

This document has not been adopted nor endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

WORKING DOCUMENT

Commission internal procedures not yet launched.

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

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of locust bean gum (E 410), guar gum (E 412), pectins (E 440) and starch sodium octenyl succinate (E 1450) and the Annex to 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 additives¹, 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 flavourings², 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.

¹ OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/2024-04-23>.

² OJ L 354, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1331/2021-03-27>.

- (2) Commission Regulation (EU) No 231/2012³ 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 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.
- (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 additive⁴. 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. However, infants and young children consuming foods for special medical purposes may show a higher susceptibility to gastrointestinal effects of locust bean gum (E 410) due to their underlying medical condition. The Authority concluded that the available data do not allow an adequate assessment of the safety of locust bean gum (E 410) when used in 'dietary foods for infants for special medical purposes and special formulae for infants' (Food category 13.1.5.1) and in 'dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' (Food category 13.1.5.2). The Authority recommended some modifications to the specifications for E 410 set out in Regulation (EU) No 231/2012. In addition, for Annex II to Regulation (EC) No 1333/2008, the Authority recommended to include carrageenan (E 407) in the footnote for food category 13.1.4 regulating the combined use of the gums.
- (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 to address 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 recommended reducing the maximum limits for toxic elements (lead, arsenic, mercury and cadmium), changing the word 'solution/soluble' to 'dispersion/dispersible' based on the consideration that hydrocolloids form colloidal dispersions in water instead of true solutions and including microbiological criteria, in its specifications as laid down in Commission Regulation (EU) No 231/2012. The Authority applied the margin of exposure (MoE) approach for the safety assessment of E 410 when used as a food additive in food categories 13.1.5.1 and 13.1.5.2 and specified that a MoE above 1 would not raise a safety concern. For infants below 16 weeks of age consuming foods belonging to food category 13.1.5.1, a MoE below 1 was obtained when considering the maximum use level. For infants above 16 weeks of age consuming foods belonging to food categories 13.1.5.1 and FC 13.1.5.2, a MoE above 1 was obtained for the mean consumption but not for the consumption at the 95th

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/2012/231/2024-04-23>).

⁴ EFSA Journal 2017;15(1):4646.

⁵ EFSA Journal 2023;21(2):7775.

percentile. For toddlers consuming foods belonging to food category 13.1.5.2, a MoE above 1 was given for all exposure levels.

- (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 specifications in light of the Authority's scientific opinion. In particular, the current maximum limits for toxic elements should be reduced and microbiological criteria should be included 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 words 'solution/soluble' should be changed to 'dispersion/dispersible'.
- (9) On 24 February 2017, the Authority issued a scientific opinion on the re-evaluation of guar gum (E 412) as a food additive⁶. 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 concluded that the available data do not allow an adequate assessment of the safety of guar gum (E 412) when used in 'dietary foods for infants for special medical purposes and special formulae for infants' (Food category 13.1.5.1) and in 'dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' (Food category 13.1.5.2). The Authority recommended some modifications to the specifications for 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 to address its recommendations for that food additive. Business operators provided data in response to the call.
- (11) The Authority adopted the '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 on 21 March 2024. 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, in its specifications as laid down in Commission Regulation (EU) No 231/2012. The Authority concluded that the submitted data are not sufficient to demonstrate that the use of guar gum (E 412) in food for infants (below and above 16 weeks of age) and young children consuming food belonging to food categories 13.1.1 (Infant formulae as defined by Directive 2006/141/EC), 13.1.5.1 and 13.1.5.2 is safe.
- (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 current maximum limits for toxic elements should be reduced and microbiological criteria should be included 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 E 412 in food categories 13.1.1 and 13.1.5.1, it is considered not needed 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 and the words 'solution/soluble' should be changed to 'dispersion/dispersible'.

⁶ EFSA Journal 2017;15(2):4669.

⁷ EFSA Journal 2024;22:e8748.

- (13) On 6 April 2017, the Authority issued a scientific opinion on the re-evaluation of acacia gum (E 414) as a food additive⁸. 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 acacia gum (E 414) for uses in foods for all population groups including infants below 16 weeks of age, to collect the data needed to address 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 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 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, in its specifications as laid down in Commission Regulation (EU) No 231/2012. The Authority applied the margin of safety (MOS) approach for the safety assessment of E 414 for infants below 16 weeks of age and concluded that there is no health concern given the large MOS.
- (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 included, the current maximum limits for toxic elements should be amended, as well as the microbiological criteria 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 in the definition that oxidases and peroxidases are inactivated during the manufacturing process. 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 is also applicable to E 414¹⁰.
- (17) On 14 July 2017, the Authority issued a scientific opinion on the re-evaluation of xanthan gum (E 415) as a food additive¹¹. 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 under the age of 12 weeks. The Authority recommended some modifications to the specifications for 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 to address its recommendations for that food additive. Business operators provided data in response to the call.

⁸ EFSA Journal 2017;15(4):4741.

⁹ EFSA Journal 2019;17(12):5922.

¹⁰ Minutes of the 63rd Working Group meeting on Specifications of Food Additives. Available at <https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/wg-fafwgSpecificationsFAs.pdf>

¹¹ EFSA Journal 2017;15(7):4909.

- (19) The Authority adopted the ‘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’¹² on 21 March 2023. The Authority recommended reducing the maximum limit for lead, including maximum limits for arsenic, mercury and cadmium, changing the words ‘solution/soluble’ to ‘dispersion/dispersible’, amending the microbiological criteria, specifying the Kjeldahl method for nitrogen analysis, specifying that the final product must not show any residual enzyme activity and that strains used to produce xanthan gum (E 415) meet the requirements of the ‘qualified presumption of safety’ (QPS) status, in its specifications as laid down in Commission Regulation (EU) No 231/2012. For infants below 16 weeks of age consuming food belonging to food category 13.1.5.1, the Authority concluded that there are no safety concerns for the use of xanthan gum (E 415) as a food additive in food category 13.1.5.1.
- (20) It is therefore appropriate to amend the specifications of xanthan gum (E 415) in light of the Authority’s scientific opinion. In particular, the current maximum limit for lead should be reduced, maximum limits for arsenic, mercury and cadmium should be included and the microbiological criteria should be amended 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 Kjeldahl method should be specified, the words ‘solution/soluble’ should be changed to ‘dispersion/dispersible’ and the definition should be revised.
- (21) 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 additives¹³. 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 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 specifications for pectin (E 440i) and amidated pectin (E 440ii) set out in Regulation (EU) No 231/2012.
- (22) 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 to address its recommendations for that food additive. Business operators provided data in response to the call.
- (23) 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’¹⁴. The Authority recommended reducing the maximum limits for toxic elements, including a maximum limit for aluminium and including microbiological criteria, in its specifications as laid down in Commission Regulation (EU) No 231/2012. Based on the information from one business operator that produces E 440 without using sulphur dioxide, the Authority recommended to reduce the maximum level for sulphur dioxide. However, producers of E 440 have clarified that this information is not representative for the majority of pectins on the market. The Authority applied the MOS approach for the safety assessment of E 440 for infants and young children consuming foods belonging to food categories 13.1.5.1 and 13.1.5.2 and

¹² EFSA Journal 2023;21(5):7951.

¹³ EFSA Journal 2017;15(7):4866.

¹⁴ EFSA Journal 2021;19(1):6387.

concluded that the MOS is too low for some scenarios. In addition, at the currently authorised use level, the internal methanol exposure could lead to adverse health effects in infants below 16 weeks of age.

- (24) 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 its specifications in light of the Authority's scientific opinion. In particular, the current maximum limits for toxic elements should be reduced, a maximum limit for aluminium should be included as well as microbiological criteria 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 E 440¹⁵.
- (25) 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 additives¹⁶. 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 specifications set out in Regulation (EU) No 231/2012.
- (26) 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 address its recommendations for that food additive. Business operators provided data in response to the call.
- (27) 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'¹⁷. The Authority recommended reducing the maximum limits for sulphur dioxide, arsenic, lead and mercury, including a maximum limit for cadmium, specifying that E 1450 should not contain gluten when used in infant formula and follow-on formula and including microbiological criteria, in its specifications as laid down in Commission Regulation (EU) No 231/2012. The Authority concluded that there is no indication for a 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.

¹⁵ Minutes of the 63rd Working Group meeting on Specifications of Food Additives. Available at <https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/wg-fafwgSpecificationsFAs.pdf>

¹⁶ EFSA Journal 2017;15(10):4911.

¹⁷ EFSA Journal 2020;18(8):5874.

