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Subject:	COMMISSION REGULATION (EU) No .../. of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyvinylpyrrolidone-vinyl acetate copolymer in solid food supplements and the Annex to Commission Regulation (EU) No 231/2012 as regards its specifications
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Delegations will find attached Commission document D029998/03.

Encl.: D029998/03.



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

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

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyvinylpyrrolidone-vinyl acetate copolymer in solid food supplements and the Annex to Commission Regulation (EU) No 231/2012 as regards its specifications

(Text with EEA relevance)

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

of XXX

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyvinylpyrrolidone-vinyl acetate copolymer in solid food supplements and the Annex to Commission Regulation (EU) No 231/2012 as regards its specifications

(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) Commission Regulation (EU) No 231/2012 of 9 March 2012³ 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) On 6 October 2009, an application was submitted for authorisation of the use of polyvinylpyrrolidone-vinyl acetate copolymer in solid food supplements as binding/coating agent. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The European Food Safety Authority evaluated the safety of polyvinylpyrrolidone-vinyl acetate copolymer⁴ when used as a food additive and concluded that the use of

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.

polyvinylpyrrolidone-vinyl acetate copolymer in solid food supplements as a binding/coating agent is unlikely to be of safety concern at the proposed uses.

- (6) There is a technological need for the addition of polyvinylpyrrolidone-vinyl acetate copolymer to a cellulosic formulation in food supplements. It improves film toughness, increases coating application rates and promotes better film adhesion. It also enables a continuous coating process, thus reducing the time of the coating process. It is therefore appropriate to authorise the use of this additive as a glazing agent in solid food supplements and to assign E 1208 as E-number to polyvinylpyrrolidone-vinyl acetate copolymer.
- (7) The specifications for polyvinylpyrrolidone-vinyl acetate copolymer (E 1208) 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.
- (8) Regulation (EC) No 1333/2008 and Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (9) 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 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*.

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

⁴ EFSA Journal 2010; 8(12):1948.

ANNEX I

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

- (1) In Part B, point 3 "Additives other than colours and sweeteners", the following new entry is inserted after the entry for E 1207 Anionic methacrylate copolymer:

E 1208	Polyvinylpyrrolidone-vinyl acetate copolymer
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- (2) In Part E, in food category 17.1 "Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms", the following new entry is inserted after the entry for E 1207 Anionic methacrylate copolymer:

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E 1208	Polyvinylpyrrolidone-vinyl acetate copolymer.	100 000	
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ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for E 1207 (Anionic methacrylate copolymer):

E 1208 POLYVINYLPIRROLIDONE-VINYL ACETATE COPOLYMER	
Synonyms	Copolyvidon; copovidone; 1-vinyl-2-pyrrolidone-vinyl acetate copolymer; 2-pyrrolidinone, 1-ethenyl-, polymer with ethenyl acetate
Definition	It is produced by free radical copolymerisation of N-vinyl-2-pyrrolidone and vinyl acetate in solution in propan-2-ol, in the presence of initiators.
Einecs	
Chemical name	Acetic acid, ethenyl ester, polymer with 1-ethenyl-2-pyrrolidinone
Chemical formula	$(C_6H_9NO)_n \cdot (C_4H_6O_2)_m$
Average Viscosity Molecular Weight	Between 26000 and 46000 g/mol.
Assay	Nitrogen content 7,0 - 8,0%
Description	The physical state is described as a white to yellowish-white powder or flakes with an average particle size of 50 – 130 µm.
Identification	
Solubility	Freely soluble in water, ethanol, ethylene chloride and ether.
Infrared absorption spectroscopy	To be identified
European Colour Test (BY Colour)	Minimum BY5
K-value ⁵ (1% solids in aqueous solution)	25,2-30,8
pH value	3.0 – 7.0 (10% aqueous solution)
Purity	
Vinylacetate component in copolymer	Not more than 42.0%
Free vinyl acetate	Not more than 5 mg/kg
Total ash	Not more than 0,1 %
Aldehyde	Not more than 2 000 mg/kg (as acetaldehyde)
Free-N-vinylpyrrolidone	Not more than 5 mg/kg

⁵ K-value: dimensionless index, calculated from kinematic viscosity measurements of dilute solutions, used to indicate the likely degree of polymerization or molecular size of a polymer.

Hydrazine	Not more than 0,8 mg/kg
Peroxide content	Not more than 400 mg/kg
Propan-2-ol	Not more than 150 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg