI FU FA 188	Unknown	IOTC
Unknown	SRI FU FA 189	Unknown	IOTC
Unknown	SRI FU FA 286	Unknown	IOTC
Unknown	SRI FU FA 67	Unknown	IOTC
Unknown	SRI FU FA 888	Unknown	IOTC
9405 [IATTC]/20130010 [ICCAT]	TA FU 1	Unknown	IATTC, ICCAT, GFCM
6818930	TCHAW (REX, CONDOR, INCA, VIKING, CISNE AZUL [CCAMLR])	Unknown (latest known flags: Togo, Belize, Seychelles) [CCAMLR, GFCM]	CCAMLR, SEAFO, GFCM
13568 [IATTC]/20130011 [ICCAT]	TCHING YE No 6 (EL DIRIA I)	Unknown (latest known flags: Belize, Costa Rica)	IATTC, ICCAT, GFCM
6905408	THUNDER (WUHAN No 4, KUKO, TYPHOON I, RUBIN, ARCTIC RANGER [CCAMLR]/ARCTIC RANGER, RUBIN, TYPHOON-I, KUKO [GFCM])	Unknown (previous flags: Nigeria, Mongolia, Togo, Seychelles, United Kingdom [CCAMLR])	CCAMLR, SEAFO, GFCM
Unknown	TIAN LUNG NO.12	Unknown	IOTC
7321374	TRINITY (ENXEMBRE, YUCATAN BASIN, FONTENOVA, JAWHARA [NEAFC, NAFO, SEAFO])	Ghana (previous flags: Panama, Morocco [NEAFC, NAFO, SEAFO])	NEAFC, NAFO, SEAFO, GFCM
8713392	VIKING (OCTOPUS I, BERBER, SNAKE, OCTOPUS I, PION, THE BIRD, CHU LIM, YIN PENG, THOR 33, ULYSES, GALE, SOUTH BOY, PISCIS) [CCAMLR, SEAFO]/OCTOPUS 1 (PISCIS, SOUTH BOY, GALE, ULYSES, THOR 33, YIN PENG, CHU LIM, THE BIRD, PION) [GFCM]	Nigeria (latest known flags: Sierra Leone, Libya, Mongolia, Honduras, North Korea (DPRK), Equatorial Guinea, Uruguay [CCAMLR]) [CCAMLR, SEAFO]/Mongolia [GFCM]	CCAMLR, SEAFO, GFCM
8994295/129 [IATTC] 20130012 [ICCAT]	WEN TENG No 688 (MAHKOIA ABADI No 196)	Unknown (latest known flag: Belize)	IATTC, ICCAT, GFCM

IMO (1) ship identification number/RFMO Reference	Vessel's name (previous name) (2)	Flag State or Flag Territory [according to a RFMO] (2)	Listed in RFMO (2)
Unknown	YI HONG 106	Bolivia	IOTC
Unknown	YI HONG 116	Bolivia	IOTC
Unknown	YI HONG 16	Unknown	IOTC
Unknown	YI HONG 3	Unknown	IOTC
Unknown	YI HONG 6	Bolivia	IOTC
9042001	YONGDING (CHENGDU, JIANGFENG, SHAANXI HENAN 33, XIONG NU BARU 33, DRACO I, LIBERTY, CHILBO SAN 33, HAMMER, SEO YANG No 88, CARRAN [CCAMLR]/CHENGDU [SEAFO]/SHAANXI HENAN 33 (XIONG NU BARU 33, LIBERTY, CHILBO SAN 33, HAMMER, CARRAN, DRACO-1) [GFCM]	Equatorial Guinea (latest known flags: Indonesia, Tanzania, Panama, Sierra Leone, North Korea (DPRK), Togo, Republic of Korea, Uruguay) [CCAMLR]/Tanzania [GFCM]	CCAMLR, SEAFO, GFCM, IOTC
20130002 [ICCAT]	YU FONG 168	Taiwan/Unknown [IOTC]	WCPFC, ICCAT, GFCM, IOTC
2009002 [ICCAT]	YU MAAN WON	Unknown (latest known flag: Georgia)	IOTC, ICCAT, GFCM
20140001 [ICCAT]/15579 [IATTC]	XIN SHI JI 16	Fiji	ICCAT, IATTC

(1) International Maritime Organization.
(2) For any additional information consult the websites of the regional fisheries management organisations (RFMOs).

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1297

of 28 July 2015

entering a name in the register of traditional specialities guaranteed (Traditional Bramley Apple Pie Filling (TSG))

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(b) of Regulation (EU) No 1151/2012, the United Kingdom's application to register the name 'Traditional Bramley Apple Pie Filling' was published in the *Official Journal of the European Union* ([2]).

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Traditional Bramley Apple Pie Filling' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Traditional Bramley Apple Pie Filling' (TSG) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.6. Fruit, vegetables and cereals, fresh or processed, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ([3]).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 July 2015.

For the Commission

The President

Jean-Claude JUNCKER

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ C 80, 7.3.2015, p. 27.
([3]) Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION REGULATION (EU) 2015/1298

of 28 July 2015

amending Annexes II and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ([1]), and in particular Article 31(1) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

(1) 3-Benzylidene Camphor is currently authorised for use in cosmetic products as a UV filter in a concentration up to maximum 2,0 %. It is listed under reference number 19 of Annex VI to Regulation (EC) No 1223/2009.

(2) The Scientific Committee on Consumer Safety (SCCS) ([2]) concluded in its opinion of 18 June 2013 that, due to a margin of safety below 100, the use of 3-Benzylidene Camphor as a UV filter in cosmetic products in a concentration up to 2,0 % is considered unsafe.

(3) In order to ensure the safety of sunscreen products for human health it is necessary to remove 3-Benzylidene Camphor from the list of UV filters allowed in cosmetic products as laid down in Annex VI to Regulation (EC) No 1223/2009.

(4) Considering that 3-Benzylidene Camphor is known not only as a UV filter but also as a UV absorber, its use should be banned in cosmetic products.

(5) Annexes II and VI to Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(6) The application of that restriction should be deferred to allow the industry to make the necessary adjustments to product formulations. In particular, undertakings should be granted 6 months to place on the market compliant products and to withdraw from the market non-compliant products after the entry into force of this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and VI to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

From 18 February 2016 only cosmetic products which comply with this Regulation shall be placed and made available on the Union market.

([1]) OJ L 342, 22.12.2009, p. 59.
([2]) Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, OJ L 241, 10.9.2008, p. 21.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Regulation (EC) No 1223/2009 is amended as follows:

(1) in Annex II, the following entry is added:

Reference number	Chemical name/INN	CAS number	EC number
'1379	3-Benzylidene Camphor	15087-24-8	239-139-9'

(2) in Annex VI the entry concerning reference number 19 is deleted.

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1299

of 28 July 2015

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 July 2015.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MA	160,9
	MK	26,3
	ZZ	93,6
0709 93 10	TR	118,4
	ZZ	118,4
0805 50 10	AR	121,6
	UY	142,0
	ZA	129,0
	ZZ	130,9
0806 10 10	EG	280,5
	MA	227,1
	TN	185,1
	TR	158,2
	US	286,0
	ZA	115,6
	ZZ	208,8
0808 10 80	AR	127,0
	BR	94,6
	CL	136,4
	NZ	132,6
	US	116,2
	UY	170,5
	ZA	129,6
	ZZ	129,6
0808 30 90	AR	255,7
	CL	196,1
	NZ	153,0
	ZA	128,8
	ZZ	183,4
0809 10 00	TR	233,0
	ZZ	233,0
0809 29 00	TR	246,2
	US	487,6
	ZZ	366,9
0809 30 10, 0809 30 90	MK	70,6
	TR	176,8
	ZZ	123,7

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0809 40 05	BA	57,2
	IL	124,7
	XS	66,1
	ZZ	82,7

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COMMISSION DECISION (EU) 2015/1300

of 27 March 2015

on the aid scheme — aid to German pharmaceutical companies in financial difficulties through the exemptions from mandatory rebates SA.34881 (2013/C) (ex 2013/NN) (ex 2012/CP) — implemented by Germany

(notified under document C(2015) 1975)

(Only the German text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 108(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to the provisions cited above ([1]), and having regard to their comments,

Whereas:

1. PROCEDURE

(1) On 24 May 2012, the Commission received a complaint from a German pharmaceutical company that alleges that the exemption from the manufacturer's rebate for pharmaceuticals granted to its competitors under German law constitutes State aid.

