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Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

2013/454/EU:

- ★ **Council Decision of 22 July 2013 amending Decision 2000/125/EC concerning the conclusion of the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement')** 1
- ★ **Amendment to the Customs Convention on the International Transport of Goods Under Cover of TIR Carnets (TIR Convention, 1975)** 3

REGULATIONS

- ★ **Commission Regulation (EU) No 879/2013 of 12 September 2013 establishing a prohibition of fishing for sandeel and associated by-catches in EU waters of IIa, IIIa and IV and EU waters of sandeel management area 1 by vessels flying the flag of the Netherlands** 5
- ★ **Commission Implementing Regulation (EU) No 880/2013 of 13 September 2013 amending for the 201st time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al Qaida network** 7

Price: EUR 3

(Continued overleaf)

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.

Commission Implementing Regulation (EU) No 881/2013 of 13 September 2013 establishing the standard import values for determining the entry price of certain fruit and vegetables	9
--	---

Commission Implementing Regulation (EU) No 882/2013 of 13 September 2013 fixing the import duties in the cereals sector applicable from 16 September 2013	11
---	----

DECISIONS

2013/455/EU:

★ Council Decision of 9 July 2013 on the position to be adopted, on behalf of the European Union, in the Joint Committee established by the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco	14
---	----

2013/456/EU:

★ Council Decision of 22 July 2013 amending Decision 97/836/EC with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement')	25
--	----

Notice to readers — Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* (see page 3 of the cover)

Note to readers — way of referring to acts (see page 3 of the cover)

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 22 July 2013

amending Decision 2000/125/EC concerning the conclusion of the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement')

(2013/454/EU)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

- (1) By Council Decision 2000/125/EC of 31 January 2000 concerning the conclusion of the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement') ⁽¹⁾ the Union acceded to the Parallel Agreement, in the framework of the United Nations Economic Commission for Europe (UNECE).
- (2) Changes to the Treaties on which the Union is founded occurred after the adoption of Decision 2000/125/EC. The Treaty on the Functioning of the European Union has substantially altered the procedure to be followed for the conclusion of Agreements between the Union and international organisations, making it necessary to adapt Decision 2000/125/EC to the new procedures.
- (3) The procedure for establishing the position to be adopted on the Union's behalf in the United Nations concerning the adoption of UNECE Regulations or amendments to UNECE Regulations should be adapted to the new procedures set out in Article 218(9) of the Treaty on the Functioning of the European Union.
- (4) It is appropriate that the procedure for adopting proposed amendments to the Parallel Agreement submitted by the Union, as well as the decision whether to raise an objection to a proposed amendment, be the same as the procedure for the accession to international agreements.

- (5) Decision 2000/125/EC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2000/125/EC is amended as follows:

- (1) Article 5 is hereby amended as follows:

- (a) paragraph 1 is replaced by the following:

'1. The Union shall vote in favour of establishing any draft global technical regulation or a draft amendment to such a regulation where the draft has been approved in accordance with the procedure set out in Article 218(9) of the Treaty on the Functioning of the European Union (TFEU).';

- (b) paragraph 3 is replaced by the following:

'3. The position of the Union with regard to the listing and reaffirmation of listing in the compendium of candidate technical regulations as well as with regard to issue resolution between Contracting Parties shall be established in accordance with the procedure laid down in Article 218(9) TFEU.';

- (2) Article 6 is replaced by the following:

'Article 6

1. The Union shall vote in favour of a proposed amendment to the Parallel Agreement where the proposed amendment has been approved in accordance with the procedure set out in Article 218(6)(a) TFEU.

Where that procedure has not been completed in time before the vote takes place, the Union shall vote against the amendment.

2. The decision whether or not to raise an objection to a proposed amendment to the Parallel Agreement put forward by another Contracting Party shall be taken in accordance with the procedure set out in Article 218(6)(a) TFEU.'.

⁽¹⁾ OJ L 35, 10.2.2000, p. 12.

Article 2

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

Done at Brussels, 22 July 2013.

For the Council
The President
C. ASHTON

Amendment to the Customs Convention on the International Transport of Goods Under Cover of TIR Carnets (TIR Convention, 1975 ⁽¹⁾)

According to the UN Depositary Notification C.N.433.2013.TREATIES — XI.A.16 the following amendments to the TIR Convention enter into force on 10 October 2013 for all Contracting Parties

In Article 6, paragraph 2 *bis* is replaced by the following:

‘2 *bis*. An international organisation shall be authorised by the Administrative Committee to take on responsibility for the effective organisation and functioning of an international guarantee system. The authorisation shall be granted as long as the organisation fulfils the conditions and requirements laid down in Annex 9, Part III. The Administrative Committee may revoke the authorisation if these conditions and requirements are no longer fulfilled.’

