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SCIENTIFIC OPINION

Scientific opinion on the extension of uses of quillaia extract (E 999) as a food additive

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The EFSA Panel on Food Additives and Flavourings (FAF Panel) evaluated the safety of the extension of uses of quillaia extract (E 999) as a food additive in food supplements supplied in a solid or liquid form, excluding food supplements for infants and young children. Quillaia extract (E 999) was re-evaluated in 2019 by the EFSA FAF Panel, which derived an acceptable daily intake (ADI) of 3 mg saponins/kg bw per day for E 999, while in 2024 a follow-up of the re-evaluation was published by the FAF Panel, recommending some modifications of the existing EU specifications for quillaia extract (E 999). Currently, quillaia extract (E 999) is authorised in two food categories (FCs) i.e. FC 4.1.4 'Flavoured drinks' and FC 14.2.3 'Cider and perry' (excluding *cidre bouché, cydr jakościowy, perry jakościowe, cydr lodowy, perry lodowe*). A 'food supplements consumers only' scenario was calculated for this opinion considering the proposed extension of uses, together with the current authorised uses at both the maximum permitted level (MPLs) and the typical reported use levels of quillaia extract (E 999) at the time of the 2019 re-evaluation. The Panel concluded that the exposure estimates using the typical reported use levels for the currently authorised food categories and considering the proposed extension of uses for E 999 in FC 17.1 'Food supplements supplied in a solid form, excluding food supplement for infants and young children' and FC 17.2 'Food supplements supplied in a liquid form, excluding food supplement for infants and young children', if authorised, would not result in an exceedance of the ADI in any population group.

KEYWORDS

E 999, extension of uses, food additive, food supplements, Quillaia extract, *Quillaja saponaria*

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SUMMARY

The current assessment deals with the safety evaluation of the extension of uses of quillaia extract (E 999) as a food additive in food supplements supplied in a solid or liquid form, excluding food supplements for infants and young children.

According to Commission Regulation (EU) No 231/2012, quillaia extract (E 999) is obtained by aqueous extraction of *Quillaia saponaria* Molina, or other *Quillaia* species, trees of the family Rosaceae. The Panel noted that according to the Compendium of botanicals, *Q. saponaria* Molina belongs to the family Quillajaceae. According to the EFSA follow-up of the re-evaluation of quillaia extract (E 999) (EFSA FAF Panel, 2024), 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.

The applicant stated that the proposed specifications to be considered for the extension of uses comply with those set out in Commission Regulation (EU) No 231/2012 for quillaia extract (E 999). The Panel noted that in 2024, the EFSA FAF Panel published a follow-up of the re-evaluation of quillaia extract (E 999) and considering the technical data submitted at the time, recommended some modifications to the existing EU specifications for quillaia extract (E 999) (see Section 1.2 and EFSA FAF Panel, 2024).

At the time of the 2019 re-evaluation of quillaia extract (E 999), the Panel concluded that any toxicity associated with quillaia extract (E 999) is due to its constituent saponins and, therefore, established an ADI of 3 mg saponins/kg bw per day for quillaia extract (E 999) (EFSA FAF Panel, 2019). For the current assessment, the applicant conducted a literature search to identify any new or additional data available since the EFSA re-evaluation of quillaia extract (E 999) in 2019. No new information was identified by the applicant in the literature search for absorption, distribution, metabolism and excretion, acute toxicity, short-term and subchronic toxicity, genotoxicity, chronic toxicity, carcinogenicity and reproductive and developmental toxicity, and for other relevant data.

Quillaia extract (E 999) is currently authorised as a food additive in the EU in two food categories (FCs 14.1.4 and 14.2.3) in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives. In the current opinion, an exposure scenario considering the requested extension of uses in food supplements supplied in a solid or liquid form (FCs 17.1 and FC 17.2) was performed. A 'food supplements consumers only' scenario was calculated considering the proposed extension of uses at the proposed maximum use levels, together with the current authorised uses at both the maximum permitted level (MPLs) and the typical reported use levels at the time of the re-evaluation (EFSA FAF Panel, 2019). The Panel noted that at the time of the follow-up of the re-evaluation of quillaia extract (E 999), an extension of uses in food supplements supplied in a solid or liquid form (FCs 17.1 and FC 17.2) was requested proposing higher use levels (EFSA FAF Panel, 2024) than those proposed in the current assessment.

The 'food supplements consumers only' scenario considers only the consumers of food supplements, which were a small subset of the total study population in some dietary surveys (Annex A, Table A.2). Not considering the whole population avoids 'diluting' the exposure with non-consumers of food supplements and the exposure estimates will thus only reflect the potential exposure to quillaia extract (E 999) of these food supplements consumers. It is also noted that in this scenario it was assumed that all food supplements will contain E 999.

The Panel considered that the 'food supplements consumers only' scenario using the typical reported use levels for the currently authorised food categories is the most appropriate for assessing the dietary exposure. These levels were used in the refined brand-loyal scenario during the re-evaluation and the follow-up of the re-evaluation of quillaia extract (E 999) and this scenario was considered by the EFSA Panel to be the most appropriate for the risk assessment of this food additive for the general population (EFSA FAF Panel, 2019, 2024).

The Panel noted, considering all uncertainties, that this scenario resulted in an overestimation of the actual dietary exposure to quillaia extract (E 999) through its use in the currently authorised food categories and its proposed use in food supplements (see Section 3.3.2, Uncertainty analysis).