(2) On 8 June 2012, the Commission submitted a non-confidential version of the complaint to the German authorities, asked for comments on the complaint and requested additional information.

(3) By letter dated 27 July 2012, Germany provided comments on the complaint and submitted the additional information requested. On 31 July 2012 Germany submitted a non-confidential version of this reply. On 24 August 2012, the Commission sent this non-confidential version to the complainant, inquiring if the complainant wanted to pursue the matter in the light of the explanations provided by Germany.

(4) The complainant maintained his allegations. By letter dated 26 September 2012, he provided comments on Germany's arguments. On 21 November 2012, the Commission submitted the complainant's reply to Germany, on which the German authorities commented by letter dated 13 December 2012.

(5) A meeting with the complainant took place on 6 December 2012.

(6) On 30 January 2013 and 5 April 2013 the complainant submitted additional information.

(7) By letter dated 24 July 2013 the Commission informed Germany that it had decided to initiate the procedure laid down in Article 108(2) of the TFEU in respect of the aid.

(8) The Commission decision to initiate the procedure was published in the *Official Journal of the European Union* ([2]). The Commission invited interested parties to submit their comments on the measure.

(9) By letter dated 30 September 2013 Germany submitted comments on the decision to initiate the formal investigation procedure. Furthermore, the Commission received several comments by interested third parties as well as by the complainant.

([1]) OJ C 297, 12.10.2013, p. 76.
([2]) See footnote 1.

(10) On 6 January non-confidential versions of these observations were forwarded to Germany, which was given the opportunity to react. Germany's comments were received by letter dated 14 February 2014.

2. THE COMPLAINT

(11) The complainant, *Allergopharma Joachim Ganzer KG*, based in Reinbek near Hamburg, is engaged and specialised in research, manufacturing and distribution of products for diagnosis and therapy of allergic diseases.

(12) The complainant alleges that the exemption from the manufacturer's rebate for pharmaceuticals granted to its competitors under Section 130a of Book V of the German Social Security Code constitutes State aid.

(13) Furthermore, the complainant alleges that the beneficiaries of the exemption are companies in difficulty. According to the complainant the measure has to be considered as illegal operating aid since the aid does not meet the legal requirements of the Community guidelines on State aid for rescuing and restructuring firms in difficulty ([3]) (hereinafter 'R&R Guidelines').

3. DESCRIPTION OF THE MEASURE

(14) The measure under scrutiny consists of a German scheme on the exemption from a mandatory rebate on certain pharmaceutical products.

3.1. Health insurance system in Germany

(15) Germany has a universal multi-payer system with two main types of health insurance: Public sickness funds (*Gesetzliche Krankenversicherung*) and private health insurance (*Private Krankenversicherung*).

(16) *Public sickness funds*: 85-90 % of the population in Germany is covered by public sickness funds. The public health insurance system is financed by a combination of contributions by members on the one hand and funds from the State's general budget on the other hand. Every individual member and his/her employer pay a percentage of that person's gross monthly salary as contribution. The percentage is determined by law and applies equally to all public providers. In addition, the State contributes a certain amount for so-called non-insurance-related expenses. The contributions of all members of the public system and the State contributions are pooled in the central 'health fund' (*Gesundheitsfonds*), administered by the Federal Insurance Authority (*Bundesversicherungsamt*). The 'health fund' then pays each provider a lump-sum per member, with the amount per member depending on the members' age, gender and health condition.

(17) *Private health insurance*: 10-15 % of the population opt for private health insurance. This private system is financed exclusively by the premiums paid by its members which are based on individual agreements with the insurance company defining the set of covered services and the percentage of coverage, which depend on the amount of services chosen and the person's risk and age of entry into the private system and which are also used to build up savings for the rising health costs at higher age as required by law.

3.2. Exemption from the manufacturer's rebate on pharmaceutical products under German law

(18) Between August 2010 and December 2013 pharmaceutical undertakings in Germany were generally obliged to grant rebates of 16 % of the price of patented prescription medicines outside the fixed-price system to all health insurances, i.e. to public sickness funds as well as private health insurance companies. Between 1 January 2014 and 31 March 2014 this mandatory rebate was lowered to 6 %, from 1 April 2014 onwards the rebate was

([3]) OJ C 244, 1.10.2004, p. 2 ('2004-Guidelines'). The validity of these Guidelines was initially set until 9 October 2009. However, the Commission decided to extend their validity first until 9 October 2012 (Commission Communication concerning the prolongation of the Community Guidelines on State aid for Rescuing and Restructuring Firms in Difficulty (OJ C 156, 9.7.2009, p. 3)) and then, in the context of the State aid modernisation (SAM) initiative, until such time as the R&R Guidelines are replaced by new rules on State aid for rescuing and restructuring firms in difficulty (Commission communication concerning the prolongation of the application of the Community guidelines on State aid for rescuing and restructuring firms in difficulty of 1 October 2004 (OJ C 296, 2.10.2012, p. 3)). On 1 August 2014 the new Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty (OJ C 249, 31.7.2014, p. 1) entered into force ('2014-Guidelines'). However, according to point 137-138 of these new Guidelines, in cases where aid was granted before the publication of the Guidelines in the *Official Journal of the European Union*, it must be assessed on the basis of the Guidelines applicable at the time the aid was granted. Germany confirmed that no new exemptions would be granted under the national scheme after the adoption of the decision to initiate the formal investigation procedure (on 24 July 2013), until a final decision on the matter is adopted by the Commission. As such, the applicable Guidelines are the 2004-Guidelines.

slightly increased to 7 % (with the exception of generic drugs, for which the rebate remains 6 % also after 1 April 2014). At the same time, pharmaceutical undertakings are, until 31 December 2017, obliged to keep their prices at the level as of 1 August 2009 (*Preismoratorium*).

(19) Both, the mandatory rebates (regardless of the exact percentage) as well as the *Preismoratorium*, constitute a 'price freeze' in the meaning of Article 4(1) of Directive 89/105 ([4]). Article 4(2) of that Directive lays down that in exceptional circumstances any holder of a marketing authorisation for medical products has the right to apply for a derogation from such a price freeze if justified by 'particular reasons'. According to the Court of Justice, Member States are, on the basis of this Article, obliged to provide, in all cases, a possibility to apply for such a derogation ([5]). German law foresees that pharmaceutical undertakings can apply for an exemption ([6]) from the mandatory rebate and that a federal authority, the Federal Office of Economics and Export Control (*Bundesamt für Wirtschaft und Ausfuhrkontrolle*, hereinafter 'BAFA'), decides whether to grant this exemption on a case-by-case basis.

(20) More specifically, under section 130a paragraph 4 of Book V of the German Social Security Code, and as further clarified by an information sheet published by BAFA concerning its decision making process ([7]), 'particular reasons' are given if the price freeze puts an unacceptable financial burden on the affected business group (or individual undertaking but only if said undertaking does not belong to a business group). A financial burden is assumed to be unacceptable if the affected undertaking is unable to avoid illiquidity through its own resources, contributions of its shareholders or other measures.

