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(<sup>1</sup>) Text with EEA relevance

EN

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## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) No 197/2014

of 28 February 2014

concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff<sup>(1)</sup>, and in particular Article 9(1)(a) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 12(6) of Council Regulation (EEC) No 2913/92<sup>(2)</sup>. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

*Article 1*

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

*Article 2*

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 12(6) of Regulation (EEC) No 2913/92 for a period of three months from the date of entry into force of this Regulation.

*Article 3*

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

<sup>(1)</sup> OJ L 256, 7.9.1987, p. 1.

<sup>(2)</sup> Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

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

Done at Brussels, 28 February 2014.

*For the Commission,  
On behalf of the President,  
Algirdas ŠEMETA  
Member of the Commission*

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## ANNEX

Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
<p>The product is a round, moulded bowl, of plastics. Its diameter is approximately 18,5 cm and its height is approximately 7 cm. The bowl holds approximately 700 ml.</p> <p>The bowl is a container for pet food to feed animals (for example, dogs).</p>	3924 90 00	<p>Classification is determined by the general rules 1 and 6 for the interpretation of the Combined Nomenclature and by the wording of CN codes 3924 and 3924 90 00.</p> <p>Heading 3924 covers a wide range of household articles and does not exclude articles not intended for use by humans. Given its objective characteristics, the pet food bowl is considered a household article of heading 3924.</p> <p>The product is therefore to be classified under CN code 3924 90 00 as other household articles and hygienic or toilet articles of plastics.</p>

**COMMISSION IMPLEMENTING REGULATION (EU) No 198/2014**  
**of 28 February 2014**  
**concerning the classification of certain goods in the Combined Nomenclature**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff<sup>(1)</sup>, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 12(6) of Council Regulation (EEC) No 2913/92<sup>(2)</sup>. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

*Article 1*

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

*Article 2*

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 12(6) of Regulation (EEC) No 2913/92 for a period of three months from the date of entry into force of this Regulation.

*Article 3*

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

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

Done at Brussels, 28 February 2014.

*For the Commission,  
On behalf of the President,  
Algirdas ŠEMETA  
Member of the Commission*

<sup>(1)</sup> OJ L 256, 7.9.1987, p. 1.

<sup>(2)</sup> Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

## ANNEX

Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
<p>A product presented in tablets, put up for retail sale in a plastic box containing 30 tablets. The content of each tablet consists of the following components:</p> <ul style="list-style-type: none"> <li>— bromelain (500 mg),</li> <li>— cellulose,</li> <li>— calcium phosphate,</li> <li>— silica,</li> <li>— magnesium stearate.</li> </ul> <p>According to the label the product is presented as a food supplement for human consumption.</p>	2106 90 92	<p>Classification is determined by General Rules 1 and 6 for the interpretation of the Combined Nomenclature, Additional Note 5 to Chapter 21 and the wording of CN codes 2106, 2106 90 and 2106 90 92.</p> <p>The product does not exhibit clearly defined prophylactic or therapeutic properties. Consequently, it cannot be classified under heading 3004 as a medicament.</p> <p>As the product is a food preparation presented in the form of measured doses and intended for use as a food supplement, the requirements of Additional Note 5 to Chapter 21 are fulfilled.</p> <p>The product is a preparation of enzymes with added substances and a presentation that renders it suitable for a specific purpose, namely as a food supplement for human consumption (see also the Harmonized System Explanatory Notes to heading 3507, point (C), first paragraph). Consequently, as the product is covered by Additional Note 5 to Chapter 21, classification under heading 3507 as a prepared enzyme is excluded.</p> <p>The product is therefore to be classified under heading 2106 as a food preparation not elsewhere specified or included.</p>

**COMMISSION IMPLEMENTING REGULATION (EU) No 199/2014**  
**of 28 February 2014**  
**concerning the classification of certain goods in the Combined Nomenclature**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff<sup>(1)</sup>, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 12(6) of Council Regulation (EEC) No 2913/92<sup>(2)</sup>. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

*Article 1*

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

*Article 2*

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 12(6) of Regulation (EEC) No 2913/92 for a period of three months from the date of entry into force of this Regulation.

*Article 3*

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

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

Done at Brussels, 28 February 2014.

*For the Commission,  
On behalf of the President,  
Algirdas ŠEMETA  
Member of the Commission*

<sup>(1)</sup> OJ L 256, 7.9.1987, p. 1.

