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COMMISSION REGULATION (EU) 2026/196

of 28 January 2026

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)

(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 Article 10(3) and Article 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) Commission Regulation (EU) No 231/2012 ([3]) lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) The Union list of food additives 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.

(4) 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) are food additives authorised in accordance with Regulation (EC) No 1333/2008.

(5) On 20 January 2017, the European Food Safety Authority ('the Authority') issued a scientific opinion on the re-evaluation of locust bean gum (E 410) as a food additive ([4]). The Authority concluded that there was no need for a numerical acceptable daily intake ('ADI') and that there would be no safety concern at the reported uses and use levels. However, infants and young children consuming foods for special medical purposes may show a higher susceptibility to the gastrointestinal effects of locust bean gum (E 410) due to their underlying medical condition. The Authority concluded that the available data did not allow an adequate assessment of the safety of locust bean gum (E 410) when used in foods for special medical purposes intended for infants and for young children (food categories 13.1.5.1 and 13.1.5.2). The Authority recommended some modifications to the specifications for locust bean gum (E 410) set out in Regulation (EU) No 231/2012. In addition, the Authority recommended including carrageenan (E 407) in Annex II to Regulation (EC) No 1333/2008 in the footnote for 'milk-based drinks and similar products intended for young children' (current food category 01.10) regulating the combined use of the gums.

([1]) OJ L 354, 31.12.2008, p. 16, ELI: http://data.europa.eu/eli/reg/2008/1333/oj.
([2]) OJ L 354, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1331/oj.
([3]) 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, ELI: http://data.europa.eu/eli/reg/2012/231/oj).
([4]) *EFSA Journal* 2017;15(1):4646 (https://doi.org/10.2903/j.efsa.2017.4646).

(6) On 18 July 2018, the Authority launched a public call for technical and toxicological data on locust bean gum (E 410) for uses in foods for all population groups including infants below 16 weeks of age, to collect the data needed for addressing its recommendations for that food additive. Business operators provided data in response to the call.

(7) On 9 February 2023, the Authority issued a 'scientific opinion on the re-evaluation of locust bean gum (E 410) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as a food additive for uses in foods for all population groups' ([5]). The Authority concluded that that the use of locust bean gum (E 410) in foods falling under food categories 13.1.5.1 and 13.1.5.2 raises safety risks.As regards the specification as laid down in Regulation (EU) No 231/2012, the Authority recommended amending the definition, reducing the maximum limits for toxic elements (lead, arsenic, mercury and cadmium), changing the word 'soluble' to 'fully dispersible' based on the consideration that hydrocolloids form colloidal dispersions in water instead of true solutions, and including microbiological criteria.

(8) It is therefore appropriate to revise the conditions of use of locust bean gum (E 410) in food categories 13.1.5.1 and 13.1.5.2 and amend its definition and specifications in light of the Authority's scientific opinion. In particular, in its specifications, the current maximum limits for toxic elements should be reduced and microbiological criteria should be laid down in accordance with the scientific opinion of the Authority and taking into account the level which is currently achievable by the application of good manufacturing practices. Furthermore, the word 'soluble' should be changed to 'fully dispersible'.

(9) On 24 February 2017, the Authority issued a scientific opinion on the re-evaluation of guar gum (E 412) as a food additive ([6]). The Authority concluded that there was no need for a numerical ADI and that there would be no safety concern at the reported uses and use levels. The Authority also concluded that the available data did not allow an adequate assessment of the safety of guar gum (E 412) when used in foods for special medical purposes intended for infants and for young children (food categories 13.1.5.1 and 13.1.5.2). The Authority recommended some modifications to the specifications for guar gum (E 412) set out in Regulation (EU) No 231/2012.

(10) On 18 July 2018, the Authority launched a public call for technical and toxicological data on guar gum (E 412) for uses in foods for all population groups including infants below 16 weeks of age, to collect the data needed for addressing its recommendations for that food additive. Business operators provided data in response to the call.