(21) According the information sheet published by BAFA, the decisive elements taken into account by it for establishing whether an exemption is to be granted are the following:

(a) Operating earnings before tax of the previous three business years;

(b) A demonstration by the applicant for an exemption of the development of its earnings and liquidity during the previous three years on the basis of its key business indicators (e.g. its EBIT margin, return on equity, equity and debt ratio, liquidity and debt ratio) and an explanation of the effects of the price freeze on these indicators;

(c) A demonstration by the applicant of the additional burden introduced on the business group/undertaking by the price freeze on the basis of a proof of the actual amount of the rebates already paid;

(d) An assessment of the overall financial and economic situation of the applicant which takes, in addition to the revenue/profit situation, in particular also its assets and liquidity into account. To this end a retrospective cash flow statement as well as a prospective cash flow statement (financial pan), as well as a liquidity plan for the coming three years and a short-term financial plan for the coming 12 months have to be submitted by the applicant.

(22) Applicants for an exemption have to prove a direct causal link between the price freeze and their financial difficulties. It must, in particular, be shown that there are no structural causes for the financial difficulties and if there are any business measures suited for avoiding or limiting the financial difficulties still available, these must primarily be taken. Any business measures already taken to that end need to be described by the affected undertaking in its application.

(23) The applicant has to prove the fulfilment of all eligibility criteria for an exemption on the basis of an expert opinion by a certified accountant. This expert opinion must expressly confirm the direct causal link between the price freeze and the financial difficulties of the applicant and must provide reasons.

(24) To this end the accountant must analyse the financial statements of the previous three years as well as the liquidity plan of the coming three years with regard to the effect of the rebates on the financial situation of the applicant. The accountant must verify the calculations and submissions concerning the key business indicators

([4]) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).
([5]) Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 A. *Menarini and Others* [2009] EU:C:2009:217, para. 58.
([6]) Exemptions either being a full exemption from the mandatory rebate or a reduction of the rebate. The latter means that, for the period between August 2010 and December 2013, during which the mandatory rebate was 16 %, the BAFA could grant a reduction of 10 % points of the rebate, after which the affected companies were obliged to only grant a 6 % rebate instead of the full 16 %.
([7]) See http://www.bafa.de/bafa/de/weitere_aufgaben/herstellerabschlaege/publikationen/merkblatt.pdf

and the revenue and liquidity situation. Against this background the accountant must assess whether the additional burden introduced by the price freeze is so significant that the financial capacities of the undertaking are in danger in the short to medium term.

(25) Applications for exemptions have to be based on the audited financial statements of the previous year (*year n-1*). If the conditions for an exemption are fulfilled, the BAFA grants a 'preliminary exemption' for the current business year (*year n*) plus 180 days. The applicant is obliged to provide the updated data for the current year (*year n*) within 120 days after the end of the business year. If this updated information is not provided within the 120 days deadline, the BAFA automatically hands down a final negative decision, which repeals the previous preliminary decision. If the updated data shows that the conditions for an exemption were actually fulfilled during *year n*, the BAFA hands down a final positive decision ('final exemption'). If, however, the data shows that the conditions were not fulfilled during *year n*, the BAFA hands down a final negative decision, which repeals the previous preliminary decision.

(26) Based on information provided by the German authorities, nine companies were granted preliminary or final exemptions between August 2010 and December 2013 for different periods (no company was granted an exemption for the whole period 2010-2013). In addition, two companies were first granted a preliminary exemption, which was however repealed by a final negative decision.

(27) Out of all the exemptions, in 2013 five preliminary exemptions were granted (by decision of the BAFA taken before July 2013), two of them until the end of the year. In accordance with the standstill obligation enshrined in Article 108(3) TFEU, the BAFA, until a final decision by the Commission on the matter is adopted, does not take any final decisions concerning these preliminary exemptions and also does not take any decision concerning five additional applications for preliminary exemption filed after the date of the decision initiating the formal investigation procedure (July 2013).

(28) According to the German authorities, the total amount of final exemptions granted until 31 December 2013 is EUR 6,268 million, of which the biggest beneficiary received EUR 5,037 million. Germany estimates that the additional amount resulting from preliminary exemptions granted for 2013 is around EUR 6 million. Thus, the total amount of exemptions granted (either final or preliminary) is, according to the German submissions, around EUR 12-13 million.

3.3. **Grounds for initiating the procedure**

(29) On 24 July 2013 the Commission decided to open the formal investigation procedure in accordance with Article 108(2) TFEU (hereinafter 'opening decision').

(30) The Commission preliminarily concluded that the measure involves State resources, in particular due to the finding that German legislation lays down the prices that insurance funds (public and private) have to pay for pharmaceutical products and that the BAFA, a State authority, by granting exemptions from the mandatory rebates, ensures that these funds pay a higher price for the products in question.

(31) As the notion of 'particular reasons' is not defined sufficiently clear and precise in Directive 89/105, but leaves the Member States discretion in how to define it, the Commission considered that the measure is imputable to Germany.

(32) The Commission, furthermore, due to a lack of a clearly defined entrustment act for each exemption rejected the argument that the measure could be regarded as a measure of general economic interest but rather considered it to constitute a selective advantage in favour of certain pharmaceutical companies active in the production of certain goods.

(33) Lastly, the Commission considered that it is likely that the measure distorts competition and affects trade between Member States.

(34) Against this background the Commission preliminarily considered that the measure constitutes State aid.

(35) The Commission raised serious doubts as to the compatibility of the aid with the internal market. It observed that the beneficiaries under the scheme have to be considered as firms in difficulty in the meaning of the R&R Guidelines and that those Guidelines should, therefore, be the legal basis on which to assess the compatibility of the aid. As the measure does not seem to fulfil the conditions under these Guidelines for rescue or restructuring aid, the Commission came to the preliminary conclusion that the aid is not compatible with the internal market.

4. COMMENTS FROM INTERESTED PARTIES

(36) In the course of the formal investigation procedure the Commission received comments from the complainant as well as from several interested parties, amongst them a substantial submission by the *Bundesverband der Pharmazeutischen Industrie* (hereinafter 'BPI') and submissions by pharmaceutical companies that were either granted an exemption under the scheme or had applied for such an exemption.

(37) The complainant upheld its arguments that the measure constitutes incompatible State aid. In particular it stressed that the measure is imputable to Germany, as Directive 89/105 merely lays down a procedural requirement to foresee the possibility to apply for exemptions but leaves the decision whether to ever grant such exemptions to the Member States.

(38) The BPI stressed that the opening decision did not take into account that applicants for exemptions from the price freeze must prove a causal link between their financial difficulties and said price freeze, meaning that the successful applicants would not have been in financial difficulties if it were not for the price freeze. It, furthermore, argued that no State resources are involved as both private and public health insurances should be regarded as being independent from the State. It submitted, in analogy to similar case law by the Court concerning general tax measures, that the measure is not selective but constitutes a general measure as the German constitution requires the legislature to foresee hardship clauses to prevent excessive interferences into the rights of private parties. Furthermore, the BPI argued that the measure is not imputable to Germany, as the German implementation of Article 4(2) of Directive 89/105 is directly required by EU primary law, namely Articles 15, 16 and 52 of the Charter of Fundamental Rights ([8]). In case the Commission, nevertheless, concludes that the measure constitutes State aid, the BPI submits that the R&R Guidelines pursue different aims (restructuring of firms in difficulties) than the measure (hardship clause preventing German legislation from forcing otherwise healthy undertakings into bankruptcy) and should, therefore, not be applicable. Thus, the compatibility should rather be assessed directly on the basis of the Treaty. In particular, the BPI points out that Article 168(7) TFEU states that the EU must respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of the resources assigned to health services and medical care.

