Safety of the extension of use of partially defatted chia seed (Salvia hispanica L.) powder with a high fibre content as a novel food pursuant to Regulation (EU) 2015/2283.

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Safety of the extension of use of partially defatted chia seed (*Salvia hispanica* L.) powder with a high fibre content 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 the safety of the extension of use of partially defatted chia seed (*Salvia hispanica* L.) powder with a high fibre content as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The NF is already authorised and included in the Union list of NFs and is produced according to the same production process. This application is limited to an assessment of the extension of use of the NF as a food ingredient in several food categories with a high moisture content that are subject to thermal processing. The target population for the extension of use is the general population. The information provided on the formation of process contaminants (acrylamide, furan and methylfurans) in a selected food category with added NF (bread) subjected to heat treatment is sufficient for this assessment and does not raise safety concerns. Noting that no safety concerns were identified from the information available on the production process, composition, specifications and proposed uses of the NF, the Panel considers that intake estimates for the NF are not needed for this assessment. The Panel concludes that the NF, partially defatted chia seeds powder with a high fibre content, is safe under the proposed conditions of use.

Keywords: novel foods, chia seeds, partially defatted chia powder, heat-treated products, process contaminants, safety

Requestor: European Commission

Question number: EFSA-Q-2021-00551

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1. Introduction

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

On 26 July 2021, the company Functional Products Trading Arica S.A./BENEXIA, Chile, submitted an application to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283[1] to authorise the change of the conditions of use of partially defatted chia seed (*Salvia hispanica* L.) powder, with high fibre content, as a novel food.

The applicant requests to extend the use of partially defatted chia seed (*Salvia hispanica* L.) powder with high fibre content, to additional food categories intended for the general population.

The applicant has also requested data protection under Article 26 of Regulation (EU) 2015/2283.

In accordance with Article 29(l)(a) of Regulation (EC) No 178/2002[2], the European Commission asks EFSA to provide a scientific opinion on the change of the conditions of use of partially defatted chia seed (*Salvia hispanica* L.) powder, with high fibre content, as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

The Commission also asks EFSA to evaluate and inform the Commission as to whether and if so, to what extent, the requirements of Article 26(2)(c) of Regulation (EU) 2015/2283 are fulfilled in elaborating its opinion on the change of the conditions of use of partially defatted chia seed (*Salvia hispanica* L.) powder with high fibre content, as a novel food, regarding the proprietary data for which the applicant is requesting data protection.

1.2. Additional information

Chia seeds (*Salvia hispanica* L.) are authorised as a novel food (NF) in a variety of food categories as listed in Commission Implementing Regulation (EU) 2017/2470[3] establishing the Union list of NFs in accordance with Regulation (EU) 2015/2283. The initial authorisation in 2009 concerning the use of chia seeds in bread products up to the level of 5% followed after EFSA's opinion on safety of chia seeds as a NF (EFSA NDA Panel, 2009).

The extension of use of chia seeds in a variety of food categories was later authorised following the EFSA Scientific opinion on the safety of chia seeds (*S. hispanica* L.) as a NF for extended uses (EFSA NDA Panel, 2019a).

During the assessment, the Panel retrieved a study (Mesías et al., 2016), assessing the formation of process contaminants in wheat-flour based biscuits with added chia flour in various percentages (0–20%). The results of this study indicated an increase in the acrylamide, hydroxymethylfurfural and furfural concentrations with the addition of chia flour in biscuits. In general, these process contaminants can be formed when certain foods are processed at temperatures above 120°C and at low moisture, especially in foods containing asparagine and reducing sugars (EFSA NDA Panel, 2020). However, the study of Mesías et al. (2016) did not examine the formation of furan and alkylfurans, other known process contaminants in heat-treated foods that can be formed in foods during thermal processing from a variety of precursors (EFSA CONTAM Panel, 2017). In the absence of further information related to the possible heat-induced formation of process contaminants in foods with added chia seeds, the 2019 EFSA opinion addressed only those NF applications and extensions of use which do not include thermal processing and/or cooking procedures (EFSA NDA Panel, 2019a). Thus, the overall safety assessment of chia seeds in accordance with Article 29(1) of Regulation (EC) No 178/2002, was only partially addressed.

