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SCIENTIFIC OPINION

Safety evaluation of pectin-rich extract derived from *Coffea arabica* as 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) provides a scientific opinion on the safety assessment of the proposed use of pectin rich extract derived from *Coffea arabica* L. as a food additive. The proposed food additive consists of 70%–85% dietary fibres (of which the major part is pectin), 4%–6.5% proteins and substances of potential concern including caffeine, chlorogenic acid, [redacted], caffeic acid, [redacted], trigonelline. The Panel integrated all available information including existing EFSA evaluations on pectins, coffee fruit pulp, and conducted a new quantitative structure–activity relationship (QSAR) analysis for the substances of potential concern. Studies from literature confirmed that the pectins are not absorbed intact but extensively fermented by intestinal microbiota. No adverse effects were reported in two 90-day toxicity studies in rats up to 7.8 g/kg body weight (bw) per day and in one human study on sugar beet pectin at 0.2 g/kg bw per day for 4 weeks. The calculated MOE for [redacted] indicated that there is a low concern from a public health point of view. The Panel considered that the exposure to caffeine, caffeic acid, [redacted], chlorogenic acid, [redacted] and trigonelline from use of the proposed food additive would contribute only to a minimal increase over existing dietary exposure and is not of safety concern. Considering the composition of the proposed food additive, the absence of genotoxic concern of its components and lack of adverse effects of the major component (i.e. pectins), the Panel considered that there was no need for a numerical acceptable daily intake. The Panel concluded that the use of pectin-rich extract derived from *Coffea arabica* as a new food additive does not raise a safety concern at the proposed use and use levels.

KEYWORDS

Coffea arabica L., coffee cherry pulp, coffee fruit, dietary fibre, food additive, pectin

CONTENTS

1 | INTRODUCTION

The present scientific opinion deals with the safety evaluation of pectin-rich extract derived from coffee fruit (*Coffea arabica* L.), also called 'Dutch gum' and 'Coffee Berry Soluble Fibre', proposed as a food additive in a variety of food categories.

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. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No. 231/2012.[2]

An application has been introduced for the authorisation of the use pectin rich extract derived from coffee fruit (*Coffea arabica* L.) as a new food additive in several food categories 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 perform a risk assessment to provide a scientific opinion on the safety of the proposed use of pectin rich extract derived from coffee fruit (*Coffea arabica* L.) as a food additive, 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

No existing authorisations or evaluations have been reported on the proposed food additive (pectin rich extract derived from *Coffea arabica*).

Regarding the starting material of the proposed food additive, i.e. the coffee fruit/coffee pulp, EFSA issued in 2021 two technical reports on traditional foods on cherry pulp and dried cherry pulp under Article 14 of Regulation (EU) No. 2015/2283 (EFSA, 2021a, 2021b), and in 2022, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) published one scientific opinion on dried coffee husk (cascara) as a novel food (EFSA NDA Panel, 2022). The three EFSA outputs stated that (dried) cherry pulp and dried coffee husk can be used as ingredients for infusions, beverages and/or flavoured drinks. In addition, for all three, EFSA considered that the available data on composition and history of use do not raise safety concerns. Regarding their caffeine content, it was noted that the consumption of beverages containing caffeine is not recommended for children, pregnant or breast-feeding women if the caffeine content exceeds 150 mg/L. The presence of the antinutritional factors tannins and phytates in the coffee cherry pulp was reported. Moreover, EFSA recommended introducing limits for catechol in the specifications of the pulp and calculated the maximum level of 0.25 mg/g of catechol in the pulp (EFSA, 2021a) and 0.16 mg/g in dried pulp (EFSA, 2021b).

According to the information provided by the applicant, in 2019, the FDA (Food and Drug Administration) designated a *Coffea arabica* coffee fruit extract (including the coffee bean) as generally recognised as safe (GRAS), marketed as an ingredient in a variety of food product categories such as ready-to-mix beverages, chocolate and other snacks at maximum use levels ranging from 20 to 300 mg per serving. In 2016, Health Canada evaluated a coffee fruit extract as a novel food for use at levels up to 300 mg/serving in foods and beverages sold in Canada and concluded that there is no food safety concern for the general population (Documentation provided to EFSA n. 1).

Pectins, part of the dietary fibre of the proposed food additive, are included in the Community list of approved food additives in Annex II and III of Regulation (EC) No. 1333/2008 under the number E 440i (pectin) and E 440ii (amidated pectin). Specifications for each are established in Regulation (EU) No. 231/2012. The safety of the food additives pectin (E 440i) and amidated pectin (E 440ii) was re-evaluated by the EFSA Panel on Food Additives and Nutrient Sources added to Food (EFSA ANS Panel) in 2017 and by this Panel in 2021 in the frame of Regulation (EU) No. 257/2010. The first re-evaluation opinion issued in 2017 concluded that there is no safety concern for the use of pectin (E 440i) and amidated pectin (E 440ii) as food additives for the general population and that there is no need for a numerical acceptable daily intake (ADI). The estimated exposure to pectins from their use as food additives was up to 442 mg/kg bw per day for toddlers at the 95th percentile (brand-loyal scenario) (EFSA ANS Panel, 2017a). The ANS Panel, however, considered that the conclusions reached on the

[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, pp. 16–33.

[2]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, pp. 1–295.

[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, pp. 1–6.

re-evaluation of the food additive were not applicable to the use of pectin (E 440i) and amidated pectin (E 440ii) in food for infants under the age of 16 weeks.

In a follow-up opinion, the safety of pectins was re-evaluated for their use as food additives in foods for infants below 16 weeks of age (EFSA FAF Panel, 2021). For infants below 16 weeks of age, it was recommended a reduction of the maximum permitted level (MPL) of pectin (E 440i) and amidated pectin (E 440ii) in food categories (FC) 13.1.5.1 (Dietary foods for special medical purposes and special formulae for infants) and 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC). The FAF Panel integrated the existing data from the 2017 ANS scientific opinion with newly submitted data and identified a reference point at 1069 mg/kg bw per day (the no observed adverse effect level, NOAEL of two 21-day feeding studies in neonatal piglets, the highest dose tested) and applied a MOE approach to conclude on the safety for use in infants below 16 weeks of age.

Prior to the re-evaluation of E 440i and E 440ii by EFSA, non-amidated and amidated pectins have also been subject of evaluations by the Scientific Committee on Food (SCF, 1978) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974, 1981, 2015, 2016).

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a dossier to support the safety evaluation of the present application on pectin-rich extract derived from coffee fruit (*Coffea arabica* L.) in a variety of food categories (Documentation provided to EFSA n. 1).

In accordance with Art. 38 of the Commission Regulation (EC) No. 178/2002[4] 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,[5] the non-confidential version of the dossier is published on Open EFSA.[6]

According to Article 32c(2) of Regulation (EC) No. 178/2002[7] 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 22 January to 12 February 2024,[8] for which no comments were received.[9]

Following the requests for additional data sent by EFSA, the applicant provided additional data on 31 October 2023 (Documentation provided to EFSA n. 2), on 11 November 2024, 15 January 2025 and 24 January 2025 (Documentation provided to EFSA n. 3), and on 14 July 2025 and 23 September 2025 (Documentation provided to EFSA n. 4), and on 3 November 2025 (Documentation provided to EFSA n. 5).

In addition, food consumption data from the[10] latest version of the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) (December 2024), including new and updated dietary surveys, were used to estimate the dietary exposure to pectin-rich extract from *Coffea arabica* using Food Additive Intake Model (FAIM, version 3.0).

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 SC, 2009a) 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) and the Guidance on the 'Safety assessment of botanicals and botanical preparations' (EFSA SC, 2009b) and 'Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles' (EFSA Scientific Committee, 2021) have been followed by the FAF Panel for evaluating the present application.

In animal studies, when the test substance is administered in the feed, but doses are not explicitly reported by the authors as mg/kg bw per day based on actual feed consumption, the daily intake is calculated by the Panel using the relevant default values. In case of rodents, the values as indicated in the EFSA Scientific Committee Guidance document (EFSA SC, 2012a) are applied. In these cases, the dose is expressed as 'equivalent to mg/kg bw per day'. If a concentration in feed was reported and the dose in mg/kg bw per day was calculated (by the authors of the study report or the Panel) based on

[4]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, pp. 1–24.

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

[6]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-2022-4750.

[7]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, pp. 1–24.

[8]Accessible at: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk0000005ukj/pc0796.

[9]Accessible at: https://open.efsa.europa.eu/consultations/a0cTk0000006RyPIAU.

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

these reported concentrations and on reported consumption data for feed, the dose is expressed as 'equal to mg/kg bw per day'.

FAIM (version 3.0) was used to estimate the exposure to the food additive. In this tool, consumption data from the Comprehensive Database coded according to the FoodEx2 classification system (up to FoodEx2 Level 7) were linked to the food categorisation system of Annex II to Regulation (EC) No. 1333/2008, part D (EFSA, 2015).

Uncertainties in the exposure assessment were identified and discussed (Section 3.3.2).

3 | ASSESSMENT

3.1 | Technical data

3.1.1 | Identity of the proposed food additive

The proposed food additive pectin-rich extract derived from coffee fruit (*Coffea arabica* L.) (commercial names: 'Dutch Gum' and 'Coffee Berry Soluble Fibre') is a dietary fibre extract derived from the coffee fruit pulp of *Coffea arabica*. The main components of the proposed food additive are dietary fibre (such as pectin, Figure 1) along with low amounts of proteins and starch (Documentation provided to EFSA n. 4).

The plant *Coffea arabica* is a flowering plant in the *Rubiaceae* family, which originates from Ethiopia and is widely cultivated in countries such as Brazil, Colombia and Ethiopia.

Scientific name of the plant: *Coffea arabica* L.
Botanical synonym: *Coffea vulgaris* Moench.
Common names: Coffee, Arabian/Arabica Coffee.
Plant Family: *Rubiaceae* (Documentation provided to EFSA n. 1).

The Panel noted that *Coffea arabica* is included in the EFSA Compendium of Botanicals,[11] which lists botanicals that are reported to contain naturally occurring substances of possible concern for human health when present in food. Initially, only caffeine was reported as a substance of possible concern, occurring in the coffee seeds and fruit. In a subsequent update of the Compendium (April 2025), trigonelline was also included, as occurring.

The applicant provided analytical data on one batch of the dried and milled coffee pulp, i.e. the starting material of pectin-rich extract derived from *Coffea arabica*, on its composition (dietary fibre [redacted] uronic acid [redacted] (being part of the total dietary fibre), lignin [redacted] total protein [redacted]%, total ash [redacted] moisture [redacted], total polyphenols [redacted] (as gallic acid equivalents)), fat [redacted] caffeine [redacted] Data on four batches were also provided on the monosaccharide composition (glucose [redacted] arabinose [redacted] mannose [redacted] xylose [redacted] rhamnose [redacted] and fucose [redacted]) (Documentation provided to EFSA n. 1, 2, 3). The Panel noted that the analytical data are generally in accordance with information for coffee cherry pulp in the literature (EFSA, 2021a).

The structure of the extracted pectin has been characterised in a patent numbered WO2014083032A1. According to the applicant, the pectin's molecular backbone is composed of D-galacturonic acid units (at least 45%) joined in chain by α-(1–4) glycosidic linkage. Other components of the pectin include neutral sugars such as rhamnose that introduces a link into the straight galacturonan (linear chain of α-(1–4)-linked D-galacturonic acids) chains and arabinose, galactose or xylose which construct the side chains (Documentation provided to EFSA n. 1). Information on the molecular weight distribution and degree of methylation and acetylation of the pectin is available in Section 3.1.2 physicochemical parameters.

[11] Available online: https://www.efsa.europa.eu/it/data/compendium-botanicals.