- (28) 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, the current maximum limits for sulphur dioxide, arsenic, lead and mercury should be reduced, a maximum limit for cadmium should be included, as well as microbiological criteria 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 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 E 1450¹⁸.
- (29) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (30) 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 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.
- (31) For the same reasons, it is appropriate that a transitional period is 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.
- (32) Considering that the Authority did not identify an immediate health concern linked to the use of locust bean gum (E 410), guar gum (E 412), pectins (E 440) and starch sodium octenyl succinate (E 1450) and to allow the food business operators, including small and medium enterprises, to find alternatives for these food additives to be used in food categories 13.1.1, 13.1.5.1 and 13.1.5.2, the application of the new conditions of use should be deferred and a transitional period should be provided for products placed on the market before the date of application.
- (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.

¹⁸ Minutes of the 63rd Working Group meeting on Specifications of Food Additives. Available at <https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/wg-fafwgSpecificationsFAs.pdf>

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

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 ... [6 months after the date of entry into force of this Regulation] may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

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 has been lawfully placed on the market before ... [6 months after the date of entry into force of this Regulation], may be placed on the market until their date of minimum durability or 'use-by date'.

Foods, not complying with the provisions laid down in Annex I applicable from ... [6 months after the date of entry into force of this Regulation] or the respective date indicated in Annex I, that have been lawfully placed on the market before the respective date of application 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 ... [6 months after the date of entry into force of this Regulation].

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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

(1) Part E is amended as follows:

(a) Category 13.1.1 ('Infant formulae as defined by Directive 2006/141/EC') is amended as follows:

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

(b) Category 13.1.4 ('Other foods for young children') is amended as follows:

(1) the entry for E 407 Carrageenan is replaced by the following:

E 407	Carrageenan	300	(X)'	
-------	-------------	-----	------	--

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

E 410	Locust bean gum	10 000	(21) (X)'	
-------	-----------------	--------	----------------------	--

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

E 412	Guar gum	10 000	(21) (X)'	
-------	----------	--------	----------------------	--

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

E 414	Gum arabic (acacia gum)	10 000	(21) (X)'	
-------	-------------------------	--------	----------------------	--

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

E 415	Xanthan gum	10 000	(21) (X)'	
-------	-------------	--------	----------------------	--

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

E 440	Pectins	5 000	(21) (X)'	
-------	---------	-------	----------------------	--

(7) footnote (21) is deleted;

(8) 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 ';

(c) Category 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants), is amended as follows:

(1) 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’;

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

‘E 410	Locust bean gum	10 000 5 300		From birth onwards in products for reduction of gastro-oesophageal reflux’;
--------	-----------------	-------------------------	--	---

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

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

‘E 440	Pectins	10 000 4 000		From birth onwards in products used in case of gastro-intestinal disorders’;
--------	---------	-------------------------	--	--

(5) 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	20 000 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]’;

(d) Category 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC), is amended as follows:

(1) 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’;

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

‘E 410	Locust bean gum	10 000 5 300	From birth onwards in products for reduction of gastro-oesophageal reflux’;
--------	-----------------	-------------------------	---

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

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

‘E 440	Pectins	10 000 4 000	From birth onwards in products used in case of gastro-intestinal disorders’;
--------	---------	-------------------------	--

(5) 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	20 000 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 strains of carob tree, <i>Cerastonia siliqua</i> (L.) Taub. (family <i>Leguminosae</i>). The seeds are peeled by using acids or by roasting. In the acid process, the seeds are heated with sulfuric acid. In the roasting process, the seeds are roasted. The seed coat is removed from the endosperm via washing and brushing. The endosperm is dried and ground. 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	Soluble 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 solution of the sample add a few drops of iodine solution. No blue colour is produced
Arsenic	Not more than 3 mg/kg Not more than 0.1 mg/kg
Lead	Not more than 2 mg/kg Not more than 0.4 mg/kg

Mercury	Not more than 1 mg/kg Not more than 0.1 mg/kg
Cadmium	Not more than 1 mg/kg 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 500 cfu/g
Yeast and moulds	Not more than 500 cfu/g
<i>Enterobacteriaceae</i>	Absent in 10 g
<i>Salmonella</i> spp.	Absent in 25 g
<i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>)	Absent in 10 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age*

