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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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2016/124**of 29 January 2016****approving PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-type 4****(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 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes PHMB (1600; 1.8).
- (2) PHMB (1600; 1.8) has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council ⁽³⁾ for use in product-type 4, food and feed area disinfectants, as defined in Annex V to that Directive, which corresponds to product-type 4 as defined in Annex V to Regulation (EU) No 528/2012.
- (3) France was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 10 April 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ⁽⁴⁾.
- (4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 17 June 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products used for product-type 4 and containing PHMB (1600; 1.8) may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain conditions concerning its use are complied with.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

⁽³⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽⁴⁾ Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

- (6) It is therefore appropriate to approve PHMB (1600; 1.8) for use in biocidal products for product-type 4 subject to compliance with certain specifications and conditions.
- (7) The opinion concludes that the characteristics of PHMB (1600; 1.8) render it very persistent (vP) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽¹⁾.
- (8) Since, pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved in accordance with Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.
- (9) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, PHMB (1600; 1.8) meets the conditions of Article 10(1)(d) of that Regulation and should therefore be considered a candidate for substitution.
- (10) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing PHMB (1600; 1.8) in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁽²⁾. Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of Regulation (EC) No 1935/2004. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.
- (11) Since PHMB (1600; 1.8) meets the criteria for being very persistent (vP) according to Annex XIII to Regulation (EC) No 1907/2006, treated articles treated with or incorporating PHMB (1600; 1.8) should be appropriately labelled when placed on the market.
- (12) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

PHMB (1600; 1.8) is approved as an active substance for use in biocidal products for product-type 4, subject to the specifications and conditions set out in the Annex.

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*.

⁽¹⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁽²⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

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

Done at Brussels, 29 January 2016.

For the Commission

The President

Jean-Claude JUNKER

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
PHMB (1600; 1.8) (polyhexamethylene bi- guanide hydrochloride with a mean number- average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8)	IUPAC Name: CoPoly(bisiminoimido- carbonyl, hexamethy- lene hydrochloride), (iminoimidocarbonyl, hexamethylene hydro- chloride) EC No: n.a. CAS No: 27083-27-8 and 32289-58-0	956 g/kg (calculated dry weight specifica- tion). The active substance as manufactured is an aqueous solution of 20 % w/w of PHMB (1600; 1.8)	1 July 2017	30 June 2027	4	PHMB (1600; 1.8) is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks identified for human health and the aquatic and soil compartments, products shall not be authorised for use as disinfectant of utensils by dipping, unless it can be demonstrated that risks can be reduced to an acceptable level. (3) In view of the risks identified for human health and the aquatic compartment, products shall not be authorised for surface disinfection by mopping, unless it can be demonstrated that risks can be reduced to an acceptable level. (4) In view of the risks identified for human health, labels, and where provided, safety data sheets of ready-to-use wipes shall indicate that the use is restricted to areas not accessible to the general public, unless it can be demonstrated that risks can be reduced to an acceptable level by other means. (5) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ⁽²⁾ or Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁾ shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
						(6) Products shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of PHMB (1600; 1.8) into food or it has been established pursuant to that Regulation that such limits are not necessary. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating PHMB (1600; 1.8) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

(¹) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 16(2) of Directive 98/8/EC. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(²) 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).

(³) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2016/125**of 29 January 2016****approving PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-types 2, 3, 11****(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 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes PHMB (1600; 1.8).
- (2) PHMB (1600; 1.8) has been evaluated for use in product-type 2, disinfectants and algacides not intended for direct application to humans or animals, product-type 3, veterinary hygiene, and product-type 11, preservatives for liquid-cooling and processing systems, as defined in Annex V to Regulation (EU) No 528/2012.
- (3) France was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, on 8 October 2013 and 14 November 2013.
- (4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 17 June 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products used for product-types 2, 3, and 11 and containing PHMB (1600; 1.8) may be expected to satisfy the requirements of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve PHMB (1600; 1.8) for use in biocidal products for product-types 2, 3, and 11 subject to compliance with certain specifications and conditions.
- (7) The opinions conclude that the characteristics of PHMB (1600; 1.8) render it very persistent (vP) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾.
- (8) PHMB (1600; 1.8) meets the conditions set out in point (d) of Article 10(1) of Regulation (EU) No 528/2012 and should therefore be considered a candidate for substitution.
- (9) Pursuant to Article 10(4) of Regulation (EU) No 528/2012, the approval of an active substance that is considered as a candidate for substitution should be for a period not exceeding 7 years.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

⁽³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (10) Since PHMB (1600; 1.8) meets the criteria for being very persistent (vP) according to Annex XIII to Regulation (EC) No 1907/2006, treated articles treated with or incorporating PHMB (1600; 1.8) should be appropriately labelled when placed on the market.
- (11) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

PHMB (1600; 1.8) is approved as an active substance for use in biocidal products for product-types 2, 3, and 11, subject to the specifications and conditions set out in the Annex.