Considering these concerns and the lack of additional data, later in 2019 the NDA Panel adopted the opinion 'Safety of chia seeds (*Salvia hispanica* L.) powders', as NFs, pursuant to Regulation (EU) 2015/2283 (EFSA NDA Panel, 2019b), concluding that the partially defatted powders of whole chia seeds are safe under the assessed conditions of use in food supplements and as ingredients in a variety of non-heat-treated foods.

[1] 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.

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

[3] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, p. 72–201.

In order to complete the assessment on the safety of chia seeds, following a request from the European Commission, EFSA has adopted a scientific opinion on the safety of chia seeds subject to thermal processing in relation to the formation of process contaminants (EFSA NDA Panel, 2020). However, the extensive literature search and a public call for data by EFSA did not result in relevant articles on the asparagine content in chia or the formation of process contaminants in thermally processed foods containing chia seeds and products thereof. The data received was limited or inconclusive and did not provide a basis for the Panel to conclude whether the addition of chia seeds to foods undergoing heat treatment (at temperatures above 120°C) would result in increased formation of acrylamide compared to these foods without chia seeds.

2. Data and methodologies

2.1. Data

The safety assessment of this NF is based on the previous assessment of the NF (EFSA NDA Panel, 2019b), data supplied in the application and information submitted by the applicant following EFSA requests for supplementary information.

During the assessment, the Panel identified additional data that were not included in the application (Mesías et al., 2023).

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[4].

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of a NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all 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 comprises an acute oral toxicity study, a human study and a study on formation of process contaminants with related certificates of analysis.

The applicant has submitted a confidential and a non-confidential version of a dossier following the EFSA guidelines on the preparation and presentation of a NF application (EFSA NDA Panel, 2021) and the EFSA administrative guidance for the preparation of applications on NFs pursuant to Article 10 of Regulation (EU) 2015/2283 (EFSA, 2021).

In accordance with Art. 38 of the Regulation (EC) No 178/2002 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 EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[5] the non-confidential version of the dossier has been published on Open.EFSA.[6]

According to Art. 32c(2) of Regulation (EC) No 178/2002 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 16 December 2022 to 6 January 2023 for which no comments were received.

2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2021) 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 Commission Implementing Regulation (EU) 2017/2469.

Additional information that 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).

[4] 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, pp. 64–71.

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

[6] The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/NF-2021-1311

This assessment concerns only the risks that might be associated with the 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, which is the subject of the application, is a partially defatted chia seed powder with a high fibre content currently authorised for use in certain food categories and placed on the market of the European Union. The NF is produced by partial defatting of the chia seeds (*S. hispanica* L.) and consists mainly of dietary fibre and proteins. The NF falls under the category (iv) of article 3 from the Regulation (EU) 2015/2283, i.e. 'food consisting of, isolated from or produced from plants or their parts'.

The NF has been authorised for use in several food categories not subjected to heat treatment (above 120°C) during processing and cooking, such as confectionery, fruit and vegetable juices and nectars, flavoured drinks and food supplements (EFSA NDA Panel, 2019b).

In this assessment, the applicant requests the extension of use of the NF as an ingredient in several food categories with a high moisture content subjected to heat treatment, such as cakes, pastries, vegetable-based dishes, bread, pasta. The target population is the general population.

The Panel notes that there are no changes in the production process and the composition of the NF. Additional data regarding the content of asparagine and glutamine in the NF has been provided by the applicant. This assessment concerns the potential risk of an increased acrylamide formation following heat treatment at temperatures above 120°C in one of the newly proposed food categories containing the NF.

3.2. Identity of the NF

The NF is a partially defatted chia seed (*S. hispanica* L.) powder with a fibre content of at least 50% and an average particle size below 400 μm.

3.3. Compositional data

The compositional data as well as the occurrence of microbiological and chemical contaminants in the NF were provided by the applicant and assessed in the previously adopted EFSA opinion (EFSA NDA Panel, 2019b).