In Annex 9, a new Part III is introduced as follows:

Part III

Authorisation of an international organisation, as referred to in Article 6, to take on the responsibility for the effective organisation and functioning of an international guarantee system and to print and distribute TIR Carnets

Conditions and requirements:

1. The conditions and requirements to be complied with by an international organisation in order to be authorised, in accordance with Article 6.2 *bis* of the Convention, by the Administrative Committee to take on the responsibility for the effective organisation and functioning of an international guarantee system and to print and distribute TIR Carnets are:
 - (a) proof of sound professional competence and financial standing for the effective organisation and functioning of an international guarantee system and the organisational capabilities to fulfil its obligations under the Convention by means of annual submissions of consolidated financial statements duly audited by internationally recognised independent auditors;
 - (b) absence of serious or repeated offences against Customs or tax legislation.
2. Pursuant to the authorisation, the international organisation shall:
 - (a) provide the Contracting Parties of the TIR Convention via the national associations affiliated to the international organisation with certified copies of the global guarantee contract and proof of guarantee coverage;
 - (b) provide the competent bodies of the TIR Convention with information on the rules and procedures set out for the issue of TIR Carnets by national associations;
 - (c) provide the competent bodies of the TIR Convention, on a yearly basis, with data on claims lodged, pending, paid or settled without payment;
 - (d) provide the competent bodies of the TIR Convention with full and complete information on the functioning of the TIR system, in particular, but not limited to, timely and well founded information on trends in the number of non-terminated TIR operations, claims lodged, pending, paid or settled without payment that might give rise to concerns with regard to the proper functioning of the TIR system or that could lead to difficulties for the continued operation of its international guarantee system;
 - (e) provide the competent bodies of the TIR Convention with statistical data on the number of TIR Carnets distributed to each Contracting Party, broken down by type;
 - (f) provide the TIR Executive Board with details of the distribution price by the international organisation of each type of TIR Carnet;
 - (g) take all possible steps to reduce the risk of counterfeiting TIR Carnets;

⁽¹⁾ Consolidated text published by Council Decision 2009/477/EC (OJ L 165, 26.6.2009, p. 1).

- (h) take the appropriate corrective action in cases where faults or deficiencies with the TIR Carnet have been detected and report these to the TIR Executive Board;
 - (j) fully participate in cases where the TIR Executive Board is called upon to facilitate the settlement of disputes;
 - (k) ensure that any problem involving fraudulent activities or other difficulties with regard to the application of the TIR Convention is immediately brought to the attention of the TIR Executive Board;
 - (l) manage the control system for TIR Carnets, provided for in Annex 10 to the Convention, together with national guaranteeing associations affiliated to the international organisation and the Customs authorities and inform the Contracting Parties and the competent bodies of the Convention of problems encountered in the system;
 - (m) provide the competent bodies of the TIR Convention with statistics and data on the performance of Contracting Parties with regard to the control system provided for in Annex 10;
 - (n) conclude, not less than two months before the provisional date of entry into force or renewal of the authorisation granted in accordance with Article 6.2 *bis* of the Convention, a written agreement with the United Nations Economic Commission for Europe secretariat, mandated by and acting on behalf of the Administrative Committee, which shall include the acceptance by the international organisation of its duties set out in this paragraph.
3. When the international organisation is informed by a guaranteeing association of a claim for payment, it shall, within a period of three (3) months inform the guaranteeing association of its position concerning the claim.
4. All information acquired, directly or indirectly, by the international organisation under the Convention, which is by nature confidential or which is provided on a confidential basis, shall be covered by the obligation of professional secrecy and shall not be used or processed neither for any commercial purpose nor for any other purpose than for which it has been provided or disclosed to any third party without the express permission of the person or authority that provided it. Such information may, however, be disclosed without permission to competent authorities of Contracting Parties to this Convention, where there is an authorisation or obligation to do so pursuant to provisions of national or international law or in connection with legal proceedings. The disclosure or communication of information shall take place in full compliance with data-protection provisions in force.
5. The Administrative Committee shall have the right to revoke the authorisation granted in accordance with Article 6.2 *bis* in case of non-compliance with the above conditions and requirements. Should the Administrative Committee decide to revoke the authorisation, the decision will become effective at the earliest six (6) months after the date of revocation.
6. The authorisation of an international organisation under the terms set out above shall be without prejudice to that organisation's responsibilities and liabilities under the Convention.'
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REGULATIONS

COMMISSION REGULATION (EU) No 879/2013

of 12 September 2013

establishing a prohibition of fishing for sandeel and associated by-catches in EU waters of IIa, IIIa and IV and EU waters of sandeel management area 1 by vessels flying the flag of the Netherlands

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy ⁽¹⁾, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) No 40/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available in EU waters and, to EU vessels, in certain non-EU waters for certain fish stocks and groups of fish stocks which are subject to international negotiations or agreements ⁽²⁾, lays down quotas for 2013.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

Article 1

Quota exhaustion

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

Article 2

Prohibitions

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

Article 3

Entry into force

This Regulation shall enter into force on the 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, 12 September 2013.

*For the Commission,
On behalf of the President,*

Lowri EVANS
Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 23, 25.1.2013, p. 54.

ANNEX

No	37/TQ40
Member State	The Netherlands
Stock	SAN/2A3A4. and management area SAN/234_1
Species	Sandeel and associated by-catches (<i>Ammodytes</i> spp.)
Zone	EU waters of IIa, IIIa and IV and EU waters of sandeel management area 1
Date	12.8.2013

COMMISSION IMPLEMENTING REGULATION (EU) No 880/2013**of 13 September 2013****amending for the 201st time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al Qaida network**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network, ⁽¹⁾ and in particular Article 7(1)(a) and 7a(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 4 September 2013 the Sanctions Committee of the United Nations Security Council (UNSC) decided to remove one entity from its list of persons, groups and

entities to whom the freezing of funds and economic resources should apply after considering a de-listing request submitted by this entity and the Comprehensive Report of the Ombudsperson established pursuant to UNSC Resolution 1904(2009).

- (3) Annex I to Regulation (EC) No 881/2002 should therefore be updated accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 13 September 2013.