<sup>(2)</sup> Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).



## ANNEX

Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
<p>A product in the form of a stylised giraffe (approximately 36 cm high and weighing approximately 820 g), consisting of a soft, textile exterior filled with various materials. The head is filled with a soft textile material while the body and limbs contain a loose millet and lavender filling (which cannot be taken out for use as a separate cushion).</p> <p>The product can be heated in either a microwave or a traditional oven and also cooled in either a fridge or a freezer in order to be used as a heating or cooling cushion.</p> <p>(*) See image.</p>	9503 00 41	<p>Classification is determined by the general rules 1 and 6 for the interpretation of the Combined Nomenclature and by the wording of CN codes 9503 00 and 9503 00 41.</p> <p>Given its design and presentation, the product is basically intended for entertaining children and adults (see also the Harmonized System Explanatory Notes to Chapter 95, General, and to heading 9503, letter (D)). Any other use based on its warming or cooling capacity is considered subsidiary to its entertainment value. The product is therefore considered to be a toy of heading 9503. Classification on the basis of one of its constituent materials (for example, as millet under heading 1008 or as other made-up textile article under heading 6307) is therefore excluded.</p> <p>The product is therefore to be classified as a stuffed toy representing an animal under CN code 9503 00 41.</p>

(\*) The image is for information purposes only.



## COMMISSION IMPLEMENTING REGULATION (EU) No 200/2014

of 3 March 2014

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance triptorelin acetate

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 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 <sup>(1)</sup>, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) The maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is to be established in accordance with Regulation (EC) No 470/2009.
- (2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 <sup>(2)</sup>.
- (3) An application for the establishment of maximum residue limits for triptorelin acetate in porcine species has been submitted to the European Medicines Agency.

- (4) The Committee for Medicinal Products for Veterinary Use recommended that there is no need to establish an MRL for triptorelin acetate in porcine species.
- (5) In accordance with Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.
- (6) The CVMP recommended the extrapolation of the evaluation results for triptorelin acetate from porcine species to all food producing species.
- (7) Regulation (EU) No 37/2010 should therefore be amended to include the substance triptorelin acetate for all food producing species, while establishing the absence of the need to establish an MRL.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

*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, 3 March 2014.

For the Commission

The President

José Manuel BARROSO

<sup>(1)</sup> OJ L 152, 16.6.2009, p. 11.

<sup>(2)</sup> 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 (OJ L 15, 20.1.2010, p. 1).

## ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the following substance is inserted in alphabetical order:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
Triptorelin acetate	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Agents acting on the reproductive system'

## COMMISSION IMPLEMENTING REGULATION (EU) No 201/2014

of 3 March 2014

## amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 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 <sup>(1)</sup>, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) The maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is to be established in accordance with Regulation (EC) No 470/2009.
- (2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 <sup>(2)</sup>.
- (3) Table 1 of the Annex to Commission Regulation (EU) No 759/2010 <sup>(3)</sup> provisionally lists tildipirosin as an allowed substance for bovine, caprine and porcine species, applicable to muscle, fat (skin and fat for porcine species), liver, and kidney, excluding animals from which milk is produced for human consumption, until

1 January 2012. In accordance with that Annex, the MRLs for muscle did not apply to the injection site for which higher levels are provided for.

- (4) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend the establishment of final MRLs for tildipirosin for bovine, caprine and porcine species, applicable to muscle, fat (skin and fat in natural proportions for porcine species), liver and kidney, excluding animals from which milk is produced for human consumption. Taking into account that the Commission and residue control authorities consider that, in order to ensure the feasibility of residue controls, a single MRL for muscle must be established, the Committee for Medicinal Products for Veterinary Use, in a revised opinion, did not recommend to provide for a separate MRL for injection site muscle as this was the case in its previous opinions.
- (5) In accordance with Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.
- (6) The Committee for Medicinal Products for Veterinary Use recommended the extrapolation of the MRLs for tildipirosin in bovine species to caprine species. It also concluded that the extrapolation to other food producing species cannot be supported for this substance.
- (7) The entry for tildipirosin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include final MRLs for the pharmaceutical substance tildipirosin for bovine, caprine and porcine species, applicable to muscle, fat (skin and fat in natural proportions for porcine species), liver and kidney. The provisions on the MRLs for the injection site as regards muscle and on provisional MRLs should be removed.
- (8) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRLs.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

<sup>(1)</sup> OJ L 152, 16.6.2009, p. 11.

