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

Delegations will find attached Commission document D026574/02.

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[...](2013) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

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

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of XXX

amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to 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 additives¹, 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 flavourings², 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 of 9 March 2012³ 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 2010⁴. The Authority concluded

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.

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*.

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

Done at Brussels,

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
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"

- (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	10000	Only icings	
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"

- (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	10000		
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"

(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	1000	only in energy drinks and in drinks containing fruit juice	
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"

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 refreshing 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	400 mg/kg in the flavouring emulsion

		sauces.	
		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 (<i>Acacia seyal</i>), or gum arabic (<i>Acacia senegal</i>) 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	
<i>Salmonella</i> sp.	Absent in 25 g
<i>Escherichia coli</i>	Absent in 1 g