*For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments*

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

ANNEX

Annex I to Regulation (EC) No 881/2002 is amended as follows:

The following entry under the heading 'Legal persons, groups and entities' is deleted:

'Lajnat Al Daawa Al Islamiya (alias (a) LDI, (b) Lajnat Al Dawa, (c) Islamic Missionary Commission). Address: (a) Afghanistan, (b) Pakistan. Other information: Associated with the Libyan Islamic Fighting Group. Date of designation referred to in Article 2a (4) (b): 20.2.2003.'

COMMISSION IMPLEMENTING REGULATION (EU) No 881/2013**of 13 September 2013****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 Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽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 multi-lateral 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, 13 September 2013.

*For the Commission,
On behalf of the President,*

Jerzy PLEWA
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽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	MK	44,1
	XS	23,1
	ZZ	33,6
0707 00 05	MK	43,1
	TR	95,4
	ZZ	69,3
0709 93 10	TR	137,2
	ZZ	137,2
0805 50 10	AR	116,3
	CL	137,1
	IL	142,1
	TR	78,9
	UY	127,6
	ZA	130,3
	ZZ	122,1
0806 10 10	EG	184,6
	TR	146,7
	ZZ	165,7
0808 10 80	AR	100,6
	BA	68,8
	BR	54,6
	CL	100,1
	NZ	146,9
	US	140,2
	ZA	103,1
	ZZ	102,0
0808 30 90	AR	202,6
	CN	61,7
	TR	128,9
	ZA	206,6
	ZZ	150,0
0809 30	TR	129,4
	ZZ	129,4
0809 40 05	BA	45,1
	MK	54,9
	XS	48,8
	ZZ	49,6

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION IMPLEMENTING REGULATION (EU) No 882/2013
of 13 September 2013
fixing the import duties in the cereals sector applicable from 16 September 2013

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EU) No 642/2010 of 20 July 2010 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of import duties in the cereals sector ⁽²⁾, and in particular Article 2(1) thereof,

Whereas:

(1) Article 136(1) of Regulation (EC) No 1234/2007 states that the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is to be equal to the intervention price valid for such products on importation and increased by 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.

(2) Article 136(2) of Regulation (EC) No 1234/2007 lays down that, in order to calculate the import duty

referred to in paragraph 1 of that Article, representative cif import prices are to be established on a regular basis for the products in question.

(3) Under Article 2(2) of Regulation (EU) No 642/2010, the price to be used for the calculation of the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is the daily cif representative import price determined as specified in Article 5 of that Regulation.

(4) Import duties should be fixed for the period from 16 September 2013 and should apply until new import duties are fixed and enter into force.

(5) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

From 16 September 2013, the import duties in the cereals sector referred to in Article 136(1) of Regulation (EC) No 1234/2007 shall be those fixed in Annex I to this Regulation on the basis of the information contained in Annex II.

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, 13 September 2013.

*For the Commission,
On behalf of the President,*

Jerzy PLEWA
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 187, 21.7.2010, p. 5.

ANNEX I

Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 16 September 2013

CN code	Description	Import duties ⁽¹⁾ (EUR/t)
1001 19 00	Durum wheat, high quality	0,00
1001 11 00	medium quality	0,00
	low quality	0,00
ex 1001 91 20	Common wheat seed	0,00
ex 1001 99 00	High quality common wheat other than for sowing	0,00
1002 10 00	Rye	0,00
1002 90 00		
1005 10 90	Maize seed other than hybrid	0,00
1005 90 00	Maize other than seed ⁽²⁾	0,00
1007 10 90	Grain sorghum other than hybrids for sowing	0,00
1007 90 00		

⁽¹⁾ The importer may benefit, under Article 2(4) of Regulation (EU) No 642/2010, from a reduction in the duty of:

- EUR 3/t, where the port of unloading is located on the Mediterranean Sea (beyond the Strait of Gibraltar) or on the Black Sea, for goods arriving in the Union via the Atlantic Ocean or the Suez Canal,
- EUR 2/t, where the port of unloading is located in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom or on the Atlantic coast of the Iberian Peninsula, for goods arriving in the Union via the Atlantic Ocean.

⁽²⁾ The importer may benefit from a flat-rate reduction of EUR 24/t where the conditions laid down in Article 3 of Regulation (EU) No 642/2010 are met.

ANNEX II

Factors for calculating the duties laid down in Annex I

30.8.2013-12.9.2013

1. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

(EUR/t)

	Common wheat ⁽¹⁾	Maize	Durum wheat, high quality	Durum wheat, medium quality ⁽²⁾	Durum wheat, low quality ⁽³⁾
Exchange	Minneapolis	Chicago	—	—	—
Quotation	211,95	142,54	—	—	—
Fob price USA	—	—	227,15	217,15	197,15
Gulf of Mexico premium	—	27,64	—	—	—
Great Lakes premium	36,18	—	—	—	—

⁽¹⁾ Premium of EUR 14/t incorporated (Article 5(3) of Regulation (EU) No 642/2010).⁽²⁾ Discount of EUR 10/t (Article 5(3) of Regulation (EU) No 642/2010).⁽³⁾ Discount of EUR 30/t (Article 5(3) of Regulation (EU) No 642/2010).

2. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

Freight costs: Gulf of Mexico-Rotterdam: 16,23 EUR/t

Freight costs: Great Lakes-Rotterdam: 50,08 EUR/t

DECISIONS

COUNCIL DECISION

of 9 July 2013

on the position to be adopted, on behalf of the European Union, in the Joint Committee established by the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco

(2013/455/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207 in conjunction with Article 218(9) thereof,

Having regard to Council Decision 2003/885/EC of 17 November 2003 concerning the conclusion of the Agreement on the application of certain Community acts on the territory of the Principality of Monaco ⁽¹⁾, and in particular Article 3(2) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco ⁽²⁾ (hereinafter referred to as 'the Agreement') entered into force on 1 May 2004.
- (2) Article 1(1) of the Agreement provides that the Annex to the Agreement shall be amended by the Joint Committee established by the Agreement to ensure that Union acts falling within the scope of the Agreement apply on the territory of Monaco.
- (3) Since the entry into force of the Agreement, the Union has adopted a number of acts that fall within its scope and some acts appearing in the Annex have been repealed. It is therefore necessary to update the Annex to include the new acts and to delete the acts that have been repealed. In addition, it is necessary to include acts falling within the scope of the Agreement but not currently referenced in the Annex, including Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ⁽³⁾ and Directive 2004/23/EC of the

European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, resting, processing, preservation, storage and distribution of human tissues and cells ⁽⁴⁾ because certain of their provisions apply to the manufacturing of medicinal products.

- (4) The position of the Union in the Joint Committee should be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken by the European Union within the Joint Committee established by the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco shall be based on the draft Decision of the Joint Committee attached to this Decision.

Technical modifications to the draft Decision may be agreed to by the representatives of the Union in the Joint Committee without further decision of the Council.

Article 2

The Decision of the Joint Committee shall be published in the *Official Journal of the European Union*.

Article 3

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

Done at Brussels, 9 July 2013.

For the Council
The President
R. ŠADŽIUS

⁽¹⁾ OJ L 332, 19.12.2003, p. 41.

⁽²⁾ OJ L 332, 19.12.2003, p. 42.

⁽³⁾ OJ L 33, 8.2.2003, p. 30.

⁽⁴⁾ OJ L 102, 7.4.2004, p. 48.

DRAFT

DECISION No .../... OF THE EU-MONACO JOINT COMMITTEE**established by the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco****of ...****amending the Annex to that Agreement**

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco ⁽¹⁾, signed in Brussels on 4 December 2003 (hereinafter referred to as 'the Agreement'), and in particular Article 1(1) thereof,

Whereas:

- (1) Since the entry into force of the Agreement on 1 May 2004, the Union has adopted a number of acts that fall within its scope and some acts appearing in the Annex have been repealed. A Decision of the Joint Committee is therefore necessary to update the Annex to include the new acts and to delete the acts that have been repealed.
- (2) It is recalled that acts of the European Commission adopted in application of the acts listed in the Annex to the Agreement are applicable on the territory of

Monaco without the need for a Joint Committee Decision, as provided for by Article 1(2) of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The text set out in the Annex to the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco is replaced by the text set out in the Annex to this Decision.

Article 2

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

By the Joint Committee
The Chairman

⁽¹⁾ OJ L 332, 19.12.2003, p. 42.

ANNEX

I. MEDICINAL PRODUCTS

ACTS REFERRED TO

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by:
 - Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1);
 - Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74);
 - Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. (OJ L 348, 31.12.2010, p. 74);
 - Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products (OJ L 242 15.9.2009, p. 3);
 - Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products. (OJ L 168, 30.6.2009, p. 33);
 - Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission (OJ L 81, 20.3.2008, p. 51);
 - Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121);
 - Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1);
 - Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34);
 - Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 85);
 - Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46) and
 - Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).
2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended by:
 - Regulation (EU) no 1027/2012 of the European Parliament and of the Council of 25 October 2012 as regards pharmacovigilance. (OJ L 316, 14.11.2012, p. 38);
 - Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1);

- Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11);
 - Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two (OJ L 87, 31.3.2009, p. 109);
 - Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004. (OJ L 324 10.12.2007, p. 121) and
 - Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. (OJ L 378, 27.12.2006, p. 1).
3. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by:
- Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009, p. 14);
 - Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (OJ L 168, 30.6.2009, p. 33);
 - Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11) and
 - Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (OJ L 44, 14.2.2009, p. 10).
 - Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).
4. Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products, as amended by:
- Council Regulation (EC) No 2743/98 of 14 December 1998 (OJ L 345, 19.12.1998, p. 3);
 - Commission Regulation (EC) No 494/2003 of 18 March 2003 (OJ L 73, 19.3.2003, p. 6);
 - Council Regulation (EC) No 1905/2005 of 14 November 2005 (OJ L 304, 23.11.2005, p. 1);
 - Commission Regulation (EC) No 312/2008 of 3 April 2008 (OJ L 93, 4.4.2008, p. 8);
 - Commission Regulation (EC) No 249/2009 of 23 March 2009 (OJ L 79, 25.3.2009, p. 34);
 - Commission Regulation (EU) No 261/2010 of 25 March 2010 (OJ L 80, 26.3.2010, p. 36);
 - Commission Regulation (EU) No 301/2011 of 28 March 2011 (OJ L 81, 29.3.2011, p. 5);
 - Commission Regulation (EU) No 273/2012 of 27 March 2012 (OJ L 90, 28.3.2012, p. 11) and
 - Commission Regulation (EU) No 220/2013 of 13 March 2013 (OJ L 70, 14.3.2013, p. 1).
5. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).
6. Commission Regulation (EC) No 668/2009 of 24 July 2009 implementing Regulation (EC) No 1394/2007 of the European Parliament and of the Council with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises (OJ L 194, 25.7.2009, p. 7).

7. Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as amended by:

- Commission Regulation (EU) No 758/2010 of 24 August 2010 (OJ L 223, 25.8.2010, p. 37);
- Commission Regulation (EU) No 759/2010 of 24 August 2010 (OJ L 223, 25.8.2010, p. 39);
- Commission Regulation (EU) No 761/2010 of 25 August 2010 (OJ L 224, 26.8.2010, p. 1);
- Commission Regulation (EU) No 890/2010 of 8 October 2010 (OJ L 266, 9.10.2010, p. 1);
- Commission Regulation (EU) No 914/2010 of 12 October 2010 (OJ L 269, 13.10.2010, p. 5);
- Commission Regulation (EU) No 362/2011 of 13 April 2011 (OJ L 100, 14.4.2011, p. 26);
- Commission Regulation (EU) No 363/2011 of 13 April 2011 (OJ L 100, 14.4.2011, p. 28);
- Commission Implementing Regulation (EU) No 84/2012 of 1 February 2012 (OJ L 30, 2.2.2012, p. 1);
- Commission Implementing Regulation (EU) No 85/2012 of 1 February 2012 (OJ L 30, 2.2.2012, p. 4);
- Commission Implementing Regulation (EU) No 86/2012 of 1 February 2012 (OJ L 30, 2.2.2012, p. 6);
- Commission Implementing Regulation (EU) No 107/2012 of 8 February 2012 (OJ L 36, 9.2.2012, p. 25);
- Commission Implementing Regulation (EU) No 122/2012 of 13 February 2012 (OJ L 40, 14.2.2012, p. 2);
- Commission Implementing Regulation (EU) No 123/2012 of 13 February 2012 (OJ L 40, 14.2.2012, p. 4);
- Commission Implementing Regulation (EU) No 201/2012 of 8 March 2012 (OJ L 71, 9.3.2012, p. 37);
- Commission Implementing Regulation (EU) No 202/2012 of 8 March 2012 (OJ L 71, 9.3.2012, p. 40);
- Commission Implementing Regulation (EU) No 221/2012 of 14 March 2012 (OJ L 75, 15.3.2012, p. 7);
- Commission Implementing Regulation (EU) No 222/2012 of 14 March 2012 (OJ L 75, 15.3.2012, p. 10);
- Commission Implementing Regulation (EU) No 436/2012 of 23 May 2012 (OJ L 134, 24.5.2012, p. 10);
- Commission Implementing Regulation (EU) No 466/2012 of 1 June 2012 (OJ L 143, 2.6.2012, p. 2);
- Commission Implementing Regulation (EU) No 1161/2012 of 7 December 2012 (OJ L 336, 8.12.2012, p. 14);
- Commission Implementing Regulation (EU) No 1186/2012 of 11 December 2012 (OJ L 338, 12.12.2012, p. 20);
- Commission Implementing Regulation (EU) No 1191/2012 of 12 December 2012 (OJ L 340, 13.12.2012, p. 35);
- Commission Implementing Regulation (EU) No 59/2013 of 23 January 2013 (OJ L 21, 24.1.2013, p. 21);
- Commission Implementing Regulation (EU) No 115/2013 of 8 February 2013 (OJ L 38, 9.2.2013, p. 11.);
- Commission Implementing Regulation (EU) No 116/2013 of 8 February 2013, (OJ L 38, 9.2.2013, p. 14);
- Commission Implementing Regulation (EU) No 394/2013 of 29 April 2013, (OJ L 118, 30.4.2013, p. 17) and
- Commission Implementing Regulation (EU) No 406/2013 of 2 May 2013, (OJ L 121, 3.5.2013, p. 42).

8. Commission Regulation (EU) No 488/2012 of 8 June 2012 amending Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 150, 9.6.2012, p. 68).
9. Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 209, 4.8.2012, p. 4).
10. Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring (OJ L 65, 8.3.2013, p. 17).
11. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).
12. Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (OJ L 109, 30.4.2009, p. 10).
13. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121), as amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ L 348, 31.12.2010, p. 1).
14. Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10).
15. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1), as amended by:
 - Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 (OJ L 152, 16.6.2009, p. 1) and
 - Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 (OJ L 378, 27.12.2006, p. 20).
16. Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6).
17. Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).
18. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).
19. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44), as amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ L 87, 31.3.2009, p. 109).
20. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28) as amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ L 87, 31.3.2009, p. 109).
21. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).
22. Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines (OJ L 135, 3.6.2003, p. 5), as amended by:

- Commission Regulation (EC) No 1876/2004 of 28 October 2004 (OJ L 326, 29.10.2004, p. 22) and
 - Commission Regulation (EC) No 1662/2005 of 11 October 2005 (OJ L 267, 12.10.2005, p. 19).
23. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1), as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14).
24. Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).
25. 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).
26. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34), as amended by:
- Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ L 378, 27.12.2006, p. 1) and
 - Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14).
27. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30) (only as regards the collection and testing of blood and blood components used as starting materials for manufacturing medicinal products).
28. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48) (only as regards the procurement, donation, coding and testing of tissue and cells, as well as the coding of donations and packaging thereof, used as starting materials for advanced therapy medicinal products as referred to in Regulation (EC) No 1394/2007 of the European Parliament and of the Council).