<sup>(2)</sup> 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 (OJ L 15, 20.1.2010, p. 1).

<sup>(3)</sup> Commission Regulation (EU) No 759/2010 of 24 August 2010 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin (OJ L 223, 25.8.2010, p. 39).

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

*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*.

It shall apply from 3 May 2014.

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

Done at Brussels, 3 March 2014.

*For the Commission*  
*The President*  
José Manuel BARROSO

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## ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance tildipirosin is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
Tildipirosin	Tildipirosin	Bovine, caprine	400 µg/kg 200 µg/kg 2 000 µg/kg 3 000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption.	Anti-infectious agents/Antibiotics'
		Porcine	1 200 µg/kg 800 µg/kg 5 000 µg/kg 10 000 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney		

**COMMISSION REGULATION (EU) No 202/2014****of 3 March 2014****amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 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<sup>(1)</sup>, and in particular Article 5(1), Article 11(3) and Article 12(6) thereof,

Whereas:

(1) Annex I to Commission Regulation (EU) No 10/2011<sup>(2)</sup> establishes a Union list of substances which may be used in the manufacture of plastic materials and articles ('Union list of authorised substances').

(2) On 24 July 2012 the European Food Safety Authority issued favourable scientific evaluations for two additional substances, namely 2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine<sup>(3)</sup> and 1,3-bis(isocyanatomethyl)benzene<sup>(4)</sup>. Those substances should now be added to the Union list of authorised substances as food contact material (FCM) substances Nos 872 and 988.

(3) From the scientific evaluation of FCM substance No 988 it follows that migration of its hydrolysis product, 1,3-benzenedimethanamine should be controlled. 1,3-benzenedimethanamine is already authorised as FCM substance No 421. As the migration of FCM substances Nos 421 and 988 is controlled on the basis of the migration of FCM substance No 421, a group restriction including both substances should be introduced. Therefore, the authorisation of FCM substance No 421 should be amended and the group restriction introduced in Table 2 of Annex I to Regulation (EU) No 10/2011.

(4) FCM substance No 340 (dicyanodiamide) is authorised as an additive in plastics in Table 1 of Annex I to Regulation (EU) No 10/2011 without a specific migration limit. The Opinion reported in the 33rd series of the Scientific Committee for Food<sup>(5)</sup> established a tolerable daily intake (TDI) of 1 mg/kg body weight resulting in a specific migration limit (SML) of 60 mg/kg food. This limit coincides with the generic specific migration limit established in Article 11(2) of Regulation (EU) No 10/2011. However, since the SML of 60 mg/kg is derived from a toxicological threshold such as the TDI, the SML should be specifically mentioned in Annex I to Regulation (EU) No 10/2011.

(5) In order to limit the administrative burden to business operators, plastic materials and articles which have been lawfully placed on the market based on the requirements set out in Regulation (EU) No 10/2011 and which do not comply with this Regulation should be able to be placed on the market until 24 March 2015. They should be able to remain on the market until exhaustion of stocks.

(6) Regulation (EU) No 10/2011 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

*Article 2*

Plastic materials and articles which have been lawfully placed on the market before 24 March 2014 and which do not comply with this Regulation may be placed on the market until 24 March 2015. Those plastic materials and articles may remain on the market after that date until the exhaustion of stocks.

<sup>(1)</sup> OJ L 338, 13.11.2004, p. 4.

<sup>(2)</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

<sup>(3)</sup> EFSA Journal 2012; 10(7):2825.

<sup>(4)</sup> EFSA Journal 2012;10(7):2824.

<sup>(5)</sup> Reports of the Scientific Committee for Food, 33rd series, p. 31, Office for Official publications of the European Communities, Luxembourg, 1995, ISBN 92-826-9275-2.

*Article 3*

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

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

Done at Brussels, 3 March 2014.

