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Safety of dried coffee husk (cascara) from *Coffea arabica* L. as a Novel food pursuant to Regulation (EU) 2015/2283

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Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on dried coffee husk (cascara) from *Coffea arabica* L. as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The NF comprises the skin (exocarp), pulp (mesocarp), mucilage (pectin), parchment (endocarp) and a portion of the silver skin of the coffee fruit, and consists mainly of digestible carbohydrates, dietary fibre and water. The Panel considers that there are no safety concerns regarding the stability of the NF if the NF complies with the proposed specification limits during its entire shelf-life. The NF as such will not be consumed, instead, beverages produced with the infusion of the NF in water will be available to consumers. Considering an 100% extraction of caffeine from the NF to the beverage, the specification limit set for caffeine and the proposed use levels, the maximum concentration of caffeine in infusions produced using the NF could be up to 600 mg/L of drink, a concentration comparable to those in coffee beverages. The Panel notes that consumption of beverages produced using the NF will add significantly to the total dietary intake of caffeine of the general population. The consumption of beverages containing caffeine is not recommended for children, pregnant or breast-feeding women if the caffeine content exceeds 150 mg/L. Taking into account the nature of the NF, the history of use of the NF as food and the proposed uses and use levels, the Panel considers that no toxicological studies are required on the NF. The risk of allergic reactions to the NF is considered low. The Panel concludes that the NF, dried husk of the fruit of *Coffea arabica* L., is safe under the proposed conditions of use.

Keywords: Novel Foods, food safety, *Coffea arabica* L. coffee husk, cascara, caffeine

Requestor: European Commission

Question number: EFSA-Q-2020-00229

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

On 6 February 2020, the company Panama Varietals GmbH[1] submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) No 2015/2283[2] to place on the EU market coffee husk (cascara) as a novel food (NF).

The NF is intended to be used in non-alcoholic, water based, infusions and drinks.

The applicant has requested data protection according to the provisions of Article 26 of Regulation (EU) 2015/2283.

On 7 September 2020 and in accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asked the European Food Safety Authority to provide a scientific opinion on coffee husk (cascara).

In the process of the evaluation of this novel food, it became apparent that the Commission should amend the title of the mandate. The term 'dried' is added to coffee husk, and the coffee plant species *Coffea arabica* L. is specified so that the novel food subject to this application is more accurately described. As the changes are editorial, they should not affect the timing of the completion of this EFSA evaluation. On that basis, the Commission amended the title to 'Request for a scientific opinion on the safety of dried coffee husk (cascara) from *Coffea arabica L*. as a novel food'.

1.2. Additional information

On 21 June 2017, the company Panama Varietals GmbH submitted a request under Article 4 of the Novel Food Regulation (EC) No 258/97[3] to place on the market dried coffee husk (cascara) as an NF. On 31 August 2017, the competent authority of Austria forwarded to the Commission its initial assessment report, which came to the conclusion that the NF meets the criteria for acceptance of a novel food ingredient defined in Article (3)1 of Regulation (EC) No 258/97. On 29 September 2017, the Commission forwarded the initial assessment report to the other Member States (MS). Several of the MS submitted comments or raised objections. The concerns of a scientific nature raised by the MS can be summarised as follows:

- Limited compositional characterisation
- Limited information on the food safety management system
- Pesticide residues (fungicides) exceeding maximum residue levels (MRL) for similar foods (azoxystrobin, propamocarb, cyproconazole and tebuconazole)
- Representativeness of testing item in the cited toxicological studies

The application was submitted under Regulation (EC) No 258/97 and since there was not a final decision taken before 1 January 2018, the application was resubmitted and treated as a novel food application under Regulation (EU) 2015/2283.

On 5 June 2020, the Federal Food Safety and Veterinary Office of Switzerland decided to authorise the placing on the Swiss market of dried peels and pulp of the coffee cherry (*Coffea arabica* L.) originating from Yemen, Ethiopia and Brazil, only for use as infusion.

On 29 April 2021, EFSA approved a technical report on the notification of cherry pulp from *Coffea arabica* L. and *Coffea canephora* Pierre ex A. Froehner as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283 (EFSA, 2021a).

On 20 July 2021, EFSA approved a technical report on the notification of dried cherry pulp from *Coffea arabica* L. and *Coffea canephora* Pierre ex A. Froehner as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283 (EFSA, 2021b). For both notifications, EFSA considered that the available data on composition and history of use do not raise safety concerns.

[1] During the evaluation, the applicant's company name changed from 'Panama Varietals GmbH' to 'Goldkind GmbH' and 'Caskai GmbH'.

[2] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, p. 1–22.

[3] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1–6.

2. Data and methodologies

2.1. Data

The safety assessment of this NF is based on data supplied in the application and information submitted by the applicant following an EFSA request for supplementary information. During the assessment, the Panel identified additional data which were not included in the application.

