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Price: EUR 3

[1] Text with EEA relevance

EN

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EN

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 816/2013

of 28 August 2013

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Neutral methacrylate copolymer and Anionic methacrylate copolymer in solid food supplements and the Annex to Commission Regulation (EU) No 231/2012 as regards the specifications for Basic methacrylate copolymer (E 1205), Neutral methacrylate copolymer and Anionic methacrylate copolymer

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [1], and in particular Article 10(3), Article 14 and Article 30(5) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings [2], and in particular Article 7(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.

(2) Commission Regulation (EU) No 231/2012 [3] lays down specifications for food additives including colours and sweeteners that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.

(4) Applications for authorisation of the use of Anionic methacrylate copolymer and Neutral methacrylate copolymer as glazing agents in solid food supplements were submitted on 25 and 27 April 2009 and were made available to the Member States.

(5) The European Food Safety Authority evaluated the safety of Neutral methacrylate copolymer [4] and Anionic methacrylate copolymer [5] when used as food additives and concluded that their use in solid food supplements at the proposed use levels is not of a safety concern.

(6) There is a technological need for the use of Neutral methacrylate copolymer and Anionic methacrylate copolymer in solid food supplements. Neutral methacrylate copolymer is intended to be used as a sustained-release glazing agent. Sustained-release formulations allow the continuous dissolution of a nutrient over a defined time. Anionic methacrylate copolymer is intended to be used as a glazing agent to protect the stomach against irritating ingredients and/or to protect sensitive nutrients against disintegration by the gastric acid. It is therefore appropriate to authorise the use of both food additives in solid food supplements and to assign E 1206 as E-number to Neutral methacrylate copolymer and E 1207 as E-number to Anionic methacrylate copolymer.

(7) Commission Regulation (EU) No 1129/2011 [6] authorised the use of Basic methacrylate copolymer (E 1205) in solid food supplements and Regulation (EU) No 231/2012 sets out the specifications for that food additive, including the maximum levels for arsenic, lead, mercury and copper. Those specifications should be updated to take into account the maximum levels for lead, mercury and cadmium in food

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 354, 31.12.2008, p. 1.
[3] OJ L 83, 22.3.2012, p. 1.
[4] EFSA Journal 2010; 8(7):1655.
[5] EFSA Journal 2010; 8(7):1656.
[6] OJ L 295, 12.11.2011, p. 1.

supplements as set out in Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs [1].

(8) Maximum level of arsenic in food supplements has not been set at the Union level. However, specific levels are laid down in the laws of Member States. Therefore, it is appropriate to update specifications of Basic methacrylate copolymer (E 1205) in Regulation (EU) No 231/2012 as regards arsenic to take into account the laws of Member States.

(9) Maximum level of copper in food supplements has not been set at the Union level and there is no indication of copper presence at toxicologically significant levels in Basic methacrylate copolymer (E 1205). It is therefore appropriate to delete copper from the purity section for Basic methacrylate copolymer (E 1205) in Regulation (EU) No 231/2012.

(10) Specifications should be adopted for Neutral methacrylate copolymer (E 1206) and Anionic methacrylate copolymer (E 1207). The purity criteria for arsenic, lead, mercury and cadmium should follow the same approach as those for Basic methacrylate copolymer (E 1205) and the maximum levels should take into account that the commercial form of Neutral methacrylate copolymer (E 1206) and Anionic methacrylate copolymer (E 1207) is a 30 % dispersion of the dry substance in water.

(11) Regulation (EC) No 1333/2008 and Regulation (EU) No 231/2012 should therefore be amended accordingly.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to 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 August 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 364, 20.12.2006, p. 5.

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part B, the following entries for E 1206 and E 1207 are inserted in point 3 'Additives other than colours and sweeteners', after the entry for E 1205 Basic methacrylate copolymer:

'E 1206	Neutral methacrylate copolymer
E 1207	Anionic methacrylate copolymer'

(2) In Part E, the following entries are inserted in food category 17.1 'Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms', after the entry for E 1205 Basic methacrylate copolymer:

	'E 1206	Neutral methacrylate copolymer	200 000			
	E 1207	Anionic methacrylate copolymer	100 000'			

ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) The purity section of the entry for E 1205 (Basic methacrylate copolymer) is replaced by the following:

'**Purity**	
Loss of drying	Not more than 2,0 % (105 °C, 3 h)
Alkali value	162-198 mg KOH/g of dried substance
Sulphated ash	Not more than 0,1 %
Residual monomers	Butylmethacrylate < 1 000 mg/kg
	Methyl methacrylate < 1 000 mg/kg
	Dimethylaminoethyl methacrylate < 1 000 mg/kg
Solvent residues	propan-2-ol < 0,5 %
	Butanol < 0,5 %
	Methanol < 0,1 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 3 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 1 mg/kg'

(2) The following entries for E 1206 and E 1207 are inserted after the entry for E 1205 (Basic methacrylate copolymer):

'**E 1206 NEUTRAL METHACRYLATE COPOLYMER**

Synonyms	Ethyl acrylate methyl methacrylate polymer; Ethyl acrylate, methyl methacrylate polymer; Ethyl acrylate, polymer with methyl methacrylate; Methyl methacrylate, ethyl acrylate polymer; Methyl methacrylate, polymer with ethyl acrylate
Definition	Neutral methacrylate copolymer is a fully polymerised copolymer of methyl methacrylate and ethyl acrylate. It is produced using a process of emulsion polymerisation. It is manufactured by redox initiated polymerisation of the monomers ethyl acrylate, methyl methacrylate by using a free radical donor redox initiator system stabilised with polyethylene glycol monostearyl ether and vinylic acid/sodium hydroxide. Residual monomers are removed by means of water vapour distillation.
CAS No	9010-88-2
Chemical name	Poly(ethylacrylate-co-methyl methacrylate) 2:1
Chemical formula	Poly[(CH_2:$CHCO_2CH_2CH_3$)-co-(CH_2:$C(CH_3)CO_2CH_3$)]
Weight average molecular weight	Approximately 600 000 g/mol
Assay/Residue on evaporation	28,5–31,5 %
	1 g dispersion is dried in an oven for 3 hours at 110 °C.
Description	Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour.

Identification	
Infrared absorption spectroscopy	Characteristic of the compound
Viscosity	Max. 50 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry)
pH-value	5,5–8,6
Relative density (at 20 °C)	1,037–1,047
Solubility	The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Not soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2.
Purity	
Sulphated ash	Not more than 0,4 % in the dispersion
Residual monomers	Total of monomers (sum of methyl methacrylate and ethyl acrylate): not more than 100 mg/kg in the dispersion
Residual emulsifier	Polyethylene glycol monostearyl ether (macrogol stearyl ether 20) not more than 0,7 % in the dispersion
Solvent residues	Ethanol not more than 0,5 % in the dispersion Methanol not more than 0,1 % in the dispersion
Arsenic	Not more than 0,3 mg/kg in the dispersion
Lead	Not more than 0,9 mg/kg in the dispersion
Mercury	Not more than 0,03 mg/kg in the dispersion
Cadmium	Not more than 0,3 mg/kg in the dispersion

E 1207 ANIONIC METHACRYLATE COPOLYMER

Synonyms	Methyl acrylate, methyl methacrylate, methacrylic acid polymer; Methacrylic acid, polymer with methyl acrylate and methyl methacrylate
Definition	Anionic methacrylate copolymer is a fully polymerised copolymer of methacrylic acid, methyl methacrylate and methyl acrylate. It is manufactured in aqueous medium by emulsion polymerisation of methyl methacrylate, methyl acrylate and methacrylic acid using a free radical initiator stabilised with sodium lauryl sulphate and polyoxyethylene sorbitan monooleate (polysorbate 80). Residual monomers are removed by means of water vapour distillation.
CAS No	26936-24-3
Chemical name	Poly (methyl acrylate-co-methylmethacrylate-co-methacrylic acid) 7:3:1
Chemical formula	Poly[(CH_2:$CHCO_2CH_3$)-co-(CH_2:$C(CH_3)CO_2CH_3$)-co-(CH_2:$C(CH_3)$ COOH)]
Weight average molecular weight	Approximately 280 000 g/mol
Assay/Residue on evaporation	28,5–31,5 % 1 g of the dispersion is dried in an oven for 5 hours at 110 °C. 9,2–12,3 % methacrylic acid units on dry substance.
Description	Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour.

