

Brussels, 23 October 2025 (OR. en)

14386/25 ADD 1

DENLEG 55 FOOD 93 SAN 664

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	22 October 2025
То:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D(2025) 109690 annex
Subject:	ANNEX to the COMMISSION REGULATION (EU)/ of XXX amending Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of carrageenan (E 407), locust bean gum (E 410), guar gum (E 412), gum arabic (acacia gum) (E 414), xanthan gum (E 415), pectins (E 440) and starch sodium octenyl succinate (E 1450) and Commission Regulation (EU) No 231/2012 as regards specifications for locust bean gum (E 410), guar gum (E 412), gum arabic (acacia gum) (E 414), xanthan gum (E 415), pectins (E 440) and starch sodium octenyl succinate (E 1450)

Delegations will find attached document $D(2025)\ 109690$ annex.

Encl.: D(2025) 109690 annex

LIFE.3 EN



Brussels, XXX PLAN/2024/2042 ANNEX REV.1 (POOL/E2/2024/2042/2042 R1-EN ANNEX.docx) D109690/02 [...](2025) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

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

amending Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of carrageenan (E 407), locust bean gum (E 410), guar gum (E 412), gum arabic (acacia gum) (E 414), xanthan gum (E 415), pectins (E 440) and starch sodium octenyl succinate (E 1450) and Commission Regulation (EU) No 231/2012 as regards specifications for locust bean gum (E 410), guar gum (E 412), gum arabic (acacia gum) (E 414), xanthan gum (E 415), pectins (E 440) and starch sodium octenyl succinate (E 1450)

EN EN

ANNEX I

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

- (1) in category 01.10 ('Milk-based drinks and similar products intended for young children'):
 - (a) the entry for E 407 Carrageenan is replaced by the following:

'E 407	Carrageenan	300	(X)'	

;

(b) the entry for E 410 Locust bean gum is replaced by the following:

'E 410 Locust bean gum 10 000 (X)'
--

,

(c) the entry for E 412 Guar gum is replaced by the following:

		'E 412	Guar gum	10 000	(X)'	
--	--	--------	----------	--------	------	--

,

(d) the entry for E 414 Gum arabic (acacia gum) is replaced by the following:

	'E 414	Gum arabic (acacia gum)	10 000	(X)'	

,

(e) the entry for E 415 Xanthan gum is replaced by the following:

'E 415 Xanthan gum 10 000 (X)'

,

(f) the entry for E 440 Pectins is replaced by the following:

			'E 440	Pectins	5 000	(X)'	
--	--	--	--------	---------	-------	------	--

.

- (g) footnote (21) is deleted;
- (h) the new footnote (X) is inserted after footnote (44):

'(X): If more than one of the substances E 407, E 410, E 412, E 414, E 415 and E 440 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff';

- (2) In category 13.1.1 ('Infant formulae as defined by Regulation (EU) No 609/2013') the entry for E 412 Guar gum is deleted;
- in category 13.1.5.1 (Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants):
 - (a) the first sentence is replaced by the following:

'The additives of categories 13.1.1 and 13.1.2 are applicable, except for E 412';

(b) the entry for E 410 Locust bean gum is replaced by the following:

	'E 410	Locust bean gum	5 300	From birth onwards in products for reduction of gastro-oesophageal reflux'
L				1 0

,

- (c) the entry for E 412 Guar gum is deleted;
- (d) the entry for E 440 Pectins is replaced by the following:

í.	E 440	Pectins	4 000		From birth onwards in products used in case of gastro-intestinal disorders'
----	-------	---------	-------	--	---

.