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in the Commission Implementing Regulation (EU) 2017/2469.

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of an NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all of the available (proprietary, confidential and published) scientific data (including both data in favour and not in favour) that are pertinent to the safety of the NF.

This NF application includes a request for protection of proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283. The data requested by the applicant to be protected comprise analytical data on the composition of the NF, stability studies and allergenicity information.

2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of the Commission Implementing Regulation (EU) 2017/2469.

Additional information which was not included in the application was retrieved by literature search following a search strategy and standard operating procedure as described by Dibusz and Vejvodova (2020).

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

3. Assessment

3.1. Introduction

The NF subject of the application is the dried husk of the coffee fruit (*Coffea arabica L.*), known also as 'cascara'. The NF falls under the category 'food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

- traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
- non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances', as described in Article 3(2)(iv) of Regulation (EU) 2015/2283.

The NF is produced by mechanical dehulling of dried coffee fruits and consists mainly of digestible carbohydrates, fibre and water. The NF is proposed to be used as an ingredient in non-alcoholic, water-based infusions and drinks. Products with the NF can be consumed by the general population.

3.2. Identity of the NF

The NF is the dried husk of the fruit of *Coffea arabica* L. (*Rubiaceae*). According to the Plants of the World Online,[4] another identified scientific synonym for *Coffea arabica* L. is *Coffea vulgaris. Coffea arabica* L. originates from Ethiopia and is widely cultivated in Brazil, Colombia and Ethiopia.'Cascara', 'dried husk of the coffee cherry', 'dried husk of the coffee fruit', 'dried coffee pulp', 'husk cascara' and

[4] https://powo.science.kew.org/

'dried coffee fruit pulp' are some of the common names identified for the NF. The NF comprises the skin (exocarp), pulp (mesocarp), mucilage (pectin), parchment (endocarp) and a portion of the silver skin of the coffee fruit. It has an irregular shape, between 1 and 6 mm, with colour ranging from 'honey to light brown to dark brown with reddish overtones', and consists mainly of digestible carbohydrates, dietary fibre and water.

3.3. Production process

According to the information provided, the NF is produced following conventional agricultural practices and Hazard Analysis Critical Control Points (HACCP) principles. The seeds for the propagation of the NF source were obtained from *Coffea arabica* L. cultivars in Panama, Nicaragua and Colombia.

The NF is obtained from coffee trees propagated, grown and harvested under the same conditions used to obtain green coffee beans used for coffee production. Six different varieties of arabica coffee (Geisha, Caturra, Typica, Catuai, Pacamara and Maragogype) are used in the NF production. The propagation (through seeding) and cultivation of the coffee plants take place in Central America (hills of former volcanic mountain ranges of Nicaragua and Panama), on various coffee farms or plantations. During cultivation, organic (e.g. compost) and inorganic fertilisers (containing e.g. nitrogen, phosphate and potassium), as well as pesticides (fungicides, acaricides and insecticides) are used. The applicant provided a detailed plan on the identity of the pesticides used, as well as information on the identity of these products.

Harvesting of the ripe coffee fruits is performed manually (multi-pass method) and occurs between December and April, 3–5 years after the propagation of coffee trees. The ripe coffee fruits are gathered in dedicated containers (e.g. woven baskets) and may undergo an initial rinsing process before drying (sun/air drying at ambient temperature). The drying process takes place on raised drying beds or concrete patios for approximately 15–24 days until reaching a moisture level of approximately 12%. The drying beds allow air circulation and are covered with a translucent material as roof to prevent potential contamination and moisture exposure from rainfall. The coffee fruits are manually rotated at varying intervals, to ensure even drying and to prevent mould formation. Under- and over-ripe, damaged or moulded cherry fruits are manually removed by visual inspection during this step. Commercial air dryers (at ambient temperature) can be used at the end of the primary drying step if needed, to achieve the intended moisture level. The whole dried coffee fruits undergo a resting period of 90–100 days in woven bags (green coffee flavour development). Subsequently, the dried coffee fruits are mechanically dehulled, separating the seed from the coffee husk. Post-processing handling involves packaging, storage and transport of the NF.

The Panel considers that the production process is sufficiently described.

3.4. Compositional data

In order to confirm that the manufacturing process is reproducible and adequate to produce on a commercial scale a product with certain characteristics, the applicant provided analytical information for several representative, independently produced batches of the NF originating from different farms and geographical locations. Certificates of accreditation for the laboratories that conducted the analyses were provided by the applicant.

The NF is a 'whole food' as defined by EFSA Scientific Committee (EFSA Scientific Committee, 2011), meaning that all its constituents cannot be fully identified and/or characterised (EFSA NDA Panel, 2016).