(39) As stated above, in addition to the submissions by the complainant and the BPI, the Commission received comments by 9 pharmaceutical companies. All these companies are either beneficiaries under the scheme or had unsuccessfully applied for an exemption. Due to partly overlapping arguments, the submissions by these 9 interested parties are summarised together below.

(40) According to these submissions the measure merely constitutes a price regulation and, due to the lack of a transfer of resources from the State to the beneficiaries, does not involve State resources. The money involved is rather money that is exclusively attributable to the beneficiaries. Furthermore, it is also questioned whether the money is ever under the control of the State, as it is argued that the health insurance funds are bodies independent from the State and as such their financial means should not be regarded as State resources.

(41) In addition, several of the third parties submit that their products are amongst the cheapest on the market. This is in particular true for parallel-importers, who offer the imported products at a price considerably lower than their producers. The third parties argue that without the exemptions to the price freeze they will be forced into bankruptcy. As this will mean that they will have to leave the market, only the more expensive products remain available. Thus, by granting exemptions and keeping them in the market, the measure actually reduces the costs for the health insurances, meaning that without the measure the costs and the transfers of public funds to pharmaceutical companies will increase.

(42) Furthermore, it is argued that the measure is not imputable to Germany, as the foreseen exemptions are merely a mandatory implementation of Article 4(2) of Directive 89/105.

(43) The interested parties further submit that the mandatory rebate of 16 % of the turnover forces mainly small and medium sized firms into bankruptcy, which were healthy firms before the introduction of the rebate, but whose profit margins are not big enough to be able to bear its additional costs. In this regard the third parties in particular point to the fact that the combination of the mandatory price freeze with the *Preismoratorium* prevents firms from compensating the additional costs of the former through an increase in prices. It is, therefore, argued

([8]) Charter of Fundamental Rights of the European Union (OJ C 326, 26.10.2012, p. 391). Hereinafter 'the Charter'.

that the possibility of granting exemptions does not lead to a selective advantage, but rather prevents discrimination of smaller undertakings with small profit margins. In this sense, the measure must be seen as a hardship clause, reducing the impact of the price freezes to a proportionate level. It is argued that the price freezes would be in breach of the freedom to conduct a business, as laid down in Article 16 of the Charter, without such a hardship clause. In this regard all beneficiaries point to the fact that they would not be firms in financial difficulties if it were not for the price freezes. In light of this direct causal link between the legislation introducing the price freezes and their financial difficulties, the beneficiaries underline the importance of a hardship clause.

(44) Several of the third parties in addition explain that the price freezes were introduced only shortly after stricter conditions concerning certification of several of their products, significantly increasing their costs, entered into force. The legislation laying down these stricter conditions recognised the fact that it will lead to additional costs. Yet, due to the *Preismoratorium* in combination with the mandatory rebate, the affected companies were not able to compensate these additional costs. They, therefore, argue that the measure is not selective as it applies to all undertakings subject to this double burden.

(45) Lastly, due to the small amounts involved the third parties submit that there is no distortion of competition. Several beneficiaries, furthermore, submit that there is no effect on trade between the Member States, as they only operate within Germany and only with products that are certified in Germany.

5. **COMMENTS FROM GERMANY**

(46) Germany maintained its position that the measure does not constitute State aid.

(47) According to the German authorities the measure merely constitutes part of a general framework regulating the price levels for pharmaceuticals. Germany points out that there are several different mechanisms regulating prices for certain medical products or certain producers, the measure at stake in the present case merely being one of them. In this regard Germany argues that the decision by the BAFA to grant exemptions does not *directly and in itself* lead to any transfer of funds from the health insurances to the eligible undertakings, but merely sets a certain price for a specific product. Such transfer of funds only occurs once a doctor prescribes a certain medicine and is, therefore, not directly linked to any action by a State authority or any public or private body set up by the State to administer the funds.

(48) In this regard Germany, in addition, submits that the measure is not imputable, as it is merely an implementation of Article 4(2) of Directive 89/105. Germany submits that this Article lays down an obligation to foresee a possibility to apply for an exemption from a price freeze. Even though it leaves the precise meaning of the term 'particular reasons' open, an interpretation that would generally and *ex ante* make the grant of an exemption impossible would not be in accordance with the obligation to implement the Directive. The BAFA carries out case-by-case assessments of applications and, amongst other possible grounds, grants exemptions from the price freeze if the applicant is in financial difficulties because of the price freeze. Germany considers that no other interpretation of Article 4(2) of Directive 89/105 than to grant exemptions to undertakings that could not carry the financial burden of a price freeze would be appropriate, as exempting companies that can carry the burden themselves (or companies that are in difficulties even without the price freeze) is not necessary.

(49) In this regard Germany additionally argues that it follows from the opening decision that the Commission came to the preliminary conclusion that *any* exemption from a price freeze constitutes a selective advantage and therefore State aid, irrespective of the grounds on which it is granted. However, Article 4(2) of Directive 89/105 forces Member States to decide upon applications for such exemptions. Thus, it is unclear to Germany whether the exemption foreseen in Article 4(2) of Directive 89/105 can ever be granted without constituting State aid and if so how this could be done in conformity with State aid law.

(50) Furthermore, Germany asserts that EU institutions must avoid inconsistencies that might arise in the implementation of various provisions of Union law, especially in circumstances as the present case, where the rules on State aid as well as Directive 89/105 pursue a common objective. It must, thus, be presumed that the European legislature has already assessed that exemptions from price freezes do not distort competition and that there is,

therefore, no room for a subsequent assessment under the State aid rules. To conclude that such exemptions constitute State aid would deprive Article 4(2) of Directive 89/105 of any content.

(51) Finally, in case the Commission comes to the conclusion that the measure constitutes incompatible aid, Germany asks that the decision should exceptionally not order recovery of the aid. It argues that this would be justified by the particular circumstances of the case, in particular since Article 4(2) of Directive 89/105 requires Member States to foresee exemptions from prices freezes while there is neither any indication in the Directive nor jurisprudence of the Court that such exemptions could constitute State aid. In this regard Germany also points to the fact that the Commission has never argued before the opening decision that exemptions based on Article 4(2) of Directive 89/105 constitute State aid and also did not raise any concerns relating to a possible conflict of that Article with the rules on State aid in the ongoing revision of Directive 89/105.

6. **ASSESSMENT**

6.1. **Existence of aid**

(52) According to Article 107(1) TFEU any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market. It follows that, for a State measure to be qualified as State aid within the meaning of Article 107(1) TFEU, the following cumulative criteria have to be fulfilled: involvement of State resources; imputability to the State; selective advantage to an undertaking; and (potential) distortive effects on competition and intra-Union trade.

Involvement of State resources

(53) For advantages to be capable of being categorised as aid within the meaning of Article 107 TFEU, they must be granted directly or indirectly through State resources. The distinction made between 'aid granted by a Member State' and aid granted 'through State resources' does not mean that all advantages granted by a State, whether financed through State resources or not, constitute aid, but is merely intended to bring within the definition of State aid both, advantages which are granted directly by the State and those granted by a public or private body designated or established by the State to administer the advantages ([9]).

(54) The fact that a measure granting an advantage is not financed directly by the State, but by a public or private body established or appointed by the State to administer the aid does not exclude that that measure is financed through State resources ([10]).

(55) In the case at hand the relevant German legislation (through the price moratorium and the manufacturer's rebate) lays down the price that the insurance funds have to pay for pharmaceutical products. By granting the exemptions under assessment, the BAFA (a federal authority) ensures that these funds pay a higher price for the products in question, namely products of companies deemed to be in sufficient financial difficulty to justify an exception to the generally applicable fixed price.