(e) the entry for E 1450 Starch sodium octenyl succinate is replaced by the following:

'E 1450	Starch sodium octenyl succinate	20 000	only in infant formulae and follow-on formulae
			Period of application: until [24 months after the date of entry into force of this Regulation]
E 1450	Starch sodium octenyl succinate	10 000	only in infant formulae and follow-on formulae Period of
			application: from [24 months after the date of entry into force of this Regulation]'

,

- (4) in category 13.1.5.2 (Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants as from four months of age and for young children):
 - (a) the first sentence is replaced by the following:

EN

^{&#}x27;The additives of categories 13.1.2 and 13.1.3 are applicable, except for E 270, E 333, E 341, E 412.';

(b) the entry for E 410 Locust bean gum is replaced by the following:

'E 410	Locust bean gum	5 300	Fron	n birth onwar	ds in	products
				reduction ophageal reflu		gastro-
			0000	pinagear refra		

,

(c) the entry for E 412 Guar gum is replaced by the following;

'E 412	Guar gum	10 000	From birth onwards in products in liquid formulae containing hydrolysed proteins, peptides or amino acids Period of application: until 27 April 2027'
--------	----------	--------	--

.

(d) the entry for E 440 Pectins is replaced by the following:

'E 440	Pectins	4 000	From birth onwards in products
			used in case of gastro-intestinal
			disorders'

.

(e) the entry for E 1450 Starch sodium octenyl succinate is replaced by the following:

'E 1450	Starch sodium octenyl succinate	20 000	Period of application: until [24 months after the date of entry into force of this Regulation]
E 1450	Starch sodium octenyl succinate	10 000	Period of application: from [24 months after the date of entry into force of this Regulation]'

ANNEX II

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

(1) the entry for 'E 410 LOCUST BEAN GUM' is replaced by the following:

'E 410 LOCUST BEAN GUM

Synonyms	Carob bean gum; Algaroba gum
Definition	Locust bean gum is the ground endosperm of the seeds of the strainsof carob tree, <i>Cerationia siliqua</i> (L.) Taub. (family <i>Leguminosae</i>). The seeds are dehusked by treating the kernels with dilute sulfuric acid or with thermal mechanical treatments, elimination of the germ, followed by milling and screening of the endosperm to obtain native locust bean gum. Locust bean gum consists mainly of a high molecular weight hydrocolloidal polysaccharide, composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan.
Einecs	232-541-5
CAS number	9000-40-2
Chemical name	
Chemical formula	
Molecular weight	50 000 - 3 000 000
Assay	Galactomannan content not less than 75 %
Description	White to yellowish-white, nearly odourless powder
Identification	
Test for galactose	Passes test
Test for mannose	Passes test
Microscopic examination	Place some ground sample in an aqueous solution containing 0,5 % iodine and 1 % potassium iodide on a glass slide and examine under microscope. Locust bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed than in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown
Solubility	Fully dispersible in hot water, insoluble in ethanol
Purity	

Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 1,2 % determined at 800 °C
Protein (N × 6,25)	Not more than 7 %
Acid-insoluble matter	Not more than 4 %
Starch	Not detectable by the following method: to a 1 in 10 dispersion of the sample add a few drops of iodine solution. No blue colour is produced.
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,4 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Ethanol and propan- 2-ol	Not more than 1 %, single or in combination
Microbiological criteria	
Total plate count	Not more than 5 000 cfu/g
Yeast and moulds	Not more than 500 cfu/g
Enterobacteriaceae	Absent in 10 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)
Escherichia coli	Absent in 1 g
Salmonella spp.	Absent in 25 g
Cronobacter spp. (Enterobacter sakazakii)	Absent in 10 g (only if added to dried infant formulae and dried foods for special medical purposes intended for infants below 6 months of age)'

(2) the entry for 'E 412 GUAR GUM' is replaced by the following:

'E 412 GUAR GUM

Synonyms	Gum cyamopsis; Guar flour
Definition	Guar gum is the ground endosperm of the seeds of strains of the
	guar plant, Cyamopsis tetragonolobus (L.) Taub.