II. COSMETICS

ACTS REFERRED TO

1. Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169), as amended by:
- Council Directive 79/661/EEC of 24 July 1979 (OJ L 192, 31.7.1979, p. 35);
 - Commission Directive 82/147/EEC of 11 February 1982 (OJ L 63, 6.3.1982, p. 26);
 - Council Directive 82/368/EEC of 17 May 1982 (OJ L 167, 15.6.1982, p. 1);
 - Commission Directive 83/191/EEC of 30 March 1983 (OJ L 109, 26.4.1983, p. 25);
 - Commission Directive 83/341/EEC of 29 June 1983 (OJ L 188, 13.7.1983, p. 15);
 - Commission Directive 83/496/EEC of 22 September 1983 (OJ L 275, 8.10.1983, p. 20);
 - Council Directive 83/574/EEC of 26 October 1983 (OJ L 332, 28.11.1983, p. 38);
 - Commission Directive 84/415/EEC of 18 July 1984 (OJ L 228, 25.8.1984, p. 31);
 - Commission Directive 85/391/EEC of 16 July 1985 (OJ L 224, 22.8.1985, p. 40);
 - Commission Directive 86/179/EEC of 28 February 1986 (OJ L 138, 24.5.1986, p. 40);
 - Commission Directive 86/199/EEC of 26 March 1986 (OJ L 149, 3.6.1986, p. 38);
 - Commission Directive 87/137/EEC of 2 February 1987 (OJ L 56, 26.2.1987, p. 20);
 - Commission Directive 88/233/EEC of 2 March 1988 (OJ L 105, 26.4.1988, p. 11);
 - Council Directive 88/667/EEC of 21 December 1988 (OJ L 382, 31.12.1988, p. 46);
 - Commission Directive 89/174/EEC of 21 February 1989 (OJ L 64, 8.3.1989, p. 10);
 - Council Directive 89/679/EEC of 21 December 1989 (OJ L 398, 30.12.1989, p. 25);

- Commission Directive 90/121/EEC of 20 February 1990 (OJ L 71, 17.3.1990, p. 40);
- Commission Directive 91/184/EEC of 12 March 1991 (OJ L 91, 12.4.1991, p. 59);
- Commission Directive 92/8/EEC of 18 February 1992 (OJ L 70, 17.3.1992, p. 23);
- Commission Directive 92/86/EEC of 21 October 1992 (OJ L 325, 11.11.1992, p. 18);
- Council Directive 93/35/EEC of 14 June 1993 (OJ L 151, 23.6.1993, p. 32);
- Commission Directive 93/47/EEC of 22 June 1993 (OJ L 203, 13.8.1993, p. 24);
- Commission Directive 94/32/EC of 29 June 1994 (OJ L 181, 15.7.1994, p. 31);
- Commission Directive 95/34/EC of 10 July 1995 (OJ L 167, 18.7.1995, p. 19);
- Commission Directive 96/41/EC of 25 June 1996 (OJ L 198, 8.8.1996, p. 36);
- Commission Directive 97/1/EC of 10 January 1997 (OJ L 16, 18.1.1997, p. 85);
- Commission Directive 97/18/EC of 17 April 1997 (OJ L 114, 1.5.1997, p. 43);
- Commission Directive 97/45/EC of 14 July 1997 (OJ L 196, 24.7.1997, p. 77);
- Commission Directive 98/16/EC of 5 March 1998 (OJ L 77, 14.3.1998, p. 44);
- Commission Directive 98/62/EC of 3 September 1998 (OJ L 253, 15.9.1998, p. 20);
- Commission Directive 2000/6/EC of 29 February 2000 (OJ L 56, 1.3.2000, p. 42);
- Commission Directive 2000/11/EC of 10 March 2000 (OJ L 65, 14.3.2000, p. 22);
- Commission Directive 2000/41/EC of 19 June 2000 (OJ L 145, 20.6.2000, p. 25);
- Commission Directive 2002/34/EC of 15 April 2002 (OJ L 102, 18.4.2002, p. 19);
- Commission Directive 2003/1/EC of 6 January 2003 (OJ L 5, 10.1.2003, p. 14);
- Commission Directive 2003/16/EC of 19 February 2003 (OJ L 46, 20.2.2003, p. 24);
- Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 (OJ L 66, 11.3.2003, p. 26);
- Commission Directive 2003/80/EC of 5 September 2003 (OJ L 224, 6.9.2003, p. 27);
- Commission Directive 2003/83/EC of 24 September 2003 (OJ L 238, 25.9.2003, p. 23);
- Commission Directive 2004/87/EC of 7 September 2004 (OJ L 287, 8.9.2004, p. 4);
- Commission Directive 2004/88/EC of 7 September 2004 (OJ L 287, 8.9.2004, p. 5);
- Commission Directive 2004/94/EC of 15 September 2004 (OJ L 294, 17.9.2004, p. 28);
- Commission Directive 2004/93/EC of 21 September 2004 (OJ L 300, 25.9.2004, p. 13);
- Commission Directive 2005/9/EC of 28 January 2005 (OJ L 27, 29.1.2005, p. 46);
- Commission Directive 2005/42/EC of 20 June 2005 (OJ L 158, 21.6.2005, p. 17);
- Commission Directive 2005/52/EC of 9 September 2005 (OJ L 234, 10.9.2005, p. 9);
- Commission Directive 2005/80/EC of 21 November 2005 (OJ L 303, 22.11.2005, p. 32);
- Commission Directive 2006/65/EC of 19 July 2006 (OJ L 198, 20.7.2006, p. 11);
- Commission Directive 2006/78/EC of 29 September 2006 (OJ L 271, 30.9.2006, p. 56);
- Commission Directive 2007/1/EC of 29 January 2007 (OJ L 25, 1.2.2007, p. 9);
- Commission Directive 2007/17/EC of 22 March 2007 (OJ L 82, 23.3.2007, p. 27);
- Commission Directive 2007/22/EC of 17 April 2007 (OJ L 101, 18.4.2007, p. 11);
- Commission Directive 2007/53/EC of 29 August 2007 (OJ L 226, 30.8.2007, p. 19);
- Commission Directive 2007/54/EC of 29 August 2007 (OJ L 226, 30.8.2007, p. 21);
- Commission Directive 2007/67/EC of 22 November 2007 (OJ L 305, 23.11.2007, p. 22);
- Commission Directive 2008/14/EC of 15 February 2008 (OJ L 42, 16.2.2008, p. 43);
- Commission Directive 2008/42/EC of 3 April 2008 (OJ L 93, 4.4.2008, p. 13);
- Commission Directive 2008/88/EC of 23 September 2008 (OJ L 256, 24.9.2008, p. 12);