The Panel concluded that the exposure estimates using the typical reported use levels for the currently authorised food categories and considering the proposed extension of uses for E 999 in FC 17.1 'Food supplements supplied in a solid form, excluding food supplement for infants and young children' and FC 17.2 'Food supplements supplied in a liquid form, excluding food supplement for infants and young children', if authorised, would not result in an exceedance of the ADI in any population group.

1 | INTRODUCTION

The present scientific opinion deals with the safety evaluation of the extension of uses of quillaia extract (E 999) as a food additive in food supplements supplied in a solid or liquid form, excluding food supplements for infants and young children.

1.1 | Background and Terms of Reference as provided by the European Commission

1.1.1 | Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008[1] on food additives. Only food additives that are included in the Union list, in particular Annex II to that Regulation, may be placed on the market and used in foods under conditions of use specified therein.

An application has been introduced for the extension of use of quillaia extract (E 999) as an emulsifier in several food categories[2] of Annex II to Regulation (EC) No 1333/2008.

1.1.2 | Terms of Reference

The European Commission requests the European Food Safety Authority to provide a scientific opinion on the safety of the proposed extension of use of quillaia extract (E 999) in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.[3]

1.2 | Information on existing authorisations and evaluations

Quillaia extract (E 999) is authorised as a food additive in the EU in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives and specifications have been defined in the Commission Regulation (EU) No 231/2012.[4]

In the EU, the Scientific Committee for Food (SCF) in 1978 (SCF, 1978) evaluated quillaia extract (E 999) and established an acceptable daily intake (ADI) of 0–5 mg spray-dried extract/kg body weight (bw) per day. In its opinion, the SCF specified that the toxicological evaluation considered was carried out on a natural extract of Quillaia bark as specified in the British Pharmacopoeia 1973 (see EFSA FAF Panel, 2019, Appendix A). The two major saponins present in quillaia extract, as described in the SCF opinion, were quillaia sapogenin which has a triterpenoid structure and quillaic acid. These two saponins were considered by the SCF to constitute about 10% of the extract. The ADI was based on two long-term studies in rats and mice [cited by the SCF as unpublished studies by Butterworth, 1977a, 1977b, later published by Phillips et al., 1979 and Drake et al., 1982, respectively].

Quillaia extract (E 999) has also been evaluated by JECFA (1982a, 1982b, 1986, 2002a, 2002b, 2004, 2005, 2006a, 2006b, 2006c, 2014). JECFA currently defines two types of quillaia extract: Type 1 extract, INS No 999(i), obtained by means of aqueous extraction and characterised by a saponins content in the range of 20%–26% and Type 2 extract, INS No 999(ii), prepared by ultrafiltration of Type 1 extract and with a saponins content of 65%–90% (JECFA, 2006c, 2014). JECFA established a group ADI of 0–1 mg/kg bw per day for Type 1 and Type 2 extracts, expressed as quillaia saponins.

Quillaia extract (E 999) is obtained by aqueous extraction of the milled inner bark or wood of *Q. saponaria* Molina, or other *Quillaia* species, trees of the family Rosaceae. *Q. saponaria* Molina is listed in the Compendium of botanicals[5] reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements, belonging to the family Quillajaceae. The chemicals of concern for *Q. saponaria* Molina, as noted in the compendium, are triterpenoid saponins (quillaja saponins) and calcium oxalate (11%).

The Committee for Veterinary Medicinal Products (CVMP) of the European Medicines Agency (EMA) evaluated quillaia saponins as pharmacologically active substances and concluded that there was no need to establish a maximum residue level (MRL) for these substances in food of animal origin (EMA, 1996).

Q. saponaria, ext. (CAS Number: 68990-67-0) has been registered under the REACH Regulation 1907/2006.[6]

The Food Standards Australia New Zealand (FSANZ) established a group ADI of 0–1 mg quillaia saponins/kg bw to permit the use of Type 1 (reported as unpurified) and Type 2 (reported as saponin enriched) extracts (FSANZ, 2013).

[1]Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[2]Several food categories were included in the initial submission. During the assessment, the proposed uses were modified to only food supplements supplied in a solid or liquid form, excluding food supplements for infants and young children.

[3]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. OJ L 354, 31.12.2008.

[4]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.

[5]https://www.efsa.europa.eu/en/microstrategy/botanical-summary-report.

[6]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 396, 30.12.2006.

In 2019, the EFSA Scientific Panel on Food Additives and Flavourings (FAF Panel) re-evaluated the safety of quillaia extract (E 999), along with the safety of its proposed extension of use as a food additive in flavourings (EFSA FAF Panel, 2019). The Panel concluded that any toxicity associated with quillaia extract (E 999) is due to its constituent saponins and, therefore, established an ADI of 3 mg saponins/kg bw per day for quillaia extract (E 999). The ADI was based on a no observed adverse effect level (NOAEL) of 1500 mg quillaia extract/kg bw per day from a 2-year study in rats and the conservative assumption that the extract contained 20% saponins, and by applying an uncertainty factor of 100. In addition, exposure estimates for the different population groups of the brand-loyal exposure assessment scenario did not exceed the ADI of 3 mg saponins/kg bw per day at the reported use levels. The Panel concluded that the proposed extension of use of quillaia extract (E 999) as a food additive in flavourings at the proposed uses and use levels would not result in an exceedance of the ADI at the brand-loyal exposure assessment scenario. However, EFSA made recommendations concerning the specifications for quillaia extract (E 999).