	(family <i>Leguminosae</i>). The germ and endosperm are separated via milling and sieving. The hull is removed via treatment with moist or dry, hot air and sieving. Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan. The gum may be partially hydrolysed by either heat treatment, mild acid or alcaline oxidative treatment for viscosity adjustment.
Einecs	232-536-0
CAS number	9000-30-0
Chemical name	
Chemical formula	
Molecular weight	50 000 - 8 000 000
Assay	Galactomannan content not less than 75 %
Description	A white to yellowish-white, nearly odourless powder
Identification	
Test for galactose	Passes test
Test for mannose	Passes test
Solubility	Dispersible in cold water
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 5,5 % determined at 800 °C
Acid-insoluble matter	Not more than 7 %
Protein	Not more than 10 % (factor N x 6,25) (Kjeldahl method)
Starch	Not detectable by the following method: to a 1 in 10 dispersion of the sample add a few drops of iodine solution. No blue colour is produced.
Organic peroxides	Not more than 0,7 meq active oxygen/kg sample
Furfural	Not more than 1 mg/kg
Pentachlorophenol	Not more than 0,01 mg/kg

Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,2 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 cfu/g
Yeast and moulds	Not more than 500 cfu/g
Enterobacteriaceae	Absent in 10 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)
Escherichia coli	Absent in 1 g
Salmonella spp.	Absent in 25 g'

(3) the entry for 'E 414 ACACIA GUM' is replaced by the following:

'E 414 GUM ARABIC (ACACIA GUM)

Synonyms	
Definition	Acacia gum is a dried exudation obtained from the stems and branches of strains of <i>Acacia senegal</i> (L) Willdenow or closely related species of Acacia (family <i>Leguminosae</i>). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid.
Einecs	232-519-5
CAS number	9000-01-5
Chemical name	
Chemical formula	
Molecular weight	Approximately 350 000
Assay	
Description	Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white

	to yellowish-white flakes, granules, powder or spray-dried material.
Identification	
Solubility	1 g dissolves in 2 ml of cold water forming a dispersion which flows readily and is acid to litmus, insoluble in ethanol.
Purity	
Loss on drying	Not more than 17 % (105 °C, 5 hours) for granular and not more than 10 % (105 °C, 4 hours) for spray-dried material
Total ash	Not more than 4 %
Acid insoluble ash	Not more than 0,5 %
Acid insoluble matter	Not more than 1 %
Starch or dextrin	Boil a 1 in 50 dispersion of the gum and cool. To 5 ml add 1 drop of iodine solution. No bluish or reddish colours are produced.
Tannin	To 10 ml of a 1 in 50 dispersion add about 0,1 ml of ferric chloride solution (9 g FeCl ₃ .6H ₂ O made up to 100 ml with water). No blackish colouration or blackish precipitate is formed.
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,05 mg/kg
Mercury	Not more than 0,05 mg/kg
Cadmium	Not more than 0,05 mg/kg
Aluminium	Not more than 100 mg/kg (only if added to foods for infants and young children)
	Not more than 200 mg/kg (for all uses except for foods intended for infants and young children)
Hydrolysis products	Mannose, xylose and galacturonic acid are absent (determined by chromatography).
Proteins	Not more than 3,5%
	Oxidases and peroxidases occurring in acacia gum naturally or as a result of processing should be inactivated during the manufacturing process of acacia gum used in foods for infants and young children.
Microbiological criteria	
Total plate count	Not more than 10 000 cfu/g
	•

Yeast and moulds	Not more than 10 000 cfu/g
Salmonella spp.	Absent in 25 g
Enterobacteriaceae	Absent in 10 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)
Escherichia coli	Absent in 5 g
Cronobacter spp. (Enterobacter sakazakii)	Absent in 10 g (only if added to dried infant formulae and dried foods for special medical purposes intended for infants below 6 months of age)'

(4) the entry for 'E 415 XANTHAN GUM' is replaced by the following:

'E 415 XANTHAN GUM

Synonyms	
Definition	Xanthan gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with strains of <i>Xanthomonas campestris</i> , which are unequivocally identified and meet the criteria for qualification for QPS status (i.e. absence of acquired antimicrobial resistance genes), purified by recovery with ethanol or propan-2-ol, dried and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid, pyruvic acid and acetic acid, and is prepared as the sodium, potassium or calcium salt. Its dispersions in water are neutral. The final product must not show any residual enzyme activity.
Einecs	234-394-2
CAS number	11138-66-2
Chemical name	
Chemical formula	
Molecular weight	Approximately 1 000 000
Assay	Yields, on dried basis, not less than 4,2 % and not more than 5 % of CO ₂ corresponding to between 91 % and 108 % of xanthan gum
Description	Cream-coloured powder
Identification	
Solubility	Dispersible in water. Insoluble in ethanol.