The NF consists mainly of digestible carbohydrates, dietary fibre and water. The results of proximate analysis are presented in Table 1. The amino acid, fatty acid, vitamin and mineral compositions are reported in section '3.9 Nutritional information'.

Table 1: Batch-to-batch proximate analysis of the NF

Parameter (unit)	Analytical method	Batch number					
		#1	#3	#6	#7	#9	#10
Total carbohydrates (g/100 g of NF)	Calculation[(a)]	74.9	69.9	69.7	74.6	74.0	72.7
Digestible carbohydrates (g/100 g of NF)	Calculation[(b)]	39.9	37.3	36.5	40.1	39.8	35.6
Dietary fibre (g/100 g of NF)	Enzymatic –gravimetry (STN 56 0031)	35.0	32.6	33.2	34.5	34.2	37.1
Total sugars (g/100 g of NF)	HPLC/RID (SPP ORG.M.040; STN EN 12630; ASU L 48.01-3)	35.6	24.7	27.2	31.0	34.2	38.1
Crude protein (g/100 g of NF)	Kjeldahl method (N × 6.25) (ŠPP INO.M.077)	6.2	7.5	7.6	6.6	6.9	7.7
Ash (g/100 g of NF)	Gravimetric method (ŠPP INO.M.036; ASU L 06.00-4)	5.9	6.1	5.7	4.4	6.2	5.9
Fat (g/100 g of NF)	Gravimetric method (ASU L 06.00-6)	0.9	0.4	0.5	0.7	0.5	0.3
Dry matter (g/100 g of NF)	Gravimetric method (ŠPP INO.M.035; ASU L 06.00-3)	87.9	83.9	83.5	86.3	87.6	86.6
Moisture (g/100 g of NF)	Calculation[(c)]	12.1	16.1	16.5	13.7	12.4	13.4
Water activity (a_w)	Hygrometry	0.483	0.498	0.546	/	0.476	0.531

HPLC/RID: High-Performance Liquid Chromatography with Refractive Index Detector.
/: not provided.
(a): 100 – (crude protein + fat + ash + moisture).
(b): total carbohydrates – dietary fibre.
(c): 100 – dry matter.

Given the possible variations in cultivation practices (e.g. propagation, harvesting, time of harvest in relation to both season and stage of the plant growth), the Panel considers that the variation of compositional values is acceptable.

The applicant provided microbiological data on five independently produced batches of the NF at various time points after production (Table 2).

Table 2: Batch-to-batch microbiological analysis of the NF

Microbiological parameters (unit)	Analytical method	#2	#3	#4	#5	#6
Total aerobic count (cfu/g)	EN ISO 4833-1 EN ISO 4833-2	1,600	5,200	7,900	9,600	1,600
Enterobacteriaceae (cfu/g)	EN ISO 21258-2	< 10	< 10	< 10	< 10	< 10
Escherichia coli (cfu/g)	ISO 16649	< 10	< 10	< 10	< 10	< 10
Yeasts (cfu/g)	ISO 21527	< 100	< 100	< 100	200	< 100
Moulds (cfu/g)	ISO 21527	< 100	< 100	< 100	< 100	< 100
Coagulase-positive staphylococci (cfu/g)	EN ISO 6888-2	< 10	< 10	< 10	< 10	< 10
Bacillus cereus (cfu/g)	EN ISO 7932	< 100	< 100	< 100	100	< 100
Salmonella spp. in 25g	EN ISO 6579	ND	ND	ND	ND	ND
Clostridium perfringens (cfu/g)	EN ISO 7937	< 10	< 10	< 10	< 10	< 10

cfu: colony forming units; ISO: International Organization for Standardization.

Concentrations of heavy metals (Pb, Cd, Hg, As) are reported in Table 3. There are no maximum limits applicable for similar products in the EU Legislation. The Panel notes that the concentrations of heavy metals reported for the NF are below maximum levels set for other foodstuffs or food

[5] Figures rounded as per (EFSA Scientific Committee, 2012).

supplements as set in Commission Regulation (EC) No 1881/2006[6] and food supplements as set in Regulation (EU) No 488/2014[7].