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, 29 January 2016.

For the Commission

The President

Jean-Claude JUNKER

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
PHMB (1600; 1.8) (polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8)	IUPAC Name: CoPoly(bisiminoimido-carbonyl, hexamethylene hydrochloride), (iminoimidocarbonyl, hexamethylene hydrochloride) EC No: n.a. CAS No: 27083-27-8 and 32289-58-0	956 g/kg (calculated dry weight specification). The active substance as manufactured is an aqueous solution of 20 % w/w of PHMB (1600; 1.8)	1 July 2017	30 June 2024	2	PHMB (1600; 1.8) is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions. (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks identified for human health and the environment, products shall not be authorised for the treatment of swimming pools, unless it can be demonstrated that risks can be reduced to an acceptable level. (3) In view of the risks identified for human health and the environment, products shall not be authorised for disinfection of medical equipment by dipping, unless it can be demonstrated that risks can be reduced to an acceptable level. (4) In view of the risks identified for human health, ready-to-use wipes shall not be authorised for non-professionals, unless it can be demonstrated that risks can be reduced to an acceptable level. (5) In view of the risks identified for human health, labels, and where provided, safety data sheets of ready-to-use wipes shall indicate that the use is restricted to areas not accessible to the general public, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
						The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating PHMB (1600; 1.8) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					3	PHMB (1600; 1.8) is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions. (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks identified for human health, products shall not be authorised for disinfection of equipment by dipping, unless it can be demonstrated that risks can be reduced to an acceptable level. In addition, in case products are authorised, in view of the risks identified for the environment, labels, and where provided, safety data sheets shall indicate that no release to sewage treatment plants shall be allowed, unless it can be demonstrated that risks can be reduced to an acceptable level by other means. (3) In view of the risks identified for human health, labels, and where provided, safety data sheets of ready-to-use wipes shall indicate that the use is restricted to areas not accessible to the general public, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
						(4) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ⁽²⁾ or Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁾ shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating PHMB (1600; 1.8) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					11	PHMB (1600; 1.8) is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions. (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks identified for human health, labels and, where provided, safety data sheets shall indicate that loading of product into the cooling system shall be automated, that the pump shall be rinsed before cleaning and that appropriate personal protective equipment shall be worn during the cleaning phase, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
						(3) In view of the risks identified for water, sediments and soil, labels and, where provided, safety data sheets shall indicate that disposal of preserved liquids following drainage of the closed recirculating system shall be handled as hazardous waste, unless it can be demonstrated at product authorisation that risks to the environment can be reduced to an acceptable level by other means. The placing on the market of treated articles is subject to the following condition. The person responsible for the placing on the market of a treated article treated with or incorporating PHMB (1600; 1.8) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

(¹) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1). The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(²) 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).

(³) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2016/126**of 29 January 2016****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, 29 January 2016.

*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	IL	236,2
	MA	83,1
	TN	116,3
	TR	86,7
	ZZ	130,6
0707 00 05	MA	86,8
	TR	178,3
	ZZ	132,6
0709 93 10	MA	50,0
	TR	154,7
	ZZ	102,4
0805 10 20	EG	47,5
	MA	61,2
	TN	56,9
	TR	65,6
	ZZ	57,8
0805 20 10	IL	147,6
	MA	79,2
	ZZ	113,4
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	121,8
	JM	154,6
	MA	114,1
	TR	105,3
	ZZ	124,0
0805 50 10	TR	105,2
	ZZ	105,2
0808 10 80	CL	87,9
	US	161,8
	ZZ	124,9
0808 30 90	CL	224,0
	CN	57,3
	TR	200,0
	ZA	87,5
	ZZ	142,2

⁽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'.

