Commission Regulation (EU) No 685/2014 of 20 June 2014 amending Annex II 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 polyvinyl alcohol-polyethylene glycol-graft-co-polymer in solid food supplements (Text with EEA relevance)

COMMISSION REGULATION (EU) No 685/2014

of 20 June 2014

amending Annex II 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 polyvinyl alcohol-polyethylene glycol-graft-co-polymer in solid food supplements

(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 Article 14 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 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 13 September 2011, an application was submitted for authorisation of the use of polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer (PVA-PEG *graft* co-polymer) in aqueous instant-release film coatings for food supplements. 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 PVA-PEG *graft* co-polymer when used as a food additive and concluded that its use in food supplements as film coating is of no safety concern for the proposed uses[(4)].

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 685/2014. (See end of Document for details)*

(6) PVA-PEG *graft* co-polymer is intended for use in aqueous instant-release film coatings for food supplements. It protects against unpleasant tastes or odours, improves appearance, makes tablets easier to swallow, gives a distinctive appearance, and protects sensitive active ingredients. A specific property of the substance is that it is extremely flexible, has low viscosity, and dissolves rapidly in acidic, neutral, and alkaline aqueous media. It is therefore appropriate to authorise the use of PVA-PEG *graft* co-polymer as a glazing agent in solid food supplements and to assign E 1209 as E-number to that additive.

(7) The specifications for PVA-PEG *graft* co-polymer should be included in Regulation (EU) No 231/2012 when it is included in the Union lists of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.

(8) Regulations (EC) No 1333/2008 and (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, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

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 food additive E 1208 Polyvinylpyrrolidone-vinyl acetate copolymer:

E 1209	Polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer

(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 food additive E 1208:

	E 1209	Polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer	100 000		

ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for E 1208 (Polyvinylpyrrolidone-vinyl acetate copolymer):

E 1209 POLYVINYL ALCOHOL-POLYETHYLENE GLYCOL-*GRAFT*-COPOLYMER

Synonyms	Macrogol poly(vinyl alcohol) grafted co-polymer; poly(ethan-1,2-diol-graft-ethanol); ethenol, polymer with oxirane, graft; oxirane, polymer with ethanol, graft; ethylene oxide-vinyl alcohol graft co-polymer
Definition	Polyvinyl alcohol-polyethylene glycol-graft-co-polymer is a synthetic co-polymer that consists of approximately 75 % PVA units and 25 % PEG units.
CAS number	96734-39-3
Chemical name	Polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer
Chemical formula	
Weight Average Molecular Weight	40 000 to 50 000 g/mol
Description	White to faintly yellow powder
Identification	
Solubility	Freely soluble in water and dilute acids and dilute solutions of alkali hydroxides;