Identification	
Infrared absorption spectroscopy	Characteristic of the compound
Viscosity	Max. 20 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry)
pH-value	2,0–3,5
Relative density (at 20 °C)	1,058–1,068
Solubility	The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2. Soluble above pH 7,0.
Purity	
Acid value	60–80 mg KOH/g of dried substance
Sulphated ash	Not more than 0,2 % in the dispersion
Residual monomers	Total of monomers (sum of methacrylic acid, methyl methacrylate and methyl acrylate): not more than 100 mg/kg in the dispersion
Residual emulsifiers	Sodium lauryl sulphate not more than 0,3 % on the dry substance Polysorbate 80 not more than 1,2 % on the dry substance
Solvent residues	Methanol not more than 0,1 % in the dispersion
Arsenic	Not more than 0,3 mg/kg in the dispersion
Lead	Not more than 0,9 mg/kg in the dispersion
Mercury	Not more than 0,03 mg/kg in the dispersion
Cadmium	Not more than 0,3 mg/kg in the dispersion'

COMMISSION REGULATION (EU) No 817/2013

of 28 August 2013

amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards Octenyl succinic acid modified gum arabic

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [1], and in particular Article 10(3), Article 14 and Article 30(5) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings [2], and in particular Article 7(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.

(2) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, flavourings, nutrients and their conditions of use.

(3) Commission Regulation (EU) No 231/2012 [3] lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

(4) Those lists and the specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 either on the initiative of the Commission or following an application.

(5) An application for authorisation of the use of Octenyl succinic acid modified gum arabic as an emulsifier in certain food categories and in flavourings was submitted on 12 November 2007 and has been made available to the Member States.

(6) The European Food Safety Authority evaluated the safety of octenyl succinic acid modified gum arabic, as emulsifier to be added to flavourings and certain other foodstuffs and expressed its opinion on 11 March 2010 [4]. The Authority concluded that, based on the results of the available studies, the information on gum acacia itself and on other Octenyl succinic acid modified starches, the use of octenyl succinic acid modified gum arabic as an emulsifier in foods at the proposed uses and use levels is not of a safety concern.

(7) There is a technological need to use Octenyl succinic acid modified gum arabic as an emulsifier in certain foodstuffs as well as an emulsifier in flavouring-oil emulsions which are added to a variety of foodstuffs as it has improved properties compared to existing emulsifiers. It is therefore appropriate to authorise the use of octenyl succinic acid modified gum arabic in the food categories applied for and to assign number E 423 to that food additive.

(8) The specifications for Octenyl succinic acid modified gum arabic should be included in Regulation (EU) No 231/2012 when it is included in the Union lists of food additives laid down in Annexes II and III to Regulation (EC) No 1333/2008 for the first time.

(9) Regulation (EC) No 1333/2008 and Regulation (EU) No 231/2012 should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to 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*.

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 354, 31.12.2008, p. 1.
[3] OJ L 83, 22.3.2012, p. 1.
[4] *EFSA Journal 2010*; 8(3):1539.

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

Done at Brussels, 28 August 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX I

A. Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part B, in Table 3 'Additives other than colours and sweeteners' the following entry is inserted after the entry for food additive E 422:

'E 423	Octenyl succinic acid modified gum arabic'

(2) Part E is amended as follows:

(a) in category 05.4 'Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4', the following entry is inserted after the entry for food additive E 416:

	'E 423	Octenyl succinic acid modified gum arabic	10 000	Only icings'	

(b) in category 12.6 'Sauces', the following entry is inserted after the entry for food additive E 416:

	'E 423	Octenyl succinic acid modified gum arabic	10 000'		

(c) in category 14.1.4 'Flavoured drinks' the following entry is inserted after the entry for food additive E 405:

	'E 423	Octenyl succinic acid modified gum arabic	1 000	only in energy drinks and in drinks containing fruit juice'	

B. Annex III to Regulation (EC) No 1333/2008 is amended as follows:

In Part 4 'Food additives including carriers in food flavourings', the following entry is inserted after the entry for food additive E 416:

'E 423	Octenyl succinic acid modified gum arabic	Flavouring-oil emulsions used in categories 03: edible ices; 07.2: Fine bakery wares; 08.2: Processed meat, only processed poultry; 09.2: Processed fish and fishery products including mollusks and crustaceans and in category 16: Desserts excluding products covered in category 1, 3 and 4.	500 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in category 14.1.4: Flavoured drinks, only flavoured drinks not containing fruit juices and in carbonated flavoured drinks containing fruit juices and in category 14.2: Alcoholic beverages, including alcohol-free and low-alcohol counterparts	220 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in categories 05.1: Cocoa and Chocolate products as covered by Directive 2000/36/EC, 05.2: Other confectionery including breath refreshening microsweets, 05.4: Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4 and in category 06.3: Breakfast cereals.	300 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in category 01.7.5: Processed cheese.	120 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in category 05.3: Chewing gum.	60 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in category 01.8: Dairy analogues, including beverage whiteners; 04.2.5: Jam, jellies and marmalades and similar products; 04.2.5.4: Nut butters and nut spreads; 08.2: Processed meat; 12.5: Soups and broths, 14.1.5.2: Other, only instant coffee and tea and in cereal based ready-to-eat-dishes.	240 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in category 10.2: Processed eggs and egg products.	140 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in category 14.1.4: Flavoured drinks, only non carbonated flavoured drinks containing fruit juices; 14.1.2: Fruit juices as defined by Directive 2001/112/EC and vegetable juices, only vegetable juices and in category 12.6: Sauces, only gravies and sweet sauces.	400 mg/kg in the flavouring emulsion
		Flavouring-oil emulsions used in category 15: Ready-to-eat savouries and snacks.	440 mg/kg in the flavouring emulsion'

ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following entry is inserted after the specifications for food additive E 422:

'**E 423 OCTENYL SUCCINIC ACID MODIFIED GUM ARABIC**

Synonyms	Gum arabic hydrogen octenylbutandioate; Gum arabic hydrogen octenylsuccinate; OSA modified gum arabic; OSA modified gum acacia
Definition	Octenyl succinic acid modified gum arabic is produced by esterifying gum arabic (*Acacia seyal*), or gum arabic (*Acacia senegal*) in aqueous solution with not more than 3 % of octenyl succinic acid anhydride. It is subsequently spray dried.
Einecs	
Chemical name	
Chemical formula	
Weight Average Molecular Weight	Fraction (i): 3,105 g/mol Fraction (ii) 1,106 g/mol
Assay	
Description	Off-white to light tan, free flowing powder
Identification	
Viscosity of a 5 % solution at 25 °C	Not more than 30 mPa.s.
Precipitation reaction	Forms flocculent precipitate in lead sub-acetate solution (TS)
Solubility	Freely soluble in water; insoluble in ethanol
pH for a 5 % aqueous solution	3,5 to 6,5
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 h)
Degree of esterification	Not more than 0,6 %
Total ash	Not more than 10 % (530 °C)
Acid-insoluble ash	Not more than 0,5 %
Water insoluble matter	Not more than 1,0 %
Test for starch or dextrine	Boil a 1 in 50 aqueous solution of the sample, add about 0,1 ml iodine TS. No bluish or reddish colour should be produced.
Test for tannin-bearing gums	To 10 ml of a 1 in 50 aqueous solution of the sample add about 0,1 ml ferric chloride TS. No blackish coloration or blackish precipitate should be formed.
Residual octenyl succinic acid	Not more than 0,3 %
Lead	Not more than 2 mg/kg
Microbiological criteria	
Salmonella sp.	Absent in 25 g
Escherichia coli	Absent in 1 g'

COMMISSION REGULATION (EU) No 818/2013

of 28 August 2013

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Sucrose esters of fatty acids (E 473) in flavourings for water based clear flavoured drinks

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [1], and in particular Article 10(3) and 30 (5) thereof,

Whereas:

(1) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food flavourings and their conditions of use.

(2) That list may be amended in accordance with the common procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings [2].

(3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.

(4) An application for authorisation of the use of Sucrose esters of fatty acids (E 473) as an emulsifier in flavourings was submitted on 20 August 2008 and has been made available to the Member States.

(5) Emulsifiers are needed to stabilise oily flavourings when these are added in water based beverages. Without the addition of an emulsifier the flavouring oil would not be soluble and would appear on the surface of the beverage as an oily ring. This prevents the even dispersal of the flavouring through the beverage and increases its exposure to oxygen, leading to reduced organoleptic acceptability. It also makes the development of clear beverages extremely difficult. These issues can be overcome to some extent with the use of washed oils, however those have reduced organoleptic acceptability. The use of Sucrose esters of fatty acids enables clear beverages with improved functionality of the added flavouring.

(6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority in order to update the Union list of food additives set out in Annex III to Regulation (EC) No 1333/2008.