(56) As indicated above (recital 16), 85-90 % of the population in Germany is covered by public sickness funds, while just a residual part of the population opt for private health insurance. This means that it is mainly public sickness funds that have to pay higher prices due to the exemptions in questions. The present measure therefore creates additional costs for public sickness funds, thereby involving a loss of State resources ([11]).

(57) Thus, the present case is different from the situation in *PreussenElektra* ([12]), where the Court only examined whether an 'obligation imposed on private electricity supply undertakings to purchase electricity produced from renewable energy sources at fixed minimum prices' involved 'any direct or indirect transfer of State resources to undertakings which produce that type of electricity' ([13]).

(58) In the light of the above, the Commission concludes that the measure involves state resources.

([9]) Case C-379/98 *PreussenElektra* EU:C:2001:160, paragraph 58.
([10]) Case C-78/76 *Steinike & Weinling* v *Germany* EU:C:1977:52, para. 21.
([11]) See, by analogy, Case C-200/97 *Ecotrade* EU:C:1998:579, paragraphs 38 and 41, and
([12]) Case C-379/98 *PreussenElektra* [2001] EU:C:2001:160.
([13]) Paragraph 59 of the judgment, emphasis added. See also paragraphs 55 and 56 of the judgment, where the Court clarified the scope of the question referred to it.

Imputability to the State

(59) In order to fall within the definition of State aid in the meaning of Article 107(1) TFEU, the measure must be imputable to the State ([14]).

(60) As stated above, Germany argues that the measure is not imputable to it, as it is merely an implementation of an obligation to foresee exemptions to price freezes laid down in Article 4(2) of Directive 89/105. While Germany admits that the term 'particular reasons' is rather broad, it asserts that the reason for this broad formulation is to make it possible for Member States to react to changing market conditions. However, according to Germany, this does not change the fact that Article 4(2) of Directive 89/105 lays down an obligation to grant exemptions on the basis of particular reasons and as such does not give Member States discretion on whether to grant exemptions or not.

(61) The Commission notes that in situations in which Member States merely transpose a clear and precise obligation put on them by a provision of Union legislation into national law, they are indeed only fulfilling their obligation under the Treaty to implement EU law into national law and that such implementation is, therefore, not imputable to them. In this regard, the General Court held, for example, in *Deutsche Bahn* v *Commission* that the implementation by Germany of a clear and precise obligation not to levy the harmonised excise duty on fuel used for the purpose of commercial air navigation laid down in Directive 92/81 ([15]) was, as an implementation of this obligation into national law, not imputable to Germany but in fact stemmed from an act of the Union legislature ([16]).

(62) However, as regards the present case, recital 6 of the preamble of Directive 89/105 clarifies that requirements under that Directive neither affect Member States' policies for determining prices for medicinal products nor national policies on price setting or the determination of social security schemes, except in so far as it is necessary to attain transparency for the purposes of the Directive. As confirmed by the Court in *Menarini and Others*, it follows that the underlying principle of Directive 89/105 is the idea of minimum interference in the organisation by Member States of their domestic social security policies ([17]).

(63) In accordance with this underlying idea, Article 4(2) of Directive 89/105 is formulated in a very wide manner and, in particular, does not define the meaning of the term 'particular reasons'. In this regard the Court clarified that, while Article 4(2) of Directive 89/105 requires Member States to provide for the possibility to apply for an exemption from a price freeze, this '*possibility is without prejudice to the ascertainment, by the competent authorities of the Member States, that it is an exceptional case and that there are particular reasons, within the meaning of that provision.*' ([18])

(64) It follows that it is for the Member States to establish when particular reasons are given and that they, therefore, have considerable discretion in defining under what conditions to grant exemptions. Thus, the term 'particular reasons' laid down in Article 4(2) of Directive 89/105 is not sufficiently clear and precise enough to be able to reach the same conclusion as in *Deutsche Bahn*, i.e. that the national measure does nothing more than to give form in the national legal order to an obligation imposed by the Union legislature.

(65) In *Deutsche Bahn* the relevant provision of Union law, namely Article 8(1)(b) of Directive 92/81, laid down a clear and precise obligation not to levy the harmonised excise duty on fuel used for the purpose of commercial air navigation. This Article left the Member States only certain discretion as to the wording of the conditions implementing this exemption ([19]), as it provided that exemptions from the excise duty are to be granted by Member States 'under conditions which they shall lay down for the purpose of ensuring the correct and straightforward application of such exemptions and of preventing any evasion, avoidance or abuse'.

([14]) See, e.g., Case C-482/99 *France* v *Commission (Stardust Marine)* [2002] EU:C:2002:294, paragraph 24; Case C-677/11 *Doux Elevage* [2013] EU:C:2013:348, paragraph 27.
([15]) Council Directive 92/81/EEC of 19 October 1992 on the harmonization of the structures of excise duties on mineral oils (OJ L 316, 31.10.1992, p. 12).
([16]) Case T-351/02 *Deutsche Bahn* v *Commission* [2006] EU:T:2006:104, paragraph 102.
([17]) Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *A. Menarini and Others* [2009] EU:C:2009:217, paragraph 36.
([18]) Ibid, paragraph 58.
([19]) Case T-351/02 *Deutsche Bahn* v *Commission* [2006] EU:T:2006:104, paragraph 105.

(66) However, in the present case, Article 4(2) of Directive 89/105 does not define the term 'particular reasons' and, thereby, gives Member States a wide margin of discretion under what conditions to grant exemptions from price freezes. This discretion goes beyond a mere discretion as to the wording of the implementing measures but rather leaves it for the Member States to decide under what conditions to grant exemptions ([20]). Thus, while in *Deutsche Bahn* the relevant Directive clearly identified when exemptions are to be granted, namely with regard to fuel used for commercial air navigation, in the present case Article 4(2) of Directive 89/105 leaves the decision when to grant exemptions to the Member States.

(67) It follows that under Article 4(2) of Directive 89/105 Member States enjoy discretion as to the *substance* of the scope of exemptions. As stated above, this makes it impossible to draw the same conclusions as in *Deutsche Bahn*.

(68) The Commission, therefore, concludes that the measure is imputable to Germany.

Selective advantage to an undertaking

(69) At the outset the Commission observes that the eligible beneficiaries are pharmaceutical undertakings that are clearly engaged in an economic activity. As such, the beneficiaries are to be regarded as undertakings in the meaning of Article 107(1) TFEU.

(70) Furthermore, the Commission notes that the grant of an exemption from the price freeze leads to increased turnover and income for the undertakings benefitting from it. The exemption must, therefore, be seen as granting an advantage to the beneficiaries as compared to their competitors.

(71) As to the selectivity of the measure, it is clear that, following an application process, a case-by-case assessment and a decision by the BAFA only a limited number of undertakings operating in a specific sector (for pharmaceutical products) and fulfilling specific criteria (of being in financial difficulties) benefit from the measure. In this sense, it cannot be seen as a mere price regulation, as it leads to prices beneficial for certain companies in deviation of the general price regulation in form of the price freeze. The measure must, therefore, be seen as selective.

(72) In this regard the arguments put forth by the BPI, according to which the condition of selectivity is not fulfilled as the measure must be seen as a general measure under German (constitutional) law cannot be upheld. To support this argument the BPI points at case law in which the Court held that a measure granting an exception to the application of the general tax system of a Member State is not selective and, thus, does not constitute aid even though conferring an advantage on an undertaking, if that measure '*results directly from the basic or guiding principles*' of said '*tax system*' ([21]). In the present case, the BPI essentially argues that the advantage conferred to the beneficiary undertakings results directly from the basic or guiding principles of the German constitution.