- Commission Directive 2008/123/EC of 18 December 2008 (OJ L 340, 19.12.2008, p. 71);
 - Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 (OJ L 345, 23.12.2008, p. 68);
 - Commission Directive 2009/6/EC of 4 February 2009 (OJ L 36, 5.2.2009, p. 15);
 - Commission Directive 2009/36/EC of 16 April 2009 (OJ L 98, 17.4.2009, p. 31);
 - Commission Directive 2009/129/EC of 9 October 2009 (OJ L 267, 10.10.2009, p. 18);
 - Commission Directive 2009/130/EC of 12 October 2009 (OJ L 268, 13.10.2009, p. 5);
 - Commission Directive 2009/134/EC of 28 October 2009 (OJ L 282, 29.10.2009, p. 15);
 - Commission Directive 2009/159/EU of 16 December 2009 (OJ L 336, 18.12.2009, p. 29);
 - Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 (OJ L 342, 22.12.2009, p. 59);
 - Commission Directive 2009/164/EU of 22 December 2009 (OJ L 344, 23.12.2009, p. 41);
 - Commission Directive 2010/3/EU of 1 February 2010 (OJ L 29, 2.2.2010, p. 5);
 - Commission Directive 2010/4/EU of 8 February 2010 (OJ L 36, 9.2.2010, p. 21);
 - Commission Directive 2011/59/EU of 13 May 2011 (OJ L 125, 14.5.2011, p. 17);
 - Council Directive 2011/84/EU of 20 September 2011 (OJ L 283, 29.10.2011, p. 36) and
 - Commission Implementing Directive 2012/21/EU of 2 August 2012 (OJ L 208, 3.8.2012, p. 8).
- Directive 76/768/EEC will be repealed with effect from 11 July 2013 and will be replaced by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).
2. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. (OJ L 342, 22.12.2009, p. 59), as amended by:
 - Commission Regulation (EU) No 344/2013 of 4 April 2013 amending Annexes II, III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 114, 25.4.2013, p. 1) and
 - Commission Regulation (EU) No 483/2013 of 24 May 2013 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 139, 25.5.2013, p. 8).
 3. Commission Directive 80/1335/EEC of 22 December 1980 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 383, 31.12.1980, p. 27), as amended by Commission Directive 87/143/EEC of 10 February 1987 (OJ L 57, 27.2.1987, p. 56).
 4. Commission Directive 82/434/EEC of 14 May 1982 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 185, 30.6.1982, p. 1), as amended by Commission Directive 90/207/EEC of 4 April 1990 (OJ L 108, 28.4.1990, p. 92).
 5. Commission Directive 83/514/EEC of 27 September 1983 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 291, 24.10.1983, p. 9).
 6. Commission Directive 85/490/EEC of 11 October 1985 on the approximation of laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 295, 7.11.1985, p. 30).
 7. Commission Directive 93/73/EEC of 9 September 1993 on the methods of analysis necessary for checking the composition of cosmetic products (OJ L 231, 14.9.1993, p. 34).
 8. Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products (OJ L 140, 23.6.1995, p. 26), as amended by:
 - Commission Directive 2006/81/EC of 23 October 2006 (OJ L 362, 20.12.2006, p. 92) and
 - Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ L 236, 23.9.2003, p. 33).

Commission Directive 95/17/EC will be repealed with effect from 11 July 2013.

9. Commission Directive 95/32/EC of 7 July 1995 relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 178, 28.7.1995, p. 20).
10. Commission Directive 96/45/EC of 2 July 1996 relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 213, 22.8.1996, p. 8).
11. Commission Decision of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (OJ L 132, 1.6.1996, p. 1) as amended by Commission Decision 2006/257/EC, (OJ L 97, 5.4.2006, p. 1).

III. MEDICAL DEVICES

ACTS REFERRED TO

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), as amended by:
 - Council Directive 93/42/EEC of 14 June 1993 (OJ L 169, 12.7.1993, p. 1);
 - Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1);
 - Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and
 - Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ L 247, 21.9.2007, p. 21).
2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1), as amended by:
 - Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1);
 - Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma (OJ L 313, 13.12.2000, p. 22);
 - Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices (OJ L 6, 10.1.2002, p. 50);
 - Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and
 - Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ L 247, 21.9.2007, p. 21).
3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), as amended by:
 - Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1);
 - Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14) and
 - Commission Directive 2011/100/EU of 20 December 2011 (OJ L 341, 22.12.2011, p. 50).
4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro diagnostic medical devices (OJ L 131, 16.5.2002, p. 17), as amended by:
 - Commission Decision 2009/108/EC of 3 February 2009 (OJ L 39, 10.2.2009, p. 34);
 - Commission Decision 2009/886/EC of 27 November 2009 (OJ L 318, 4.12.2009, p. 25) and
 - Commission Decision 2011/869/EU of 20 December 2011 (OJ L 341, 22.12.2011, p. 63).
5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).
6. Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (OJ L 105, 26.4.2003, p. 18).

7. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).
 8. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45).
 9. Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).
 10. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3).
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COUNCIL DECISION

of 22 July 2013

amending Decision 97/836/EC with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement')

(2013/456/EU)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) By Council Decision 97/836/EC⁽¹⁾, the Union has acceded to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement').

(2) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)⁽²⁾ replaced the Member States' approval systems with a Union approval procedure, establishing a harmonised framework containing the administrative provisions and general technical requirements for all new vehicles, systems, components and separate technical units. That Directive incorporated UNECE Regulations in the EU vehicle type-approval system, either as requirements for type-approval or as alternatives to EU legislation. Since the adoption of Directive 2007/46/EC, UNECE Regulations have increasingly been incorporated into Union legislation in the framework of EU vehicle type-approval.

(3) Changes to the Treaties on which the Union is founded occurred after the adoption of Decision 97/836/EC. The

Treaty on the Functioning of the European Union has substantially altered the procedure to be followed for the conclusion of agreements between the Union and international organisations, making it necessary to adapt Decision 97/836/EC to the new procedures.

(4) The procedure for establishing the position to be adopted on the Union's behalf in the United Nations concerning the adoption of UNECE Regulations or amendments to UNECE Regulations should be adapted to the new procedures set out in Article 218(9) of the Treaty on the Functioning of the European Union.

(5) The same procedure should also be followed when the Union decides to apply UNECE Regulations to which it had not acceded at the time of its accession to the Revised Agreement, or decides to cease to apply a UNECE Regulation that it has previously accepted.

(6) It is appropriate that the procedure for adopting proposed amendments to the Revised Agreement submitted by the Union, as well as the decision whether to raise an objection to a proposed amendment, be the same as the procedure for the accession to international agreements.

(7) Decision 97/836/EC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 97/836/EC is hereby amended as follows:

(1) Paragraphs 2 and 3 of Article 3 are replaced by the following:

'2. Pursuant to Article 1(6) of the Revised Agreement, the Union may, in accordance with the procedure laid down in Article 218(9) of the Treaty on the Functioning of the European Union (TFEU), decide to cease to apply a UN/ECE Regulation that it has previously accepted.

⁽¹⁾ OJ L 346, 17.12.1997, p. 78.

⁽²⁾ OJ L 263, 9.10.2007, p. 1.

3. Pursuant to Article 1(7) of the Revised Agreement, the Union may, in accordance with the procedure laid down in Article 218(9) TFEU, decide to apply one, some or all of the UN/ECE Regulations to which it has not acceded at the time of its accession to the Revised Agreement.’.

(2) Article 4 is hereby amended as follows:

(a) Paragraph 2 is replaced by the following:

‘2. The Union shall vote in favour of adopting any draft UN/ECE Regulation or a draft amendment to a UN/ECE Regulation where the draft has been approved in accordance with the procedure set out in Article 218(9) TFEU.’;

(b) Paragraph 4 is deleted. References to Article 4(4) in Directive 2007/46/EC and Regulation (EC) No 661/2009 of the European Parliament and of the Council ⁽¹⁾ shall be construed as references to Article 4(2).

(3) Article 5 is replaced by the following:

Article 5

1. The proposed amendments to the Revised Agreement submitted to the Contracting Parties on behalf of the Union shall be adopted in accordance with the procedure set out in Article 218(6)(a) TFEU.

2. The decision whether or not to raise an objection to a proposed amendment to the Revised Agreement put forward by another Contracting Party shall be taken in accordance with the procedure set out in Article 218(6)(a) TFEU.

Where that procedure has not been completed a week before expiry of the deadline provided for in Article 13(2) of the Revised Agreement, the Union shall state an objection to the amendment before that deadline expires.’.

(4) Annex III is hereby amended as follows:

(a) Point 1 is amended as follows:

(i) The first paragraph is replaced by the following:

‘The contribution of the Union with regard to the priorities of the work programme shall be established as appropriate in accordance with the procedure laid down in Articles 218(3) and (4) TFEU in conjunction with Article 207(2) TFEU.’;

(ii) In the third paragraph, the first sentence is replaced by the following:

‘Following this preparatory phase, the Commission shall represent the Union in the Administrative Committee as set up by Article 1 of the Revised Agreement as spokesman for the Union, in conformity with Article 207 TFEU.’.

(b) In point 2, the second sentence of the second paragraph is replaced by the following:

‘For this purpose the Commission shall submit its proposal as soon as all of the essential components of the draft UN/ECE Regulation have been supplied.’.

Article 2

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

Done at Brussels, 22 July 2013.

For the Council
The President
C. ASHTON

⁽¹⁾ OJ L 200, 31.7.2009, p. 1.

NOTICE TO READERS

Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union*

In accordance with Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* (OJ L 69, 13.3.2013, p. 1), as of 1 July 2013, only the electronic edition of the Official Journal shall be considered authentic and shall have legal effect.

Where it is not possible to publish the electronic edition of the Official Journal due to unforeseen and exceptional circumstances, the printed edition shall be authentic and shall have legal effect in accordance with the terms and conditions set out in Article 3 of Regulation (EU) No 216/2013.

NOTE TO READERS — WAY OF REFERRING TO ACTS

As of 1 July 2013 the way of referring to acts has changed.

During a transitional period this new practice will coexist with the previous one.

EUR-Lex (<http://new.eur-lex.europa.eu>) offers direct access to European Union legislation free of charge. The *Official Journal of the European Union* can be consulted on this website, as can the Treaties, legislation, case-law and preparatory acts.

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2985 Luxembourg
LUXEMBOURG

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