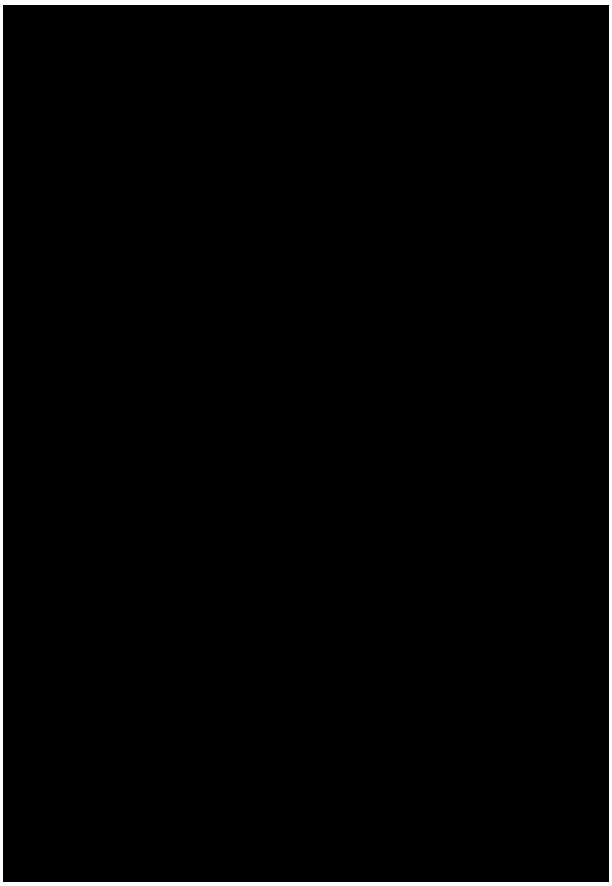

FIGURE 1 Depiction of the structure of the pectin of pectin-rich extract derived from *Coffea arabica* L.

3.1.2 | Proposed specifications

The specifications for pectin-rich extract derived from *Coffea arabica* specifications, as proposed by the applicant, are presented in Table 1.

TABLE 1 Specifications for the pectin-rich extract derived from *Coffea arabica* as proposed by the applicant.

Definition	[redacted]
Description	White, light yellow, light grey or light brown powder
Purity	
Dietary fibre	70%–85% (AOAC 2017.16)
Total starch	≤ 4% (Spectrophotometry)
Protein	4%–6.5% (Dumas (NEN-ENISO 16634); Kjeldahl)
Total fat	≤ 3% (Crude fat content after acidic hydrolysis, gravimetry, Soxhlet gravimetry)
Loss on drying	4%–12% (103°C; 70°C (6 h))
Ash	≤ 7% (500–550°C)
Uronic acid	45%–66% (Spectrophotometry)
Caffeine	1400–3700 mg/kg (HPLC-MS)

TABLE 1 (Continued)

[redacted]	[redacted]
Mercury	≤ 0.05 mg/kg (ICP-MS, equal to NEN-EN 13805/13806)
Cadmium	≤ 0.05 mg/kg (ICP-MS, equal to NEN-EN 13805/15763)
Arsenic	≤ 0.1 mg/kg (ICP-MS, equal to NEN-EN 13805/15763)
Lead	≤ 1 mg/kg (ICP-MS, equal to NEN-EN 13805/15763)
Copper	< 15 mg/kg (ICP-OES + ICP-MS)
Polycyclic aromatic hydrocarbons	
Benzo(a)pyrene	≤ 7 µg/kg (GC-MS/MS acc. to EPA + GC-MS/MS acc. to Recomm. 2005/108/EC)
Sum PAH4	≤ 24 µg/kg (GC-MS/MS acc. to EPA + GC-MS/MS acc. to Recomm. 2005/108/EC)
Pesticides	Below LOQ except (GC-MS/MS, LC-MS/MS)
Chlorpyrifos (mg/kg)	0.02
Cypermethrin (sum) (mg/kg)	0.02
Captan (Sum of captan and THPI, expressed as captan) (mg/kg)	0.03
Clothianidin (mg/kg)	0.02
Cyproconazole (mg/kg)	0.05
Thiamethoxam (mg/kg)	0.1
Chlorantraniliprole (mg/kg)	0.04
Flutriafol (mg/kg)	0.02
Azoxystrobin (mg/kg)	0.03
Mycotoxins	
Aflatoxin B1	≤ 0.5 µg/kg (UHPLC-MS/MS according to NEN-EN 17194:2017)
Sum of Aflatoxins (B1, B2, G1, G2)	≤ 2.2 µg/kg (UHPLC-MS/MS according to NEN-EN 17194:2017)
Ochratoxin A	≤ 1 µg/kg (UHPLC-MS/MS according to NEN-EN 17194:2017)
Alternariol	≤ 6.5 µg/kg (LC-MS/MS)
Alternariol monoethylether (AME)	< 5 µg/kg (LC-MS/MS)
Microbiological criteria	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

The manufacturing process included in the definition of the specifications of the proposed food additive was considered not sufficiently detailed. The Panel would propose a more detailed description of the manufacturing process of the food additive (see Section 3.1.3) in the definition.

For some impurities listed in the specifications, i.e [redacted] and certain pesticides, specific values have been provided instead of a limit for their presence in the proposed food additive. The Panel noted that limits should be established for these impurities. Furthermore, the proposal for regulating the potential presence of pesticides in the food additive is unclear. With the exception of the specific pesticides for which individual values are provided, as mentioned above, a general proposal of 'pesticides below LOQ' is made, without specifying the LOQ.

Analytical results for 18 independently produced batches have been provided to show that each batch complies with the proposed specifications (Documentation provided to EFSA n. 1, 2, 3, 4).

The independently produced batches of pectin-rich extract derived from *Coffea arabica* were analysed for pectin, uronic acid, dietary fibre, free sugars and carbohydrate-bound sugars, moisture, protein, ash, starch, fat, minerals, toxic elements, caffeine, phenolic compounds (e.g. [redacted]), mycotoxins, pesticide residues, polycyclic aromatic hydrocarbons (PAHs), microbiological criteria and physicochemical parameters (i.e. water activity, degree of methylation and acetylation, solubility and particle size).

Components

Regarding the composition of pectin-rich extract derived from *Coffea arabica*, dietary fibre ranged from [redacted] starch from below the LOQ of 0.3%–3.6%, free sugars from below the [redacted] protein from [redacted] fat from below the LOQ [redacted] moisture from 5.0% to 11.3% and ash from 1.4% to 6.4% in eight independently produced batches (Documentation provided to EFSA n. 1, 2, 3).

The carbohydrate profile of the pectin was analysed in six batches of the proposed food additive reported above, using high-performance anion-exchange chromatography with pulsed amperometric detection (HPAEC-PAD). The concentration of pectin ranged from 64.3% to 71.9%, calculated as the sum of uronic acid and total carbohydrate-bound sugars (arabinose, galactose, rhamnose, glucose, mannose, xylose and fucose). In more detail, uronic acid ranged from 46.1% to 52.5%, carbohydrate-bound sugars from 17.7% to 25.8%, of which [redacted] was arabinose[redacted] was galactose, [redacted] was rhamnose, [redacted] was glucose, [redacted] was mannose, [redacted] was xylose and [redacted] was fucose (Documentation provided to EFSA n. 1).

In addition, the applicant determined in seven batches the concentration of pectin which ranged from 73.5% to 77.2%, calculated as the sum of uronic acid and total of carbohydrate-bound sugars (arabinose, galactose, rhamnose, glucose, mannose, xylose and fucose). In more detail, uronic acid ranged from 53% to 66% and carbohydrate-bound sugars from 17.2% to 21.3%, of which [redacted] was arabinose, [redacted] was galactose, [redacted] was rhamnose, [redacted] was glucose, [redacted] was mannose, [redacted] was xylose and [redacted] was fucose (Documentation provided to EFSA n. 2).

The analytical data provided by the applicant meet the proposed specifications.

The Panel considered that the range of pectins (expressed in percentage) should be included in the specification.

Toxic elements

As regards the toxic elements, the applicant provided analytical data obtained by inductively coupled plasma mass spectrometry (ICP-MS), according to the NEN EN 15763 method, on eight batches. Arsenic (As) was quantified in one of the analysed batches at [redacted] mg/kg and was reported as below the LOQ of [redacted]; cadmium (Cd) was quantified in three batches from [redacted] mg/kg and below the LOQ of [redacted] mg/kg in five batches; lead (Pb) was quantified from [redacted] mg/kg; and mercury (Hg) was quantified from [redacted] mg/kg in three batches and below the LOQ of [redacted] in five batches (Documentation provided to EFSA n. 1, 2, 3).

The anticipated impact of the proposed specifications and of the reported analytical data on the potential exposure to these toxic elements is described in Section 3.3.3.

Polycyclic aromatic hydrocarbons (PAHs)

The applicant provided analytical data on PAHs in 12 batches of pectin-rich extract derived from *Coffea arabica* analysed, determined with gas chromatography tandem mass spectrometry (GC-MS/MS). In eight batches, benzo(a)pyrene ranged from 1.0 to 6.5 µg/kg, while PAH4 ranged from 7.6 to 23.7 µg/kg (Documentation provided to EFSA n. 1, 2, 3).

In four batches reported, data were above the proposed specification limits for [redacted] µg/kg) and [redacted] (Documentation provided to EFSA n. 1, 2, 3). [redacted] The applicant also reported that process improvements have resulted in batches respecting the proposed specifications (Documentation provided to EFSA n. 4).

The Panel considered that the data provided support the proposed specifications for PAHs.

Taking into account the analytical data and the manufacturing process, the Panel considered that the proposed specification limits would ensure that the potential presence of PHAs in the proposed food additive would not raise a safety concern.

Microbiological criteria

Initially, the applicant provided analytical data on the presence of possible microbiological contaminants in pectin-rich extract derived from *Coffea arabica* .

Salmonella spp. was consistently not detectable in five tested batches (25 g tested). *E. coli*, Enterobacteriaceae, sulfite-reducing bacteria, moulds and yeasts were below 10 cfu/g in four analysed batches, while aerobic mesophilic count was below 10 cfu/g in four analysed batches and below [redacted] cfu/g in one analysed batch. *Bacillus cereus* was reported to be below 10 cfu/g in seven analysed batches, 10 cfu/g in one analysed batch and below 100 cfu/g in one analysed batch (Documentation provided to EFSA n. 1, 2, 3).

Two batches appeared with high levels of [redacted] (Documentation provided to EFSA n. 1, 2, 3). [redacted] The applicant also reported that process improvements have resulted in batches respecting the proposed specifications (Documentation provided to EFSA n. 4).

The Panel considered that the data provided support the proposed specifications for microbiological criteria.

Mycotoxins

Because of the botanical origin of the proposed food additive, mycotoxins might be possible contaminants occurring in the proposed food additive. The applicant provided analytical data on mycotoxins using liquid chromatography with tandem mass spectrometry (LC-MS/MS) on 11 independently produced batches of the proposed food additive (Documentation provided to EFSA n. 1,2,3). The Panel noted that the analyses were performed in different laboratories and at different times and, as a result, different LOQs were provided.

Aflatoxin B1 was reported to be below the LOQ of [redacted] or 0.5 µg/kg in eight analysed batches, aflatoxin B2 and G1 were reported below the LOQ of [redacted] µg/kg in six analysed batches, aflatoxin G2 was reported to be below the LOQ of [redacted] µg/kg in six analysed batches and the sum of aflatoxins B1, B2, G1 and G2 was reported to be below the LOQ of [redacted] µg/kg or 2.2 µg/kg in eight analysed batches. Patulin was below the reporting limit of 20 µg/kg in six analysed batches, while tenuazonic acid was below the reporting limit of 10 µg/kg in six analysed batches and altenuene and tentoxin were below the reporting limit of 10 µg/kg in 11 analysed batches.

Ochratoxin A ranged from below the LOQ of [redacted] to below the LOQ of 1 µg/kg in eight analysed batches; alternariol ranged from below the LOQ of [redacted]–[redacted] µg/kg in six analysed batches, while alternariol monoethylether ranged from below the LOQ of 2.0–[redacted] µg/kg in 11 analysed batches.

The Panel noted that the analytical results respect the proposed specifications for mycotoxins.

Minerals

Minerals were analysed in six batches of the proposed food additive by inductively coupled plasma with atomic emission spectroscopy (ICP-OES) or mass spectrometry (ICP-MS). Calcium ranged from 1130 to 1540 mg/kg, iron from 199 to 300 mg/kg, manganese from 11.4 to 22.0 mg/kg, magnesium from 197 to 250 mg/kg, phosphorus from 350 to 620 mg/kg, potassium from 4000 to 5000 mg/kg, silicon from 77 to 143 mg/kg, sodium from 220 to 320 mg/kg and zinc from 22 to 33 mg/kg.

In addition, copper ranged from [redacted] to 11.3 mg/kg in eight batches of pectin-rich extract derived from *Coffea arabica*, respecting the proposed specification limit of ≤ 15 mg/kg (Documentation provided to EFSA n. 1, 2, 3).