(11) On 21 March 2024, the Authority issued a 'scientific opinion on the re-evaluation of guar gum (E 412) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as a food additive for uses in foods for all population groups' ([7]). As regards its specifications as laid down in Regulation (EU) No 231/2012, the Authority recommended reducing the maximum limits for toxic elements, changing the words 'solution/soluble' to 'dispersion/dispersible', including microbiological criteria and specifying the Kjeldahl method for protein analysis. The Authority concluded that the submitted data are not sufficient to demonstrate the safety of the use of guar gum (E 412) in infant formula and foods for special medical purposes falling under food categories 13.1.1, 13.1.5.1 or 13.1.5.2.

(12) It is therefore appropriate to withdraw the authorisation of guar gum (E 412) in food categories 13.1.1, 13.1.5.1 and 13.1.5.2 and amend its specifications in light of the Authority's scientific opinion. In particular, the definition should contain the way of processing. In the specifications, the current maximum limits for toxic elements should be reduced and microbiological criteria should be laid down in accordance with the scientific opinion of the Authority and taking into account the level which is currently achievable by the application of good manufacturing practices. Given the withdrawal of the authorisation of guar gum (E 412) in food categories 13.1.1, 13.1.5.1 and 13.1.5.2 it is not necessary to establish a criterion for *Cronobacter* spp. (*Enterobacter sakazakii*), which is particularly relevant for foods intended for infants below 6 months of age. Furthermore, the Kjeldahl method should be specified for protein analysis and the words 'solution/soluble' should be changed to 'dispersion/dispersible'.

([5]) *EFSA Journal* 2023;21(2):7775 (https://doi.org/10.2903/j.efsa.2023.7775).
([6]) *EFSA Journal* 2017;15(2):4669 (https://doi.org/10.2903/j.efsa.2017.4669).
([7]) *EFSA Journal* 2024;22:e8748 (https://doi.org/10.2903/j.efsa.2024.8748).

(13) On 6 April 2017, the Authority issued a scientific opinion on the re-evaluation of gum arabic (acacia gum) (E 414) as a food additive ([8]). The Authority concluded that there was no need for a numerical ADI and that there would be no safety concern at the reported uses and use levels. The Authority recommended some modifications to the specifications for gum arabic (acacia gum) (E 414) set out in Regulation (EU) No 231/2012.

(14) On 10 October 2018, the Authority launched a public call for technical and toxicological data on gum arabic (acacia gum) (E 414) for uses in foods for all population groups including infants below 16 weeks of age, to collect the data needed for addressing its recommendations for that food additive. Business operators provided data in response to the call.

(15) On 13 December 2019, the Authority issued a 'scientific opinion on the re-evaluation of gum arabic (acacia gum) (E 414) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as a food additive for uses in foods for all population groups' ([9]). The Authority concluded that the use of gum arabic (acacia gum) (E 414) at the current use levels does not raise health risks. As regards its specifications as laid down in Regulation (EU) No 231/2012, the Authority recommended reducing the maximum limits for toxic elements, including a maximum limit for aluminium and proteins, amending the microbiological criteria, and specifying that oxidases and peroxidases are inactivated.

(16) It is therefore appropriate to amend the specifications of gum arabic (acacia gum) (E 414) in light of the Authority's scientific opinion. In particular, maximum limits for aluminium and proteins should be laid down, the current maximum limits for toxic elements as well as the microbiological criteria should be amended, in accordance with the scientific opinion of the Authority and considering the level which is currently achievable by the application of good manufacturing practices. Furthermore, it should be specified that oxidases and peroxidases should be inactivated during the manufacturing process when used in foods for infants and young children. Considering that gum arabic (acacia gum) (E 414) is a hydrocolloid that forms colloidal dispersions in water instead of true solutions, the recommendation by the Authority to change the words 'solution/soluble' to 'dispersion/dispersible' made for other hydrocolloids should also be applied as regards gum arabic (acacia gum) (E 414).

(17) On 14 July 2017, the Authority issued a scientific opinion on the re-evaluation of xanthan gum (E 415) as a food additive ([10]). The Authority concluded that there was no need for a numerical ADI and that there would be no safety concern at the reported uses and use levels. The Authority specified that re-evaluation of xanthan gum (E 415) as a food additive did not cover infants below 12 weeks of age. The Authority recommended some modifications to the specifications for xanthan gum (E 415) set out in Regulation (EU) No 231/2012.

(18) On 18 July 2018, the Authority launched a public call for technical and toxicological data on xanthan gum (E 415) for uses in foods for all population groups including infants below 16 weeks of age, to collect the data needed for addressing its recommendations for that food additive. Business operators provided data in response to the call.

(19) On 21 March 2023, the Authority issued a 'scientific opinion on the re-evaluation of xanthan gum (E 415) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as a food additive for uses in foods for all population groups' ([11]). The Authority concluded that there are no safety concerns for infants below 16 weeks of age resulting from the use of xanthan gum (E 415) as a food additive in food category 13.1.5.1. As regards its specifications as laid down in Regulation (EU) No 231/2012, the Authority recommended to modify the definition of xanthan gum (E 415), reducing the maximum limit for lead and considering the adoption of maximum limits for arsenic, mercury and cadmium. The Authority also recommended changing the words 'solution/soluble' to 'dispersion/dispersible', amending the microbiological criteria and specifying the Kjeldahl method for nitrogen analysis. It is therefore appropriate to amend the specifications of xanthan gum (E 415) accordingly. In light of the Authority's scientific opinion, it is therefore appropriate to amend the definition and the specifications of xanthan gum (E 415).

([8]) *EFSA Journal* 2017;15(4):4741 (https://doi.org/10.2903/j.efsa.2017.4741).
([9]) *EFSA Journal* 2019;17(12):5922 (https://doi.org/10.2903/j.efsa.2019.5922).
([10]) *EFSA Journal* 2017;15(7):4909 (https://doi.org/10.2903/j.efsa.2017.4909).
([11]) *EFSA Journal* 2023;21(5):7951 (https://doi.org/10.2903/j.efsa.2023.7951).

(20) On 6 July 2017, the Authority issued a scientific opinion on the re-evaluation of pectin (E 440i) and amidated pectin (E 440ii) as food additives ([12]). The Authority concluded that there was no need for a numerical ADI and that there would be no safety concern at the reported uses and use levels. It considered that the available data did not allow for an adequate assessment of the safety of pectins (E 440) in infants and young children consuming foods belonging to food categories 13.1.5.1 and 13.1.5.2. The Authority recommended some modifications to the definition and specifications of pectin (E 440i) and amidated pectin (E 440ii) set out in Regulation (EU) No 231/2012.

(21) On 18 July 2018, the Authority launched a public call for technical and toxicological data on pectin (E440i) and amidated pectin (E 440ii) for uses as food additives in foods for all population groups including infants below 16 weeks of age, to collect the data needed for addressing its recommendations for those food additives and to carry out the assessment of the safety of pectins (E 440) for infants and young children consuming foods belonging to food categories 13.1.5.1 and 13.1.5.2. Business operators provided data in response to the call.

(22) On 29 January 2021, the Authority issued a 'scientific opinion on the re-evaluation of pectin (E 440i) and amidated pectin (E 440ii) as food additives in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additives for uses in foods for all population groups' ([13]). The Authority concluded that the use of pectins (E 440) in food categories 13.1.5.1 and 13.1.5.2 at the currently authorised levels raise health risks. As regards their specifications as laid down in Regulation (EU) No 231/2012, the Authority recommended reducing the maximum limits for toxic elements, including a maximum limit for aluminium and including microbiological criteria.

(23) It is therefore appropriate to revise the conditions of use of pectins (E 440) in food categories 13.1.5.1 and 13.1.5.2 and amend their definition and specifications in light of the Authority's scientific opinion. In particular, in their specifications, the current maximum limits for toxic elements should be reduced, a maximum limit for aluminium should be laid down, and microbiological criteria should be laid down in accordance with the scientific opinion of the Authority and considering the level which is currently achievable by the application of good manufacturing practices. Considering that pectins (E 440) are hydrocolloids that form colloidal dispersions in water instead of true solutions, the recommendation by the Authority to change the words 'solution/soluble' to 'dispersion/dispersible' made for other hydrocolloids is also applicable to pectins (E 440).

(24) On 5 October 2017, the Authority issued a scientific opinion on the re-evaluation of oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives ([14]). The Authority concluded that there was no need for a numerical ADI and that there would be no safety concern at the reported uses and use levels. It was specified that the available data did not allow for an adequate assessment of the safety of starch sodium octenyl succinate (E 1450) in infants and young children consuming foods belonging to food categories 13.1.5.1 and 13.1.5.2. The Authority recommended some modifications to the definition and specifications of starch sodium octenyl succinate (E 1450) set out in Regulation (EU) No 231/2012.

(25) On 18 July 2018, the Authority launched a public call for technical and toxicological data on starch sodium octenyl succinate (E 1450) for uses as a food additive in foods for all population groups including infants below 16 weeks of age, to collect the data needed to carry out the assessment of its safety for infants and young children consuming foods belonging to food categories 13.1.5.1 and 13.1.5.2. Business operators provided data in response to the call.

([12]) *EFSA Journal* 2017;15(7):4866 (https://doi.org/10.2903/j.efsa.2017.4866).
([13]) *EFSA Journal* 2021;19(1):6387 (https://doi.org/10.2903/j.efsa.2021.6387).
([14]) *EFSA Journal* 2017;15(10):4911 (https://doi.org/10.2903/j.efsa.2017.4911).

(26) On 13 August 2020, the Authority issued a 'scientific opinion on the re-evaluation of starch sodium octenyl succinate (E 1450) as a food additive in foods for infants below 16 weeks of age and the follow-up of its re-evaluation as a food additive for uses in foods for all population groups' ([15]). As regards its specifications as laid down in Regulation (EU) No 231/2012, the Authority recommended reducing the maximum limits for sulphur dioxide, arsenic, lead and mercury, including a maximum limit for cadmium, specifying that starch sodium octenyl succinate (E 1450) is not to contain gluten when used in infant formula and follow-on formula and including microbiological criteria. The Authority concluded that there is no indication for safety concern when the dietary exposure of infants and young children consuming foods belonging to food categories 13.1.5.1 and 13.1.5.2 is within the dose range reported in the clinical studies (up to 2 725 mg/kg bw per day). However, the Authority noted that at the reported use levels, the estimates of exposure could exceed this dose.

(27) It is therefore appropriate to revise the conditions of use of starch sodium octenyl succinate (E 1450) in food categories 13.1.5.1 and 13.1.5.2 and amend its specifications in light of the Authority's scientific opinion. In particular, in its specifications, the current maximum limits for sulphur dioxide, arsenic, lead and mercury should be reduced, a maximum limit for cadmium as well as microbiological criteria should be laid down in accordance with the scientific opinion of the Authority and considering the level which is currently achievable by the application of good manufacturing practices. Furthermore, it should be specified that starch sodium octenyl succinate (E 1450) used in infant formula and follow-on formula should not contain gluten. Considering that starch sodium octenyl succinate (E 1450) is a hydrocolloid that forms colloidal dispersions in water instead of true solutions, the recommendation by the Authority to change the words 'solution/soluble' to 'dispersion/dispersible' made for other hydrocolloids is also applicable to starch sodium octenyl succinate (E 1450).

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

(29) Considering that the Authority did not identify an immediate health concern linked to the current 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) and in order to allow the food business operators, including small and medium enterprises, to adapt to the new more stringent specifications laid down in this Regulation, the application of the new specifications should be deferred and a transitional period should be provided for the use of those food additives lawfully placed on the market before the date of application of this Regulation.

(30) For the same reasons, a transitional period should be provided for foods containing locust bean gum (E 410), guar gum (E 412), gum arabic (acacia gum) (E 414), xanthan gum (E 415), pectins (E 440) or starch sodium octenyl succinate (E 1450) that have been lawfully placed on the market before the date of application of this Regulation.

(31) Considering that the Authority did not identify an immediate health concern linked to the conditions of use of certain food additives which are amended by this Regulation and in order to allow the food business operators, including small and medium enterprises, to adapt to the new conditions of use laid down in this Regulation, the application of those conditions should be deferred by six months and a transitional period should be provided for food lawfully placed on the market before the date of application of this Regulation. However, considering the different steps needed for the reformulation of foods belonging to food categories 13.1.5.1 and 13.1.5.2 to adapt to the new conditions of use of starch sodium octenyl succinate (E 1450), in order to ensure the availability of foods belonging to these food categories, the application of the new conditions of use for that food additive should be deferred for a longer period.

([15]) *EFSA Journal* 2020;18(8):5874 (https://doi.org/10.2903/j.efsa.2020.5874).

(32) Considering that the Authority did not identify an immediate health concern linked to the use of guar gum (E 412) in food categories 13.1.1, 13.1.5.1 and 13.1.5.2 and in order to allow the food business operators, including small and medium enterprises, to find alternative, the withdrawal of the authorisation concerning that use should be deferred by six months and a transitional period should be provided for products placed on the market before the withdrawal of the authorisation. However, since guar gum (E 412) in foods belonging to food category 13.1.5.2 is used in combination with sodium carboxy methyl cellulose, cellulose gum (E 466) for which the authorisation was withdrawn by Commission Regulation (EU) 2025/666 ([16]) as of 27 April 2027, it is appropriate that the withdrawal of the authorisation of use for guar gum (E 412) for that food category is deferred until that date.

(33) 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

1. The food additives 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) that have been lawfully placed on the market before 18 August 2026 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

2. Foods, to which locust bean gum (E 410), guar gum (E 412), gum arabic (acacia gum) (E 414), xanthan gum (E 415), pectins (E 440) or starch sodium octenyl succinate (E 1450) that have been lawfully placed on the market before 18 August 2026 are added, may be placed on the market until their date of minimum durability or 'use-by date'.

3. Foods, not complying with provisions laid down in Annex I, that have been lawfully placed on the market before 18 August 2026 or, in the case of foods containing starch sodium octenyl succinate (E 1450) before 18 February 2028, may continue to be marketed until their date of minimum durability or 'use-by' date.

4. Foods, that have been lawfully placed on the market before 18 August 2026 belonging to food categories 13.1.1 'Infant formulae as defined by Regulation (EU) No 609/2013' and 13.1.5.1 'Foods for special medical purposes, as defined by Regulation (EU) No 609/2013, intended for infants' and containing guar gum (E 412) may continue to be marketed until their date of minimum durability or 'use-by date'.

([16]) Commission Regulation (EU) 2025/666 of 4 April 2025 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) (OJ L, 2025/666, 7.4.2025, ELI: http://data.europa.eu/eli/reg/2025/666/oj).

5. Foods, that have been lawfully placed on the market before 27 April 2027 belonging to food 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' and containing guar gum (E 412) may continue to be marketed until their date of minimum durability or 'use-by date'.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 18 August 2026.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 January 2026.

For the Commission
The President
Ursula VON DER LEYEN

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;

(3) 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'

(c) the entry for E 412 Guar gum is deleted;

(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		only in infant formulae and follow-on formulae Period of application: until 18 February 2028
	E 1450	Starch sodium octenyl succinate	10 000		only in infant formulae and follow-on formulae Period of application: from 18 February 2028'

(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:
'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		From birth onwards in products for reduction of gastro-oesophageal reflux'

(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 18 February 2028
	E 1450	Starch sodium octenyl succinate	10 000		Period of application: from 18 February 2028'

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, *Ceratonia siliqua* (L.) Taub. (family *Leguminosae*). 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 *Leguminosae*). 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 × 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 *Acacia senegal* (L) Willdenow or closely related species of Acacia (family *Leguminosae*). 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 $FeCl_3.6H_2O$ 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 *Xanthomonas campestris*, 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 uses 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 (*)
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 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)

(*) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1, ELI: http://data.europa.eu/eli/reg_del/2016/127/oj).'.