Table 3: Concentrations of contaminants in the NF

Parameter	Analytical method	Batch number					
		#1	#2	#3	#4	#5	#6
Heavy metals (mg/kg)							
Pb	ICP-MS; ICP-OES (DIN EN 15763:2010 or EN ISO 11885)	0.06	< 0.01	0.072	0.03	< 0.05	0.03
Cd		< 0.01	0.02	< 0.005	< 0.009	< 0.005	0.009
Hg		< 0.01	< 0.005	0.005	< 0.005	< 0.005	< 0.005
As		0.06	0.020	0.011	< 0.005	0.01	< 0.005
Mycotoxins (μg/kg)							
Ochratoxin A	HPLC-FLD (EN 16007, EN 14132, EN 15829, EN 15835)	/	< 0.050	< 0.050	< 0.050	0.250 ± 0.10	< 0.05
Aflatoxin B1	HPLC-FLD; (EN 14123 and EN 12955)	/	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Aflatoxin B2		/	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Aflatoxin G1		/	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Aflatoxin G2		/	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Sum of aflatoxins		/	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Polycyclic Aromatic Hydrocarbons (μg/kg)							
Benzo[*a*]anthracene	HS-GC/MS	/	/	0.8	/	/	< 0.05
Benzo[*a*]pyrene		/	/	< 0.05	/	/	< 0.05
Benzo[*b*]fluoranthene		/	/	< 0.05	/	/	< 0.05
Chrysene		/	/	1.2	/	/	0.9
Sum PAH4		/	/	2.00	/	/	0.9

ICP-MS: Inductively Coupled Plasma Mass Spectrometry; ICP-OES: Inductively Coupled Plasma - Optical Emission Spectroscopy; HPLC-FLD: High-Performance Liquid Chromatography with Fluorescence Detection; HS-GC/MS: Headspace-Gas Chromatography/Mass Spectrometry; PAH: Polycyclic Aromatic Hydrocarbons; PAH4: Sum of benzo[*a*]pyrene, benz[*a*]anthracene, benzo[*b*]fluoranthene and chrysene; /: not provided.

Analytical data on the concentrations of aflatoxins B1, B2, G1, G2 and ochratoxin A were provided (Table 3). Values were lower than the maximum levels set for other foodstuffs in Regulation (EC) No 1881/2006 (e.g. roasted coffee beans and ground roasted coffee, or dried fruit to be subjected to sorting, or other physical treatment before human consumption/use as ingredient in foodstuffs).

Polycyclic aromatic hydrocarbons (PAHs) were initially analysed in two batches of the NF. Chrysene and benzo[*a*]anthracene were quantified in one and two batches, respectively. Upon EFSA's request, the applicant provided further analytical data (three additional batches of the NF, other than those described in Table 3) on benzo[*a*]anthracene, benzo[*a*]pyrene, benzo[*b*]fluoranthene and chrysene. Among these samples, benzo[*a*]pyrene and benzo[*b*]fluoranthene were found to be below 0.05 μg/kg (LOQ), and the highest levels of benzo[*a*]anthracene and chrysene were 0.653 and 0.561 μg/kg, respectively. The applicant argued that the NF may be contaminated with such compounds through air, soil and water, as well as due to the burning of material (e.g. wood, fossil fuels) in the regions close to the farms. The Panel notes that the reported levels for benzo[*a*]pyrene and sum of PAH4 in the NF are below the respective maximum levels set e.g. for powders of food of plant origin for the preparation of beverages in Commission Regulation (EC) No 1881/2006.

Moreover, the applicant investigated by LC-GC-FID the levels of mineral oil hydrocarbons (MOSH, POSH, MOAH) in two batches of the NF, and the reported results were below the LOD (0.6 mg/kg for MOSH/POSH and < 0.15 mg/kg for MOAH).

Analytical data of the pesticide levels for five independently produced batches of the NF have been provided. The results showed that most of the analysed pesticide residue levels in the NF are below

[6] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance). OJ L 364, 20.12.2006, p. 5–24.
[7] Commission Regulation (EU) No 488/2014 of 12 May 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in foodstuffs. OJ L 138, 13.5.2014, p. 75–79.

the LOD of the analytical method used. Azoxystrobin, carbendazim, cypermethrin, cyproconazole, deltamethrin, epoxiconazole, flutriafol, imidacloprid, propamocarb, propiconazole, tebuconazole, triadimenol and trifloxystrobin have been quantified in some of the analysed NF batches. The Panel notes that five of these active substances, i.e. azoxystrobin, cyproconazole, epoxiconazole, tebuconazole and triadimenol, have been quantified at concentrations higher than the MRL set for coffee bean in EU. The quantified levels of these five substances are lower than the MRL set for other foodstuffs by EU Regulations.

Additionally, the applicant investigated the concentration of anthraquinone in the NF (in-house HPLC/MS method, LOQ = 0.05 mg/kg and LOD = 0.01 mg/kg). The Panel notes that the reported values, which were below the LOD, are below the MRL (0.02 mg/kg) for anthraquinone in tea, coffee, herbal infusions and cocoa, set in Commission Regulation (EU) No 1146/2014[8].

The Panel considers that the information provided on the composition is sufficient for characterising the NF.

