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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	14 January 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D102103/02 ANNEXES 1 to 3
Subject:	ANNEXES to the COMMISSION REGULATION amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium carboxy methyl cellulose, cellulose gum (E 466) and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469)

Delegations will find attached document D102103/02 ANNEXES 1 to 3.

Encl.: D102103/02 ANNEXES 1 to 3



EUROPEAN
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ANNEXES 1 to 3

ANNEXES

to the

COMMISSION REGULATION

amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium carboxy methyl cellulose, cellulose gum (E 466) and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469)

ANNEX I

Part E of Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (1) in category 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants), the entry concerning the food additive E 466 (Sodium carboxy methyl cellulose, Cellulose gum) is deleted;
- (2) in category 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC), the entry concerning the food additive E 466 (Sodium carboxy methyl cellulose, Cellulose gum) is deleted.

ANNEX II

In Section B of Part 5 of Annex III to Regulation (EC) No 1333/2008 the entry concerning the food additive E 466 (Sodium carboxy methyl cellulose, Cellulose gum) is deleted.

ANNEX III

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) the entry for 'E 460 (i) Microcrystalline cellulose, cellulose gel' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-34-6';
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(b) the specification 'Purity' is replaced by the following:

'Purity'	
Loss on drying	Not more than 7 % (105 °C, 3 hours)
Water soluble matter	Not more than 0,24 %
Sulphated ash	Not more than 0,5 % (800 ± 25 °C)
Starch	Not detectable To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Carboxyl groups	Not more than 1 %
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg';

(2) the entry for 'E 460 (ii) powdered cellulose' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-34-6';
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(b) the specification 'Purity' is replaced by the following:

'Purity'	
Loss on drying	Not more than 7 % (105 °C, 3 hours)
Water soluble matter	Not more than 1,0 %

Sulphated ash	Not more than 0,3 % (800 ± 25 °C)
Starch	Not detectable To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,3 mg/kg
Mercury	Not more than 0,2 mg/kg
Cadmium	Not more than 0,1 mg/kg';

(3) the entry for 'E 461 methyl cellulose' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-67-5';
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(b) the specification 'Einecs' is replaced by the following:

'Einecs	618-391-7';
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(c) the specification 'Identification' is replaced by the following:

'Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)';

(d) the specification 'Purity' is replaced by the following:

'Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % (800 ± 25 °C)
Arsenic	Not more than 0,1 mg/kg

Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg’;

(4) the entry for ‘E 462 ethyl cellulose’ is amended as follows:

(a) the following specification is inserted after the ‘Definition’:

‘CAS number	9004-57-3’;
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(b) the specification ‘Einecs’ is replaced by the following:

‘Einecs	618-384-9’;
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(c) the specification ‘pH’ is replaced by the following:

‘pH	Neutral to litmus (1 % colloidal dispersion)’;
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(d) the specification ‘Purity’ is replaced by the following:

‘Purity	
Loss on drying	Not more than 3 % (105 °C, 2 hours)
Sulphated ash	Not more than 0,4 %
Arsenic	Not more than 0,5 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,5 mg/kg’;

(5) the entry for ‘E 463 hydroxypropyl cellulose’ is amended as follows:

(a) the following specification is inserted after the ‘Definition’:

‘CAS number	9004-64-2’;
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(b) the specification ‘Einecs’ is replaced by the following:

‘Einecs	618-388-0’;
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(c) the specification ‘Identification’ is replaced by the following:

‘Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Soluble in ethanol. Insoluble in ether
Gas chromatography	Determine the substituents by gas chromatography
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)’;

(d) the specification ‘Purity’ is replaced by the following:

‘Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 0,5 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,5 mg/kg’;

(6) the entry for ‘E 463a low-substituted hydroxypropyl cellulose (L-HPC)’ is amended as follows:

(a) the specification ‘Einecs number’ is replaced by the following:

‘Einecs	618-388-0’;
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(b) the specification ‘pH’ is replaced by the following:

‘pH	Not less than 5,0 and not more than 7,5 (1 % colloidal dispersion)’;
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(c) the specification ‘Purity’ is replaced by the following:

‘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 0,5 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,15 mg/kg’;

(7) the entry for ‘E 464 hydroxypropyl methyl cellulose’ is amended as follows:

(a) the following specification is inserted after the ‘Definition’:

‘CAS number	9004-65-3’,
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(b) the specification ‘Einecs’ is replaced by the following:

‘Einecs	618-389-6’;
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(c) the specification ‘Identification’ is replaced by the following:

‘Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Insoluble in ethanol
Gas chromatography	Determine the substituents by gas chromatography
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)’;

(d) the specification ‘Purity’ is replaced by the following:

‘Purity	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % for products with viscosities of 50 mPa.s or above

	Not more than 3 % for products with viscosities below 50 mPa.s
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg’;

(8) the entry for ‘E 465 ethyl methyl cellulose’ is amended as follows:

(a) the following specification is inserted after the ‘Definition’:

‘CAS number	9004-59-5. The CAS number 9004-69-7 has also been assigned to ethyl methyl cellulose’;
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(b) the specification ‘Identification’ is replaced by the following:

‘Identification	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Soluble in ethanol. Insoluble in ether
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)’;

(c) the specification ‘Purity’ is replaced by the following:

‘Purity	
Loss on drying	Not more than 15 % for the fibrous form, and not more than 10 % for the powdered form (105 °C to constant weight)
Sulphated ash	Not more than 0,6 %
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg’;

(9) the entry for 'E 466 sodium carboxy methyl cellulose, cellulose gum' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-32-4';
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(b) the specification 'Einecs' is replaced by the following:

'Einecs	618-378-6';
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(c) the specification 'Identification' is replaced by the following:

'Identification	
Solubility	Yields a viscous colloidal dispersion in water. Insoluble in ethanol
Foam test	A 0,1 % dispersion of the sample is shaken vigorously. No layer of foam appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers)
Precipitate formation	To 5 ml of a 0,5 % dispersion of the sample, add 5 ml of 5 % solution of copper sulphate or of aluminium sulphate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers and from gelatine, locust bean gum and tragacanth)
Colour reaction	Add 0,5 g powdered carboxy methyl cellulose sodium to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear dispersion is produced, and use the dispersion for the following test: To 1 mg of the sample, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol solution. Incline the test tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
pH	Not less than 5,0 and not more than 8,5 (1 % colloidal dispersion)';

(d) the specification 'Purity' is replaced by the following:

'Purity	
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups (-CH ₂ COOH) per anhydroglucose unit
Loss on drying	Not more than 12 % (105 °C to constant weight)

Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Total glycolate	Not more than 0,4 %, calculated as sodium glycolate on the anhydrous basis
Sodium	Not more than 12,4 % on the anhydrous basis’;

(10) the entry for ‘E 468 cross-linked sodium carboxymethyl cellulose, cross-linked cellulose gum’ is amended as follows:

(a) the following specification is inserted after the ‘Definition’:

‘CAS number	74811-65-7’;
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(b) the specification ‘Einecs’ is replaced by the following:

‘Einecs	629-739-2’;
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(c) the specification ‘pH’ is replaced by the following:

‘pH	Not less than 5,0 and not more than 7,0 (1 % dispersion)’;
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(d) the specification ‘Purity’ is replaced by the following:

‘Purity	
Loss on drying	Not more than 6 % (105 °C, 3 hours)
Water soluble matter	Not more than 10 %
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit
Sodium content	Not more than 12,4 % on anhydrous basis
Arsenic	Not more than 0,2 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg

Cadmium	Not more than 0,1 mg/kg’;
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(11) the entry for ‘E 469 enzymatically hydrolysed carboxymethylcellulose, enzymatically hydrolysed cellulose gum’ is amended as follows:

(a) the specification ‘Identification’ is replaced by the following:

‘Identification	
Solubility	Soluble in water, insoluble in ethanol
Foam test	Vigorously shake a 0,1 % dispersion of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from alginates and natural gums
Precipitate formation	To 5 ml of a 0,5 % dispersion of the sample, add 5 ml of a 5 % solution of copper or aluminium sulphate. A precipitate appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from gelatine, carob bean gum and tragacanth gum
Colour reaction	Add 0,5 g of the powdered sample to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear dispersion is produced. Dilute 1 ml of the dispersion with 1 ml of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
Viscosity (60 % solids)	Not less than 2 500 kgm– 1s– 1 at 25 °C corresponding to an average molecule weight of 5 000 Da
pH	Not less than 6,0 and not more than 8,5 (1 % colloidal dispersion)’;

(b) the specification ‘Purity’ is replaced by the following:

‘Purity	
Loss on drying	Not more than 12 % (105 °C to constant weight)
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit on the dried basis
Sodium chloride and sodium glycolate	Not more than 0,5 % singly or in combination
Residual enzyme activity	Passes test. No change in viscosity of test dispersion occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose

Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg'

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