Caffeine and phenolic compounds

The applicant provided analytical data on caffeine and different phenolic compounds.

Caffeine ranged from 1420 to 3610 mg/kg, respecting the proposed specification limit (Documentation provided to EFSA n. 1, 3).

In terms of phenolic compounds, tannins ranged from 0.9% to 1.3%, procyanidins from 0.9% to 2.5%, chlorogenic acid from [redacted] caffeic acid from [redacted] and [redacted] (Documentation provided to EFSA n. 1).

The applicant provided analytical data on [redacted], which was consistently below the limit of detection ([redacted]) in six batches of the proposed food additive (Documentation provided to EFSA n. 2). In addition, the applicant provided analytical data on [redacted] in five additional batches of the proposed food additive using a more sensitive method (LC-MS/MS, LOD [redacted] µg/g and LOQ of [redacted]) which ranged from [redacted] µg/g (Documentation provided to EFSA n. 4). The applicant set the highest reported value as the specification limit for [redacted] ([redacted] µg/g).

The Panel noted that a step to remove the phenolic compounds is applied in the manufacturing process of pectin-rich extract derived from *Coffea arabica*. [redacted]

Antinutritional factors

Following EFSA's request, the applicant submitted analytical data on [redacted]) in six batches of pectin-rich extract derived from *Coffea arabica* that was reported ranging from [redacted] Other [redacted] were reported from [redacted] (Documentation provided to EFSA n. 2).

Pesticide residues

Regarding pesticide residues, the applicant provided results of the analysis by gas chromatography with GC-MS/MS and LC-MS/MS of 11 batches of the proposed food additive (Documentation provided to EFSA n. 1, 2, 3). The monitored pesticides were reported to be below the respective LOQs, except for chlorpyrifos which ranged from below the LOQ of 0.01–0.02 mg/kg, for cypermethrin (sum of isomers) from below the LOQ of 0.01–[redacted] mg/kg, for captan (sum of captan and THPI, expressed as captan) below the LOQ of [redacted]–0.03 mg/kg, for clothianidin from below the LOQ of 0.01–0.02 mg/kg, for cyproconazole from below the LOQ of 0.01–0.05 mg/kg, for thiamethoxam from below the LOQ of 0.01–0.1 mg/kg, for chlorantraniliprole from below the LOQ of 0.01–0.04 mg/kg, for flutriafol from below the LOQ [redacted]–0.02 mg/kg, [redacted]

The applicant proposed specification limits for the pesticides cypermethrin (sum), captan (sum of captan and THPI, expressed as captan), clothianidin, cyproconazole, thiamethoxam, chlorantraniliprole, flutriafol and azoxystrobin.

The Panel noted that no maximum residue limits (MRLs) for the pesticides potentially present in the source (cherry pulp) of the proposed food additive exist in the EU. The pesticide residue levels quantified in the pectin-rich extract derived from *Coffea arabica* were compared to established MRLs of other foodstuffs already consumed in the EU (e.g. coffee beans and other small fruits and berries in Annex II of Regulation (EC) No. 396/2005[12]). The Panel considered that coffee beans are less exposed to pesticides than the coffee fruit and coffee pulp.

The establishment of MRLs of pesticides for pectin-rich extract derived from *Coffea arabica* is out of the scope of the food additive safety assessment since it is considered a risk management issue. The Panel noted that any food containing the proposed food additive should comply with the relevant legislation.

Physicochemical characterisation

Molecular weight distribution

Six batches of the proposed food additive were analysed with high pressure size exclusion chromatography (HPSEC) to determine the molecular weight distribution of the pectin, which was found to range from 27 to 57 kDa with an average of 45 kDa (Documentation provided to EFSA n. 1)

Degree of methylation and acetylation

The degree of methylation of the pectin was analysed by gas chromatography with flame ionisation detector (GC-FID) and the degree of acetylation of the pectin was analysed by high-performance liquid chromatography with refractive index detector (HPLC-RI). For six independently produced batches, the pectin was found to be moderately methylated (41%–47%) and low in acetylation (2%–4%) (Documentation provided to EFSA n. 1).

Water activity (Aw)

In the six analysed batches of the proposed food additive, water activity ranged from 0.304 to 0.475 (Documentation provided to EFSA n. 1).

Particle size

In the response to a request from EFSA for additional information, the applicant provided results from scanning electron microscopy–energy-dispersive X-ray (SEM-EDX) analysis of six batches of the proposed food additive (Documentation provided to EFSA n. 2). The analyses showed that d10 (thickness) of the analysed particles was in the range 38–52 nm, d50 in the range 2330–3330 nm and d90 in the range 7815–11,680 nm. The applicant concluded that all analysed batches contained more than 10% of small particles including nanoparticles according to the EFSA Guidance on Particle-TR (EFSA Scientific Committee, 2021).

The changes in particle size and shape of the proposed food additive in different solvents (water, ethanol, acetone, isopropyl alcohol, toluene and n-hexane at 1 mg/mL) were investigated by the applicant (one batch tested). SEM analysis showed that, in water, particles of the pristine product are dissolved and form an almost continuous layer on the sample

[12]Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance.

grid where lumps of material are present. Morphology of pristine particles is completely changed by the action of water. In all other tested solvents, except for toluene, the particles changed in morphology and/or size. According to the applicant, this indicates that the food additive is soluble to a certain degree in the above-mentioned solvents (Documentation provided to EFSA n. 2). The Panel agreed with the applicant that, based on data provided, the proposed food additive is expected to be soluble in water at the tested concentration (1 mg/mL).

The Panel noted that, based on the data provided and the criteria set in the EFSA Guidance on Particle-TR (EFSA Scientific Committee, 2021), the presence of small particles including nanoparticles in the food additive is confirmed.

Solubility

The applicant provided information on the water solubility of the proposed food additive in six batches by applying the OECD TG 105 (shake flask method) with gravimetric analysis (Documentation provided to EFSA n. 3). The solubility at 20°C and pH 1.5 ranged from 44 to 76 g/L across the six batches. The Panel noted that the pH value of ~1.5 was set by the applicant and does not represent the pH of the proposed food additive in water.

After EFSA's request, the applicant provided analytical data on the water solubility for five batches of the proposed food additive at its pH in water, i.e. ~3.5, by applying the OECD TG 105 (Documentation provided to EFSA n. 4). Solubility determined by gravimetric analysis ranged from 55 to 70 g/L across the batches.

The Panel considered that the water solubility tests were not performed in full accordance with the EFSA Guidance on Particle-TR (EFSA Scientific Committee, 2021); the main limitations were: no ultrafiltration/ultracentrifugation was applied and the concentration of the solubilised substance was not determined using a substance-specific method as indicated in the OECD TG 105 (Documentation provided to EFSA n. 2). The Panel considered that the results of the submitted solubility test do not accurately reflect the exact solubility of the proposed food additive.

3.1.3 | Manufacturing process

According to the information provided, the proposed food additive is manufactured in line with Hazard Analysis Critical Control Points (HACCP) principles. Coffee cherries are obtained from cultivated coffee trees (*Coffea arabica* L.), which are propagated, grown and harvested under the same conditions as those from which green coffee beans used for coffee production are obtained. The ripe coffee cherries are harvested manually, washed and processed immediately after the selection. Specifically, the fruits undergo a wet milling step, in which the coffee pulp, consisting of the exocarp (i.e. outer skin) and the mesocarp (i.e. the fleshy pulp beneath the skin), is separated from the green coffee beans (consisting of the mucilage (i.e. pectin layer), parchment (i.e. endocarp), and silver skin), which are removed with the aid of running water. [redacted] According to the applicant, the coffee pulp is monitored for contaminants, such as toxic elements, mycotoxins, and pesticides, and is discarded in case that it does not comply with the relevant EU regulations (Documentation provided to EFSA n. 2).

[redacted] (Documentation provided to EFSA n. 2).

[redacted] (Documentation provided to EFSA n. 2)

[redacted] (Documentation provided to EFSA n. 2).

3.1.4 | Methods of analysis in food

According to the applicant, the main component of the proposed food additive, i.e. dietary fibre has been determined with AOAC 2017.16: Total dietary fibre in foods and food ingredients: Rapid Integrated enzymatic-gravimetric-high-pressure liquid chromatography method. Pectin has been quantified, initially, in food as the sum of uronic acid ([redacted]) and total carbohydrate-bound sugars (arabinose, galactose, rhamnose, glucose, mannose, xylose and fucose) (quantified by high-performance anion-exchange chromatography with pulsed amperometric detection (HPAEC-PAD)) (Documentation to EFSA n. 2). The applicant mentioned that uronic acid is the most characteristic component of the proposed food additive to monitor the presence of the pectin (Documentation to EFSA n. 3).

In addition, according to the applicant, other important components of the proposed food additive are caffeine, which is characterised in food by high-performance liquid chromatography-mass spectrometry (HPLC-MS), and protein by Kjeldahl or Dumas method (6.25xN, NEN-EN-ISO 16634) (Documentation to EFSA n. 3).

3.1.5 | Stability, reaction and fate in food of the proposed food additive

The microbiological stability of four batches of pectin-rich extract derived from *Coffea arabica* was studied at a temperature of 20°C and relative humidity (RH) of 60%–80% for 6 months stored in a high-density polyethylene (HDPE) container. The water activity (Aw) ranged from 0.30 to 0.50 and *Salmonella* spp. was consistently not detectable in 25 g. *E. coli*, Enterobacteriaceae, and moulds were below 10 cfu/g in all batches and time points, while sulfite-reducing bacteria and yeasts ranged from below 10 cfu/g to below 20 cfu/g. Aerobic mesophilic count ranged from below 10 cfu/g to below 80 cfu/g. *Bacillus cereus* was reported to be below 10 cfu/g or below 100 cfu/g (Documentation provided to EFSA n. 1).

In addition, the applicant provided another stability study on four independently produced batches of pectin-rich extract derived from *Coffea arabica*, analysed at time 0 and after 3 years of storage (Documentation provided to EFSA n. 2).

[redacted] (Documentation provided to EFSA n. 2).

The Panel noted that even though pectin is expected to be stable, de-esterification of the pectin has been demonstrated.

The stability of pectin-rich extract derived from *Coffea arabica* was tested in a water–oil emulsion imitating soft drinks. The emulsion consisted of orange oil and water (pH 3.5) with pectin-rich extract added at different concentrations (0.5%, 1.0% or 1.5%). The emulsion was stored at 37°C in HDPE containers for 4 weeks. There was no change in the emulsion droplet size after the storage period and the applicant took this as indirect evidence that the proposed food additive used as the emulsifier in the model study was stable over 4 weeks of storage at 37°C (Documentation provided to EFSA n. 1).

3.2 | Proposed uses and use levels

Through the current application, an authorisation of pectin-rich extract derived from *Coffea arabica* as a food additive is sought with regard to the food categories (FCs) listed in Table 2.

The Panel noted that the applicant has submitted proposed maximum and typical use levels of pectin-rich extract derived from *Coffea arabica* (in mg/kg) for 10 food categories according to Annex II of Regulation (EC) No. 1333/2008, part D (Documentation provided to EFSA n. 4). The Panel noted that for all these categories, except for FCs 05.2 'Other confectionery including breath freshening micro-sweets' and 05.3 'Chewing gum', the maximum and typical use levels were the same.

TABLE 2 Proposed uses and maximum/typical use levels for pectin-rich extract derived from *Coffea arabica*.

Food category number	Food category name	Restrictions or exceptions	Proposed use levels (mg/kg)	
			Typical	Maximum
01.8	Dairy analogues, including beverage whiteners	Dairy and cheese analogues	100	100
03	Edible ices	Ice creams based on dairy analogues	250	250
04.2.4.1	Fruit and vegetable preparations excluding compote	Fruit-based fillings	450	450
05.2	Other confectionery including breath freshening micro-sweets	Candies and coating of candies	1000	2000
05.3	Chewing gum		1000	2000
05.4	Decorations, coatings and fillings except for fruit-based fillings covered in category 4.2.4	Coating of nuts, biscuits (see fine bakery wares), etc.	250	250
12.7	Salads and savoury-based sandwich spreads	Plant-based spreads and salad dressing	500	500
12.9	Protein products, excluding products covered in category 1.8	Meat and fish analogues, hybrid meat, protein bars and protein drinks, gelatine replacement	500	500
13.4[a]	Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No 41/2009	Gluten-free cakes (including mixes for preparation), cookies (including mixes for preparation), biscuits, pies, pastries (including mixes for preparation and prepared doughs), cereal bars	500	500
14.1.4	Flavoured drinks	Cream or cocoa beverages	100	100

[a]The Panel noted that Commission Regulation (EU) No 2025/2058 of 15 October 2025 deletes FC 13.4 covering 'Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No 41/2009' and moves this food category to FC 18 as a new subcategory FC 18.3 'Foods specially produced to reduce the gluten content of gluten-containing ingredients or substitute the gluten-containing ingredients'. In this opinion, FC 13.4 Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No 41/2009 was kept.