(7) The European Food Safety Authority issued an opinion on sucrose esters of fatty acids (E 473) and established an Acceptable Dalily Intake of 40 mg/kg bw/day [3]. The exposure to sucrose esters of fatty acids resulting from the additional proposed use in clear flavoured soft drinks represents less than 0,1% of the ADI [4]. Taking into account that the exposure due to the additional use of this additive is negligible compared to the ADI, this additional use of Sucrose esters of fatty acids (E 473) is not liable to have an effect on human health.

(8) It is therefore appropriate to authorise the use of Sucrose esters of fatty acids (E 473) as a food additive in flavourings for water based clear flavoured drinks.

(9) Therefore, Annex III to Regulation (EC) No 1333/2008 should be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1333/2008 is amended in accordance with 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*.

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 354, 31.12.2008, p. 1.
[3] EFSA Journal (2004) 106, 1-24.
[4] EFSA Journal 2012; 10(5):2658.

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

Done at Brussels, 28 August 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Part 4 of Annex III to Regulation (EC) No 1333/2008 the following entry is inserted after the entry for food additive E 459:

"E 473	Sucrose esters of fatty acids	Flavourings for water based clear flavoured drinks that belong to category 14.1.4	15 000 mg/kg in flavourings, 30 mg/l in the final food"

COMMISSION IMPLEMENTING REGULATION (EU) No 819/2013

of 28 August 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 multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 28 August 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
0707 00 05	TR	95,4
	ZZ	95,4
0709 93 10	TR	127,5
	ZZ	127,5
0805 50 10	AR	122,1
	CL	123,1
	TR	70,0
	UY	79,4
	ZA	107,9
	ZZ	100,5
0806 10 10	EG	179,1
	TR	140,5
	ZZ	159,8
0808 10 80	AR	100,3
	BR	108,7
	CL	130,5
	CN	67,2
	NZ	129,2
	US	130,9
	ZA	108,3
	ZZ	110,7
0808 30 90	AR	194,7
	CN	88,3
	TR	147,4
	ZA	84,5
	ZZ	128,7
0809 30	TR	141,5
	ZZ	141,5
0809 40 05	BA	47,5
	MK	52,2
	XS	55,6
	ZZ	51,8

(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'.

DIRECTIVES

COMMISSION DIRECTIVE 2013/46/EU

of 28 August 2013

amending Directive 2006/141/EC with regard to protein requirements for infant formulae and follow-on formulae

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses [1], and in particular Article 4(1) thereof,

Whereas:

(1) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC [2] lays down, inter alia, compositional and labelling rules for infant formulae and follow-on formulae.

(2) Directive 2006/141/EC specifically provides for infant formulae and follow-on formulae to only be manufactured from protein sources defined in that Directive. Those protein sources are cows' milk proteins and soya protein isolates, alone or in a mixture, as well as protein hydrolysates.

(3) On request from the Commission, the European Food Safety Authority delivered, on 28 February 2012, a scientific opinion on the suitability of goat milk protein as a source of protein in infant formulae and in follow-on formulae. That opinion concluded that protein from goats' milk can be suitable as a protein source for infant formulae and follow-on formulae provided that the final product complies with the compositional criteria laid down in Directive 2006/141/EC.

(4) On the basis of that opinion, infant formulae and follow-on formulae manufactured from goats' milk proteins should be allowed on the market provided that the final product complies with the compositional criteria laid down in Directive 2006/141/EC. Directive 2006/141/EC should therefore be amended accordingly.

(5) On request from the Commission, the European Food Safety Authority delivered, on 5 October 2005, a scientific opinion on the safety and suitability for particular nutritional use by infants of formula based on whey protein partial hydrolysates with a protein content of at least 1,9 g/100 kcal, which was below the minimum level provided for in the Union legislation at that time. That opinion concluded that infant formula, based on hydrolysates of whey protein derived from cows' milk with a protein content of 1,9 g/100 kcal (0,47 g/100 kJ) and corresponding to the protein formulation assessed, is safe and suitable for use as the sole source of nutrition of infants. On the basis of that opinion, Directive 2006/141/EC, as amended by Commission Regulation (EC) No 1243/2008 of 12 December 2008 amending Annexes III and VI to Directive 2006/141/EC as regards compositional requirements for certain infant formulae [3], authorises the marketing of infant formulae manufactured from protein hydrolysates with such a protein content provided that the product complies with certain specific criteria set out therein.