(2) the entry for 'E 410 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, <i>Cyamopsis tetragonolobus</i> (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 alkaline 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	Soluble 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 solution 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 3 mg/kg Not more than 0.1 mg/kg
Lead	Not more than 2 mg/kg Not more than 0.2 mg/kg
Mercury	Not more than 1 mg/kg Not more than 0.1 mg/kg
Cadmium	Not more than 1 mg/kg Not more than 0.1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>Enterobacteriaceae</i>	Absent in 10 g
<i>Salmonella</i> spp.	Absent in 25 g

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

'E 414 ACACIA GUM

Synonyms	Gum arabic
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. Oxidases and peroxidases present in acacia gum are inactivated during the manufacturing process.
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 solution 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 solution 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 solution 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 3 mg/kg Not more than 0.1 mg/kg
Lead	Not more than 2 mg/kg Not more than 0.05 mg/kg
Mercury	Not more than 1 mg/kg Not more than 0.05 mg/kg
Cadmium	Not more than 1 mg/kg 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 120 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 present in acacia gum are inactivated during the manufacturing process if added to foods for infants and young children <i>[possible alternative for the inclusion under the definition]</i>
Microbiological criteria	
Total plate count	Not more than 10 000 cfu/g
Yeast and moulds	Not more than 10 000 cfu/g
<i>Salmonella</i> spp.	Absent in 10 g Absent in 25 g
<i>Escherichia coli</i> <i>Enterobacteriaceae</i>	Absent in 5 g Absent in 10 g
<i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>)	Absent in 10 g if added to dried infant formulae and dried dietary 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, and pyruvic acid and acetic acid, and is prepared as the sodium, potassium or calcium salt. Its solutions 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	Soluble 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 2 mg/kg 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 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>Escherichia coli</i>	Absent in 5 g
<i>Enterobacteriaceae</i>	Absent in 10 g
<i>Salmonella</i> spp.	Absent in 10 g Absent in 25 g
<i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>)	Absent in 10 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age
<i>Xanthomonas campestris</i>	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. Esterases, polygalacturonases, pectin lyases and amylases are used to clarify the extract and to hydrolyse glycosidic bonds and ester groups. 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	Soluble Dispersible in water forming a colloidal, opalescent solution 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 3 mg/kg Not more than 0.1 mg/kg
Lead	Not more than 5 mg/kg 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 1 mg/kg Not more than 0.1 mg/kg
Cadmium	Not more than 1 mg/kg 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	

<i>Enterobacteriaceae</i>	Absent in 10 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae
<i>Salmonella</i> spp.	Absent in 25 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae
<i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>)	Absent in 10 g if added to dried infant formulae and dried dietary 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. Esterases, polygalacturonases, pectin lyases and amylases are used to clarify the extract and to hydrolyse glycosidic bonds and ester groups. 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	Soluble Dispersible in water forming a colloidal, opalescent solution 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 3 mg/kg Not more than 0.1 mg/kg
Lead	Not more than 5 mg/kg 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 1 mg/kg Not more than 0.1 mg/kg
Cadmium	Not more than 1 mg/kg 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	
<i>Enterobacteriaceae</i>	Absent in 10 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae
<i>Salmonella</i> spp.	Absent in 25 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae
<i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>)	Absent in 10 g if added to dried infant formulae and dried dietary 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 50 mg/kg for modified cereal starches (on an anhydrous basis) Not more than 10 mg/kg for other modified starches, unless otherwise specified (on an anhydrous basis) Not more than 10 mg/kg on the anhydrous basis
Arsenic	Not more than 1 mg/kg Not more than 0,05 mg/kg (only if added to foods for infants and young children). Not more than 0,1 mg/kg (for all uses except for foods intended for infants and young children).
Lead	Not more than 2 mg/kg (on an anhydrous basis) Not more than 0,03 mg/kg (only if added to foods for infants and young children). Not more than 0,2 mg/kg (for all uses except for foods intended for infants and young children).
Mercury	Not more than 0,1 mg/kg Not more than 0,05 mg/kg
Cadmium	Not more than 0,01 mg/kg (only if added to foods for infants and young children). Not more than 0,1 mg/kg (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	
<i>Enterobacteriaceae</i>	Absent in 10 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae
<i>Salmonella</i> spp.	Absent in 25 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age and dried follow-on formulae
<i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>)	Absent in 10 g if added to dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age

DRAFT