3.3 | Exposure assessment

The Panel acknowledged that the applicant provided exposure estimates considering all the proposed food categories using the FAIM (version 2.1) as indicated in the EFSA ANS Panel guidance on food additive applications (2012) (Documentation provided to EFSA n. 4). However, the applicant did not correctly allocate the proposed use levels to the food categories (subcategories missing) and/or to the parent food categories. Furthermore, the Panel noted that, as of July 2025, a new version of the tool is available (FAIM version 3.0). For these reasons, the Panel performed a new exposure assessment using this version.

3.3.1 | Food consumption data used for exposure assessment

3.3.1.1 | *EFSA comprehensive European food consumption database*

FAIM (version 3.0) contains food consumption data of different population groups, infants, toddlers, children, adolescents, adults and the elderly, from the Comprehensive Database. These data were derived from 46 dietary surveys carried out in 23 European countries.[13] Details of the population groups considered and the countries with food consumption surveys available in FAIM (version 3.0) are presented in Annex A, Table A1.

3.3.1.2 | *Food categories considered for the exposure assessment of pectin-rich extract derived from* Coffea arabica

For the safety assessment of pectin-rich extract derived from *Coffea arabica* as a new food additive, the Panel considered the maximum and typical use levels as proposed by the applicant for all food categories in which its use is proposed (Table 2).

Proposed uses for pectin-rich extract derived from *Coffea arabica* include FC 13.4 'Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No. 41/2009' (Documentation provided to EFSA n. 4). This food category covers foods for special medical purposes (FSMPs) consumed by children, adolescents, adults and the elderly population groups. FAIM does not include this food category. Foods belonging to this food category are very diverse and their consumption is not always well reported in dietary surveys. Therefore, eating occasions of these foods have been reclassified in the Comprehensive Database under other food categories in accordance with their main component. Considering the restrictions of FC 13.4 as provided by the applicant, the foods within this food category for which the use of the additive is proposed were comparable to foods belonging to FC 07.2 'Fine bakery wares'. Therefore, use levels of FC 13.4 were mapped to the consumption of FC 07.2 in FAIM to include this use in the assessment.

3.3.2 | Exposure estimates to pectin-rich extract derived from *Coffea arabica* from its proposed use as food additive

3.3.2.1 | *Dietary exposure estimates for the general population*

TABLE 3 Summary of dietary exposure to pectin-rich extract derived from *Coffea arabica* from its proposed maximum/typical use levels as a food additive in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day) calculated with FAIM (version 3.0).

	Infants (4–12 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Proposed maximum use level exposure assessment scenario						
Mean	< 0.1–0.8	0.6–5.0	1.3–4.6	0.7–2.4	0.3–1.4	0.2–1.1
95th percentile	0.2–3.5	2.0–10.1	3.4–9.2	1.9–6.5	1.3–3.9	0.7–2.2
Proposed typical use level exposure assessment scenario						
Mean	< 0.1–0.8	0.6–3.9	1.0–3.8	0.6–2.0	0.3–1.2	0.2–1.0
95th percentile	0.2–3.5	2.0–8.9	2.8–7.2	1.8–4.9	1.1–2.9	0.7–2.2

Detailed information is reported in Annex A, Table A3.

[13]Not all Member States provided consumption information for all population groups, and in some cases, the same country provided food consumption data from more than one consumption survey. In most cases, when, for one country and age class, different dietary surveys were available, only the most recent was used. However, when two national surveys from the same country gave a better coverage of the age range than using only the most recent one, both surveys were kept. For details on each survey, see Annex A.

3.3.2.2 | *Main food categories contributing to exposure to pectin-rich extract derived from* Coffea arabica

Using the proposed maximum and typical use levels, the main food category contributing to the total mean exposure for all population groups was FC 07.2 'Fine bakery wares' which was used as a surrogate for FC 13.4 (see Section 3.3.1). Additionally, FC 14.1.4 'Flavoured drinks' contributed greatly to the exposure for infants and toddlers.

Detailed information for each exposure scenario is reported in Annex A, Table A4.

3.3.2.3 | *Uncertainty analysis*

In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessments (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 4.

TABLE 4 Qualitative evaluation of influence of uncertainties on the dietary exposure estimates.

Sources of uncertainties	Direction[a]
Consumption data	
Different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Mapping food items from the Comprehensive Database to the food categories of the Annex II, Reg. (EC) No. 1333/2008	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Restrictions proposed by the applicant could not be taken into account	+
Concentration data	
Proposed maximum and typical use levels considered applicable to all foods within an entire food category, whereas it is not likely that pectin-rich extract from *Coffea arabica* will be added as a food additive to all foods belonging to a proposed food category	+
Methodology	
Proposed use level exposure assessment scenario:	
– Exposure calculations based on the proposed maximum use levels	+
– Exposure calculations based on the proposed typical use levels	+/–
Proposed use levels of pectin-rich extract in *Coffea arabica* for FC 13.4 'Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No. 41/2009' were assumed applicable to all food items belonging to FC 07.2 'Fine bakery wares'	+

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

Pectin-rich extract derived from *Coffea arabica* is proposed to be authorised in 10 food categories. Overall, the panel considered that the uncertainties identified resulted in an overestimation of the actual exposure to pectin-rich extract derived from *Coffea arabica* if authorised and used at its proposed use as a food additive. The main factors contributing to this overestimation were the assumptions that all foods belonging to nine food categories will contain pectin-rich extract derived from *Coffea arabica*, when authorised, at the proposed maximum or typical use level, which is not likely; and that the use levels of FC 13.4 'Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No. 41/2009' were applicable to all foods belonging to FC 07.2 'Fine bakery wares'.

3.3.3 | Anticipated exposure to toxic elements from proposed specifications

Toxic elements

The applicant provided limits for As (0.1 mg/kg), Pb (1.0 mg/kg), Cd (0.05 mg/kg) and Hg (0.05 mg/kg) in the proposed food additive for the purpose of defining appropriate specifications (Table 1). The panel noted that the occurrence data on toxic elements for eight independently produced batches of the proposed food additive submitted by the applicant are below the proposed specification limits. In the analysed samples, As, Pb, Cd and Hg were reported up to 0.08, 0.89, 0.04 and 0.02 mg/kg, respectively (Documentation provided to EFSA n. 1).

The potential exposure to impurities from the use of the proposed food additive was calculated by assuming that they are present in the food additive up to a certain limit value and then by calculation pro-rata to the estimates of exposure to the food additive itself.

The highest exposure levels to the proposed food additive at the mean and 95th percentile among the different population groups were considered, i.e. 5 and 10 mg/kg bw per day, respectively, for toddlers (Table 3).

The potential levels of the toxic elements in the proposed food additive combined with the estimated exposure levels to the proposed food additive presented in Table 3 result in exposure estimates that can be compared with the following reference points (RP) or health-based guidance values (HBGV) (Table 5) for the toxic elements. It is considered that any Hg or As in the proposed food additive corresponds to the element in the inorganic form rather than an organic form. Consequently, the HBGV for inorganic mercury and the RP for inorganic arsenic were used for comparison (Table 5).

TABLE 5 Reference points/health-based guidance values for toxic elements potentially present in the proposed food additive.

Element/RP/HBGV	Basis
Lead (Pb)/0.5 mg/kg bw per day ($BMDL_{01}$)	The reference point is based on a study demonstrating perturbation of intellectual development in children with the critical response size of 1 point reduction in IQ. The EFSA CONTAM Panel mentioned that a 1 point reduction in IQ is related to a 4.5% increase in the risk of failure to graduate from high school and that a 1 point reduction in IQ in children can be associated with a decrease of later productivity of about 2%. A risk cannot be excluded if the exposure exceeds the $BMDL_{01}$ (MOE lower than 1) EFSA CONTAM Panel (2010)
Inorganic mercury (iHg)/4 mg/kg bw per week (TWI)	The HBGV was set using kidney weight changes in male rats as the pivotal effect. Based on the $BMDL_{10}$ of 0.06 mg/kg bw per day, expressed as mercury, and an uncertainty factor of 100 to account for inter- and intra-species differences, with conversion to a weekly basis and rounding to one significant figure, a TWI for inorganic mercury of 4 μg/kg bw per week, expressed as mercury was established EFSA CONTAM Panel (2012)
Cadmium (Cd)/2.5 mg/kg bw per week (TWI)	The derivation of the reference point is based on a meta-analysis to evaluate the dose–response relationship between selected urinary cadmium and urinary beta-2-microglobulin as the biomarker of tubular damage recognised as the most useful biomarker in relation to tubular effects. A group-based $BMDL_5$ of 4 μg Cd/g creatinine for humans was derived. A chemical-specific adjustment factor of 3.9 was applied to account for human variability in urinary cadmium within each dose-subgroup in the analysis resulting in a reference point of 1.0 μg Cd per g creatinine. In order to remain below 1 μg Cd/g creatinine in urine in 95% of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 μg Cd/kg bw, corresponding to a weekly dietary intake of 2.5 μg Cd/kg bw EFSA CONTAM Panel (2009)
Inorganic arsenic (iAs)/0.06 μg/kg bw per day (BMDL05)	The reference point is based on a benchmark dose lower confidence limit ($BMDL_{05}$) of 0.06 μg/kg bw per day identified for skin cancer. The reference point is considered to cover lung cancer, bladder cancer, skin lesions, ischaemic heart disease, chronic kidney disease, respiratory disease, spontaneous abortion, stillbirth, infant mortality and neurodevelopmental effects. An MOE of 1 would correspond to the exposure level that is associated with a 5% increase relative to the background incidence for skin cancer, based on the available data. An MOE of 1 raises a health concern Because there are no precedents in EFSA for identification of an MOE of low concern, when using a BMDL derived from human cancer data the CONTAM Panel decided not to determine a value for an MOE of low concern EFSA CONTAM Panel (2024)

Abbreviations: BMDL, benchmark dose (lower confidence limit); HBGV, health-based guidance value; IQ, Intelligence quotient; MOE, margin of exposure; RP, reference point; TWI, tolerable weekly intake.

The risk assessment of the toxic elements helps to determine whether there could be a possible health concern if these impurities would be present at a certain level in the proposed food additive. The assessment is performed by calculating e.g. the MOE (margin of exposure) by dividing the RP (i.e. BMDL, Table 5) by the exposure estimate (Table 3).

The Panel assessed the risk that would result if these toxic elements were present in pectin-rich extract derived from *Coffea arabica* according to two concentration scenarios: (i) considering their presence at the proposed specification limits, and (ii) considering the maximum analytical value provided by the applicant for each toxic element.

The outcome of the risk assessment of the Panel is presented in Table 6.

TABLE 6 Risk assessment for toxic elements from the use of pectin-rich extract derived from *Coffea arabica*.

Exposure to pectin-rich extract derived from *Coffea arabica* (mg/kg bw per day)	(i) Considering the presence of toxic elements at the proposed specification limits			
	MOE for Pb at 1.0 mg/kg	**% of the TWI for iHg at 0.05 mg/kg**	**% of the TWI for Cd at 0.05 mg/kg**	**MOE for iAs at 0.1 mg/kg**
5[a]	100	0.04	0.1	120
10[b]	50	0.1	0.1	60
Exposure to pectin-rich extract derived from *Coffea arabica* (mg/kg bw per day)	**(ii) Considering the maximum analytical value provided by the applicant for each toxic element**			
	MOE for Pb at 0.9 mg/kg	**% of the TWI for iHg at 0.02 mg/kg**	**% of the TWI for Cd at 0.04 mg/kg**	**MOE for iAs at 0.08 mg/kg**
5[a]	112	0.02	0.06	150
10[b]	56	0.04	0.1	75

Abbreviations: As, arsenic; BW, body weight; Cd, cadmium; Hg, mercury; LOQ, limit of quantification; MOE, margin of exposure; Pb, lead; TWI, tolerable weekly intake.

[a]Highest mean exposure among different population groups (proposed maximum use level exposure assessment scenario–toddlers, Table 3).

