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## COVER NOTE

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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 22 October 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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No. Cion doc.: D(2025) 109690

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

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Delegations will find attached document D(2025) 109690.

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Brussels, **XXX**  
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[...] (2025) **XXX** draft

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

**of XXX**

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

(Text with EEA relevance)

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

of **XXX**

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

(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<sup>1</sup>, 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<sup>2</sup>, 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<sup>3</sup> 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<sup>4</sup>. 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

<sup>1</sup> OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1331/oj>.

<sup>3</sup> 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>).

<sup>4</sup> EFSA Journal 2017;15(1):4646, <https://doi.org/10.2903/j.efsa.2017.4646>.

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.

- (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’<sup>5</sup>. The Authority concluded 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<sup>6</sup>. 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

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<sup>5</sup> EFSA Journal 2023;21(2):7775, <https://doi.org/10.2903/j.efsa.2023.7775>.

<sup>6</sup> EFSA Journal 2017;15(2):4669, <https://doi.org/10.2903/j.efsa.2017.4669>.

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’<sup>7</sup>. As regards its specifications as laid down in Commission 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’.
- (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<sup>8</sup>. 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’<sup>9</sup>. 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 Commission Regulation (EU) No 231/2012, the Authority recommended reducing the maximum limits for toxic elements, including a

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<sup>7</sup> EFSA Journal 2024;22:e8748, <https://doi.org/10.2903/j.efsa.2024.8748>.

<sup>8</sup> EFSA Journal 2017;15(4):4741, <https://doi.org/10.2903/j.efsa.2017.4741>.

<sup>9</sup> EFSA Journal 2019;17(12):5922, <https://doi.org/10.2903/j.efsa.2019.5922>.

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<sup>10</sup>. 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'<sup>11</sup>. 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 Commission 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).
- (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<sup>12</sup>. 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

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<sup>10</sup> EFSA Journal 2017;15(7):4909, <https://doi.org/10.2903/j.efsa.2017.4909>.

<sup>11</sup> EFSA Journal 2023;21(5):7951, <https://doi.org/10.2903/j.efsa.2023.7951>.

<sup>12</sup> EFSA Journal 2017;15(7):4866, <https://doi.org/10.2903/j.efsa.2017.4866>.

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’<sup>13</sup>. 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 Commission 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<sup>14</sup>. 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.

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<sup>13</sup> EFSA Journal 2021;19(1):6387, <https://doi.org/10.2903/j.efsa.2021.6387>.

<sup>14</sup> EFSA Journal 2017;15(10):4911, <https://doi.org/10.2903/j.efsa.2017.4911>.

- (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.
- (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’<sup>15</sup>. As regards its specifications as laid down in Commission 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

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<sup>15</sup> EFSA Journal 2020;18(8):5874, <https://doi.org/10.2903/j.efsa.2020.5874>.

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.
- (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<sup>16</sup> 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.

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<sup>16</sup> 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>).

### 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 [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.
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 [6 months after the date of entry into force of this Regulation] 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 [6 months after the date of entry into force of this Regulation] or, in the case of foods containing starch sodium octenyl succinate (E 1450) before [24 months after the date of entry into force of this Regulation], 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 [6 months after the date of entry into force of this Regulation] 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'.
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 [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*