Therefore, the European Commission published on 15 December 2020 a call for data[7] requesting business operators to submit new technical data to address the issues identified by EFSA in the re-evaluation of the safety of quillaia extract (E 999) as a food additive.

In 2024, the EFSA FAF Panel published a follow-up of the re-evaluation of quillaia extract (E 999) and the safety of the proposed extension of uses in food supplements supplied in a solid or liquid form, excluding food supplements for infants and young children, and in botanical nutrients as a carrier (EFSA FAF Panel, 2024). Considering the technical data submitted, the Panel recommended some modifications of the existing EU specifications for E 999, mainly to lower the maximum limits for lead, mercury and arsenic and to include a maximum limit for cadmium and for calcium oxalate, all expressed on a saponins basis. The Panel proposed to revise the definition of E 999 to better describe the composition in a qualitative way. Additionally, the Panel concluded that the exposure estimates considering the proposed extension of uses for E 999 in food supplements supplied in a solid or liquid form, excluding food supplements for infants and young children (FC 17.1 and FC 17.2) and as a carrier in botanical nutrients according to Annex III of Regulation (EU) No 1333/2008, for use in flavoured drinks and food supplements, if authorised, could result in an exceedance of the ADI at the maximum of the ranges of the mean exposure for children, adolescents and the elderly, and for all populations at the 95th percentile of exposure. The Panel noted that in the performed exposure scenarios, all food supplements were considered to contain E 999 and that all flavoured drinks were considered to have added botanical nutrients containing quillaia extract (E 999), resulting in an overestimation of the dietary exposure.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a dossier to support the safety evaluation of the present application on the safety of the proposed extension of uses of quillaia extract (E 999) in a variety of food categories (Documentation provided to EFSA No. 1).

In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002[8] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[9] the non-confidential version of the dossier is published on Open EFSA.[10]

According to Article 32c(2) of Regulation (EC) No 178/2002[11] and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 19 June to 10 July 2024,[12] for which no comments were received.[13]

Following the request for additional data sent by EFSA on 12 April 2024, the applicant provided additional data on 25 September 2024 (Documentation provided to EFSA No. 2) and on 08 October 2024 (Documentation provided to EFSA No. 3).

[7] https://food.ec.europa.eu/system/files/2020-12/fs_food-improvement-agents_reeval_call_20201215_e999_data.pdf.

[8] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

[9] Decision https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[10] The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FAD-2023-15592.

[11] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

[12] https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001Hezl/pc1006.

[13] https://open.efsa.europa.eu/consultations/a0cTk000003OeO8IAK.

2.2 | Methodologies

This opinion was formulated following the principles described in the EFSA Guidance of the Scientific Committee on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing Guidance documents from the EFSA Scientific Committee.

The current '*Guidance for submission for food additive evaluation*' (EFSA ANS Panel, 2012) has been followed by the FAF Panel for evaluating the present application.

