Commission Regulation (EU) No 264/2014 of 14 March 2014 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 264/2014

of 14 March 2014

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 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) 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 copolymer[(4)] when used as a food additive and concluded that the use of polyvinylpyrrolidone-vinyl acetate copolymer in solid food supplements as a binding/coating agent is unlikely to be of safety concern at the proposed uses.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 264/2014. (See end of Document for details)*

(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*.

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

Done at Brussels, 14 March 2014.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 264/2014. (See end of Document for details)*

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

(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:

	E 1208	Polyvinylpyrrolidone-vinyl acetate copolymer.	100 000		

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 POLYVINYLPYRROLIDONE-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	$(C_6H_9NO)_n.(C_4H_6O_2)_m$
Average Viscosity Molecular Weight	Between 26 000 and 46 000 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	

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