[b]Highest 95th percentile exposure among different population groups (proposed maximum use level exposure assessment scenario–toddlers, Table 3).

The panel noted that the results for these two scenarios (Table 6) are rather similar since the specifications proposed by the applicant (and used in scenario (i)) are well matched to the analytical data obtained by the applicant (and used in Scenario (ii)). Considering the results of these calculations for the exposure to the toxic elements iAs, Pb, Cd and iHg, the

panel noted that their presence in pectin-rich extract derived from *Coffea arabica* at both scenarios would not give rise to concern.

The panel considered that the choice of maximum limits for toxic elements in the specifications is in the remit of risk manager(s). The values used here were merely taken to support the risk assessment of these toxic elements as presented above.

[redacted]

The applicant proposed a specification limit for [redacted] (see Section 3.1.2) as an impurity in the proposed food additive. The panel noted that the manufacturing process entails few steps to remove the phenolic compounds, among them [redacted], from the proposed food additive, therefore considered [redacted] as an impurity in the proposed food additive.

In order to address the safety of [redacted], the panel considered the information in the ECHA Risk Assessment Committee (RAC) opinion on [redacted] and its background documents. The Risk Assessment Committee evaluated dietary studies on carcinogenic or co-carcinogenic effects of [redacted] including carcinogenicity studies in mouse and different rat strains. The stomach was identified as the main target organ with benign and malignant tumours in rodents. Based on these findings, the RAC proposed a harmonised classification and labelling at EU level for [redacted] The resulting entry in Annex VI of the Regulation (EC) No. 1272/2008 (CLP Regulation)[14] includes classification as mutagenic category 2 and carcinogenic category 1B. To assess the safety of [redacted] potentially present in the proposed food additive, the Panel considered that the 'Statement on the applicability of the Margin of Exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed' was considered applicable (EFSA SC, 2012b).

In order to identify a reference point, the panel recalculated from the studies considered in the RAC opinion the daily dose from the concentration of [redacted] in feed using a default conversion factor (0.05 for chronic rat studies) (EFSA SC, 2012a). The reference point was identified from the Hagiwara et al.'s (2001) study, based on an increased incidence of submucosal hyperplasia in the glandular stomach at the lowest dose tested (LOAEL: 50 mg/kg bw per day). Considering a continuum of effects progressing from hyperplasia to adenocarcinomas and the high incidence of hyperplasia at 50 mg/kg bw per day (i.e. in 14 out of 25 rats), the panel considered it appropriate to apply an uncertainty factor of 10 to derive a NOAEL from LOAEL. The reference point was established at 5 mg/kg bw per day.

The potential exposure to [redacted] from the use of the proposed food additive was calculated by assuming that it was present in the proposed food additive at the proposed specification limit and then by calculation pro-rata to the estimates of exposure to the food additive itself (at the mean and 95th percentile, 5 and 10 mg/kg bw per day respectively, in toddlers, Table 3). The highest estimated intake of [redacted] from the proposed food additive is 0.0037 μg/kg bw per day.

The calculated MOE in both scenarios and in all population groups is two orders of magnitude higher than the MOE of 10,000 of low concern for impurities which are both genotoxic and carcinogenic (the lowest calculated MOE is 1336070). Therefore, the Panel considered that the human exposure to [redacted] via the proposed food additive is likely to be of low concern from a public health perspective (EFSA SC, 2012b).

The panel considered that the proposed food additive can be assessed following conventional risk assessment, i.e. the Guidance for submission for food additive evaluations should be followed (EFSA ANS Panel, 2012) based on the following elements: (i) the estimate of solubility, (ii) the manufacturing process (the proposed food additive is [redacted] from the coffee pulp), (iii) the proposed use levels (max 2000 mg/kg food) and (iv) the volume of gastric secretion (ranging from 215 mL within a single meal to 2000 mL daily; ICRP, 2002; Mudie et al., 2014). The panel considered that the consumers will not be exposed to small particles, including nanoparticles of pectin-rich extract derived from *Coffea arabica* under the proposed conditions of use.

The proposed food additive is a soluble dietary fibre derived from coffee fruit pulp of *Coffea arabica* L. It consists of 70%–85% total dietary fibres (of which the major fraction is pectin), 4%–6.5% total proteins and substances of potential concern (see Section 3.1.1) including caffeine, chlorogenic acid, [redacted], caffeic acid, [redacted] and trigonelline. The applicant did not perform any new toxicological studies on the proposed food additive; instead, a literature review and quantitative structure–activity relationship (QSAR) modelling have been submitted.

The panel integrated all the available information including existing evaluations by EFSA, particularly on pectin, coffee fruit pulp, and conducted a new QSAR analysis applying a component-based approach.

In addition, in relation to the substances of potential concern characterised in the proposed food additive, the EFSA SC guidance on Botanicals (EFSA SC, 2009b) was applied. For caffeine, the significance of the exposure via the food additive was assessed considering the intakes of no concern derived for acute caffeine consumption by adults (EFSA NDA Panel, 2015). For the other substances of potential concern, the presumption of safety was established comparing the exposure via the proposed food additive and the intake compared to dietary intake from other food sources.

Pectin

In 2017, the ANS panel re-evaluated pectin (E 440i) and amidated pectin (E 440ii) and considered that for these food additives '*the main end products of this colonic anaerobic digestive process are SCFA, such as acetic, propionic and butyric acids,*

[14]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

which are absorbed from the colon and considered of no safety concern by the Panel. These data indicated that pectins and amidated pectins would not be absorbed intact but extensively fermented by intestinal microbiota in animals and humans'.

In addition to the studies already assessed by the ANS Panel in 2017, the applicant provided new studies summarised below (Documentation provided to EFSA n. 3).

The panel analysed the publications submitted by the applicant which consisted of studies using in vitro incubation of human faecal bacteria with pectins of various sources and differing in their composition (Khodaei et al., 2016; Manderson et al., 2005; Van den Abbeele et al., 2020; Wilkowska et al., 2019). Most of the studies compared the pectins with alternative carbohydrate sources, such as starch, inulin and/or fructo-oligosaccharides. All studies share several limitations, i.e. use of a few faecal donors only and no full simulation of the complexity of a living human gut with profound inter-individual variations in the immune system, dietary habits, etc. The Panel considered that the studies submitted did not investigate endpoints relevant for the safety assessment.

In a randomised, double-blinded, placebo-controlled parallel study in human volunteers, An et al. (2019) investigated the effect of dietary supplementation with sugar beet pectin on the composition of faecal microbiota, short-chain fatty acid generation and on the exhalation of volatile organic compounds. The study collected data before and after treatment and compared the values obtained from 51 young male or female adults (18–40 years) with those from 48 male or female elderly (65–75 years). Main exclusion criteria were diseases or abdominal surgery interfering with the function of the gastrointestinal tract or use of nonsteroidal anti-inflammatory drugs, pro–/pre–/antibiotics and/or vitamin supplementation. The test persons were told to consume either sugar beet pectin or maltodextrin at 15 g/day twice daily (before breakfast and dinner) for 4 weeks. Faecal and exhaled breath samples were collected before and after the intervention period. Young adults and elderly showed similar profiles of baseline faecal short-chain fatty acids (C2–C5; acetic, propionic, (iso)butyric, (iso)valeric acids; analysed by GC) and 15 exhaled volatile organic compounds. Basal faecal microbiomes were similar, with five out of 224 genera analysed differing significantly in relative abundance between young and elderly test persons. However, intervention with pectin altered neither the microbiome nor faecal short-chain fatty acids or volatile organic compounds in the exhaled air.

Jonker et al. (2020) investigated the effects of pectin derived from carrots (*Daucus carota* L.) consisting predominantly of rhamnogalacturonan-I in a 90-day oral toxicity study in rats (Documentation provided to EFSA n.2). The study followed the OECD guideline 408 and was performed in compliance with GLP.

Specific pathogen-free-bred male and female Wistar Hannover rats (Crl:(WI)Han) male and female Wistar rats, at the age of 6–7 weeks, were kept under standardised conditions, randomised by weight and allocated to experimental groups ($n = 10$/sex/dose). Animals received the experimental diets supplemented with carrot pectin at 2.5% (low dose), 5% (mid-dose) or 10% (high dose), equal to 1800, 3400 or 6900 mg/kg bw per day for males and 1900, 3900 or 7800 mg/kg bw per day for females; the control chow with no pectin as well as the low- and mid-dose chow were supplemented to 10% with corn starch. Body weight and food consumption were not affected during the study. Mid- and high-dose males showed lower forelimb grip strength. No treatment-related alterations were noted in clinical chemistry and haematological parameters. In mid-dose males and in high-dose animals of both sexes, there were statistically significant increases in the full and empty caecum due to elevated caecal contents and in the weight of the caecal wall. There were no further alterations in organ/tissue weights, attributable to the administration of the carrot pectin. No treatment-related alterations in organ/tissue weights were reported. At microscopic examination, minimal lymphogranulocytic inflammatory cell infiltrates in the mucosa of the caecum were observed in 2/10 high-dose males and minimal hypertrophy of the mucosa in 3/10 high-dose females. Since these alterations were not considered adverse, the authors concluded that the NOAEL of carrot pectin was 10% in the diet, the highest concentration tested, corresponding to 6900 mg/kg bw per day for males and 7800 mg/kg bw per day for females. The panel agreed with this conclusion considering the small magnitude of the inflammatory cell infiltrate and the local nature of this effect. Furthermore, the panel noted that signs of caecum mucosal inflammation at relatively high doses have been reported in previous EFSA evaluations (i.e. after pectin administration to neonatal piglets (FAF Panel in 2021) and after rhamnogalacturonan-I enriched carrot fibre (cRG-I) administration to Wistar rat (EFSA NDA Panel 2025)), and thus, that the current conclusion is in line with the previous assessments.

Heimbach et al. (2010) tested several products from the whole coffee fruit, i.e. whole powder, a water extract and a water-ethanol extract (Documentation provided to EFSA n.1). The water-ethanol extract contained 35%–40% phenolic acids (chlorogenic, caffeic, quinic and ferulic acid) and up to 9.1% caffeine and will not be considered further, because it is not representative of the proposed food additive. The powder and the water extract consisted of ~2%–5% total phenolic acids and ~1% caffeine, resembling to some extent the pectin-rich extract of the present opinion, although the pectin content was not specified. With these two preparations, short-term studies were performed in male and female SD rats. Groups of 10 rats/sex/dose were fed the powder for 7 days (males: 0, 6586, 7904, 9055 mg/kg bw per day; females: 0, 7419, 8758, 10.574 mg/kg bw per day) or 14 days (males: 0, 2188, 4335 and 8309 mg/kg bw per day; females: 0, 2108, 4458 and 8858 mg/kg bw per day) or the water extract for 14 days (males: 0, 2179, 4382, 7889 mg/kg bw per day; females: 0, 2234, 4393, 8861 mg/kg bw per day). Neither mortality nor treatment-related abnormal findings at the macroscopical examination during necropsy were reported for any of the test groups. In the groups receiving the powder, body weight gains and/or body weights were reduced transiently in the mid- and high-dose males but reached control values at the end of the study. In the water extract group, feed consumption, body weight gain and/or body weights were decreased transiently significantly in the mid-dose males and in high-dose males throughout the study. Females exhibited no significant alterations. The authors concluded that the male and female animals tolerated well doses of up to 2100 and 8800 mg/kg bw per day, respectively, when given as whole powder or water extract in the diet. The panel noted limitations of the study design,

such as short duration of treatment and no information on the pectin content of the tested preparations, and therefore did not consider further the results of this study in the safety assessment.

Kleijn et al. (2024) studied an extract from pumpkin (*Cucurbita moschata* Duchesne) containing pectins with a molecular weight distribution of 30–70 KDa. The animal experiment followed the OECD guideline 408. Male and female Sprague–Dawley rats were randomly assigned to experimental groups ($n = 10$/sex/dose). The animals received the pumpkin extract via food for 13 weeks at levels of 0, 9000, 18,000 or 36,000 mg/kg. The calculated average consumptions of the pumpkin extract were 0, 455, 894 and 1899 mg/kg bw per day for the males and 0, 549, 1192 and 2361 mg/kg bw per day for the females. At the end of the experiment, five extra animals of each sex and of the controls and the highest dose-level group were subjected to a recovery phase of 5 weeks. Insignificant increases and decreases in body weights (male and female) were observed over the experimental period. Significant increases were reported for caecal weights with and without content in males of the highest dose group and for weights of empty caecum in females of the mid- and high-dose groups; however, histological evaluations did not reveal any alterations. In the females that had received the highest dose and had been subjected to recovery, the elevated caecum weight was persistent. Relative liver weights were reduced significantly in the mid- and high-dose males, again without any microscopic alterations. No further notable and test substance-related findings were reported at the end of the treatment period. The authors concluded that the NOAEL for the pumpkin pectin was at the highest doses tested, i.e. 1.899 and 2.361 mg/kg bw per day for male and female rats, respectively. The panel agreed with this conclusion.