3 | ASSESSMENT

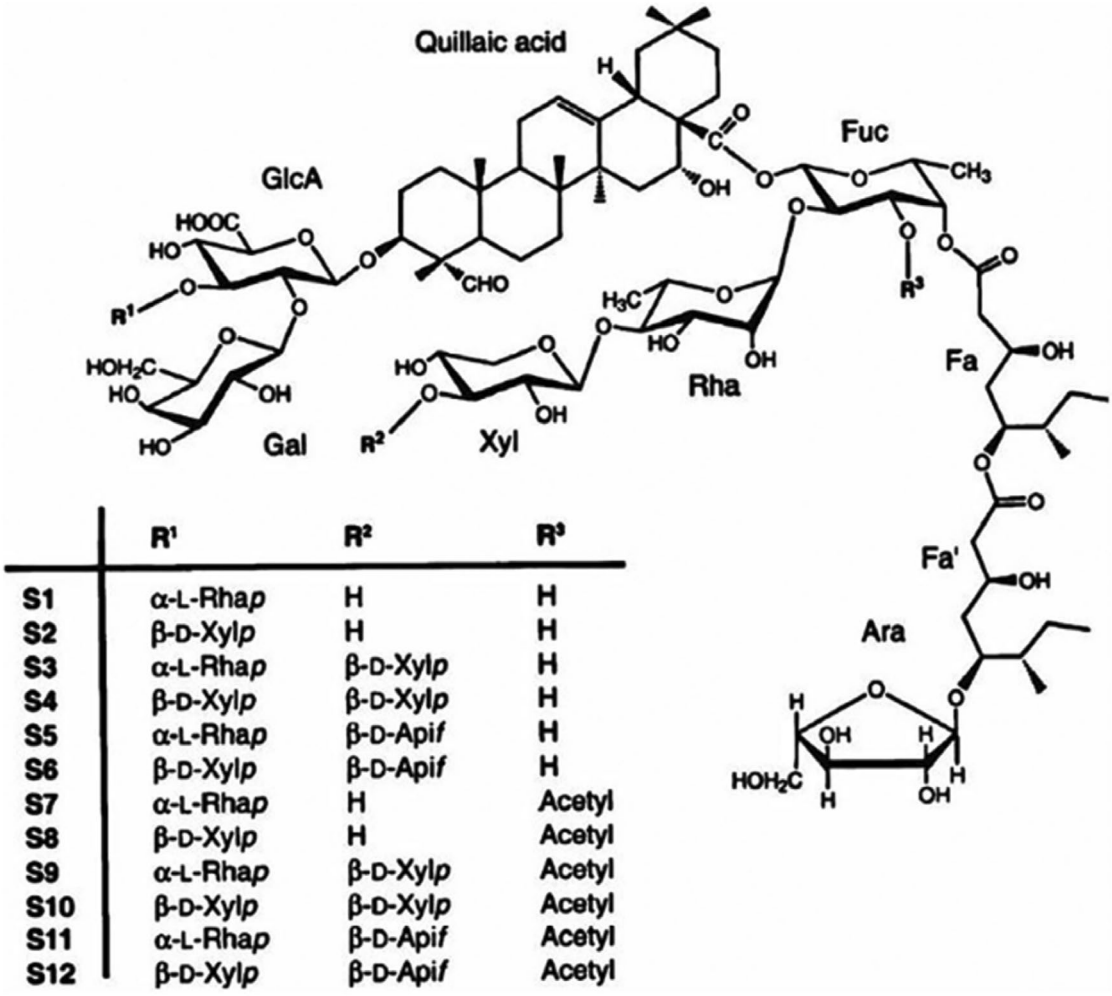
3.1 | Technical data

3.1.1 | Identity and specifications of E 999

According to Commission Regulation (EU) No 231/2012, quillaia extract (E 999) is obtained by aqueous extraction of *Quillaia saponaria* Molina, or other *Quillaia* species, trees of the family Rosaceae. The Panel noted that according to the Compendium of botanicals, *Q. saponaria* Molina belongs to the family Quillajaceae. According to the EFSA follow-up of the re-evaluation of quillaia extract (E 999) (EFSA FAF Panel, 2024), 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. The general structural formulae of quillaia saponins is shown in Figure 1.

The applicant stated that the proposed specifications to be considered for this extension of uses comply with those set out in Commission Regulation (EU) No 231/2012[14] for quillaia extract (E 999) (Documentation provided to EFSA No. 1).

The Panel noted that in 2024, the EFSA FAF Panel published a follow-up of the re-evaluation of quillaia extract (E 999) and considering the technical data submitted at the time, recommended some modifications to the existing EU specifications for E 999 (see Section 1.2 and EFSA FAF Panel, 2024).



	R¹	R²	R³
S1	α-L-Rhap	H	H
S2	β-D-Xylp	H	H
S3	α-L-Rhap	β-D-Xylp	H
S4	β-D-Xylp	β-D-Xylp	H
S5	α-L-Rhap	β-D-Apif	H
S6	β-D-Xylp	β-D-Apif	H
S7	α-L-Rhap	H	Acetyl
S8	β-D-Xylp	H	Acetyl
S9	α-L-Rhap	β-D-Xylp	Acetyl
S10	β-D-Xylp	β-D-Xylp	Acetyl
S11	α-L-Rhap	β-D-Apif	Acetyl
S12	β-D-Xylp	β-D-Apif	Acetyl

FIGURE 1 General structure of quillaia saponins (quillaic acid as aglycone (sapogenin) component) (Güçlü-Ustündağ & Mazza, 2007). Apif, apiofuranose; Ara, d- arabinose; Gal, d- galactose; GlcA, d- glucoronic acid; Rha, d- rhamnose; Rhap, d- rhamnopyranose; Xyl, d- xylose; Xylp, d- xylopyranose.

3.2 | Authorised uses and use levels

Maximum permitted levels (MPLs) of use of quillaia extract (E 999) have been defined in Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives, as amended.

Currently, quillaia extract (E 999) is an authorised food additive in the EU in two food categories (FCs), i.e. FC 14.1.4. 'Flavoured drinks' and FC 14.2.3 'Cider and perry (excluding *cidre bouché, cydr jakościowy, perry jakościowe, cydr lodowy, perry lodowe*)', at an MPL of 200 mg/L or mg/kg as appropriate, calculated as anhydrous extract. Table 1 lists the two food categories that are permitted to contain quillaia extract (E 999) and the corresponding MPLs as set out in Annex II to Regulation (EC) No 1333/2008, as amended.

The Panel noted in the 2024 follow-up of the re-evaluation of quillaia extract (E 999) (EFSA FAF Panel, 2024) that the 2019 recommendation in the re-evaluation (EFSA FAF Panel, 2019) to express the MPLs for quillaia extract (E 999) on saponins content had not yet been implemented. In order to calculate the MPLs expressed as saponins, and in line with the 2024 follow-up of the re-evaluation, a maximum content of saponins of 83.41% in quillaia extract (E 999) was used, resulting in MPLs expressed as saponins of 167 mg/L or mg /kg for the food additive. The Panel noted that this would represent a worst-case scenario.

TABLE 1 Authorised uses and maximum permitted use levels for quillaia extract (E 999).

Food category number	Food category	Restrictions or exceptions	MPL calculated as anhydrous extract[a] (mg/L or mg/kg as appropriate)	MPL expressed as saponins[b] (mg/L or mg/kg as appropriate)
14.1.4	Flavoured drinks		200	167
14.2.3	Cider and perry	Excluding *cidre bouché, cydr jakościowy, perry jakościowe, cydr lodowy, perry lodowe*	200	167

Abbreviation: MPL, maximum permitted level.

[a]Terminology as in Regulation No 1333/2008, dried basis is the terminology used in this document.

[b]Rounded value calculated by the Panel, considering the maximum saponins content of 83.41% on the dried basis.

Quillaia extract (E 999) is not authorised in Annex III of Regulation (EC) No 1333/2008.

3.2.1 | Proposed extension of uses

The applicant proposed two new uses of quillaia extract (E 999) in food supplements supplied in a solid form or in a liquid form, excluding food supplements for infants and young children (Documentation provided to EFSA No. 2). Table 2 summarises the proposed extension of uses in the two relevant food categories and the proposed maximum use levels.