(6) That opinion also concluded that, while no data on follow-on formulae based on hydrolysed whey protein with a protein content of 1,9 g/100 kcal (0,47 g/100 kJ) had been submitted, a formula with that protein formulation would be suitable for older infants in conjunction with complementary foods.

(7) On the basis of that opinion, and in order to allow the development of innovative products, such follow-on formulae should be allowed on the market. Directive 2006/141/EC should therefore be amended accordingly.

(8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2006/141/EC is amended as follows:

[1] OJ L 124, 20.5.2009, p. 21.
[2] OJ L 401, 30.12.2006, p. 1.
[3] OJ L 335, 13.12.2008, p. 25.

(1) Article 7 is amended as follows:

(a) in paragraph 1, the second subparagraph is replaced by the following:

'In the case of infant formulae manufactured from cows' milk or goats' milk proteins defined in point 2.1 of Annex I with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.';

(b) in paragraph 2, the following subparagraph is added:

'In the case of follow-on formulae manufactured from protein hydrolysates defined in point 2.2 of Annex II with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal), the suitability of the follow-on formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies and shall be in accordance with the appropriate specifications set out in Annex VI.';

(2) in Article 12, the introductory phrase is replaced by the following:

'The name under which infant formulae and follow-on formulae manufactured entirely from cows' milk or goats' milk proteins are sold shall be respectively:';

(3) Annexes I, II, III and VI are amended in accordance with the Annex to this Directive.

Article 2

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

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 28 February 2014 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 28 August 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annexes I, II, III and VI to Directive 2006/141/EC are amended as follows:

(1) Annex I is amended as follows:

(a) point 2.1 is amended as follows:

(i) the title is replaced by the following:

'2.1. **Infant formulae manufactured from cows' milk or goats' milk proteins**';

(ii) footnote 1 is replaced by the following:

'([1]) Infant formulae manufactured from cows' milk or goats' milk protein with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal) shall be in accordance with the second subparagraph of Article 7(1).';

(b) in point 2.3, the title is replaced by the following:

'2.3. **Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins**';

(c) in point 10.1, the title is replaced by the following:

'10.1. **Infant formulae manufactured from cows' milk or goats' milk proteins or protein hydrolysates**';

(d) in point 10.2, the title is replaced by the following:

'10.2. **Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins**';

(2) Annex II is amended as follows:

(a) in point 2.1, the title is replaced by the following:

'2.1. **Follow-on formulae manufactured from cows' milk or goats' milk proteins**';

(b) in point 2.2, the table is replaced by the following:

'Minimum ([1])	Maximum
0,45 g/100 kJ (1,8 g/100 kcal)	0,8 g/100 kJ (3,5 g/100 kcal)

([1]) Follow-on formulae manufactured from protein hydrolysates with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal) shall be in accordance with the second subparagraph of Article 7(2).'

(c) in point 2.3, the title is replaced by the following:

'2.3. **Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins**';

(d) in point 8.1, the title is replaced by the following:

'8.1. **Follow-on formulae manufactured from cows' milk or goats' milk proteins or protein hydrolysates**';

(e) in point 8.2, the title is replaced by the following:

'8.2. **Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins**';

(3) in point 3 of Annex III, footnote 1 is replaced by the following:

'([1]) L-arginine and its hydrochloride shall only be used in the manufacture of infant formulae referred to in the third subparagraph of Article 7(1) and follow-on formulae referred to in the second subparagraph of Article 7(2).';

(4) the title of Annex VI is replaced by the following:

'Specification for the protein content and source and the processing of protein used in the manufacture of infant formulae and follow-on formulae with a protein content less than 0,56 g/100 kJ (2,25 g/100 kcal) manufactured from hydrolysates of whey proteins derived from cows' milk protein'.

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 27 August 2013

concerning certain protective measures in relation to highly pathogenic avian influenza of subtype H7N7 in Italy including the establishment of further restricted zones and repealing Implementing Decision 2013/439/EU

(notified under document C(2013) 5623)

(Only the Italian text is authentic)

(Text with EEA relevance)

(2013/443/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ([1]), and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ([2]), and in particular Article 10(4) thereof,

Whereas:

(1) Avian influenza is an infectious viral disease in birds, including poultry. Infections with avian influenza viruses in domestic poultry cause two main forms of that disease that are distinguished by their virulence. The low pathogenic form generally only causes mild symptoms, while the highly pathogenic form results in very high mortality rates in most poultry species. That disease may have a severe impact on the profitability of poultry farming.

(2) Avian influenza is mainly found in birds, but under certain circumstances infections can also occur in humans even though the risk is generally very low.

(3) In the event of an outbreak of avian influenza, there is a risk that the disease agent might spread to other holdings where poultry or other captive birds are kept. As a result it may spread from one Member State to other Member States or to third countries through trade in live birds or their products.

(4) Council Directive 2005/94/EC ([3]) sets out certain preventive measures relating to the surveillance and the early detection of avian influenza and the minimum control measures to be applied in the event of an outbreak of that disease in poultry or other captive birds. That Directive provides for the establishment of protection and surveillance zones in the event of an outbreak of highly pathogenic avian influenza.

(5) Council Directive 2009/158/EC ([4]) lays down rules for trade within the Union in those commodities, including the veterinary certificates to be used.

(6) Following the notification by Italy of an outbreak of highly pathogenic avian influenza of subtype H7N7 in a holding in the commune of Ostellato, in the province of Ferrara in the Region Emilia-Romagna on 15 August 2013, the Commission adopted Implementing Decision 2013/439/EU ([5]), that lays down provisions for protection and surveillance zones to be established around the outbreak.

(7) On 21 August 2013 Italy notified the occurrence of a second outbreak of disease in the commune of Mordano in the province of Bologna and on 23 August 2013 of a third outbreak of disease in the commune of Portomaggiore in the province of Ferrara, both in the Region Emilia-Romagna and it immediately took the measures required pursuant to Directive 2005/94/EC, including the establishment of protection, surveillance and further restricted zones, which should be defined in Parts A, B and C of the Annex to this Decision.

([1]) OJ L 395, 30.12.1989, p. 13.
([2]) OJ L 224, 18.8.1990, p. 29.
([3]) Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza (OJ L 10, 14.1.2006, p. 16).
([4]) Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ L 343, 22.12.2009, p. 74).
([5]) Commission Implementing Decision 2013/439/EU of 19 august 2013 concerning certain protective measures in relation to highly pathogenic avian influenza of subtype H7N7 in Italy (OJ L 223, 21.8.2013, p. 10).

(8) The Commission has examined those measures in collaboration with Italy, and it is satisfied that the borders of those zones established by the competent authority in that Member State are at a sufficient distance to the actual holding where the outbreak was confirmed.

(9) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to rapidly define those zones established in Italy at Union level and to provide that no consignments of live poultry, ready-to-lay poultry, day-old chicks and hatching eggs are dispatched from those zones to other Member States or to third countries.

(10) Day-old chicks present a negligible risk for the spread of the disease provided that in accordance with the provisions of Article 30(c)(iii) second subparagraph of the Directive 2005/94/EC they have hatched from hatching eggs originating from poultry holdings located outside the protection and surveillance zones and the hatchery of dispatch can ensure by its logistics and by its biosecurity working conditions that no contact has occurred between those eggs and any other hatching eggs or day-old chicks originating from poultry flocks within the established protection or surveillance zones and which are therefore of a different health status.

(11) Hatching eggs equally present a negligible risk for the spread of the disease provided that in accordance with the provisions of Article 30(c)(iv) of Directive 2005/94/EC they originate from holdings located outside the protection and surveillance zones and their packaging is disinfected before dispatch to a designated hatchery.

(12) It is therefore appropriate that the competent authority of Italy may authorise the dispatch of consignments of day-old chicks and hatching eggs from the further restricted zones defined in this Decision according to the requirements laid down in Directive 2005/94/EC provided that Italy gives written notification in advance and the Member State or third country of destination confirms its prior agreement to receive these consignments.

(13) In order to verify compliance with the provisions of this Decision, it is appropriate that the veterinary certificates provided for in Directive 2009/158/EC include a reference to that effect.

(14) For the sake of clarity, Implementing Decision 2013/439/EU should be repealed.

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

HAS ADOPTED THIS DECISION:

Article 1

Italy shall ensure that the protection, surveillance and further restricted zones established in accordance with Article 16(1) and (4) of Directive 2005/94/EC comprise at least the areas listed in Parts A, B and C of the Annex to this Decision.