3.4.1. Stability

The applicant provided data on the microbiological profile of eight independently produced batches of the NF analysed at various time points after the dehulling, i.e. the last step of the production process before packaging, took place (Table 4). The Panel notes that the NF batches analysed at the various time points are not always the same ones, and that the NF has not been analysed at time = 0. The proposed shelf-life by the applicant is 3.5 years (after dehulling).

The applicant declared that the intended storage conditions of the NF are 15–20°C and 50–65% relative humidity (after transportation from the farms to the applicant's facilities), in hermetically closed packaging.

Table 4: Microbiological status of the NF during storage

Parameter (unit)	**Batch number**												
	#2	**#3**	**#4**	**#5**	**#6**	**#13**	**#6**	**#2**	**#3**	**#6**	**#7**	**#3**	**#6**
Time after dehulling (days)	**180**				**465**		**480**	**520**		**1,000**	**1,560**	**1,740**	**2,220**
Total aerobic counts (cfu/g)	1,600	5,200	7,900	9,600	3,960	4,240	1,600	5,200	4,700	3,100	2,380	2,480	3,420
Enterobacteriaceae (cfu/g)	< 10	< 10	< 10	< 10	/	/	< 10	/	/	/	/	/	/
E. coli (cfu/g)	< 10	< 10	< 10	< 10	/	/	< 10	< 10	< 10	< 10	/	/	/
Yeasts (cfu/g)	< 100	< 100	< 100	200	/	/	< 100	< 10	< 10	< 10	/	/	/
Moulds (cfu/g)	< 100	< 100	< 100	< 100	/	/	< 100	< 10	< 10	< 10	/	/	/
Coagulase-positive staphylococci (cfu/g)	< 10	< 10	< 10	< 10	/	/	< 10	/	/	/	/	/	/
B. cereus (cfu/g)	< 100	< 100	< 100	100	/	/	< 100	/	/	/	/	/	/
Salmonella sp. in 25g	nd	nd	nd	nd	/	/	nd	/	/	/	/	/	/
Clostridium perfringens (cfu/g)	< 10	< 10	< 10	< 10	/	/	< 10	/	/	/	/	/	/
Water activity (aw)	/	/	/	/	0.491	0.495	0.483	/	/	/	0.460	0.461	0.546

cfu: colony forming units.
/: not provided.

Stability in the intended for use matrices

Since the NF is going to be used as an ingredient for the manufacturing of other foods, the applicant investigated its stability when used as an ingredient in the intended-for-use matrices (see

[8] Commission Regulation (EU) No 1146/2014 of 23 October 2014 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for anthraquinone, benfluralin, bentazone, bromoxynil, chlorothalonil, famoxadone, imazamox, methyl bromide, propanil and sulfuric acid in or on certain products. OJ L 308, 29.10.2014, p. 3–60.

Section 3.7.2 Proposed uses and use levels). The applicant described how the NF is going to be used (via infusion) for the production of beverages and provided data on the total aerobic counts of beverages produced using the NF. The Panel notes that the food items containing the NF have to comply with any applicable existing legislative limits.

Provided that the specifications are met also at the end of shelf-life and that products containing the NF are compliant with respective legislative limits, the stability data do not raise safety concerns.

3.5. Specifications

The specifications of the NF are indicated in Table 5.

Table 5: Specifications of the NF

Description: dried coffee husk (cascara) from *Coffea arabica* L.		
Parameter	**Unit**	**Specification**
Moisture	g/100 g	< 17
Crude protein (N × 6.25)	g/100 g	6–8
Fat	g/100 g	< 1%
Ash	g/100 g	4–7
Digestible carbohydrates	g/100 g	35–41
Sugars	g/100 g	24–40
Total dietary fibre	g/100 g	32–38
Caffeine	mg/100 g	100–1,000
Heavy metals		
Lead	mg/kg	< 0.1
Cadmium	mg/kg	< 0.1
Mercury	mg/kg	< 0.1
Arsenic	mg/kg	< 0.1
Mycotoxins		
Aflatoxin B1	μg/kg	< 2.0
Aflatoxin B1+ B2 + G1 + G2	μg/kg	< 4.0
Ochratoxin A	μg/kg	< 5.0
Polycyclic Aromatic Hydrocarbons		
Benzo[*a*]pyrene	μg/kg	< 10.0
Sum of benzo[*a*]pyrene, benz[*a*]anthracene, benzo[*a*]fluoranthene, chrysene	μg/kg	< 50.0
Microbiological parameters		
Total aerobic colony count	cfu/g	< 10^4
Bacillus cereus	cfu/g	< 100
Yeasts and moulds	cfu/g	< 100
Salmonella spp.	In 25 g	Not detected
Escherichia coli	cfu/g	< 50
water activity (a_w)	Not applicable	< 0.60

cfu: colony forming units.

The Panel amended the specification limits for heavy metals and microbiological parameters considering the analytical data presented by the applicant in the batch-to-batch analysis.

The Panel considers that the information provided on the specifications of the NF is sufficient and does not raise safety concerns.

3.6. History of use of the NF and/or of its source

3.6.1. History of use of the source

The source of the NF is the fruit of *Coffea arabica* L. The whole coffee fruit, or portions thereof, has a long history of consumption in Yemen, Ethiopia, Uganda and more recently in Bolivia and Brazil (Weinberg and Bealer, 2004; Wild, 2005; Soux, 2016; Alves et al., 2017).

3.6.2. History of use of the NF

The coffee husk is traditionally consumed in the Middle East, Africa and South America in the form of infusion or as an ingredient in various dishes (Hestler and Spilling, 2010; Thurston et al., 2013; Hattox, 2014). The Oromo ethnic group from Ethiopia was reported as the first consumers of coffee fruits during different cultural or religious rituals, as slightly roasted and melted in butter in a dish called 'bunaqalaa' or coffee husks mixed with milk ('hoja') (Hussen et al., 2008; Wayessa, 2011; Bacha et al., 2018). Infusions of coffee husks have been also consumed in Yemen (named 'qishr' or 'al Kahwa al Kishria', i.e. husk coffee, flavoured with spices) since the 16th century (Thesiger, 1947; Hestler and Spilling, 2010; Hattox, 2014; Alves et al., 2017; Keiko, 2018).

3.7. Proposed uses and use levels and anticipated intake

3.7.1. Target population

As the NF is intended to be used as an ingredient in standard food categories, the NF may be consumed by any groups of the population. Therefore, the safety data and the exposure assessment shall cover all population groups (Commission implementing Regulation (EU) 2017/2469, article 5(6)[9]).

The Panel notes that the consumption of beverages containing caffeine is not recommended to children, pregnant or breast-feeding women if the caffeine content exceeds 150 mg/L, as stipulated by Regulation (EU) No 1169/2011[10].

3.7.2. Proposed uses and use levels

The NF is proposed to be used as an ingredient for the preparation of non-alcoholic drinks and infusions. The food categories defined using the FoodEx2 hierarchy (EFSA, 2015), and the maximum use levels are reported in Table 6.

Table 6: Food categories and maximum use levels intended by the applicant

FoodEx2 level	FoodEx2 code	Food category	Max use level (g NF/100 mL)
A03LG	3	Herbal and other non-tea infusions	4
A03GA	4	Energy drinks	6
A03DZ	3	Soft drinks	2

Upon EFSA's request, the applicant clarified that the NF as such will not be consumed, beverages produced with the infusion of the NF in water will be available to consumers.

Additionally, the applicant proposed food categories defined according to the guidance document describing the food categories for Food Additives[11] and the respective maximum use levels, i.e. 'Flavoured drinks with sugar' (6 g NF/100 mL), 'Flavoured drinks with sweetener' (6 g NF/100 mL) and 'Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions, and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these

[9] Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, p. 64–71.

[10] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18–63.

[11] Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives (https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_1333-2008_annex-2.pdf).

products' (4 g NF/100 mL). The Panel notes that the food categories for Food Additives have been used also in the context of EFSA's technical report on coffee cherry pulp (EFSA, 2021a).

3.7.3. Anticipated intake of the NF

The Panel concluded that, considering the compositional information on the Novel Food, the specification limits and the proposed uses, a calculation of the anticipated intake of the NF and an exposure assessment for the NF do not provide meaningful information for this assessment. Aspects regarding the intake of caffeine due to consumption of beverages produced using the NF is discussed in section '3.9 Nutritional information'.

3.7.4. Precautions and restrictions of use

Considering the maximum caffeine concentrations in drinks/infusions produced using the NF (Section 3.9 Nutritional information), the Panel notes that labelling provisions in Regulation (EU) No 1169/2011 apply if caffeine exceeds 150 mg/L in the products containing the NF.

3.8. Absorption, distribution, metabolism and excretion (ADME)

No ADME data have been provided for the NF.

3.9. Nutritional information

The applicant provided a nutritional analysis of the NF which consists mainly of digestible carbohydrates, dietary fibre, water and ash (described in Section 3.4 Compositional data). Analytical data on the amino acid composition, the fatty acids content, vitamins and minerals have been provided for three to six batches of the NF.

The applicant provided information on the NF vitamin and mineral content. Considering the reported concentrations in the NF and the fact that beverages produced using the NF (via infusion) are consumed and not the NF as such, the Panel is of the view that the contribution to the overall dietary intake is not of relevance.

Given the possible variations in cultivation practices, the Panel considers that the variation regarding the content of vitamins and minerals among the NF batches is acceptable.