(73) In this regard, the Commission observes that the point of reference to establish whether the exceptions in question grant a selective advantage to certain undertakings is the price freeze system, from which they derogate, and not the general principles of the German constitution. However, the BPI did not argue, nor *a fortiori* show, that the exceptions in question result directly from the basic or guiding principles of the price freeze system.

(74) In any event, in the judgment invoked by the BPI the Court ruled that exemptions from tax measures subject to an authorisation procedure are only regarded as not being selective if the latitude of the competent national authorities is limited to verifying that certain conditions laid down by law are fulfilled ([22]). However, in the present case the German constitution does not define in any way when exemptions are to be granted. As such, it does not define any conditions for granting exemptions to price freezes and does not limit BAFA's discretion to merely verifying that these conditions are fulfilled.

(75) In the light of the above the Commission concludes that the measure grants a selective advantage to undertakings.

Distortion of competition and intra-Union trade

(76) Lastly, in order to fall under the definition of State aid in the meaning of Article 107(1) TFEU, the measure must distort or threaten to distort competition and affect trade between the Member States.

([20]) See also, as stated above, Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *A. Menarini and Others* [2009] EU:C:2009:217, paragraph 58.
([21]) See, e.g., Case C-6/12 *P Oy* [2013] EU:C:2013:525, para. 22.
([22]) Ibid, paras. 23-25.

(77) In this regard the Commission notes that the beneficiaries under the scheme trade with pharmaceutical products and that there is strong competition among market participants in the pharmaceutical sector. As such, the advantage granted to the beneficiaries under the scheme is likely to distort competition.

(78) In addition, according to the Court, when an advantage granted by a Member State strengthens the position of an undertaking compared with that of other undertakings competing in intra-Union trade, the latter must be regarded as affected by that aid ([23]). It is sufficient that the recipient of the advantage competes with other undertakings on markets open to competition. In this regard the Commission observes that pharmaceutical products are widely traded between Member States and that the pharmaceutical market is open to competition.

(79) Hence, the Commission concludes that the measure at least threatens to distort competition and to affect trade between Member States.

Conclusion on the existence of aid

(80) In light of the above the Commission concludes that exemptions from price freezes granted under the scheme at stake constitute State aid in the meaning of Article 107(1) TFEU.

6.2. **Compatibility with the internal market**

(81) Since the measure constitutes State aid it is necessary to examine its compatibility with the internal market.

(82) As stated above, the exemptions from the price freeze are granted if an undertaking is, due to the mandatory rebate, subject to an unacceptable financial burden. A financial burden is assumed to be unacceptable if the company in question is unable to avoid illiquidity through its own resources, contributions of its shareholders or other measures.

(83) This concept of an unacceptable financial burden is similar to the definition of firms in difficulty under the R&R Guidelines, which provide that a firm is regarded as being in difficulty if 'it is unable, whether through its own resources or with the funds it is able to obtain from its owner/shareholders or creditors, to stem losses which, without outside intervention by the public authorities, will almost certainly condemn it to going out of business in the short or medium term.' ([24])

(84) Thus, by applying the definition of unacceptable burden laid down in the scheme it is likely that firms in difficulty in the meaning of the R&R Guidelines will be eligible for an exemption, which would, in principle, make it necessary to assess the aid under these Guidelines.

(85) However, the Commission takes note of the unique circumstances of the present case.

(86) Under Directive 89/105 Member States are allowed to introduce price freezes if all conditions under said Directive are fulfilled. As stated above, Article 4(2) of the Directive provides that undertakings affected by a price freeze may, in exceptional cases, apply for a derogation if this is justified by particular reasons.

(87) In its judgment in *Menarini and Others* the Court clarified that Article 4(2) of Directive 89/105 must be interpreted as meaning that: Member States must, in all cases, provide for the possibility for an undertaking, which is concerned by a measure freezing or reducing the prices of all, or of certain categories of, medicinal products, of applying for a derogation from the price imposed pursuant to such measure ([25]).

(88) Thus, Article 4(2) of Directive 89/105 lays down an obligation for Member States to provide for a possibility to apply for a derogation from a price freeze (even if, as noted above, such obligation is not clear and precise enough to come to the conclusion that its implementation is not imputable to the State). Germany introduced the scheme under assessment in implementation of this obligation.

(89) In this regard the Commission, in particular, points to the fact, which was also emphasised by the submissions received by interested parties and by Germany in the course of the formal investigation procedure, that only

([23]) See, in particular, Case 730/79 *Philip Morris* v *Commission* [1980] EU:C:1980:209, para. 11; Case C-53/00 *Ferring* [2001] EU:C:2001:627, para. 21.
([24]) See point 9 of the R&R Guidelines.
([25]) Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *Menarini and Others* [2009] EU:C:2009:217, para. 58.

undertakings that can prove a direct causal link between their financial difficulties and the price freeze introduced by German legislation are eligible for aid under the scheme. In other words, without the price freeze the beneficiaries under the scheme would not be firms in difficulty, meaning that without the exemption, the price freeze, and thus German legislation, would force otherwise healthy undertakings into bankruptcy.

(90) The guiding principle of the R&R Guidelines is to ensure that inefficient firms are not artificially kept on the market. As such, the Guidelines are based on the premise that the exit of inefficient firms is a normal part of the operation of the market and must, as such, remain the norm, whereas rescuing or restructuring such firms must remain the exception ([26]).

(91) Inefficient firms cannot survive (i.e. cover their costs and a sufficient profit margin) on the basis of market prices. However, in the present case and given the direct and strict causal link between the difficulties of the beneficiaries and the price freeze, these beneficiaries cannot be regarded as inefficient firms. Their survival on the market is not threatened by their inability to cover their costs on the basis of market prices but rather by the State intervention in the form of the price freeze, which prevents them from charging such market prices. As such, the exemptions from the price freeze introduced by the scheme under assessment therefore do not aim at keeping inefficient firms artificially on the market and thus do not run counter to the underlying principles of the R&R Guidelines.

(92) In the light of the above and under the specific circumstances of the present case the Commission considers it, therefore, exceptionally appropriate to assess the compatibility of the aid directly under the Treaty. This decision, therefore, assesses the compatibility of the particular exemptions, as defined in the German scheme under assessment in the present case, with the internal market on the basis of Article 107(3)(c) TFEU.

(93) Article 107(3)(c) TFEU provides for the authorisation of aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest.

(94) In order to be compatible under Article 107(3)(c) TFEU, an aid measure must meet a clearly defined objective of common interest, must be well designed to deliver said objective and must not affect competition and intra-EU trade to an extent contrary to the common interest.

Well-defined objective of common interest

(95) Recital 3 of Directive 89/105 recognises the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost as the primary objective of price freezes. The need for sustainable health systems, especially in the economic climate in Europe during the recent years, has also been stressed by the Council of Health Ministers in December 2013 ([27]) and the 2014 Annual Growth Survey ([28]), which emphasised the need to improve financial sustainability of healthcare systems.

(96) Thus, price freezes, such as the ones introduced by Germany, are intended to maintain a sustainable level of costs in the public health system to promote public health. However, price freezes introduce a distortion of the free market ([29]) and it can, therefore, be necessary to foresee exemptions under particular circumstances, in particular where the distortion caused by the price freeze would be of such a nature that its introduction would not be feasible in the first place. In this sense Article 4(2) of Directive 89/105 provides that the measures introduced by Member States to reach the objective of common interest of maintaining a sustainable cost level in the public health system must take account of this fact and must foresee the possibility of exemptions from price freezes on the basis of particular reasons.