Purity	
Loss on drying	Not more than 15 % (105 °C, 2,5 hours)
Total ash	Not more than 16 % on the anhydrous basis determined at 650 °C after drying at 105 °C for four hours
Pyruvic acid	Not less than 1,5 %
Nitrogen	Not more than 1,5 % (Kjeldahl method)
Ethanol and propan-2-ol	Not more than 500 mg/kg singly or in combination
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 0,05 mg/kg
Cadmium	Not more than 0,3 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 cfu/g
Yeast and moulds	Not more than 300 cfu/g
Enterobacteriaceae	Absent in 10 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)
Escherichia coli	Absent in 5 g
Salmonella spp.	Absent in 25 g
Cronobacter spp. (Enterobacter sakazakii)	Absent in 10 g (only if added to dried infant formulae and dried foods for special medical purposes intended for infants below 6 months of age)
Xanthomonas campestris	Viable cells absent in 1 g'

.

(5) the entry for 'E 440 (i) PECTIN' is replaced by the following:

'E 440 (i) PECTIN

Synonyms									
Definition	Pectin	consists	mainly	of	the	partial	methyl	esters	of

	polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of strains of appropriate edible plant material, usually citrus fruits or apples. The final product must not show any residual enzyme activity. No organic precipitant shall be used other than methanol, ethanol and propan-2-ol.
Einecs	232-553-0
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 65 % of galacturonic acid on the ash-free and anhydrous basis after washing with acid and alcohol
Description	White, light yellow, light grey or light brown powder
Identification	
Solubility	Dispersible in water forming a colloidal, opalescent dispersion. Insoluble in ethanol.
Purity	
Loss on drying	Not more than 12 % (105 °C, 2 hours)
Acid insoluble ash	Not more than 1 % (insoluble in approximately 3N hydrochloric acid)
Sulphur dioxide	Not more than 50 mg/kg on the anhydrous basis
Nitrogen content	Not more than 1,0 % after washing with acid and ethanol
Total insolubles	Not more than 3 %
Solvent residues	Not more than 1 % of free methanol, ethanol and propan-2-ol, singly or in combination, on the volatile matter-free basis
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,3 mg/kg (only if added to foods for infants and young children)
	Not more than 1 mg/kg (for all uses except for foods intended for infants and young children)
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg (only if added to foods for infants and

	young children)	
	Not more than 0,5 mg/kg (for all uses except for foods intended for infants and young children)	
Aluminium	Not more than 120 mg/kg (only if added to foods for infants and young children)	
	Not more than 200 mg/kg (for all uses except for foods intended for infants and young children)	
Microbiological criteria		
Enterobacteriaceae	Absent in 10 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)	
Escherichia coli	Absent in 10 g	
Salmonella spp.	Absent in 25 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)	
Cronobacter spp. (Enterobacter sakazakii)	Absent in 10 g (only if added to dried infant formulae and dried foods for special medical purposes intended for infants below 6 months of age)'	

;

(6) the entry for 'E 440 (ii) AMIDATED PECTIN' is replaced by the following:

'E 440 (ii) AMIDATED PECTIN

Synonyms	
Definition	Amidated pectin consists mainly of the partial methyl esters and amides of polygalacturonic acid and their ammonium, sodium, potassium and calcium salts. It is obtained by extraction in an aqueous medium of appropriate strains of edible plant material, usually citrus fruits or apples and treatment with ammonia under alkaline conditions. The final product must not show any residual enzyme activity. No organic precipitant shall be used other than methanol, ethanol and propan-2-ol.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content not less than 65 % of galacturonic acid on the ash-free and