*For the Commission*  
*The President*  
José Manuel BARROSO

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## ANNEX

Annex I to Regulation (EU) No 10/2011 is amended as follows:

(1) Table 1 is amended as follows:

(a) the entry concerning FCM substance No 340 (dicyanodiamide) is replaced by the following:

'340	47440	0000461-58-5	dicyanodiamide	Yes	No	No	60'			
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(b) the entry concerning FCM substance No 421 (1,3-benzenedimethanamine) is replaced by the following:

'421	13000	0001477-55-0	1,3-benzenedimethanamine	No	Yes	No		(34)'		
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(c) the following entry is inserted in accordance with the numerical order:

'872		0006607-41-6	2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine	No	Yes	No	0,05		To be used only as a co-monomer in polycarbonate copolymers	(20)'
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(d) the following entry is added:

'988		3634-83-1	1,3-bis(isocyanatomethyl)benzene	No	Yes	No		(34)	SML(T) applies to the migration of its hydrolysis product, 1,3-benzenedimethanamine To be used only as co-monomer in the manufacture of a middle layer coating on a poly(ethylene terephthalate) polymer film in a multilayer film'	
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(2) In Table 2, the following entry is added:

'34	421 988	0,05	Expressed as 1,3-benzenedimethanamine'
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(3) In Table 3, the following entry is added:

'(20)	The substance contains aniline as an impurity; verification of compliance with the restriction set for primary aromatic amines in Annex II (2) is necessary.'
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**COMMISSION IMPLEMENTING REGULATION (EU) No 203/2014****of 3 March 2014****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) <sup>(1)</sup>,

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 <sup>(2)</sup>, 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, 3 March 2014.

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

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

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<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> 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 <sup>(1)</sup>	Standard import value
0702 00 00	MA	56,2
	TN	78,1
	TR	102,6
	ZZ	79,0
0707 00 05	JO	188,1
	MA	176,8
	TR	159,5
	ZZ	174,8
0709 91 00	EG	45,1
	ZZ	45,1
0709 93 10	MA	32,9
	TR	123,8
	ZZ	78,4
0805 10 20	EG	48,0
	IL	67,4
	MA	64,2
	TN	47,1
	TR	71,3
	ZZ	59,6
0805 50 10	TR	62,2
	ZZ	62,2
0808 10 80	CN	115,7
	MK	30,8
	US	156,1
	ZZ	100,9
0808 30 90	AR	89,5
	CL	190,5
	CN	73,6
	TR	156,2
	US	123,6
	ZA	98,3
	ZZ	122,0

<sup>(1)</sup> 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'.

# DECISIONS

## COMMISSION DECISION

of 3 March 2014

### on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC

(2014/113/EU)

THE EUROPEAN COMMISSION,

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

Whereas:

- (1) The Scientific Committee on Occupational Exposure Limits for Chemical Agents (hereinafter the Committee) was set up by Commission Decision 95/320/EC<sup>(1)</sup> to evaluate the health effects of chemical agents on workers at work. The work of the Committee directly supports Union regulatory activity in the field of occupational safety and health. It develops high quality comparative analytical knowledge and it ensures that Commission proposals, decisions and policy relating to the protection of workers' health and safety are based on sound scientific evidence.
- (2) The Committee assists the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limits (OELs) for the protection of workers from chemical risks, to be set at Union level pursuant to Council Directive 98/24/EC<sup>(2)</sup> and Directive 2004/37/EC of the European Parliament and of the Council<sup>(3)</sup>.
- (3) Members of SCOEL are highly qualified, specialized, independent experts selected on the basis of objective criteria. They are appointed in their personal capacity and

provide the Commission with Recommendations and Opinions that are necessary for the development of EU policy on workers' protection. The nature of the contribution is such that without it the Commission could not reach its social policy objectives to protect workers' health and safety. Therefore, these independent experts should receive remuneration beyond reimbursement of expenses, which is proportionate to the particular tasks attributed to them.

- (4) The work of the Committee makes an effective contribution to improving the working environment to protect workers' health and safety by providing the Commission with scientific evidence on the health effects of chemical agents on workers at work which is indispensable in order that the Commission is able to attain the relevant Union social policy objectives. Therefore, the financing of its activities will be provided by the relevant budget line that is dedicated to supporting initiatives in the social policies and working conditions field.
- (5) There is also a need to introduce improvements to the structure and working procedures of the Committee.
- (6) The Committee members should be selected through a call for expression of interest. This will ensure that the procedure respects the principles of equal opportunities and transparency.
- (7) With a view to ensuring continuity and efficiency of the Committee's work, the members appointed by Commission Decision 2009/985/EU<sup>(4)</sup> should remain in office until new members of the Committee are appointed.
- (8) Scientific advice that is given on matters relating to the protection of workers' health and safety must be based on the ethical principles of excellence, independence,

<sup>(1)</sup> Commission Decision 95/320/EC of 12 July 1995 setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents (OJ L 188, 9.8.1995, p. 14).