(97) The German scheme under assessment pursues the objective spelt out in Directive 89/105 of keeping the costs of the public health system at a sustainable level and, thereby, to promote public health while at the same time ensuring, through the introduction of exemptions, that the effects of these measures for the affected undertakings are not so far reaching as to making their introduction not feasible in the first place ([30]). In this sense the German scheme introduced a hardship clause that ensures that the aim of maintaining a sustainable cost level in the public health system does not force otherwise healthy undertakings into bankruptcy.

([26]) See in this regard recital 4 or the R&R Guidelines.
([27]) See Council Conclusions on the Reflection process on modern, responsive and sustainable health systems (10 December 2013).
([28]) COM(2013) 800.
([29]) As they make it impossible for undertakings to set prices freely.
([30]) See for a similar approach the Guidelines on State aid for environmental protection and energy 2014-2020 (OJ C 200, 28.6.2014, p. 1), chapter 3.7.

(98) As such, the Commission concludes that the scheme under assessment pursues, in accordance with Directive 89/105, a well-defined objective of common interest.

Well defined measure to deliver the objective of common interest

(99) As stated above, in order to be compatible with the internal market an aid measure must be well defined to achieve the identified objective of common interest. It must, thus, in particular be an appropriate instrument to achieve this objective and must do so in a proportionate way.

(100) Under the German scheme, only undertakings that can prove that the general price freeze affects them particularly hard, in the sense that the financial burden stemming from the price freeze becomes unacceptable, can apply for an exemption. Thus, in line with the objective of maintaining a sustainable level of costs in the health care system, exemptions are only granted under limited circumstances. As described above, these circumstances are, in essence, limited to preventing a situation in which the effects of the price freeze would make its introduction not feasible in the first place. In this sense, only undertakings that can prove a direct causal link between the price freeze and their financial difficulties are eligible for the exemption. Such exemptions are necessary to ensure that the price freeze does not force otherwise healthy undertakings into bankruptcy.

(101) Thus, the Commission concludes that the scheme under assessment constitutes an appropriate instrument for achieving the aim of maintaining a sustainable cost level in the health care system while ensuring that the measures introduced to this end (the price freeze) does not lead to the result of forcing healthy undertakings into bankruptcy, which would make the introduction of the price freeze appear not to be feasible in the first place. The Commission, furthermore, observes that no less distortive instrument than to limit the eligibility to such firms that can prove a direct causal link between the price freeze and their financial difficulties seems to be available.

(102) In this regard, the Commission observes, as was described above in recitals 20-21, that any potential beneficiary for aid under the scheme must prove a direct causal link between the price freeze and its financial difficulties. This, in particular, means that it must be proven that there are no structural causes for the financial difficulties. If there are any business measures suited for avoiding or limiting the financial difficulties still available, these must primarily be taken. Any business measures already taken to that end need to be described by the affected undertaking in its application.

(103) All these conditions for eligibility in relation to the causal link between the price freeze and the financial difficulties need to be verified in an expert opinion by a certified accountant. The certified accountant, in particular, needs to expressly confirm said causal link and needs to provide reasons. The accountant, in addition, needs to assess the business measures already taken by the undertaking to avoid or limit its financial difficulties.

(104) As described above in recital 25 these conditions are subject to a strict *ex ante* and *ex post* control exercised by the BAFA. If the *ex post* control shows that the conditions were not fulfilled during the entire period covered by a preliminary exemption, the BAFA takes a final negative decision repealing the preliminary exemption.

(105) In light of the above the Commission concludes that the eligibility criteria for exemptions from the price freeze ensure that the aid is strictly limited to the minimum necessary. In addition, the few exemptions granted under the scheme (only 9 undertakings were granted exemptions during the years 2010-2013, for details see above recitals 26-28) show that the BAFA applied these eligibility criteria strictly. The Commission, thus, concludes that the aid under the scheme is proportionate.

Distortion of competition and effect on intra-EU trade

(106) Finally, the Commission notes that the scheme does not lead to distortions of competition or affectation of intra-EU trade contrary to the common interest. Due to the strict eligibility criteria described above only very few undertakings benefitted from aid under the scheme and the total amount of aid granted under the scheme (EUR 11-12 million for the period August 2010 to December 2013) must be considered, in light of the relevant market of pharmaceutical products, as relatively small. As such, the effects of the aid on competition and intra-EU trade are very limited and, in any event, do not lead to any distortions on the market contrary to the common interest.

7. **CONCLUSION**

(107) The Commission finds that Germany has unlawfully implemented the aid scheme in question in breach of Article 108(3) of the Treaty on the Functioning of the European Union. However, in light of the assessment above, the Commission finds that the scheme is compatible with the internal market under Article 107(3)(c) TFEU,

HAS ADOPTED THIS DECISION:

Article 1

The measure which Germany has implemented on the basis of Section 130a(4) of Book V of the German Social Security Code in conjunction with Article 4 of Directive 89/105 is compatible with the internal market within the meaning of Article 107(3)(c) of the Treaty on the Functioning of the European Union.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 27 March 2015.

For the Commission
Margrethe VESTAGER
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2015/1301

of 20 July 2015

on the publication with a restriction in the *Official Journal of the European Union* of the reference of standard EN 13241-1:2003+A1:2011 on industrial, commercial and garage doors and gates under Directive 2006/42/EC of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC ([1]), and in particular Article 10 thereof,

Having regard to the opinion of the committee established by Article 22 of the 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 ([2]),

Whereas:

(1) Where a national standard transposing a harmonised standard, the reference of which has been published in the *Official Journal of the European Union*, covers one or more essential health and safety requirements set out in Annex I to Directive 2006/42/EC, the machine built in accordance with this standard is presumed to meet the essential health and safety requirements concerned.

(2) In November 2012, the United Kingdom updated its previous formal objection made in December 2010 in respect of standard EN 12635:2002+A1:2008 'Industrial, commercial and garage doors and gates — Installation and use' by adding EN 13241-1:2003+A1:2011 'Industrial, commercial and garage doors and gates — Product standard — Part 1: Products without fire resistance or smoke control characteristics' proposed by the European Committee for Standardization (CEN) to be harmonized under Directive 2006/42/EC and which was first published in the *Official Journal of the European Union* on 18 November 2011 ([3]).

(3) The ground of this formal objection is based on the failure of the referenced standards EN 12453:2000 — 'Industrial, commercial and garage doors and gates — Safety in use of powered operated doors — Requirements' mentioned in points 4.2.2 Force for manual operation, 4.2.6 Protection against cutting, 4.3.2 Protection against crushing, shearing and drawing-in, 4.3.3 Operating forces, 4.3.4 Electrical safety and 4.3.6 Alternative requirements, and EN 12445:2000 'Industrial, commercial and garage doors and gates — Safety in use of power operated doors — Test methods' mentioned in clause point 4.3.3 Operating forces, to comply with the essential health and safety requirements of Annex I to Directive 2006/42/EC.

(4) Having examined the standard EN 13241-1:2003+A1:2011 together with the representatives of the committee established by Article 22 of Directive 2006/42/EC, the Commission concluded that the standard fails to meet the essential health and safety requirements provided for in points 1.3.7 Moving parts and 1.4.3 Protective devices of Annex I to Directive 2006/42/EC, ascribed to the referenced standard EN 12453:2000 and EN 12445:2000.

(5) Taking into consideration the need to improve the safety aspects of standard EN 13241-1:2003+A1:2011 and pending a suitable revision of that standard, the publication in the *Official Journal of the European Union* of the reference of the standard EN 13241-1:2003+A1:2011 should be accompanied by an appropriate warning.

HAS ADOPTED THIS DECISION:

Article 1

The reference of standard EN 13241-1:2003+A1:2011 'Industrial, commercial and garage doors and gates — Product standard — Part 1: Products without fire resistance or smoke control characteristics', shall be published in the *Official Journal of the European Union* with restriciton as set out in the Annex.