The Panel noted that the applicant proposed maximum use levels calculated as dried basis of 4000 mg/L or mg/kg as appropriate. The proposed typical use levels were the same. The applicant converted these two use levels to use levels expressed as saponins based on a maximum content of saponins in E 999 of 83.41% (Table 2) (Documentation provided to EFSA No. 2).

TABLE 2 Proposed extension of uses for quillaia extract (E 999) and proposed maximum use levels (Documentation provided to EFSA No. 2).

Food category number	Food category	Proposed maximum use levels calculated as dried basis (mg/L or mg/kg as appropriate)	Proposed maximum use levels expressed as saponins[a] (mg/L or mg/kg as appropriate)
17.1	Food supplements supplied in a solid form, excl. food supplement for infants and young children	4000	3336
17.2	Food supplements supplied in a liquid form, excl. food supplement for infants and young children	4000	3336

[a]Rounded value calculated by the Panel, considering the maximum saponins content of 83.41% on the dried basis.

3.3 | Exposure assessment

3.3.1 | Exposure data

Available information on use levels of quillaia extract (E 999) in food

Data on the occurrence of quillaia extract (E 999) in food were collected at the time of its re-evaluation by the FAF Panel by means of a call for data launched in 2016.[15] In response to this call, four use levels were submitted to EFSA by the industry (EFSA FAF Panel, 2019) for the currently authorised food categories (EFSA FAF Panel, 2019, Appendix B).

Concentration levels used to estimate the dietary exposure to quillaia extract (E 999) are listed in Annex A, Table A.1.

Food consumption data used for exposure assessment

EFSA comprehensive European Food Consumption Database

To assess whether the proposed extension of uses (Table 2) poses a possible health concern, the potential chronic dietary exposure to quillaia extract (E 999) was calculated by the Panel by combining the MPLs and proposed use levels with food consumption data from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database). Since 2010, this database has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. 'Guidance of EFSA on the Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011)). The version of the Comprehensive database[16] taken into account in the exposure assessment was published in December 2022 and its linkage with the food classification system[17] was updated in November 2023. Only data from EU Member States were considered for the estimations.

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons of the exposure estimates should be interpreted with caution. Depending on the food category and the level of detail used for the exposure calculations, uncertainties could be introduced owing to possible subjects' under-reporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

As FC 17 does not consider food supplements for infants and toddlers as defined in the legislation, exposure to quillaia extract (E 999) from food supplements was not estimated for these two population groups. Food consumption data from children, adolescents, adults and the elderly were used in the exposure assessment.

For the present assessment, food consumption data were available from 43 different dietary surveys carried out in 22 EU Member States (Table 3). Not all Member States provided consumption information for all population groups, and in some cases food consumption data from more than one consumption survey of one country were available. In most cases, when, for one Member State and population group, different dietary surveys were available, the data from the most recent survey were used. However, when two national surveys from the same Member State gave a better coverage of the age range than using only the most recent one, both surveys were kept.

TABLE 3 Population groups considered for assessing the dietary exposure to quillaia extract (E 999).

Population	Age range	EU member states with food consumption surveys covering more than 1 day
Children[a]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, the Netherlands, Portugal, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, the Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, the Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
The elderly[a]	From 65 years of age and older	Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, the Netherlands, Portugal, Romania, Slovenia, Spain, Sweden

[a]The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Comprehensive Database (EFSA, 2011).

[15]https://www.efsa.europa.eu/en/data/call/160524.

[16]https://www.efsa.europa.eu/en/data-report/food-consumption-data.

[17]Food categories in Part D of Annex II to Regulation (EC) No 1333/2008 on Food Additives.

Since 2018, all consumption records in the Comprehensive Database have been codified according to the FoodEx2 classification system (EFSA, 2015). Nomenclature from the FoodEx2 classification system was linked to the food categorisation system of Annex II of Regulation (EC) No 1333/2008, part D, to perform the exposure assessments of food additives. In practice, the FoodEx2 food codes were matched to the food categories of the Regulation.

To assess the safety of an extension of use in food supplements, the 'food supplements consumers only' exposure assessment scenario should be performed. The Panel noted that the applicant provided exposure estimates for the two food categories for which an extension of uses for quillaia extract (E 999) was requested (Table 2) using the Food Additive Intake Model 2.0 (FAIM) and the Dietary Exposure (DietEx) tool. As such a scenario cannot be performed with these publicly available tools by the applicant, the exposure estimates by the applicant were considered not appropriate and are not reported in the current opinion.

Food categories considered for the exposure assessment of quillaia extract (E 999)

The food categories in which the use of quillaia extract (E 999) is currently authorised and in which the extension of uses is proposed were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx2 classification system), at the most detailed level possible (up to FoodEx2 Level 7) (EFSA, 2015).

- All flavoured drinks were selected for FC 14.1.4.
- All cider and perry were selected for FC 14.2.3, as the exclusion of 'cidre bouché, cydr jakościowy, perry jakościowe, cydr lodowy, perry lodowe' could not be considered.
- All food supplements were selected for FC 17, in the extension of uses scenario, as the applicant requested use of quillaia extract (E 999) in both liquid and solid food supplements at the same use level.

Concentration levels used to estimate the dietary exposure to quillaia extract (E 999) are listed in Annex A, Table A.1.