<sup>(2)</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

<sup>(3)</sup> Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

<sup>(4)</sup> Commission Decision 2009/985/EU of 18 December 2009 appointing members of the Scientific Committee for Occupational Exposure Limits to Chemical Agents for a new term of office (OJ L 338, 19.12.2009, p. 98).

impartiality and transparency, as developed in the Commission Communication on 'The collection and use of expertise by the Commission: principles and guidelines. Improving knowledge for better policies' <sup>(1)</sup>, and it must be organised in accordance with best practice principles of risk assessment.

- (9) Since substantive amendments are to be made to Decision 95/320/EC, that Decision should be repealed and replaced by a new Decision in the interest of clarity,

HAS ADOPTED THIS DECISION:

#### Article 1

### Scientific Committee on Occupational Exposure Limits to Chemical Agents

A Scientific Committee on Occupational Exposure Limits for Chemical Agents to evaluate the health effects of chemical agents on workers at work ('the Committee') shall be set up.

#### Article 2

##### Mission

1. The mission of the Committee shall be to provide the Commission with Recommendations or Opinions at the latter's request on any matter relating to the toxicological evaluation of chemicals for their effects on the health of workers.

2. The Committee, after consulting the Secretariat provided for in Article 5(3), shall adopt a methodology for the derivation of Occupational Exposure Limits ('OELs') and keep it under review, to reflect all relevant scientific factors relating to the setting of OELs. It shall ensure that its methodology reflects current risk assessment practice.

3. The Committee shall in particular recommend OELs based on scientific data, as defined in Directives 98/24/EC and 2004/37/EC, which shall include, but not be limited to:

- the eight-hour time weighted average (TWA);
- short-term limits/excursion limits (STEL);
- biological limit values/biological guidance values (BLV/BGV).

The OELs shall be supplemented, as appropriate, by further notations which shall include:

- likely absorption through the skin;
- sensitising potential;
- carcinogenic properties.

Additional appropriate notations may be introduced by amendments to the Committee's methodology document.

4. Any Recommendation for an OEL shall be supported and explained in detail by information on the basic data, a description of the critical effects, the extrapolation techniques used and any data on possible risks to human health. The feasibility of monitoring exposure at any proposed OEL shall also be noted.

5. The Commission may request the Committee to carry out other actions relating to the toxicological evaluation of chemical agents.

6. The Committee shall identify any lack of specific scientific information which may be necessary for the evaluation of chemical risks and shall inform the Commission accordingly.

7. The Committee shall identify current priority issues regarding health effects of chemicals and shall inform the Commission accordingly.

8. At the request of the Commission, the Committee shall set up thematic workshops in order to review data and scientific knowledge on chemical agents or issues related to its methodology. These workshops shall be organised with the support of the Secretariat of the Committee.

9. In carrying out its tasks the Committee, in accordance with article 5(5), shall seek to ensure cooperation with the relevant other bodies established under EU law, including Union Agencies, carrying out similar tasks in relation to issues of common concern.

#### Article 3

##### Appointment of Committee members

1. The Committee shall be composed of not more than twenty-one individual experts selected from a list of suitable candidates established following publication of a call for expression of interest in the *Official Journal of the European Union* and on the Commission website. A link from the Register of Commission expert groups and other similar entities ('the Register') to the web page where the call is published shall also be provided.

The members shall be appointed in a personal capacity by the Commission.

The members shall be selected on the basis of their proven scientific expertise and experience, having regard to the need to ensure:

- that the full range of scientific expertise which is necessary to fulfil the mission is reflected, including, in particular, chemistry, toxicology, epidemiology, occupational medicine and industrial hygiene, and general competence in setting OELs;
- a balanced geographical distribution of the members of the Committee.

<sup>(1)</sup> COM(2002) 713 final of 11 December 2002.

2. The members' names shall be published in the Register as well as in the *Official Journal of the European Union* for information purposes.

Personal data shall be collected, processed and published in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council <sup>(1)</sup>.

3. Members appointed by Decision 2009/985/EU in accordance with Decision 95/320/EC shall remain in office under the present Decision until the appointment of members for a new term of office in accordance with the procedure set out in paragraphs 1 and 2.

#### Article 4

##### Term of office

1. The term of office for members of the Committee shall be three years. After expiry of the three-year period, members of the Committee shall remain in office until they are replaced or until their appointments are renewed.