Overall, no adverse effects were reported in one human study on sugar beet pectin, given at 15 g per day (0.2 g/kg bw per day) for 4 weeks, and in two 90-day toxicity studies in rats, treated either with carrot pectin at up to 6.9 g/kg bw per day (males) and 7.8 g/kg bw per day (females) or with pumpkin pectin at up to 1.9 g/kg bw per day (males) and 2.4 g/kg bw per day (females).

Pectins contained in the proposed food additive consist of galacturonic acid and several bound sugars. Despite that the already authorised pectin additives (E 440i and E 440ii) are different in terms of characteristics and purity, the panel noted that the galacturonic acid units are similar and that the differences in purity and composition between the pectins do not pose a safety concern. Therefore, the panel considered that the pectins in the proposed food additive have similar structure to pectin (E 440i) and amidated pectin (E 440ii), and that the same absorption profile applies: pectins are not absorbed intact but are fermented to short-chain fatty acids (SCFA) by the intestinal microbiota in humans. Hence, the studies on pectin (E 440i) and amidated pectin (E 440ii) are applicable for the assessment of pectins in the proposed food additive.

Substances of potential concern

Caffeine

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was asked to deliver a scientific opinion on the safety of caffeine (EFSA NDA Panel, 2015). The NDA Panel concluded that *'habitual caffeine consumption up to 400 mg per day does not give rise to safety concerns for non-pregnant adults'. Habitual caffeine consumption up to 200 mg per day by pregnant women does not give rise to safety concerns for the fetus. Single doses of caffeine and habitual caffeine intakes up to 200 mg consumed by lactating women do not give rise to safety concerns for breastfed infants. For children and adolescents, the information available was insufficient to derive a safe caffeine intake. However, the NDA Panel considered that caffeine intakes of no concern derived for acute caffeine consumption by adults (3 mg/kg bw per day) may serve as a basis to derive single doses of caffeine and daily caffeine intakes of no concern for these population subgroups*.

The potential exposure to caffeine from the use of the proposed food additive was calculated by assuming that it was present in the proposed food additive at the proposed specification limit and then by calculation pro-rata to the estimates of exposure to the food additive itself (at the mean and 95th percentile, 5 and 10 mg/kg bw per day respectively, in toddlers, Table 3).

The highest estimated intake of caffeine from the proposed food additive is 0.037 mg/kg bw per day, which is below the levels of consumption estimated to be of no safety concern by the NDA.

Caffeic acid, chlorogenic acid, [redacted]

Caffeic acid, [redacted] are hydroxycinnamic acids (HCAs), which are the major classes of phenolic compounds in nature. Chlorogenic acid, which is formed by the condensation of caffeic acid with quinic acid (5-O-caffeoylquinic acid), is probably the most abundant soluble hydroxycinnamic acid derivative (El-Seedi et al., 2012). Hydroxycinnamic acids are ubiquitous in food and feeds of plant origin. They are readily metabolised and excreted and are not expected to accumulate in animal tissues and products (EFSA FEEDAP Panel, 2025). The main dietary sources of HCAs are coffee and fruits, but also vegetables, herbs and cereal grains.

Caffeic acid is a constituent of numerous plant species and is present mainly in green coffee beans (33–141 mg caffeic acid/100g fresh weight), fruits (up to 15.6 mg caffeic acid/100g fresh weight of cranberries), lettuce (4–55 mg caffeic acid/100g fresh weight), carrots (14 mg caffeic acid/100g fresh weight) and potatoes (3.6 mg caffeic acid/100g fresh weight) (Reddy, 2001).

Caffeic acid was considered 'possibly carcinogenic to humans (Group 2B)' by IARC (IARC monograph, 1993). The Panel acknowledged the IARC assessment and review of the carcinogenicity data of caffeic acid in rats and mice, which indicate

that there are tumours in the lung, kidney and forestomach. The panel noted that the doses at which the tumours occurred were quite high. The panel deemed that the relevance of these findings for humans is questionable.

Coffee contains a high amount of chlorogenic acid. A single cup of coffee (200 mL) may contain 70–350 mg of chlorogenic acid (Clifford, 1999). Tea and mate also contain chlorogenic acid (tea shoots contain up to 674 mg chlorogenic acid/100 g fresh weight; mate contains up to 8080 mg chlorogenic acid/100 g dry weight).

[redacted] is present in potatoes (up to 5 mg/100 g dry weight), in spinach (0.13–2.87 mg/100 g fresh weight), in raw common beans (0.32–0.68 mg/100 g fresh weight), in tomatoes (0.13 mg/100 g fresh weight), in eggplant-purple (0.05 mg/100 g fresh weight) (Rashmi & Negi, 2020).

[redacted] is present in cereal grains (rice 24 mg [redacted]/100 g fresh weight). People who consume large amounts of cereal products consume high/appreciable/significant levels (more than 100 mg/day) of [redacted] (El-Seedi et al., 2012). [redacted] is a permitted food flavouring [FL-no: 08.089] included in the Union list of flavouring substances of Regulation (EU) No. 1334/2008.

[redacted]

[redacted] is a derivative of hydroxybenzoic acid mainly found in vegetables (Rashmi & Negi, 2020). Potato peel contains 10–400 mg/100 g of fresh weight, cauliflower 0.44 mg/100 g of fresh weight, eggplant – purple 0.58 mg/100 g of fresh weight, onion 2.0–1.0 mg/100 g of fresh weight, Shallot 1.0 mg/100 g of fresh weight. Among the hydroxybenzoic acids, [redacted] is the major phenolic acid widely distributed in vegetables.

In 2011, the EFSA CEF Panel assessed [redacted] as a flavouring substance, i.e. [FL-no: 08.133], in FGE.20Rev3 and concluded that there is no safety concern with respect to genotoxicity for any of the substances evaluated in that flavouring group (EFSA CEF Panel, 2011b).

In addition, [redacted] is a product of metabolism of flavonols and anthocyanins in the small intestine (Reddy, 2001). Both flavonols and anthocyanins are a well-known group of plant-derived compounds with antioxidant activity.

[redacted]

[redacted], chemically known as [redacted], has the property of strongly chelating cations such as calcium (Ca), magnesium (Mg), iron (Fe), copper (Cu), zinc (Zn) and potassium (K). Because of this chelating property, it is considered an antinutrient factor; however, if present in small amount in the human diet, it is considered beneficial because of its antioxidant activity (Kumar et al., 2021).

[redacted] is a major constituent of plant-derived foods such as legumes and cereals. The daily intake of [redacted] for the human population on a vegetarian diet was reported to be 2000–2600 mg for the rural population of developing nations, whereas the population on a mixed diet consumes around 15–1400 mg (Reddy, 2001).

The panel estimated the amount of these substances in food products containing the proposed food additive taking into account their concentrations in the proposed food additive (see Section 3.1.2) and the proposed level of the food additive in different foods (maximum proposed use levels from 10 mg/100 g of food (FC 01.8 and 14.1.4) to 200 mg/100 g of food (FC05.2 and 05.3); see Section 3.2).

The calculations are reported in Table 7.

TABLE 7 Levels of substances of potential concern in food (mg/100 g food).

Substance of potential concern	Range (mg/100 g food) at proposed maximum use level of 10 mg food additive per 100 g food	Range (mg/100 g food) at proposed maximum use level of 200 mg food additive per 100 g food
Chlorogenic acid	0.005–0.016 mg	0.10–0.32 mg
Caffeic acid	0.0004–0.0018 mg	0.008–0.036 mg
[redacted]	0.0001–0.0010 mg	0.002–0.020 mg
[redacted]	0.0003–0.0020 mg	0.006–0.040 mg
[redacted]	0.003–0.004 mg	0.060–0.080 mg
[redacted]	0.003–0.010 mg	0.06–0.2 mg

All these substances are present in other food sources normally consumed, such as coffee, fruit, seeds and cereals. Considering their very low concentration in the proposed food additive and the small contribution from the use of the food additive (even at its proposed maximum use levels) to the overall dietary intake, the panel considered that the resulting additional exposure from the use of the proposed food additive would contribute only to a minimal increase over existing dietary exposure and is not of safety concern.

Trigonelline

Trigonelline (1-methyl-3-pyridiniumcarboxylate) was identified as a substance of potential concern in the 2025 update of the EFSA Compendium of Botanicals (updated in April 2025). Trigonelline, first isolated in 1885 from fenugreek seeds, is

found in high concentrations in seeds of coffee and some members of the *Fabaceae family* and occurs in trace amounts in several other species (Ashihara et al., 2015).

Data from literature indicate that trigonelline can be present in *Coffea arabica* cherry pulp up to 5.4 g/kg (Konstantinidis et al., 2023). By comparison, trigonelline in roasted coffee beans can be up to 7.5 g/kg and in coffee beverages up to 7.2 g/kg (Konstantinidis et al., 2023). Trigonelline is a small organic molecule (MW 138) with a quaternary nitrogen that carries a permanent positive charge along with a carboxylic acid group at the 3-position, meaning that the molecule forms a zwitterion. Trigonelline is thus polar, hydrophilic and water soluble.

About 10 parts of *Coffea arabica* fruit pulp are required to produce one part of the proposed food additive (Documentation provided to EFSA n. 5). The manufacturing process consists of several steps that are expected to remove trigonelline; [redacted] are expected to separate trigonelline from the pectins and overall contribute to its removal from the proposed food additive. Therefore, the manufacturing process is not expected to concentrate trigonelline but, rather, it is expected to efficiently remove it during the manufacturing of the proposed food additive from coffee pulp. Taking into account (i) that the levels of trigonelline reported in the literature are rather similar for coffee pulp, roasted coffee beans and brewed coffee, (ii) the manufacturing process and the nature of the food additive, which is largely pectin dietary fibre, and (iii) the estimates of exposure to the proposed food additive (Table 3) by comparison with the normal consumption of coffee, the panel considers that any exposure to trigonelline from use of the proposed food additive would contribute only to a minimal increase over existing dietary exposure and is not of safety concern.

3.3.4 | Genotoxicity

The applicant originally provided a publication by Heimbach et al. (2010) that describes genotoxicity studies on coffee fruit extract obtained from whole coffee. The bacterial reverse mutation assay was reported to be negative; however, the numerical values of the results were not reported; in the in vivo micronucleus test, there is no evidence of bone marrow exposure; it is not possible to establish the relevance of the tested material to the food additive. Thus, the panel considered that the studies reported in Heimbach et al. (2010) were not adequate to conclude on the genotoxicity of the proposed new food additive. The applicant was requested to provide information on the genotoxicity of each single component of the proposed new food additive using all available information (e.g. read across, QSAR considerations, literature data) and to follow the indications in the EFSA Scientific Committee guidance (EFSA SC, 2019) in case of need for testing.

The panel considered the proposed food additive as sufficiently characterised. Therefore, it falls under the definition of 'chemically fully defined mixture', according to the SC Statement on genotoxicity assessment of chemical mixtures (EFSA SC, 2019). For the genotoxicity assessment of this type of mixtures, the Scientific Committee recommends applying a component-based approach, i.e. if the mixture does not contain any genotoxic chemical substances, it can be concluded that the mixture does not raise a concern with respect to genotoxicity.

The applicant did not provide specific genotoxicity studies on the main component of the proposed food additive, the extracted pectin. Instead, it supported its assessment reporting information on pectin (E 440i) and amidated pectin (E 440ii) from the 2017 ANS Panel opinion on the re-evaluation of these food additives. The ANS Panel considered that there was no concern with respect to the genotoxicity of pectins and amidated pectins (EFSA ANS Panel, 2017b). The Panel agreed with the approach proposed by the applicant, considering that the studies on pectin (E 440i) and amidated pectin (E 440ii) are applicable for the assessment of pectins in the proposed food additive (see Section 3.4).

In addition, the panel assessed two publications (Jonker et al., 2020; Kleijn et al., 2024) reporting studies in which some genotoxicity endpoints have been investigated. The panel considered the data of these studies only as supportive information given that the source of the pectins is different from the source of the pectins in the proposed food additive.

A pectic polysaccharide extract from carrot (*Daucus carota*), enriched for pectin fragments comprising mainly rhamnogalacturonan-I (cRG-I), was tested for genotoxicity in a bacterial reverse mutation assay (OECD TG 471), in a mouse lymphoma gene mutation assay (OECD TG 490) and in a micronucleus assay in human peripheral blood lymphocytes (OECD TG 487) (Jonker et al., 2020).

Two different batches of cRG-I were initially used (the relevant analytical data are reported in the article). The authors of the study noted that the first tested batch carried a microbial contamination; therefore, the results obtained with this batch were considered unreliable, and the following experiments were conducted on a second batch sterilised by gamma-irradiation. In all these assays, the test items were formulated in purified water, resulting in a clear solution at concentrations below 500 µg/mL and a hazy homogenous suspension at higher concentrations.

cRG-I was tested in Salmonella Typhimurium strains TA98, TA100, TA1535, TA1537 and *E. coli* (WP2*uvr*A) in the presence and absence of metabolic activation (rat liver S9) in two separate experiments using the plate incorporation method, in compliance with GLP principles and OECD TG 471. The following concentrations were tested: 52, 164, 492, 512, 878, 1568, 1600, 2800, 5000 µg/plate. Assay acceptability was confirmed by positive and negative controls falling within normal ranges.

There were no increases in revertant frequencies in any tested strain in the presence and absence of S9 up to 5000 µg/plate. One exception was noted at an intermediate concentration in TA1537 (2800 µg/plate in the presence of S9) in the second experiment with a fourfold increase in revertant frequency. However, as this increase was not observed at the same concentration tested in the previous experiment and the effect was not seen at higher concentrations and all values

laid within historical ranges, this increase was considered not to be biologically relevant. A further repeat of the TA1537 treatment at concentrations between 1000 and 5000 μg/plate gave again negative results, confirming that the observed increase was not reproducible.

The test item cRG-I was tested also in a mammalian cell mutation assay (MLA) at the thymidine kinase (TK) locus in the presence and absence of metabolic activation (rat liver S9) using microwell methodology, in compliance with GLP principles and OECD TG 490. Based on a preliminary range finding experiment, the maximum concentration applied was 5000 μg/mL, as recommended by OECD for products of complex composition. The following concentrations were tested: 156.3, 312.5, 625, 1250, 2500, 5000 μg/mL.

Induced mutation frequencies were all well below the global evaluation factor (GEF) (126×10^{-6}) and within the laboratory's historical background range. No cytotoxicity was reported at any concentration tested. In the treatment without S9, a linear trend test showed a statistically significant ($p \leq 0.05$) response. However, as all induced mutation frequency values were well below the GEF and all values were within the laboratory's historical control range, this was not considered to be biologically relevant. cRG-I was therefore considered negative for induction of mutations at the TK locus of L5178Y cells.

Finally, the test item cRG-I was tested in an in vitro micronucleus test in human peripheral blood lymphocytes, in the presence and absence of metabolic activation, in compliance with GLP principles and OECD TG 487. The cells were sourced freshly from single healthy non-smoker donors. Based on a range-finding experiment, the maximum concentration applied was 5000 μg/mL, as recommended by OECD for products of complex composition. The following concentrations were tested: 0, 1250, 2500, 5000 μg/mL. The cells were exposed to cRG-I for 3 h with and without metabolic activation (short-term treatment) and exposure for 24 h without metabolic activation (extended treatment). Cytochalasin B (final concentration 6 μg/mL), used to arrest cells at cytokinesis, was added after washing at the end of treatment (3-hr treatment) or present throughout treatment (24-hr treatment). For the micronucleus endpoint, a total of 2000 binucleate cells per concentration (two cultures of 1000) were scored (blind) using a light microscope.

For all experiments, background micronucleus frequencies were within acceptable laboratory control ranges. Positive controls induced adequate responses, confirming assay sensitivity. In the main experiment, no overt toxicity was observed at any tested concentration. Micronucleus frequencies were not statistically different from concurrent solvent controls and lay within historical background ranges in all the experimental conditions. Accordingly, the in vitro micronucleus test was negative with respect to induction of clastogenicity or aneugenicity.

A pumpkin-derived pectin preparation (G3P-01) was tested in the bacterial reverse mutation test in four strains of Salmonella Typhimurium (TA98, TA100, TA1535, and TA1537) and one strain of *Escherichia coli* (WP2 uvrA), with and without metabolic activation (S9 from rat liver), in compliance with GLP principles and OECD TG 471 (Kleijn et al., 2024). The test item was dissolved in sterile water. Differently from what was reported in the study by Jonker et al. (2020), formation of a precipitate was observed at high concentrations and at 5000 μg/plate the precipitates interfered with interpretation of the result. Therefore, the following concentrations were tested: 25, 50, 100, 250, 500, 1000, 2500 μg/plate. No cytotoxicity was observed.

No increase in the number of mean revertant colonies was observed in any experimental condition. The mean revertant colonies in all positive control groups were clearly increased, demonstrating the validity of the test system.

The test item G3P-01 was also tested in an in vitro micronucleus test in human TK6 cells, in the presence and absence of metabolic activation, in compliance with GLP principles and OECD TG 487. Three treatment conditions were applied: a 4-h treatment with and without metabolic activation (S9 from rat liver) and a 27-h treatment without metabolic activation.

Micronuclei were evaluated in at least 10,000 cells per culture using a flow cytometric scoring. Cytotoxicity was determined by measuring the relative population doubling.

The concentration range used for micronucleus evaluation was limited by the formation of precipitates. The following concentrations were tested: 4-h treatment without S9: 100, 118, 152, 165, 179 μg/mL; 4-h treatment with S9 and 27-h treatment without S9: 62.5, 100, 128, 165, 179 μg/mL. At the maximum concentration used (179 μg/mL in all the experimental conditions), cytotoxicity was 17% in the 4-h treatment without S9; 15% in the 4-h treatment with S9; 59% in the 27-h treatment without S9. No statistically significant increases in the percent of micronucleated cells were found in comparison with the concurrent control under any assay condition. However, it is noted that, in the 4-h treatment, with and without S9, the cytotoxicity level was far below the one recommended by the OECD TG 487 (50%–60%), limiting the relevance of this study result.

Based on all the available data, the Panel considered that there is no genotoxicity concern for pectins.

The applicant submitted a QSAR analysis (by QSAR Platform T.E.S.T. and VEGA) for [redacted], caffeic acid and [redacted], while the genotoxicity of the free forms of chlorogenic acid, [redacted] and [redacted] could not be determined by using QSAR and read across due to lack of reliable data. The applicant also considered that, because these compounds are mainly excreted via the faeces and only limited metabolisation by the intestinal microbiota occurs, these compounds are poorly absorbed and therefore non-toxicologically relevant.

The panel considered the QSAR report provided by the applicant not adequately detailed and a conclusion could not be reached; therefore, the panel performed an additional QSAR analysis of the eight compounds of potential concern (caffeine, chlorogenic acid, [redacted], caffeic acid, [redacted] and trigonelline) with the profilers contained in the OECD QSAR Toolbox (version 4.7).

The profilers selected were those linked specifically to genotoxicity mechanistic endpoints, namely (a) DNA alerts for Ames, chromosomal aberrations, and micronuclei by OASIS; (b) in vitro mutagenicity (Ames test) alerts by ISS; (c) in vivo mutagenicity (micronucleus) alerts by ISS; (d) protein binding alerts for chromosomal aberrations by OASIS.

No genotoxicity alerts were found for the eight compounds, except an alert with low positive predictivity (Hacceptor-path3-Hacceptor, in vivo micronucleus by ISS) for some of them (caffeic acid, [redacted], chlorogenic acid, [redacted], trigonelline). The alert was not confirmed by the profiler 'DNA alerts for Ames, chromosomal aberrations and micronuclei by OASIS' (Appendix A). Therefore, the Toolbox analysis performed by the panel did not show any alerts of concern for genotoxicity.

Overall, based on (i) the nature of the proposed food additive, mainly consisting of dietary fibres, and its source, (ii) the similar properties between the pectins present in the proposed food additive and the already authorised pectins (E 440 and E 440i), (iii) the absence of structural alerts for genotoxicity for the substances of potential concern present in the proposed food additive and (iv) the absence of by-products of concern from the manufacturing process, the panel considered that the proposed food additive does not raise a concern for genotoxicity.

3.3.5 | Hypersensitivity, allergenicity and food intolerance

The applicant did not provide studies with pectin-rich extract of *Coffee arabica* to test the allergenic potential but provided the results of a literature review retrieving data on pectins and caffeine.

In 2017, the ANS panel re-evaluated pectin (E 440i) and amidated pectin (E 440ii) and considered that: '*there is no indication that the reported immune-modulatory properties of pectin may lead to an adverse response, the data being rather indicative of an effect which would limit the hypersensitivity response. Therefore, the Panel did not consider the food additives pectin (E 440i) and amidated pectin (E 440ii) as having an allergenic potential*'.

The applicant submitted three new reports. A toddler had an anaphylactic reaction after consuming yoghurt containing fruit pectin (Harada et al., 2021). Capucilli et al. (2019) presented two cases of allergic reaction after consuming pectin-containing strawberry pouch and a gummy bear with pectin, probably due to cross-reactivity. The pectin allergy was identified by skin-prick test, and in both cases, there was a pre-existing allergy to nuts. Uno et al. (2017) reported that frozen citrus fruit was creating an allergic reaction in a case of a pre-existing allergy to nuts.

One case (Sugiyama et al., 2015) was identified by the applicant in relation to caffeine (from candy) allergenicity. Anaphylaxis was experienced after consumption of candy containing 42 mg caffeine. There was a positive prick test.

In general, consumers are exposed to a high quantity of caffeine ranging from 4.3 to 10.0 mg/kg bw per day in adults and from 1.4 to 4.1 mg/kg bw per day for adolescents (EFSA NDA Panel, 2015). The highest estimated intake of caffeine from the proposed food additive is 0.037 mg/kg bw per day which is below the levels of consumption estimated to be of no safety concern by the NDA Panel (EFSA NDA Panel, 2015).

The applicant concluded that the risk for an allergic response to one of the potential allergic components of the proposed food additive is very low. The panel considered there are only limited case reports for the components of the proposed food additive. In addition, the components are frequently consumed. Overall, the panel agreed with the applicant's conclusion.

4 | DISCUSSION

The European Commission requests EFSA to provide a scientific opinion on the safety of the proposed use of pectin-rich extract derived from *Coffea arabica* as a food additive, in accordance with Regulation (EC) No. 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

The proposed food additive pectin-rich extract derived from *Coffea arabica* is a dietary fibre extract derived from the coffee fruit pulp of *Coffea arabica*. The main components of the proposed food additive are dietary fibres (mainly pectin) and lower amounts of proteins and starch. The manufacturing process begins with the coffee fruits undergoing a wet milling step, in which the coffee pulp is separated from the green coffee beans, which are removed with the aid of running water. [redacted]

The panel considered that the applicant's description of the manufacturing process, included in the proposed specifications, does not contain sufficient details; therefore, the panel would propose a more detailed description of the manufacturing process of the food additive (see Section 3.1.3) in the definition. In addition, for the impurities [redacted] and certain pesticides, specific values rather than limits were proposed. The panel noted that limits should be established for these parameters.

The applicant provided analytical data on different batches of the proposed food additive, showing that pectin-rich extract derived from *Coffea arabica* is produced according to the proposed specifications.

Results for the analysis of As, Pb, Cd and Hg were provided by the applicant for eight batches of the proposed food additive. The panel assessed the risk that would result if those toxic elements were present in pectin-rich extract derived from *Coffea arabica* at two concentration scenarios (i) considering their presence at the proposed specification limits and (ii) considering the maximum analytical value provided by the applicant for each toxic element. The panel noted that the results for these two scenarios are rather similar since the specifications proposed by the applicant are well matched to the

analytical data obtained by the applicant. Considering the results of these calculations for the toxic elements iAs, Pb, Cd and iHg, the panel noted that their presence in pectin-rich extract derived from *Coffea arabica* at both scenarios would not give rise to concern. The panel considered that the choice of maximum limits for toxic elements in the specifications is in the remit of risk manager(s).