3.3.2 | Exposure estimates

For this opinion, exposure to quillaia extract (E 999) was estimated by multiplying the concentration levels for each food category with the average daily consumption of foods belonging to that food category at individual level. Exposure estimates were summed across foods per individual and subsequently divided by the individual's body weight resulting in a distribution of daily individual average exposures per kg body weight. Based on these distributions, the mean and 95th percentiles (P95) of exposure were calculated per survey and per population group. Mean estimates based on dietary surveys/population groups with less than six consumers and P95 estimates with less than 60 consumers are not considered (EFSA, 2011).

For the proposed request for extension of uses of quillaia extract (E 999) in food supplements, the exposure was estimated for the population of 'food supplements consumers only' (EFSA ANS Panel, 2017), in which only the consumers of food supplements and their whole diet were considered. Consumers of food supplements are only a small subset of the total study population in some dietary surveys (Annex A, Table A.2). Not considering the whole population avoids 'diluting' the exposure with lower exposure levels of non-consumers of food supplements and the estimates will thus reflect the potential exposure to quillaia extract (E 999) of consumers of food supplements.

Two scenarios were performed: (1) considering the MPLs as defined for the already authorised food categories (i.e. FCs 14.1.4 and 14.2.3) and the proposed maximum use levels for FCs 17.1 and 17.2; and (2) considering the typical use levels for the already authorised food categories as reported at the time of the re-evaluation of quillaia extract (EFSA FAF Panel, 2019), and the proposed maximum use levels for FCs 17.1 and 17.2.

The exposure was calculated using concentration levels expressed as saponins.

Dietary exposure to quillaia extract (E 999) including the proposed extension of uses

The summary of the dietary exposure (results per population group) to quillaia extract (E 999) including the proposed extension of uses, expressed as saponins, is provided in Table 4. Detailed results per population group and survey are presented in Annex A, Table A.2.

As FC 17 does not consider food supplements for infants and toddlers as defined in the legislation, exposure to quillaia extract (E 999) from food supplements was not estimated for these two population groups.

TABLE 4 Summary of estimated dietary exposure (mean and 95th percentile) to quillaia extract (E 999) as a food additive in four population groups of consumers only of food supplements (minimum-maximum across the dietary surveys in mg/kg bw per day expressed as saponins) for the current uses and use levels and the proposed extension of uses.

	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
'Food supplements consumers only' scenario 1 using the MPLs for the authorised food categories and the proposed maximum use levels for FC 17 expressed as saponins				
Mean	0.4–3.4	0.3–1.8	0.07–0.7	0.03–0.8
95th percentile	1.3–7.3	1.3–4.3	1.0–2.4	0.5–1.9
'Food supplements consumers only' scenario 2 using the typical use levels for the authorised food categories and the proposed maximum use levels for FC 17 expressed as saponins				
Mean	0.2–1.0	0.1–0.9	0.03–0.5	0.03–0.7
95th percentile	0.5–2.2	0.3–2.9	0.3–2.3	0.3–1.2

Abbreviations: FC, food category; MPL, maximum permitted level.

In the 'food supplements consumers only' scenario 1, using the MPLs for the authorised food categories and the proposed maximum use levels for food supplements (FC 17), the lowest estimate of mean exposure to quillaia extract (E 999), expressed as saponins, from its use as a food additive was 0.03 mg/kg bw per day in the elderly and the highest 3.4 mg/kg bw per day in children. The lowest and highest estimates of the 95th percentile were 0.5 mg/kg bw per day in the elderly and 7.3 mg/kg bw per day in children, respectively.

In the 'food supplements consumers only' scenario 2, using the typical use levels for the authorised food categories and the proposed maximum use levels for food supplements (FC 17), the lowest estimate of mean exposure to quillaia extract (E 999), expressed as saponins, from its use as a food additive was 0.03 mg/kg bw per day in adults and the elderly and the highest 1.0 mg/kg bw per day in children. The lowest and highest estimates of the 95th percentile were 0.3 mg/kg bw per day in adolescents, adults and the elderly and 2.9 mg/kg bw per day in adolescents, respectively.

Main food categories contributing to exposure to quillaia extract (E 999) including the proposed extension of uses

In the 'food supplements consumers only' scenario 1, using the MPLs for the authorised food categories and the proposed maximum use levels for the food supplements, the main contributing food categories to the total mean exposure were FC 17.1 'Food supplements supplied in a solid form, excl. food supplement for infants and young children' and FC 14.1.4 'Flavoured drinks' for all population groups. Additionally, FC 17.2 'Food supplements supplied in a liquid form, excl. food supplement for infants and young children' was an important contributor to exposure to quillaia extract (E 999) expressed as saponins.

In the 'food supplements consumers only' scenario 2, using the typical levels for the authorised food categories and the proposed maximum use levels for the food supplements, the main contributing food categories to the total mean exposure estimates were the two food supplement food categories (FCs 17.1 and 17.2) in all population groups.

Annex A, Table A.3 lists the contribution of all four food categories to the mean exposure for each population group and exposure scenario.

Uncertainty analysis

Potential sources of uncertainty in the exposure assessment of quillaia extract (E 999) have been presented above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 5.

TABLE 5 Qualitative evaluation of influence of uncertainties on the dietary exposure estimate.