2. In the event of resignation of a member of the Committee before expiry of the three-year period or where a member is absent from more than one third of the meetings or is for any other reason no longer capable of contributing effectively to the Committee's deliberations, he/she may be replaced for the remainder of their term of office. In such a case, the Commission shall appoint a new member from the previous list of candidates in accordance with the procedure provided for in Article 3.

#### Article 5

##### Committee's Board and Secretariat

1. At the beginning of each term of office, the Committee shall elect from among its members, by simple majority, a chair and two vice-chairs. Those three members shall constitute the Board of the Committee ('the Board').

2. The Board shall be responsible for internal procedural Committee matters and shall chair the meetings with a view to achieving a scientific consensus on the Recommendations or Opinions to be adopted.

3. The Commission shall provide the Secretariat for the Committee and its working groups, along with the administrative support necessary for the efficient functioning of the Committee.

4. The Secretariat shall ensure effective cooperation of the Committee with other Scientific Committees and Union Agencies.

<sup>(1)</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

5. The Secretariat shall take care to ensure early identification of potential sources of conflict between the Committee's Recommendations and Opinions and those of other bodies established under EU law, including Union Agencies, carrying out a similar task in relation to issues of common concern.

#### Article 6

##### Working groups

1. At the request of the Board, the Committee may set up working groups from among its members, in agreement with the Commission services.

2. The working groups shall be required to discuss specific issues relevant to the work of the Committee, on the basis of terms of reference defined by the Committee, and to report back on the results of their deliberations. Such working groups shall be disbanded as soon as their task is completed.

#### Article 7

##### Plenary meetings of the Committee and meetings of the working groups

1. The Committee shall adopt its rules of procedure on the basis of the standard rules of procedure for Commission expert groups.

2. The plenary meetings of the Committee shall take place, as a general rule, four times a year.

3. The Commission services shall convene and take part in the plenary meetings of the Committee and shall convene the meetings of the working groups.

4. The Committee as well as the working groups shall normally meet at the headquarters of the Commission. However, in exceptional cases, meetings may be held elsewhere.

#### Article 8

##### Procedures and methodology

1. The deliberations of the Committee shall relate to any request for a Recommendation on an OEL for a specific substance or group of substances or any other scientific Opinion ('Opinion') requested by the Commission.

2. The Commission, in requesting any Recommendation or Opinion of the Committee, in accordance with paragraph 1, may fix the period of time within which those are to be given.

3. The Committee, and in particular the Board, shall make every effort to base its Recommendations or Opinions on a consensus. The Committee's deliberations shall not be followed by a vote. In the absence of unanimous agreement, the various positions taken in the course of the deliberations shall be reported to the Commission by the Committee.

4. The Committee shall ensure, with the support of the Secretariat, that its methodology reflects the latest scientific standards and that it is implemented.

5. Without prejudice to the provisions on confidentiality referred to in Article 9(3), the Commission shall publish the updated methodology, along with adopted Recommendations and Opinions of the Committee, in the part of its website dedicated to the Committee.

#### Article 9

##### **Ethical principles**

###### 1. Independence

Members of the Committee shall undertake to act independently of any external influence. They shall not delegate their responsibilities to any other person.

They shall make a declaration of commitment to act in the public interest and to declare either the absence or existence of any direct or indirect interest which might be considered prejudicial to their independence.

The Commission services will take note of and decide on the relevance of any declared interests.

###### 2. Transparency

The Committee shall ensure that its Recommendations and Opinions clearly present the reasoning used in its decision-making process, as outlined in its methodology.

###### 3. Confidentiality

Without prejudice to Article 339 of the Treaty on the Functioning of the European Union and Article 12 of this Decision, the members of the Committee shall not divulge information coming to their knowledge as a result of the work of the Committee, thematic workshops, working groups or other activities related to this Decision.

A written declaration of confidentiality shall be signed by the members of the Committee at the beginning of each term of office.

#### Article 10

##### **Observers and external experts**

1. The Commission services shall invite EEA/EFTA countries to submit proposals for scientists to attend meetings as observers.

2. When appropriate, the Commission services may invite scientific experts from outside the Committee with specific competence in a subject on the agenda to participate in the work of the Committee or in a working group on an ad hoc basis.

#### Article 11

##### **Special allowances**

1. Members of the Committee and external experts invited on the initiative of the Commission shall be entitled to a special allowance of a maximum of EUR 450 in the form of a daily unit cost for each full working day. The total allowance shall be calculated and rounded upwards to the amount corresponding to the nearest half working day. The payment shall be made in euro.

