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To:	General Secretariat of the Council
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Subject:	ANNEXES to the COMMISSION REGULATION (EU) .../... 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

Delegations will find attached document D056136/03 - ANNEXES 1 to 2.

Encl.: D056136/03 - ANNEXES 1 to 2

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ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION (EU) .../...

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

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.
IUPAC name	Cellulose, 2-hydroxypropyl ether (low substituted)
CAS number	9004-64-2
EINECS number	
Chemical name	Hydroxypropyl ether of cellulose, low-substituted
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $C_6H_7O_2(OR_1)(OR_2)(OR_3)$ where R_1, R_2, R_3 each may be one of the following: –H $–CH_2CHOHCH_3$ $–CH_2CHO(CH_2CHOHCH_3)CH_3$ $–CH_2CHO[CH_2CHO(CH_2CHOHCH_3)CH_3]CH_3$
Molecular weight	From about 30,000 to 150,000 g/mol
Assay	The average number of hydroxypropoxy groups ($–OCH_2CHOHCH_3$) corresponds to 0,2 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis
Particle size	by laser diffraction method - Not less than 45 μm (not more than 1% in weight of particles of less than 45 μm) and not

	more than 65 μm by size-exclusion chromatography (SEC) - Average (D50) particle size between 47.3 μm and 50.3 μm; D90 value (90% below given value) between 126.2 μm and 138 μm
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	Passes test
Solubility	Insoluble in water; swelling in water. It dissolves in a solution of 10% sodium hydroxide producing a viscous solution.
Assay	Determination of the degree of molar substitution by gas chromatography
pH	Not less than 5.0 and not more than 7.5 (1% colloidal suspension)
Purity	
Loss on drying	Not more than 5.0 % (105 °C, 1 hour)
Residue on ignition	Not more than 0.8 % determined at 800°C ± 25°C
Propylene chlorohydrins	Not more than 0.1 mg/kg (on an anhydrous basis) (gas chromatography–mass spectrometry (GC–MS))
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 0.5 mg/kg
Cadmium	Not more than 0.15 mg/kg'