Sources of uncertainties	Direction[a]
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Uncertainty in possible national differences in use levels of food categories	+/–
Concentration data: • MPLs and typical use levels considered applicable to all foods within the four food categories, whereas not all foods/food supplements belonging to a food category will contain quillaia extract (E 999) as a food additive (EFSA FAF Panel, 2024)	+
Food categories selected for the exposure assessment of quillaia extract (E 999) from the currently permitted uses and use levels: inclusion of the complete FC 14.2.3 'Cider and perry', because the exception 'excluding *cidre bouché, cydr jakościowy, perry jakościowe, cydr lodowy, perry lodowe*' could not be taken into account	+

TABLE 5 (Continued)

Sources of uncertainties	Direction[a]
'Food supplements consumers only' scenario using MPLs for the authorised food categories and the proposed maximum use level for FCs 17.1 and 17.2: • exposure calculations based on the MPLs according to Annex II to Regulation (EC) No 1333/2008	+
'Food supplements consumers only' scenario using typical use levels for the authorised food categories and the proposed maximum use level for FCs 17.1 and 17.2: • exposure calculations based on the typical use levels submitted by industry (EFSA FAF Panel, 2019)	+/–

[a]+, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Quillaia extract (E 999) is currently authorised in two food categories (FCs 14.1.4 and 14.2.3) and an extension of uses in food supplements (FCs 17.1 and 17.2) was requested.

To evaluate the safety of this request for extension, the 'food supplements consumers only' scenario was used. It is noted that this scenario considered that all food supplements contain quillaia extract (E 999), resulting in an overestimation of the dietary exposure.

The Panel considered that overall, the uncertainties identified in Table 5 resulted in an overestimation of the dietary exposure to quillaia extract (E 999) in the EU Member States available in the EFSA Comprehensive database in both 'food supplements consumers only' scenarios.

3.4 | Biological and toxicological data

At the time of the 2019 re-evaluation of quillaia extract (E 999) (EFSA FAF Panel, 2019), the Panel concluded that any toxicity associated with quillaia extract (E 999) is due to its constituent saponins and, therefore established an ADI of 3 mg saponins/kg bw per day for quillaia extract (E 999).

For the current assessment, the applicant conducted a literature search to identify any new or additional data available since the EFSA re-evaluation of quillaia extract (E 999) (EFSA FAF Panel, 2019). No new information was identified by the applicant in the literature search for absorption, distribution, metabolism and excretion, acute toxicity, short-term and subchronic toxicity, genotoxicity, chronic toxicity, carcinogenicity, and reproductive and developmental toxicity, and for other relevant data (Documentation provided to EFSA No. 1).

4 | DISCUSSION

The current assessment deals with the safety evaluation of the extension of uses of quillaia extract (E 999) as a food additive in food supplements supplied in a solid or liquid form, excluding food supplements for infants and young children.

According to Commission Regulation (EU) No 231/2012, quillaia extract (E 999) is obtained by aqueous extraction of *Quillaia saponaria* Molina, or other *Quillaia* species, trees of the family Rosaceae. The Panel noted that according to the Compendium of botanicals, *Q. saponaria* Molina belongs to the family Quillajaceae. According to the EFSA follow-up of the re-evaluation of quillaia extract (E 999) (EFSA FAF Panel, 2024), 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.

The applicant stated that the proposed specifications to be considered for the extension of uses comply with those set out in Commission Regulation (EU) No 231/2012 for quillaia extract (E 999). The Panel noted that in 2024, the EFSA FAF Panel published a follow-up of the re-evaluation of quillaia extract (E 999) and considering the technical data submitted at the time, recommended some modifications to the existing EU specifications for quillaia extract (E 999) (see Section 1.2 and EFSA FAF Panel, 2024).

At the time of the 2019 re-evaluation of quillaia extract (E 999), the Panel concluded that any toxicity associated with quillaia extract (E 999) is due to its constituent saponins and, therefore, established an ADI of 3 mg saponins/kg bw per day for quillaia extract (E 999) (EFSA FAF Panel, 2019). For the current assessment, the applicant conducted a literature search to identify any new or additional data available since the EFSA re-evaluation of quillaia extract (E 999) in 2019. No new information was identified by the applicant in the literature search for absorption, distribution, metabolism and excretion, acute toxicity, short-term and subchronic toxicity, genotoxicity, chronic toxicity, carcinogenicity and reproductive and developmental toxicity, and for other relevant data.

Quillaia extract (E 999) is currently authorised as a food additive in the EU in two food categories (FCs 14.1.4 and 14.2.3) in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives. At the time of the 2019 re-evaluation, another extension of use for quillaia extract (E 999) to be included in Annex III Part 4 'Food additives including carriers in food flavourings' of Regulation (EC) No 1333/2008 was evaluated. It was noted that exposure estimates considering such an extension of uses were almost identical to those considering only the food categories in which quillaia extract (E 999) is authorised (EFSA FAF Panel, 2019). Since then, the authorised uses and use levels of quillaia extract (E 999) have not been modified in Regulation (EC) No 1333/2008 and, therefore, the proposed extension of uses evaluated in 2019 was not considered in the current assessment.

The dietary exposure to this food additive based on the currently authorised uses was estimated in the 2024 follow-up of the re-evaluation of quillaia extract (E 999), at both the MPLs and at the reported use levels at the time of the 2019 re-evaluation. The Panel considered that since quillaia extract (E 999) is used in FC 14.1.4 'Flavoured drinks', the refined brand-loyal exposure assessment scenario was the most relevant for its risk assessment. Using this scenario, exposure, expressed as saponins, ranged between 0 mg/kg bw per day at the mean up to 0.9 mg/kg bw per day at the 95th percentile across the different population groups. Thus, none of the exposure estimates exceeded the ADI of 3 mg saponins/kg bw per day.