The EFSA Scientific Committee (EFSA SC, 2023) concluded that no retention of copper is expected to occur with intake of 5 mg/day and established an acceptable daily intake (ADI) of 0.07 mg/kg bw. Based on this, the panel assessed the presence of copper in pectin-rich extract derived from *Coffea arabica* and concluded that at the proposed specification limit (< 15 mg/kg), copper would not give rise to concern.

Regarding [redacted], as an impurity, and considering the calculated MOE, the panel considered that there is a low concern from a public health point of view (see Section 3.3.3).

Regarding pesticide residues, the applicant provided analysis of 13 independently produced batches of the proposed food additive, and some pesticides were detected and quantified. The panel noted that no maximum residue limits (MRLs) for the pesticides potentially present in the source (cherry pulp) of the proposed food additive exist in the EU. The pesticide residue levels quantified in the pectin-rich extract derived from *Coffea arabica* were compared to established MRLs of other foodstuffs already consumed in the EU (e.g. coffee beans and other small fruits and berries in Annex II of Regulation (EC) No. 396/2005[15]). The panel considered that coffee beans are less exposed to pesticides than the coffee fruit and coffee pulp. Furthermore, the panel deemed that the establishment of MRLs of pesticides for pectin-rich extract derived from *Coffea arabica* is out of the scope of the food additive safety assessment since it is considered a risk management issue. The panel noted that any food containing the proposed food additive should comply with the relevant legislation.

The applicant provided data on the particle size distribution for six batches of the proposed food additive, using SEM-EDX. Based on the data provided, the presence of small particles, including nanoparticles in the proposed food additive, is confirmed. Furthermore, in the same study, the applicant demonstrated that the proposed food additive was expected to be soluble in water at the tested concentration of 1 g/L. The applicant also provided the water solubility of the proposed food additive, which ranged from 44 to 76 g/L across six batches at pH set to ~1.5 and 55 to 70 g/L at the pH in water of ~3.5. The panel considered that, due to the method limitations, the results of the submitted solubility do not accurately reflect the exact solubility of the proposed food additive.

Taking into account: (i) this estimate of solubility, (ii) the manufacturing process (the proposed food additive is [redacted] from the coffee pulp), (iii) the proposed use levels (max 2000 mg/kg food) and (iv) the volume of gastric secretion (ranging from 215 mL within a single meal to 2000 mL daily; ICRP, 2002; Mudie et al., 2014), the panel considered that consumers will not be exposed to small particles, including nanoparticles of pectin-rich extract derived from *Coffea arabica* under the proposed conditions of use. Therefore, the panel considered that the proposed food additive can be assessed following conventional risk assessment, i.e. the Guidance for submission for food additive evaluations should be followed (EFSA ANS Panel, 2012).

The applicant conducted stability tests under normal conditions (20°C, 60%–80% RH) for 6 months on five batches and for 3 years on four batches of the proposed food additive and on one batch in a water–oil emulsion imitating soft drinks (37°C, 60%–80% RH). The panel noted that even though pectin is expected to be stable, de-esterification of the pectin was observed.

The exposure to the proposed food additive was estimated using FAIM and based on the proposed maximum and typical use levels. The highest P95th percentiles of exposure were 10.1 and 8.9 mg/kg bw per day, respectively, both in toddlers. Based on the uncertainties, the panel noted that these estimates are overestimates of the actual exposure if the food additive is authorised at the proposed uses and use levels.

The applicant did not perform any new toxicological studies on the proposed food additive, but supported its safety based on existing EFSA evaluations, studies from literature and QSAR data. The panel integrated all the available information including a new QSAR analysis and used a component-based approach to address the substances of potential concern present in the proposed food additive (caffeine, chlorogenic acid, [redacted] caffeic acid, [redacted], trigonelline).

The panel considered that the proposed food additive has a similar structure of pectin (E 440i) and amidated pectin (E 440ii), and thus, that the same toxicokinetic profile applies: pectins are not absorbed intact but are fermented to short-chain fatty acids (SCFA) by the intestinal microbiota in humans, which are not considered of concern. Studies from published literature not previously assessed in the context of the re-evaluation of E 440i and E 440ii confirm that pectins are not absorbed intact but extensively fermented by intestinal microbiota. No adverse effects were reported in two 90-day toxicity studies in rats, fed either with carrot pectin at up to 6.9 g/kg bw per day (males) and 7.8 g/kg bw per day (females) or with pumpkin pectin at up to 1.9 g/kg bw per day (males) and 2.4 g/kg bw per day (females); similarly, no adverse effects occurred in one human study on sugar beet pectin, given at 0.2 g/kg bw per day for 4 weeks.

Dietary fibre present in pectin-rich extract derived from *Coffea arabica* ranged from 71.3% to 84.4% in the eight analysed batches, while it is specified in a range of 70%–85%. Considering the highest value of 85% of dietary fibre in the proposed food additive and the maximum dietary exposure estimates (Table 3), the corresponding estimated dietary intake of fibres from pectin-rich extract derived from *Coffea arabica* in adults (bw 70 kg) would be 0.08 g/day at the mean and 0.23 g/day at the 95th percentile. In toddlers (bw 12 kg), the estimated dietary intake of fibres from the proposed food additive

[15]Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance.

would be 0.05 g/day at the mean and 0.10 g/day at the 95th percentile. The NDA Panel considered dietary fibre intakes of 25 and 10 g/day to be adequate for normal bowel function in adults and toddlers, respectively (EFSA NDA Panel, 2010). The panel considered that the additional contribution of fibres from the proposed food additive to the total fibre intake would be minimal, taking into account the levels that are considered to be adequate for normal bowel function by the NDA Panel, also noting the health benefit of a diet rich in fibre (EFSA NDA Panel, 2010).

Considering the concentration of caffeine in the proposed food additive and its proposed uses and use levels, the panel noted that the exposure to the proposed food additive would not significantly add to the total dietary intake [redacted] caffeine of all population groups.

The panel considered that the exposure to caffeic acid, [redacted], chlorogenic acid, [redacted] and trigonelline from the use of the proposed food additive would contribute only to a minimal increase over existing dietary exposure and is not of safety concern.

Taking into account the composition of the proposed food additive, the absence of genotoxicity concern of its components and the lack of adverse effects of the major compound (i.e. pectin up to 5000 mg/kg bw per day in a chronic toxicity study in rats as reported in the re-evaluation of E 440i and E 440ii), the panel considered that there is no need for a numerical ADI.

The ANS Panel had previously concluded that exposure to pectins as food additives up to 442 mg/kg bw per day was of no safety concern. Therefore, taking into account that the maximum estimated exposure to the proposed food additive is approximately 40 times lower than the exposure to E 440i and E 440ii, the panel considered there is no safety concern for the proposed food additive.

5 | CONCLUSIONS

The panel concluded that the use of pectin-rich extract derived from *Coffea arabica* as a new food additive does not raise a safety concern at the proposed use and use levels.

6 | DOCUMENTATION PROVIDED TO EFSA

1. PectCof B.V., 2022. Technical dossier for the request on the safety in use of pectin rich extract derived from *Coffea arabica* as a food additive. Submitted on 16 December 2022.
2. PectCof B.V., 2023. Clarification on the data submitted for request on the safety in use of pectin rich extract derived from *Coffea arabica* as a food additive. Submitted on 31 October 2023.
3. PectCof B.V., 2024. Clarification on the data submitted for request on the safety in use of pectin rich extract derived from *Coffea arabica* as a food additive. Submitted on 11 November 2024, 15 January 2025 and 24 January 2025.
4. PectCof B.V., 2025. Clarification on the data submitted for request on the safety in use of pectin rich extract derived from *Coffea arabica* as a food additive. Submitted on 14 July 2025 and 23 September 2025.
5. PectCof B.V., 2025. Additional information submitted following a request from EFSA November 2025 (via email).

ABBREVIATIONS

ADI	acceptable daily intake
ANS panel	Panel on Food Additives and Nutrient Sources added to Food
AOAC	Association of Official Analytical Collaboration
As	arsenic
Aw	water activity
BMDL	benchmark dose lower confidence limit
BW	body weight
Cd	cadmium
CFU	colony-forming unit
CONTAM Panel	Panel on Contaminants in the Food Chain
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency
FAF panel	Panel on Food Additives and Flavourings
FAIM	Food Additive Intake Model
FAO/WHO	Food and Agriculture Organization/the World Health Organization
FC	food category
FDA	Food and Drug Administration
FID	flame ionisation detector
FoodEx2	food classification standardisation
FSMP	foods for special medical purposes
GC–MS/MS	gas chromatography with tandem mass spectrometry
GRAS	generally recognised as safe

HACCP	Hazard Analysis Critical Control Point
HBGV	health-based guidance values
HDPE	high-density polyethylene
Hg	mercury
HPAEC-PAD	high-performance anion-exchange chromatography with pulsed amperometric detection
HPLC	high-performance liquid chromatography
HPSEC	high pressure size exclusion chromatography
ICP-MS	inductively coupled plasma mass spectrometry
ICP-OES	inductively coupled plasma optical emission spectroscopy
IQ	Intelligence quotient
ISO	International Organisation for Standardisation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOD	limit of detection
LOQ	limit of quantification
MOE	margin of exposure
MPL	maximum permitted level
MS	mass spectrometry
NOAEL	no observed adverse effect level
NDA panel	Panel on Nutrition, Novel food and Food Allergens
OECD	Organisation for Economic Co-operation and Development
PAHs	polycyclic aromatic hydrocarbons
Pb	lead
QSAR	quantitative structure–activity relationship
RH	relative humidity
RI	refractive index
RP	reference point
SCF	Scientific Committee on Food
SEM–EDX	Scanning Electron Microscopy with Energy Dispersive X-ray Spectroscopy
THPI	tetrahydrophthalimide
TR	technical requirements
TWI	tolerable weekly intake
UHPLC	ultra-high performance liquid chromatography

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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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APPENDIX A

(Q)SAR analysis of substances of potential concern

Chemical name	CAS no.	QSAR ToolBox
Caffeic acid	331-39-5	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found **In vivo mutagenicity (Micronucleus) by ISS:** • **H-acceptor-path3-H-acceptor** Protein binding alerts for CA by OASIS: No alert found
[redacted]	[redacted]	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found **In vivo mutagenicity (Micronucleus) by ISS:** • **H-acceptor-path3-H-acceptor** Protein binding alerts for CA by OASIS: No alert found
[redacted]	[redacted]	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found In vivo mutagenicity (Micronucleus) by ISS: No alert found Protein binding alerts for CA by OASIS: No alert found
Chlorogenic acid	327-97-9	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found **In vivo mutagenicity (Micronucleus) by ISS:** • **H-acceptor-path3-H-acceptor** Protein binding alerts for CA by OASIS: No alert found
[redacted]	[redacted]	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found **In vivo mutagenicity (Micronucleus) by ISS:** • **H-acceptor-path3-H-acceptor** Protein binding alerts for CA by OASIS: No alert found
[redacted]	83-86-3	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found **In vivo mutagenicity (Micronucleus) by ISS:** • **H-acceptor-path3-H-acceptor** Protein binding alerts for CA by OASIS: No alert found
Caffeine	58-08-2	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found **In vivo mutagenicity (Micronucleus) by ISS:** • **H-acceptor-path3-H-acceptor** Protein binding alerts for CA by OASIS: • **AN2**
Trigonelline	535-83-1	DNA alerts for Ames, CA and MNT by OASIS: No alert found In vitro mutagenicity (Ames) by ISS: No alert found **In vivo mutagenicity (Micronucleus) by ISS:** • **H-acceptor-path3-H-acceptor** Protein binding alerts for CA by OASIS: No alert found

Abbreviations: CA, chromosomal aberration; MNT, micronucleus test.

ANNEX A

Exposure data

Table A1. Population groups considered for the exposure estimates of pectin rich extract derived from *Coffea arabica*.

Table A2. Concentration levels of pectin rich extract derived from *Coffea arabica* used in the exposure assessment scenarios (mg/kg).

Table A3. Summary of total estimated exposure to pectin rich extract derived from *Coffea arabica* from use as a food additive for the proposed maximum level exposure scenario and the proposed typical level exposure assessment scenario per population group and survey: mean and 95th percentile (mg/kg bw per day).

Table A4. Main food categories contributing to exposure to pectin rich extract derived from *Coffea arabica* using the maximum and typical use level exposure assessment scenario (> 5% to the total mean exposure).

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