	anhydrous basis after washing with acid and alcohol		
Description	White, light yellow, light greyish or light brownish powder		
Identification			
Solubility	Dispersible in water forming a colloidal, opalescent dispersion. Insoluble in ethanol.		
Purity			
Loss on drying	Not more than 12 % (105 °C, 2 hours)		
Acid-insoluble ash	Not more than 1 % (insoluble in approximately 3N hydrochloric acid)		
Degree of amidation	Not more than 25 % of total carboxyl groups		
Sulphur dioxide	Not more than 50 mg/kg on the anhydrous basis		
Nitrogen content	Not more than 2,5 % after washing with acid and ethanol		
Total insolubles:	Not more than 3 %		
Solvent residues	Not more than 1 % of methanol, ethanol and propan-2-ol, singly or in combination, on a volatile matter-free basis		
Arsenic	Not more than 0,1 mg/kg		
Lead	Not more than 0,3 mg/kg (only if added to foods for infants and young children)		
	Not more than 1 mg/kg (for all uses except for foods intended for infants and young children)		
Mercury	Not more than 0,1 mg/kg		
Cadmium	Not more than 0,1 mg/kg (only if added to foods for infants and young children)		
	Not more than 0,5 mg/kg (for all uses except for foods intended for infants and young children)		
Aluminium	Not more than 120 mg/kg (only if added to foods for infants and young children)		
	Not more than 200 mg/kg (for all uses except for foods intended for infants and young children)		
Microbiological criteria			
Enterobacteriaceae	Absent in 10 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of		

	age and dried follow-on formulae)
Escherichia coli	Absent in 10 g
Salmonella spp.	Absent in 25 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)
Cronobacter spp. (Enterobacter sakazakii)	Absent in 10 g (only if added to dried infant formulae and dried foods for special medical purposes intended for infants below 6 months of age)'

(7) the entry for 'E 1450 STARCH SODIUM OCTENYL SUCCINATE' is replaced by the following:

'E 1450 STARCH SODIUM OCTENYL SUCCINATE

Synonyms	SSOS
Definition	Starch sodium octenyl succinate is a modified starch. It is manufactured by treatment of a slurry of food starch with octenylsuccinic anhydride. After the appropriate extent of esterification is achieved, the modified starch is recovered by neutralisation with acid, washing with water, dewatering and drying.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	White or nearly white powder or granules or (if pregelatinised) flakes, amorphous powder or coarse particles
Identification	
Microscopic observation	Passes test (if not pregelatinised)
Iodine staining	Passes test (dark blue to light red colour)
Purity	
Loss on drying	Not more than 15,0 % for cereal starch Not more than 21,0 % for potato starch Not more than 18,0 % for other starches

Octenylsuccinyl groups	Not more than 3 % (on an anhydrous basis)	
Octenylsuccinic acid residue	Not more than 0,3 % (on an anhydrous basis)	
Sulphur dioxide	Not more than 10 mg/kg on the anhydrous basis	
Arsenic	Not more than 0,05 mg/kg (on an anhydrous basis) (only if added to foods for infants and young children)	
	Not more than 0,1 mg/kg (on an anhydrous basis) (for all u except for foods intended for infants and young children)	
Lead	Not more than 0,03 mg/kg (on an anhydrous basis) (only if added to foods for infants and young children)	
	Not more than 0,2 mg/kg (on an anhydrous basis) (for all uses except for foods intended for infants and young children)	
Mercury	Not more than 0,05 mg/kg (on an anhydrous basis)	
Cadmium	Not more than 0,01 mg/kg (on an anhydrous basis) (only if added to foods for infants and young children)	
	Not more than 0,1 mg/kg (on an anhydrous basis) (for all uses except for foods intended for infants and young children)	
Gluten	Gluten free, only in infant formula and follow-on formula, in accordance with Commission Delegated Regulation (EU) 2016/127/EC of 25 September 2015	
Microbiological criteria		
Enterobacteriaceae	Absent in 10 g (only if added to dried infant formulae, dried foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae)	
Escherichia coli	Absent in 10 g (only if added to foods for infants)	
Salmonella spp.	Absent in 25 g (only if added to dried infant formulae, dried for special medical purposes intended for infants below 6 months age and dried follow-on formulae)	
Cronobacter spp. (Enterobacter sakazakii)	Absent in 10 g (only if added to dried infant formulae and dri foods for special medical purposes intended for infants below months of age)'	