Article 2

1. Italy shall ensure that no consignments of live poultry, ready to-lay-poultry, day-old chicks and hatching eggs are dispatched from the zones listed in Parts A, B and C of the Annex to other Member States or third countries.

2. By way of derogation from paragraph 1, the competent authority of Italy may authorise the dispatch of consignments of day-old chicks and hatching eggs from the zones listed in Part C of the Annex to other Member States or third countries provided that:

(a) the measures laid down in Article 30(c)(iii) second subparagraph and (iv) of Directive 2005/94/EC are applied;

(b) the competent authority of the Member State or third country of destination is given written notification in advance and undertakes to receive the consignments of the day-old chicks and hatching eggs and notify their date of arrival at the holding of destination on its territory to the competent authority of Italy.

3. Italy shall ensure that the veterinary certificates accompanying the consignments referred to in paragraph 2 to be dispatched to other Member States include the words:

'The consignment complies with the animal health conditions laid down in Commission Implementing Decision 2013/443/EU (*).

(*) OJ L 230, 29.8.2013, p. 20'.

Article 3

Implementing Decision 2013/439/EU is repealed.

Article 4

This Decision is addressed to the Italian Republic.

Done at Brussels, 27 August 2013.

For the Commission

Tonio BORG

Member of the Commission

ANNEX

PART A

Protection zones as referred to in Article 1:

ISO Country Code	Member State	Postal Code	Name	Date until applicable in accordance with Article 29 of Directive 2005/94/EC
IT	Italy		Area comprising the municipalities of:	
		44020	Ostellato	14.9.2013
		40027	Mordano	30.9.2013
		48010	Bagnara di Romagna	
		40026	Part of the territory of the municipality of Imola situated east of the state road 610 and north of the state road 9 'Via Emilia'.	
		48027	Part of the territory of the municipality of Solarolo situated north of the junction of highway A14 to Ravenna.	
		44015	Portomaggiore	18.9.2013

PART B

Surveillance zones as referred to in Article 1:

ISO Country Code	Member State	Postal Code	Name	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
IT	Italy		Area comprising the municipalities of:	
		44011	Argenta	23.9.2013
		44022	Comacchio	
		44027	Migliarino	
		44020	Migliaro	
		44015	Portomaggiore	
		44039	Tresigallo	
		48014	Castelbolognese	9.10.2013
		40023	Castelguelfo	
		48017	Conselice	
		48010	Cotignola	
		48018	Faenza	
		40026	Imola (remaining part of the municipality)	

ISO Country Code	Member State	Postal Code	Name	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
		48022	Lugo	
		48024	Massalombarda	
		48020	Sant'Agata sul Santerno	
		48027	Solarolo (remaining part of the municipality)	
		44020	Masi Torello	27.9.2013
		44123	Part of the territory of the municipality of Ferrara situated east of the state road 15 'Via Pomposa' and the provincial road 'Via Ponte Assa'.	

PART C

Further restricted zone as referred to in Article 1:

ISO Country Code	Member State	Postal Code	Name	Date until the measures are applicable
IT	Italy		Area comprising the municipalities of:	
		48011	Alfonsine	11.9.2013
		29002	Ariano nel Polesine	
		39002	Bagnacavallo	
		38002	Berra	
		40003	Brisighella	
		39004	Bertinoro	
		39005	Casola Valsenio	
		40005	Castrocaro Terme e Terra del Sole	
		39007	Cervia	
		40007	Cesena	
		40008	Cesenatico	
		38005	Codigoro	
		29017	Corbola	
		40011	Dovadola	
		40013	Forlimpopoli	
		40012	Forlì	
		39011	Fusignano	

ISO Country Code	Member State	Postal Code	Name	Date until the measures are applicable
		40015	Gambettola	
		40016	Gatteo	
		38025	Goro	
		38010	Jolanda di Savoia	
		38011	Lagosanto	
		40018	Longiano	
		38013	Massa Fiscaglia	
		40019	Meldola	
		38014	Mesola	
		40022	Modigliana	
		29034	Papozze	
		29039	Porto Tolle	
		29052	Porto Viro	
		40032	Predappio	
		39014	Ravenna	
		39015	Riolo Terme	
		39016	Russi	
		40041	San Mauro Pascoli	
		40045	Savignano sul Rubicone	
		29046	Taglio di Po	

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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