([1]) OJ L 157, 9.6.2006, p. 24.
([2]) OJ L 316, 14.11.2012, p. 12.
([3]) OJ C 338, 18.11.2011, p. 1.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Publication of titles and references of harmonised standards under Union harmonisation legislation

ESO ([1])	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 13241-1:2003+A1:2011 Industrial, commercial and garage doors and gates — Product standard — Part 1: Products without fire resistance or smoke control characteristics	18.11.2011	—	—

Warning: With regard to paragraphs 4.2.2, 4.2.6, 4.3.2, 4.3.3, 4.3.4, 4.3.6, this publication does not concern the reference to EN 12453:2000, the application of which does not confer a presumption of conformity to the essential health and safety requirements 1.3.7 and 1.4.3 of Annex I to Directive 2006/42/EC.

([1]) ESO: European standardisation organisation:

— CEN: Avenue Marnix 17, B-1000, Brussels, Tel. +32 2 5500811; fax + 32 2 5500819 (http://www.cen.eu)

Note 1: Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European standardisation organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 2: The new (or amended) standard has the same scope as the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential or other requirements of the relevant Union legislation.

COMMISSION DECISION (EU) 2015/1302

of 28 July 2015

on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 [1] and in particular Article 13(1) thereof,

After consulting the European multi-stakeholder platform on ICT standardisation and sectoral experts,

Whereas:

(1) Standardisation plays an important role in supporting the Europe 2020 strategy, as set out in the Communication from the Commission entitled 'Europe 2020: A strategy for smart, sustainable and inclusive growth' [2]. Several flagship initiatives of the Europe 2020 strategy underline the importance of voluntary standardisation in product or services markets to assure the compatibility and interoperability between products and services, foster technological development and support innovation.

(2) The completion of the Digital Single Market is a key priority for the European Union as highlighted in the Annual Growth Strategy 2015 [3]. The Commission has launched the Digital Single Market strategy [4] where the role of standardisation and interoperability in creating a European Digital Economy with a long-term growth potential is highlighted.

(3) In the digital society standardisation deliverables become indispensable to ensure the interoperability between devices, applications, data repositories, services and networks. The Communication from the Commission entitled 'A strategic vision for European standards: moving forward to enhance and accelerate the sustainable growth of the European economy by 2020' [5] recognises the specificity of ICT standardisation where ICT solutions, applications and services are often developed by global ICT Fora and Consortia that have emerged as leading ICT standards development organisations.

(4) Regulation (EU) No 1025/2012 aims at modernising and improving the European standardisation framework. It establishes a system whereby the Commission may decide to identify the most relevant and most widely accepted ICT technical specifications issued by organisations that are not European, international or national standardisation organisations. The possibility to use the full range of ICT technical specifications when procuring hardware, software and information technology services will enable interoperability, will help avoid lock-in for public administrations and will encourage competition in the supply of interoperable ICT solutions.

(5) The ICT technical specifications that may be eligible for referencing in public procurement must comply with the requirements set out in Annex II to Regulation (EU) No 1025/2012. Compliance with those requirements guarantees the public authorities that the ICT technical specifications are established in accordance with the principles of openness, fairness, objectivity and non-discrimination that are recognised by the World Trade organisation in the field of standardisation.

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[1] OJ L 316, 14.11.2012, p. 12.
[2] COM(2010) 2020 final of 3 March 2010.
[3] COM(2014) 902.
[4] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a Digital Single Market Strategy for Europe COM(2015) 192 final of 6 May 2015.
[5] COM(2011) 311 final of 1 June 2011.

(6) The decision to identify the ICT specification is to be adopted after consultation of the European multi-stakeholder platform on ICT standardisation set up by Commission Decision 2011/C 349/04 ([1]) complemented by other forms of consultation of sectoral experts.

(7) On 2 October 2014, the European multi-stakeholder platform on ICT standardisation evaluated 27 'Integrating the Healthcare Enterprise' (IHE) profiles against the requirements set out in Annex II to Regulation (EU) No 1025/2012 and gave a positive advice to their identification for referencing in public procurement. The evaluation of the 27 IHE profiles was subsequently submitted to consultation of the eHealth network established by Article 14 of Directive 2011/24/EU of the European Parliament and of the Council ([2]) that confirmed the positive advice to their identification.

(8) IHE develops ICT technical specifications in the field of healthcare information technology. The 27 IHE profiles are detailed specifications developed over a period of 15 years within the committees of IHE that optimise the selection of well-established standards describing the different layers of interoperability (i.e. protocol communication, technical, syntactical, semantic and application levels) with a view to find interoperability solutions for exchanging or sharing medical data.

(9) The 27 IHE profiles have the potential to increase interoperability of eHealth services and applications to the benefit of patients and medical community. The 27 IHE profiles should therefore be identified as ICT technical specifications eligible for referencing in public procurement,

HAS ADOPTED THIS DECISION:

Article 1

The 'Integrating the Healthcare Enterprise' profiles listed in the Annex are eligible for referencing in public procurement.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 28 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

([1]) Commission Decision 2011/C 349/04 of 28 November 2011 setting up the European multi-stakeholder platform on ICT standardisation (OJ C 349, 30.11.2011, p. 4).
([2]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

ANNEX

LIST OF 'INTEGRATING THE HEALTHCARE ENTERPRISE' PROFILES ELIGIBLE FOR REFERENCING IN PUBLIC PROCUREMENT

1. IHE XCPD: Cross-Community Patient Discovery;
2. IHE XCA: Cross-Community Access;
3. IHE XCF: Cross-Community Fetch;
4. IHE XDR: Cross-Enterprise Document Reliable Interchange;
5. IHE CT: Consistent Time;
6. IHE ATNA: Audit Trail and Node Authentication;
7. IHE BPPC: Basic Patient Privacy Consents;
8. IHE XUA: Cross-Enterprise User Assertion;
9. IHE PRE: Pharmacy Prescription;
10. IHE DIS: Pharmacy Dispense;
11. IHE XPHR: Exchange of Personal Health Record Content;
12. IHE XD-MS: Cross-Enterprise Sharing of Medical Summaries Integration Profile;
13. IHE XD-SD: Cross-Enterprise Sharing of Scanned Documents;
14. IHE PIX: Patient Identifier Cross-Referencing;
15. IHE PDQ: Patient Demographics Query;
16. IHE XDS.b: Cross-Enterprise Document Sharing;
17. IHE XDS-I.b: Cross-Enterprise Document Sharing for Imaging;
18. IHE XD-LAB: Laboratory Reports;
19. IHE XDM: Cross-Enterprise Document Media Interchange;
20. IHE SVS: Sharing Value Sets;
21. IHE SWF: Radiology Scheduled Workflow;
22. IHE SWF.b: Radiology Scheduled Workflow;
23. IHE PIR: Patient Information Reconciliation;
24. IHE PAM: Patient Administration Management;
25. IHE LTW: Laboratory Testing Workflow;
26. IHE LCSD: Laboratory Code Sets Distribution;
27. IHE LWA: Laboratory Analytical Workflow.

CORRIGENDA

Corrigendum to Council Implementing Regulation (EU) No 284/2014 of 21 March 2014 implementing Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

(Official Journal of the European Union L 86 of 21 March 2014)

On page 28 in the Annex, in the third entry, first column:

for: 'Matviyenko, Valentina Ivanova'

read: 'Matviyenko, Valentina Ivanovna'.

Corrigendum to Council Implementing Decision 2014/151/CFSP of 21 March 2014 implementing Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

(Official Journal of the European Union L 86 of 21 March 2014)

On page 31, Annex, third entry, first column:

for: 'Matviyenko, Valentina Ivanova',

read: 'Matviyenko, Valentina Ivanovna'.

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