COMMISSION REGULATION (EU) 2017/1399

of 28 July 2017

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 potassium polyaspartate

(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 Articles 10(3) and 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) Only food additives included in the Union list in Annex II to Regulation (EC) No 1333/2008 may be placed on the market as such and used in foods under the conditions of use specified therein.

(3) Some food additives are intended for specific uses for certain oenological practices and processes. The use of such food additives should comply with Regulation (EC) No 1333/2008 and with the specific provisions laid down in the relevant Union legislation.

(4) The specific provisions authorising the use of additives in wine are laid down in Regulation (EU) No 1308/2013 of the European Parliament and of the Council ([3]), Council Decision 2006/232/EC ([4]) and Commission Regulation (EC) No 606/2009 ([5]) and their implementing measures.

(5) Commission Regulation (EU) No 231/2012 ([6]) lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

(6) The Union list 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.

(7) On 24 February 2015, an application was submitted for the authorisation of the use of potassium polyaspartate as a stabiliser in wine. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(8) The European Food Safety Authority evaluated the safety of potassium polyaspartate as a food additive and in its opinion ([7]) of 9 March 2016 concluded that there was no safety concern from the proposed use in wine at a maximum use level of 300 mg/L and typical levels in the range of 100-200 mg/L.

([1]) OJ L 354, 31.12.2008, p. 16.
([2]) OJ L 354, 31.12.2008, p. 1.
([3]) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).
([4]) Council Decision 2006/232/EC of 20 December 2005 on the conclusion of the Agreement between the European Community and the United States of America on trade in wine (OJ L 87, 24.3.2006, p. 1).
([5]) Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions (OJ L 193, 24.7.2009, p. 1).
([6]) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).
([7]) *EFSA Journal* 2016;14(3):4435.

(9) Potassium polyaspartate acts as a stabiliser against tartrate crystal precipitation in wine (red, rosé and white wine). It enhances the keeping quality and stability of wine and its use does not have an impact on the sensory properties. It is therefore appropriate to include potassium polyaspartate in the Union list of food additives and to assign E 456 as E-number to that additive to enable its authorisation as a stabiliser in wine in the specific provisions of the relevant Union legislation.

(10) The specifications for potassium polyaspartate (E 456) should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.

(11) Regulations (EC) No 1333/2008 and (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 Plants, Animals, Food and Feed,

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 July 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX I

In Part B of Annex II to Regulation (EC) No 1333/2008, in point 3 'Additives other than colours and sweeteners', the following new entry is inserted after the entry for food additive E 452:

'E 456	Potassium polyaspartate'

ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for food additive E 452(iv):

'E 456 POTASSIUM POLYASPARTATE	
Synonyms	
Definition	Potassium polyaspartate is the potassium salt of polyaspartic acid, produced from L-aspartic acid and potassium hydroxide. The thermic process transforms the aspartic acid in polysuccinimide that is insoluble. Polysuccinimide is treated with potassium hydroxide allowing the opening of the ring and polymerisation of the units. The last step is the spray drying phase, which results in a light tan powder
CAS number	64723-18-8
Chemical name	L-aspartic acid, homopolymer, potassium salt
Chemical formula	$[C_4H_4NO_3K]_n$
Weight average molecular weight	Approximately 5 300 g/mol
Assay	Not less than 98 % on dry weight basis
Particle size	Not less than 45 μm (not more than 1 % in weight of particles of less than 45 μm)
Description	A light brown odourless powder
Identification	
Solubility	Very soluble in water and slightly soluble in organic solvents
pH	7,5-8,5 (40 % aqueous solution)
Purity	
Degree of substitutions	Not less than 91,5 % on dry weight basis
Loss on drying	Not more than 11 % (105 °C,12 hours)
Potassium hydroxide	Not more than 2 %
Aspartic acid	Not more than 1 %
Other impurities	Not more than 0,1 %
Arsenic	Not more than 2,5 mg/kg
Lead	Not more than 1,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,1 mg/kg'