



2025/2084

20.10.2025

**COMMISSION REGULATION (EU) 2025/2084**

**of 17 October 2025**

**amending Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of quillaia extract (E 999) and Commission Regulation (EU) No 231/2012 as regards the specifications for quillaia extract (E 999)**

(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. Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives, including carriers approved for use in food additives, food enzymes, food flavourings, nutrients 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 lists of food additives and the specifications for them 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) Quillaia extract (E 999) is an authorised food additive under Regulation (EC) No 1333/2008.
- (5) On 11 February 2013, an application was submitted for the authorisation of the use of quillaia extract (E 999) as an emulsifier in flavourings, to be added to several categories of food. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (6) Quillaia extract (E 999), when used as an emulsifier in spray-dried flavourings, ensures the necessary emulsification, emulsion stability and flavour retention.
- (7) On 6 March 2019, the European Food Safety Authority ('the Authority') issued a scientific opinion on the re-evaluation of quillaia extract (E 999) as a food additive and the safety of the proposed extension of use <sup>(4)</sup>. The Authority established an acceptable daily intake (ADI) for this food additive at 3 mg saponins/kg bw per day. None of the exposure estimates for the different population groups of the refined brand-loyal scenario, which the Authority selected to assess possible risks related to the use of quillaia extract (E 999), exceeded the ADI of 3 mg saponins/kg bw per day. The proposed extension of use of quillaia extract as a food additive in flavourings also would not give rise to a safety concern. The Authority recommended to amend the specifications for quillaia extract (E 999) set out in Regulation (EU) No 231/2012 and to express its maximum use levels on a saponin basis.

<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 2019; 17(3):5622.

- (8) On 15 December 2020, the Commission launched a public call for technical data on the authorised food additive quillaia extract (E 999), to collect the data needed for addressing the recommendations of the Authority.
- (9) Based on the data submission by interested business operators, the Commission requested the Authority to provide a scientific opinion to confirm that the technical data provided by the business operators adequately supported an amendment to the specifications for the food additive quillaia extract (E 999), to bring them in line with current standards, as recommended by the Authority.
- (10) In its scientific opinion published on 6 February 2024 <sup>(5)</sup>, the Authority recommended reducing the maximum limits for lead, mercury and arsenic for the food additive quillaia extract (E 999), adopting maximum limits for cadmium and calcium oxalate, adopting microbiological criteria and the minimum content for saponins, which is the functional component, including the CAS number in the specifications, and changing the definition of quillaia extract (E 999) to better describe the composition in a qualitative way. The Authority also recommended to express the maximum use levels on a saponin basis.
- (11) On 3 April 2023, an application was submitted for the authorisation of the use of quillaia extract (E 999) as an emulsifier in solid and liquid food supplements under food categories 17.1 'Food supplements supplied in a solid form, excluding food supplements for infants and young children' and 17.2 'Food supplements supplied in a liquid form, excluding food supplements for infants and young children'. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (12) Quillaia extract (E 999), when used as an emulsifier in food supplements, improves water or lipid solubility, permitting the inclusion of poorly soluble ingredients in the final food supplement matrix. It allows for the development of various alternate applications of food supplements, such as sachets of powder to be diluted in water, gummies, ready-to-drink liquid forms and liquid shots in place of conventional pills, gels or tablets.
- (13) On 13 December 2024, the Authority issued a scientific opinion on the extension of uses of quillaia extract (E 999) as a food additive <sup>(6)</sup>. The Authority concluded that the exposure estimates to quillaia extract (E 999) based on the typical reported use levels for the currently authorised food categories and, on the proposed extension of use would not result in an exceedance of the established ADI in any population group.
- (14) Taking into account the Authority's scientific opinions, it is appropriate to express the maximum use levels for quillaia extract (E 999) on a saponin basis, and to authorise the use of quillaia extract (E 999) in flavourings, and in food supplements in solid and liquid form, excluding food supplements for infants and young children. It also appropriate to amend the specifications for quillaia extract (E 999). In particular, quillaia extract (E 999) should be better defined by describing the composition in a qualitative way, the CAS number should be included in the specifications, the minimum content for saponins, as the functional component, should be set out, the current maximum limits for toxic elements should be reduced and a limit for cadmium and calcium oxalate should be included in the specifications to ensure that the food additive will not be a significant source of exposure to those toxic elements in food. For that purpose, the level which is currently achievable by the application of good manufacturing practices should be applied. Furthermore, the relevant microbiological criteria should be adopted
- (15) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

<sup>(5)</sup> EFSA Journal 2024; 22:e8563. Follow-up of the re-evaluation of quillaia extract (E 999) as a food additive and safety of the proposed extension of uses.

