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WORKING DOCUMENT

Commission internal procedures not yet launched.

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

of **XXX**

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 quillaia extract (E 999) and the Annex to 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 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. Annex III to Regulation (EC) No

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>.

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 231/2012³ 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 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 in accordance with 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 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 flavourings, ensures the necessary emulsification, emulsion stability and flavour retention in spray-dried flavourings.
- (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 safety of the proposed extension of use⁴. The Authority established an acceptable daily intake (ADI) of 3 mg saponins/kg bw per day. None of the exposure estimates for the different population groups of the refined brand-loyal scenario exceeded the ADI of 3 mg saponins/kg bw per day. The proposed extension of use as a food additive in flavourings also would not give rise to a safety concern. The Authority recommended to revise the EU specifications for E 999 set out in Regulation (EU) No 231/2012 and to express the maximum use levels for quillaia extract (E 999) on a saponin basis.
- (8) On 15 December 2020, the Commission launched a public call for technical data on the permitted food additive quillaia extract (E 999), to collect the data needed to address the recommendations made by the Authority.
- (9) Following 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 interested 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 issued on 6 February 2024⁵, the Authority recommended reducing the maximum limits for lead, mercury and arsenic, including maximum limits for cadmium and calcium oxalate, including microbiological criteria, including the minimum content for the functional component, and modifying the definition of quillaia extract (E 999) to better describe the composition in a qualitative way, in its specifications as laid down in Commission Regulation (EU) No 231/2012. The Authority also recommended that the limits would be expressed on a saponins basis.

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 2019;17(3):5622.

⁵ EFSA Journal. 2024;22:e8563.

- (11) 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 in Annex II, Part E to Regulation (EC) No 1333/2008, to authorise the use of quillaia extract (E 999) in flavouring preparations and to amend the specifications for quillaia extract (E 999). In particular, the current maximum limits for toxic elements should be reduced and a limit for cadmium should be included to ensure that food additives will not be a significant source of exposure to those toxic elements in food and by taking into account the level which is currently achievable by the application of good manufacturing practices. A maximum limit for calcium oxalate and microbiological criteria should be included. Furthermore, quillaia extract (E 999) should be better defined by describing the composition in a qualitative way and by including the minimum content for the functional component .
- (12) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (13) Considering that the Authority did not identify an immediate health concern linked to the current specifications 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 food additive quillaia extract (E 999) lawfully placed on the market before the date of application of this Regulation.
- (14) For the same reasons, it is appropriate that a transitional period is provided for foods, containing quillaia extract (E 999) that has been lawfully placed on the market before the date of application of this Regulation.
- (15) 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 ... [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 quillaia extract (E 999) 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'.

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 ... *[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*

DRAFT

ANNEX I

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

(1) PART E is amended as follows:

(a) category 14.1.4 (Flavoured drinks) is amended as follows:

(1) the entry for E 999 Quillaia extract is replaced by the following:

	'E 999	Quillaia extract	200 140	(45)'	
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(2) the footnote (45) is replaced by the following:

'(45): ~~Calculated as anhydrous extract~~ Expressed on saponin content';

(b) category 14.2.3 (Cider and perry) is amended as follows:

(1) the entry for E 999 Quillaia extract is replaced by the following:

	'E 999	Quillaia extract	200 140	(45)	excluding <i>cidre bouché, cydr jakościowy, perry jakościowe, cydr lodowy, perry lodowe</i> '
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(2) the footnote (45) is replaced by the following:

'(45): ~~Calculated as anhydrous extract~~ Expressed on saponin content'.

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 categories	
		05.2: Other confectionery including breath refreshing microsweets	4 mg/kg in the final food (expressed on saponin content)
		05.3: Chewing gum	2 mg/kg in the final food (expressed on saponin content)
		12.5: Soups and broths	2 mg/l in the final food (expressed on saponin content)
		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 on saponin content)
		15.1: Potato-, cereal-, flour- or starch-based snacks	0,2 mg/kg in the final food (expressed on saponin content)

ANNEX III

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

(1) the entry for 'E 999 Quillaia extract' is replaced by the following:

'E 999 QUILLAIA EXTRACT

Synonyms	Soapbark extract; Quillay bark extract; Panama bark extract; Quillai extract; Murillo bark extract; China bark extract
Definition	Quillaia extract is obtained by aqueous extraction of <i>Quillaia saponaria Molina</i> , 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. Some sugars including glucose, galactose, arabinose, xylose, and rhamnose are also present, along with tannin, calcium oxalate and other minor components
CAS number	68990-67-0
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Saponin content not less than 20% on dried basis
Description	Quillaia extract in the powder form is light brown with a pink tinge. It is also available as an aqueous solution
Identification	
pH	Between 3,7 and 5,5 (4 % solution)
Purity	
Water content	Not more than 6,0 % (Karl Fischer method) (powder form only)
Arsenic	Not more than 2 mg/kg Not more than 5 mg/kg saponins
Lead	Not more than 2 mg/kg Not more than 3 mg/kg saponins
Mercury	Not more than 1 mg/kg 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
Microbiological criteria	
Total aerobic count	Not more than 100 colonies per gram
Yeast	Not more than 10 colonies per gram
Moulds	Not more than 10 colonies per gram'