The applicant quantified the amino acids in three batches of the NF, and the fatty acids in five batches of the NF. Erucic acid has been detected in three out of the tested five batches of the NF in levels varying from 0.3% to 2.62% of total fatty acids. The Panel notes that, considering the low level of total fat (0.5 $\pm$ 0.2% w/w) in the NF, and the proposed uses, the concentration of erucic acid does not raise any safety concern.

It has been reported that coffee husk may contain antinutritional factors (Augur et al., 2006; Akande et al., 2010; Didanna, 2014) such as tannins (Clifford and Ramirez-Martinez, 1991; De Colmenares et al., 1994; Ramirez-Coronel et al., 2004) and chlorogenic acid (Mullen et al., 2013). The applicant determined the concentrations of total polyphenols, tannins, chlorogenic acid, caffeine, oxalic acid and catechol in the NF (Table 7). The reported values in the NF are lower or comparable to the occurrence levels of these compounds in other foodstuffs (Charrier et al., 2002; Hečimović et al., 2011; Kopjar et al., 2015; Król et al., 2019).

Table 7: Batch-to-batch analysis of antinutritional factors in the NF

Parameter	Units	Analytical method	Batches						
			#3	#5	#6	#7	#9	#10	#11
Total polyphenol content	mg GAE/ 100 g	UV/VIS	1,194.1	/	1,362.8	/	1,650	1,280	1,330
Tannins (total)	g/100 g	UV/VIS	3.06	/	/	4.25	3.57	4.09	3.54
Tannins (condensed)	g/100 g	UV/VIS	2.36	/	/	3.39	2.86	4.09	2.83
Tannins (hydrolysable)	g/100 g	UV/VIS	0.702	/	/	0.858	0.706	0.661	0.708
Oxalic acid	g/100 g	HPLC/UV	0.0412	/	/	0.0509	0.0636	0.0283	0.0782
Catechol (free)	g/100 g	HPLC/UV	< 0.01	/	/	< 0.01	< 0.01	< 0.01	< 0.01

Parameter	Units	Analytical method	Batches						
			#3	#5	#6	#7	#9	#10	#11
Chlorogenic acid	mg/100 g	HPLC/UV	73.4	51.3	/	/	52.6	41.9	61.9

The safety of caffeine has been previously assessed by EFSA (EFSA NDA Panel, 2015) and it was concluded that the estimated habitual intake of caffeine from all sources, i.e. 400 mg/day for adults other than pregnant and lactating women, did not raise safety concerns. Regarding pregnant and lactating women, a 200 mg/day intake of caffeine was considered not to raise safety concerns. With regard to children and adolescents, the available body of evidence was not sufficient to derive a safe level of caffeine intake, and the level of no safety concern derived for single doses of caffeine for adults (i.e. 3 mg/kg body weight (bw) per day) for habitual caffeine consumption by children and adolescents was considered as safe (EFSA NDA Panel, 2015).

The applicant quantified the caffeine levels in the NF (Table 8) and investigated the caffeine extraction rate (i.e. caffeine in the NF/caffeine in the infusion) in hot infusions, and the extraction rates for five individual batches of the NF (3 g of NF in 100 mL distilled water at 95°C for 5 min) ranged from 78.2% to 100%.

Table 8: Batch-to-batch analysis of caffeine concentration in the NF

Parameter	Units	Analytical method	Batches						
			#1	#2	#3	#4	#5	#6	#7
Caffeine	mg/100 g	HPLC/UV with external standardisation; DIN 10811-2	202	460	533	652	350	639	135

Considering the proposed uses and use levels (Section 3.7 Proposed uses and use levels and anticipated intake), a maximum concentration of caffeine at 1000 mg/100 g (Section 3.5 Specifications) and assuming an 100% extraction of caffeine from the NF to the infusion, the Panel notes that the concentration of caffeine among the proposed food categories may result into a caffeine concentration of 200 mg/L in soft drinks, 400 mg/L in herbal and other non-tea infusions and 600 mg/L in energy drinks. Based on literature data, the highest estimated caffeine concentration in the NF's infusions was compared with those in commonly consumed caffeine-containing beverages. Caffeine content in coffees ranges from 270 to 1,340 mg/L, in teas from 150 to 220 mg/L and in energy drinks ~320 mg/L (EFSA NDA Panel, 2015).

The Panel notes that the consumption of beverages produced using the NF may lead to coverage or exceedance of the habitual intake of caffeine previously considered as safe for adults other than pregnant and lactating women (i.e. 400 mg/day), pregnant and lactating women (i.e. 200 mg/day) and children (i.e. 3 mg/kg bw per day). The Panel also notes that parts of the population already exceed the habitual intake of caffeine from other sources than the NF (EFSA NDA Panel, 2015).