<sup>(6)</sup> EFSA Journal 2024; 22:e9140.

- (16) Considering that the Authority did not identify an immediate health concern linked to the current specifications and in order to allow 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 transitional rules should be provided for the use in food of the food additive quillaia extract (E 999) lawfully placed on the market before the date of application of those specifications and for the placing on the market of foods containing such quillaia extract (E 999).
- (17) 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*

Annex III to Regulation (EC) No 1333/2008 is amended in accordance with Annex II to this Regulation.

*Article 3*

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

*Article 4*

The food additive quillaia extract (E 999) that has been lawfully placed on the market before 9 May 2026 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

Foods, to which quillaia extract (E 999) that has been lawfully placed on the market before 9 May 2026 is added, may be placed on the market until their date of minimum durability or 'use-by date'.

*Article 5*

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

Article 3 shall apply from 9 May 2026.

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

Done at Brussels, 17 October 2025.

*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:

- (a) in category 14.1.4 (Flavoured drinks), the entry for E 999 Quillaia extract is replaced by the following:

E 999	Quillaia extract	170	(45)	
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(45): Expressed as saponins;

- (b) in category 14.2.3 (Cider and perry), the entry for E 999 Quillaia extract is replaced by the following:

E 999	Quillaia extract	170	(45)	excluding <i>cidre bouché, cydr jakościowy, perry jakościowe, cydr lodowy, perry lodowe</i>
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(45): Expressed as saponins;

- (c) in category 17.1 (Food supplements supplied in a solid form, excluding food supplements for infants and young children), the following entry is inserted after the second entry for E 969:

E 999	Quillaia extract	3350	(45)	
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(45): Expressed as saponins;

- (d) in category 17.2 (Food supplements supplied in a liquid form, excluding food supplements for infants and young children), the following entry is inserted after the second entry for E 969:

E 999	Quillaia extract	3350	(45)	
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(45): Expressed as saponins'.

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## ANNEX II

In Part 4 of Annex III to Regulation (EC) No 1333/2008, the following entry is inserted after the entry for food additive 'E 901 Beeswax':

E 999	Quillaia extract	All flavourings used in the following categories:	
		05.2: Other confectionery including breath refreshing microsweets	4 mg/kg in the final food (expressed as saponins)
		05.3: Chewing gum	2 mg/kg in the final food (expressed as saponins)
		12.5: Soups and broths	2 mg/l in the final food (expressed as saponins)
		14.1.5: Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	1,2 mg/l in the final food (expressed as saponins)
		15.1: Potato-, cereal-, flour- or starch-based snacks	0,2 mg/kg in the final food (expressed as saponins)

## ANNEX III

In the Annex to Regulation (EU) No 231/2012, the entry for 'E 999 Quillaia extract' is replaced by the following:

**E 999 QUILLAIA EXTRACT**

<b>Synonyms</b>	Soapbark extract; Quillay bark extract; Panama bark extract; Quillai extract; Murillo bark extract; China bark extract
<b>Definition</b>	Quillaia extract is obtained by aqueous extraction of <i>Quillaia saponaria</i> Molina, or other <i>Quillaia</i> species, trees of the family <i>Rosaceae</i> . The extraction process is followed by clarification, filtration, ultrafiltration, concentration and pasteurisation. It contains a number of triterpenoid saponins consisting of glycosides of quillaic acid, polyphenols, carbohydrates, in particular polysaccharides and reducing sugars and, to a minor extent, proteins.
CAS number	68990-67-0
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Saponin content not less than 20 % on dried basis
<b>Description</b>	Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution.
<b>Identification</b>	
pH	Between 3,7 and 5,5 (4 % solution)
<b>Purity</b>	
Water content	Not more than 6,0 % (Karl Fischer method) (powder form only)
Arsenic	Not more than 5 mg/kg saponins
Lead	Not more than 3 mg/kg saponins
Mercury	Not more than 0,5 mg/kg saponins
Cadmium	Not more than 0,5 mg/kg saponins
Calcium oxalate	Not more than 6 g/kg saponins
<b>Microbiological criteria</b>	
Total aerobic count	Not more than 100 colonies per gram
<i>Salmonella</i> spp.	Absent in 25 g
<i>Staphylococcus aureus</i>	Absent in 1 g
<i>Escherichia coli</i>	Absent in 1 g
Yeast	Not more than 10 colonies per gram
Moulds	Not more than 10 colonies per gram'