2. Travel and subsistence expenses incurred by participants in the activities of the Committee shall be reimbursed by the Commission in accordance with the applicable provisions<sup>(1)</sup>. Those expenses shall be reimbursed within the limits of the available appropriations allocated under the annual procedure for the allocation of resources.

3. Article 11(1) shall only come into effect on the date on which members are appointed for the next term of office of the Committee in accordance with the procedure set out in Article 3.

#### Article 12

##### **Transparency**

1. The Commission shall publish all relevant documents (such as agendas, minutes and participants' submissions) either in the Register or via a link from the Register to a dedicated website.

2. Exceptions to publication shall be possible on the basis of a case-by-case assessment where disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council<sup>(2)</sup>.

<sup>(1)</sup> Commission Decision C(2007) 5858 Rules on the reimbursement of expenses incurred by people from outside the Commission invited to attend meetings in an expert capacity.

<sup>(2)</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43). Those exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

*Article 13***Repeal**

1. Decision 95/320/EC is hereby repealed.
2. References to the repealed Decision shall be construed as references to this Decision.

*Article 14***Entry into force**

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

Done at Brussels, 3 March 2014.

*For the Commission*  
*The President*  
José Manuel BARROSO

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# GUIDELINES

## GUIDELINE OF THE EUROPEAN CENTRAL BANK

of 28 November 2013

amending Guideline ECB/2008/5 on the management of the foreign reserve assets of the European Central Bank by the national central banks and the legal documentation for operations involving such assets

(ECB/2013/45)

(2014/114/EU)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular to the third indent of Article 127(2) thereof,

Having regard to the third indent of Article 3.1 and Articles 12.1 and 30.6 of the Statute of the European System of Central Banks and of the European Central Bank,

Whereas:

- (1) Pursuant to Article 30.1 of the Statute of the European System of Central Banks and of the European Central Bank (hereinafter the 'Statute of the ESCB'), the European Central Bank (ECB) is provided by the national central banks (NCBs) of the Member States whose currency is the euro (hereinafter the 'euro area NCBs') with foreign reserve assets and has the full right to hold and manage the foreign reserves that are transferred to it.
- (2) Pursuant to Articles 9.2 and 12.1 of the Statute of the ESCB, the ECB may manage certain of its activities through the euro area NCBs and have recourse to the euro area NCBs to carry out certain of its operations. Accordingly, the ECB considers that the euro area NCBs should manage the foreign reserves transferred to it as its agents.
- (3) Guideline ECB/2008/5 of 20 June 2008 on the management of the foreign reserve assets of the European Central Bank by the national central banks and the legal documentation for operations involving such assets<sup>(1)</sup> states that each euro area NCB may: (a) participate in the operational management of the foreign

reserve assets transferred to the ECB; or (b) either abstain from such management or pool such management with one or more other euro area NCBs. However, Guideline ECB/2008/5 does not explicitly state that a euro area NCB may request the ECB or one or more other euro area NCBs to assume certain tasks on its behalf in relation to this management.

- (4) Therefore, Guideline ECB/2008/5 should be amended accordingly,

HAS ADOPTED THIS GUIDELINE:

### Article 1

#### Amendment

Article 2(1) of Guideline ECB/2008/5 is replaced by the following:

'1. Each euro area NCB shall be entitled to participate in the operational management of the foreign reserve assets transferred to the ECB. A euro area NCB may decide to: (a) abstain from such management or (b) pool such management with one or more other euro area NCBs. If a euro area NCB decides to abstain from such management, then the other euro area NCBs shall manage the assets that otherwise would have been managed by the abstaining euro area NCB. A request by a euro area NCB to the ECB or another euro area NCB to assume certain tasks whilst retaining other tasks relating to the management of the foreign reserve assets transferred to the ECB shall also be possible. The ECB and the relevant euro area NCB are free to consent to or to reject such a request.'

### Article 2

#### Taking effect

This Guideline shall take effect on the day of its notification to the euro area NCBs.

<sup>(1)</sup> OJ L 192, 19.7.2008, p. 63.

*Article 3***Addressees**

This Guideline is addressed to the euro area NCBS.

Done at Frankfurt am Main, 28 November 2013.

*For the Governing Council of the ECB*  
*The President of the ECB*  
Mario DRAGHI

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