The Panel notes that consumption of beverages produced using the NF will significantly add to the total dietary intake of caffeine of the general population. The consumption of beverages containing caffeine is not recommended to children, pregnant or breast-feeding women if the caffeine content exceeds 150 mg/L and the labelling provisions of Regulation (EU) No 1169/2011 would apply.

3.10. Toxicological information

The Panel notes that no toxicological studies with the NF were provided. Taking into account the nature of the NF, the history of use of the NF as food and the proposed uses and use levels, the Panel considers that no toxicological studies are required on the NF.

3.10.1. Human data

No human studies with the NF were submitted by the applicant, apart from the skin-prick test.

3.11. Allergenicity

In order to investigate the allergenic potential of the NF, the applicant commissioned a skin-prick test study. The NF (in the form of powder) was suspended in water and was tested on 40 individuals

(with previously diagnosed reactions to other allergens), alongside a series of established allergens, as well as positive and negative controls. None of the individuals had an allergic reaction to the aqueous suspension of the NF.

The NF contains detectable amounts of protein (7.1 ± 0.6% w/w); thus, allergic reactions are possible. However, the Panel considers the allergenic risk to be low.

4. Discussion

The NF which is the subject of the application is the dried husk of the fruit of *Coffea arabica* L. The production process is sufficiently described and does not raise safety concerns. The Panel considers that the NF is sufficiently characterised. The NF consists mainly of carbohydrates (both digestible carbohydrates and dietary fibre) and water. The concentration of contaminants (e.g. heavy metals, pesticide residues, organic contaminants) depends mainly on the production process (cultivation). The Panel notes that there are no safety concerns regarding stability, if the NF complies with the proposed specification limits during its entire shelf-life.

The applicant intends to market the NF as an ingredient in beverages. The consumers will not have access to the actual NF but will consume the final products, i.e. beverages, produced using the NF (via infusion). The target population is the general population.

Caffeine concentration in the NF was analysed. Considering an 100% extraction of caffeine from the NF to the beverage, the specification limit set for caffeine and the proposed use levels, the maximum concentration of caffeine in infusions of the NF could be up to 600 mg/L of drink, a concentration comparable to those in coffee beverages. The Panel notes that consumption of beverages produced using the NF will significantly add to the total dietary intake of caffeine of the general population. The consumption of beverages containing caffeine is not recommended to children, pregnant or breast-feeding women if the caffeine content exceeds 150 mg/L and the labelling provisions of Regulation (EU) No 1169/2011 would apply.

Considering the nature of the NF, the thorough compositional characterisation, the long history of use of the NF as food and the proposed uses and use levels, the Panel did not deem further toxicological studies with the NF as testing material necessary.

The risk of allergic reactions to the NF is considered low.

5. Conclusions

The Panel concludes that the NF, dried husk of the fruit of *Coffea arabica L*., is safe under the proposed conditions of use.

The Panel could not have reached the conclusion on the safety of the NF under the proposed conditions of use without the data claimed as proprietary by the applicant (detailed description of the production process, analytical data on the composition of the NF and stability data).

6. Steps taken by EFSA

1) On 07 September 2020 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of coffee husk (Cascara) as a novel food [Ref. Ares (2020)4646086-07/09/2020].
2) On 07 September 2020, a valid application on coffee husk (Cascara), which was submitted by Panama Varietals GmbH, was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2018/0192) and the scientific evaluation procedure was initiated.
3) On 12 February 2021, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
4) On 07 December 2021, EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of dried coffee husk (cascara) from *Coffea arabica L*. as a novel food [Ref. Ares (2021)7536867-07/12/2021].
5) On 08 December 2021, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
6) During its meeting on 16 December 2021, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of dried coffee husk (cascara) from *Coffea arabica* L. as a NF pursuant to Regulation (EU) 2015/2283.

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Abbreviations

ADME	Absorption, Distribution, Metabolism and Excretion
bw	Body Weight
FAIM	Food Additive Intake Model
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Points
HPLC/MS	High Performance Liquid Chromatography Mass Spectrometer
HPLC/UV	High-Pressure Liquid Chromatography with Ultraviolet Detector
ISO	International Organization for Standardization
LC-GC-FID	Coupled Liquid Chromatography-Gas Chromatography with Flame Ionisation Detection
LOD	Limit of Detection
LOQ	Limit of Quantification
MOAH	Mineral Oil Aromatic Hydrocarbons
MOSH	Mineral Oil Saturated Hydrocarbons
MRL	Maximum Residue Level
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	Novel Food
PAH	Polycyclic aromatic hydrocarbons
PAH4	Sum of benzo*[a]*pyrene, benz*[a]*anthracene, benzo*[b]*fluoranthene and chrysene
POSH	Polyolefin Oligomeric Saturated Hydrocarbons
UV/VIS	Ultraviolet-Visible Spectroscopy