In the current opinion, an exposure scenario considering the requested extension of uses in food supplements supplied in a solid or liquid form (FCs 17.1 and FC 17.2) was performed. A 'food supplements consumers only' scenario was calculated considering the proposed extension of uses at the proposed maximum use levels, together with the current authorised uses at both the MPLs and the typical reported use levels at the time of the re-evaluation (EFSA FAF Panel, 2019). The Panel noted that at the time of the follow-up of the re-evaluation of quillaia extract (E 999), an extension of uses in food supplements supplied in a solid or liquid form (FCs 17.1 and FC 17.2) was requested proposing higher use levels (EFSA FAF Panel, 2024) than those proposed in the current assessment.

In the 'food supplements consumers only' scenario 1, using the MPLs for the authorised food categories and the proposed maximum use levels for food supplements (FC 17), the lowest estimate of mean exposure to quillaia extract (E 999), expressed as saponins, from its use as a food additive was 0.03 mg/kg bw per day in the elderly and the highest 3.4 mg/kg bw per day in children. The lowest and highest estimates of the 95th percentile were 0.5 mg/kg bw per day in the elderly and 7.3 mg/kg bw per day in children, respectively. In the 'food supplements consumers only' scenario 2, using the typical use levels for the authorised food categories and the proposed maximum use levels for food supplements (FC 17), the lowest estimate of mean exposure to quillaia extract (E 999), expressed as saponins, from its use as a food additive was 0.03 mg/kg bw per day in adults and the elderly and the highest 1.0 mg/kg bw per day in children. The lowest and highest estimates of the 95th percentile were 0.3 mg/kg bw per day in adolescents, adults and the elderly and 2.9 mg/kg bw per day in adolescents, respectively.

The 'food supplements consumers only' scenario considers only the consumers of food supplements, which were a small subset of the total study population in some dietary surveys. Not considering the whole population avoids 'diluting' the exposure with non-consumers of food supplements and the exposure estimates will thus only reflect the potential exposure to quillaia extract (E 999) of these food supplements consumers. It is also noted that in this scenario it was assumed that all food supplements will contain E 999.

The Panel considered that the 'food supplements consumers only' scenario 2 using the typical reported use levels for the currently authorised food categories is the most appropriate for assessing the dietary exposure. These levels were used in the refined brand-loyal scenario during the re-evaluation and the follow-up of the re-evaluation of quillaia extract (E 999) and this scenario was considered by the Panel to be the most appropriate for the risk assessment of this food additive for the general population (EFSA FAF Panel, 2019, 2024).

The Panel noted, considering all uncertainties, that this scenario resulted in an overestimation of the actual dietary exposure to quillaia extract (E 999) through its use in the currently authorised food categories and its proposed use in food supplements (see Section 3.3.2, Uncertainty analysis).

The Panel also noted that the exposure estimates in the 'food supplements consumers only' scenario 2 using the typical reported use levels for the authorised food categories and the proposed maximum use levels for food supplements (FC 17) did not exceed the ADI of 3 mg saponins/kg bw per day in any population group.

5 | CONCLUSIONS

The Panel concluded that the exposure estimates using the typical reported use levels for the currently authorised food categories and considering the proposed extension of uses for E 999 in FC 17.1 'Food supplements supplied in a solid form, excluding food supplement for infants and young children' and FC 17.2 'Food supplements supplied in a liquid form, excluding food supplement for infants and young children', if authorised, would not result in an exceedance of the ADI in any population group.

6 | DOCUMENTATION PROVIDED TO EFSA

1. Givaudan International SA, 2023. Technical dossier for the request on the extension of use: Modification of the condition of use of quillaia extract (E 999). Submitted on 31 March 2023.[18]
2. Givaudan International SA, 2024. Clarification on the data submitted for the request on the extension of use: Modification of the condition of use of quillaia extract (E 999). Submitted on 25 September 2024.
3. Givaudan International SA, 2024. Clarification on the data submitted for the request on the extension of use: Modification of the condition of use of quillaia extract (E 999). Submitted on 08 October 2024.

[18]The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FAD-2023-15592.

ABBREVIATIONS

ADI	acceptable daily intake
ANS Panel	Panel on Food Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
CVMP	Committee for Veterinary Medicinal Products
DietEx	Dietary Exposure
EMA	European Medicines Agency
FAF Panel	Panel on Food Additives and Flavourings
FAIM	Food Additives Intake Model
FC	Food Category
FSANZ	Food Standards Australia New Zealand
INS	International Numbering System for Food Additives
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	maximum permitted level
MRL	maximum residue level
NOAEL	no observed adverse effect level
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCF	Scientific Committee on Food

REQUESTOR

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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ANNEX A

Table A.1 – Concentration levels of quillaia extract (E 999) used in the exposure assessment scenarios (mg/kg or mg/L as appropriate).

Table A.2 – Summary of total estimated exposure to quillaia extract (E 999) from use as a food additive for the 'food supplements consumers only' scenario using the MPLs and typical use levels for the authorised food categories and the proposed maximum use levels for FC 17 per population group and survey: mean and 95th percentile (mg/kg bw per day expressed as saponins).

Table A.3 – Main food categories contributing to exposure to quillaia extract (E 999) from use as a food additive for the 'food supplements consumers only' scenario using the MPLs and typical use levels for the authorised food categories and the proposed maximum use levels for FC 17 per population group (consumers only) and survey (> 5% to the total mean exposure).

Annex A can be found in the online version of this output ('Supporting information' section).