Commission Regulation (EU) 2018/1461 of 28 September 2018 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 the use of Low-substituted hydroxypropyl cellulose (L-HPC) in food supplements (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/1461

of 28 September 2018

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 the use of Low-substituted hydroxypropyl cellulose (L-HPC) in 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 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 food 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) Commission Regulation (EU) No 231/2012[(3)] lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

(4) 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.

(5) On 21 October 2016 an application was submitted for the authorisation of the use of low-substituted hydroxypropyl cellulose (L-HPC) as a food additive in food supplements in tablet form falling under the food category 17.1 ‘Food supplements supplied in a solid form’ in Part E of Annex II to Regulation (EC) No 1333/2008. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1461. (See end of Document for details)*

(6) The European Food Safety Authority evaluated the safety of L-HPC as a food additive and in its opinion[4] of 20 January 2018 concluded that there was no safety concern from the proposed use in food supplements in solid form (tablet), at a maximum use level of 20 000 mg/kg and a typical use level of 10 000 mg/kg.

(7) Low-substituted hydroxypropyl cellulose (L-HPC) is water insoluble cellulose that facilitates the manufacturing of solid food supplements in tablet form due to its good compressibility and binding properties. Being insoluble in water, it absorbs water while increasing in volume. The increased volume makes the tablet disintegrating rapidly providing a fast release of the nutrients in the stomach.

(8) It is therefore appropriate to include low-substituted hydroxypropyl cellulose (L-HPC) in the Union list of food additives and to assign E 463a as E-number to that additive to enable its authorisation as a glazing agent in food supplements in solid form (tablet) at a maximum use level of 20 000 mg/kg.

(9) The specifications for low-substituted hydroxypropyl cellulose (L-HPC) (E 463a) 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.

(10) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

(11) 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1461. (See end of Document for details)*

Done at Brussels, 28 September 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1461. (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 E 463a for Low-substituted hydroxypropyl cellulose (L-HPC) is inserted after the entry for E 463 Hydroxypropyl cellulose:

E 463a	Low-substituted hydroxypropyl cellulose (L-HPC)

(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 for Low-substituted hydroxypropyl cellulose (L-HPC) is inserted after the entry for E 459 Beta-cyclodextrin:

	E 463a	Low-substituted hydroxypropyl cellulose (L-HPC)	20 000		only food supplements in tablet form	

ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry for E 463a (Low-substituted hydroxypropyl cellulose (L-HPC)) is inserted after the entry for E 463 (Hydroxypropyl cellulose):

E 463a LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (L-HPC)	
Synonyms	Cellulose hydroxypropyl ether, low substituted
Definition	L-HPC is a low-substituted poly (hydroxypropyl) ether of cellulose. L-HPC is manufactured by partial etherification of the anhydroglucose units of pure cellulose (wood pulp) with propylene oxide/hydroxypropyl groups. The resulting product is then purified, dried and milled to yield low-substituted hydroxypropyl cellulose. L-HPC contains not less than 5,0 % and not more than 16,0 % of hydroxypropoxy groups, calculated on the dried basis. L-HPC differs from hydroxypropyl cellulose (E 463) with respect to the degree of molar substitution with hydroxypropoxy groups of the glucose ring unit (0,2 for L-HPC vs 3,5 for E 463) of the cellulose backbone.