The NF is mostly composed of dietary fibre (≥ 50%), protein (≥ 24%) and fat (≤ 12%), with a moisture content of ≤ 9%.

3.3.1. Stability

No additional data were provided by the applicant concerning the stability of the NF itself as well as the stability of the NF used in the proposed food categories. Instead, the applicant submitted the same stability study with the NF assessed in the previously adopted scientific opinion (EFSA NDA Panel, 2019b).

3.3.2. Study on the formation of process contaminants

The applicant provided a study (Unpublished report, 2021) assessing the formation of process contaminants during heat treatment of a chosen food category (bread) containing the NF to address the concerns outlined in the previous assessments of chia seeds (EFSA NDA Panel, 2019a,b). For the purpose of the study, three samples of the NF (batches #1, #2 and #3) with different geographical origin (Bolivia or Mexico) and different year of harvest (2018, 2019 or 2020) and one batch of wheat flour (origin Spain; control) were used.

The study investigated the formation of acrylamide, furan and alkylfurans in bread composed of wheat flour with an added content of the NF in various percentages (0, 5 or 10%). The acrylamide content in the 21 loaves prepared with various composition and cooking methods, was determined in triplicates by LC–MS/MS, whereas the content of furan and alkylfurans were determined by HS-GC/MS, also in triplicates.

Acrylamide is a product of the Maillard reaction between amino acids (predominantly asparagine and glutamine) and reducing sugars (Mottram et al., 2002; Stadler et al., 2002). Thus, the content of free asparagine, as one of the precursors in the acrylamide formation pathway, and of free glutamine, were also determined in the three samples of the NF and in the control wheat flour sample by IC-UV/Vis, carried out in triplicates. No significant difference was established in the asparagine content in the NF of various geographical origin and year of harvest compared with wheat flour. Glutamine content was below the limit of quantification (LOQ) (0.005 g/100 g).

The determination of the humidity of the bread products was carried out after drying of the bread. The applicant reported that more water was needed in the samples containing the NF than in the control samples in order to achieve the same consistency. The applicant hypothesised that this is due to the high water-binding capacity of the mucilage from the fibre fraction of the NF powder. The water retention in the final product containing the NF was higher than in the control sample both before and after baking.

Each bread product was baked at 210 or 220°C for 20 min or at 210°C for 25 min.

According to the study protocol, one whole bread loaf (~ 360–400 g) of each formula and cooking condition was used for the analyses of the process contaminants. The average crust to crumb ratio in the bread was approximately 1:4.

The current study found that control samples had a higher acrylamide content compared to samples containing both 5% and 10 % of the NF. The reason for this finding is presumed to be the inhibition of the Maillard reaction due to the increased absorption and retention of water even after baking, especially in bread formulations containing a higher percentage of the NF (10%). The acrylamide content in all final bread products containing the NF was significantly lower compared to the control samples despite the similar asparagine content in the NF as in the wheat flour in the control samples.

The results of the current study are summarised in Table 1 below:

Table 1: Process contaminants (acrylamide, furan and methylfurans) in bread containing the NF[7] (Unpublished report, 2021)

NF content (% of flour basis)	Batch no.	Baking T (°C) and time (min)	Moisture (%)	Acrylamide (μg/kg)	Furan (μg/kg)	2-Methyl furan (μg/kg)	3-Methyl furan (μg/kg)
0	Control	210°C /20 min	29.2	46.6	< 5	< 5	< 5
		220°C/20 min	28.7	52.3	< 5	< 5.7	< 5
		210°C/25 min	27.7	51.2	< 5	< 6.3	< 5
5	#1	210°C/20 min	30.6	35.7	< 5	< 6	< 5
		220°C/20 min	31.9	36.8	4.6	9.8	< 5
		210°C/25 min	29.2	41.5	6.7	10.3	< 5
	#2	210°C/20 min	30.2	41.2	< 5	10	< 5
		220°C/20 min	32.4	32.4	< 5	13.1	< 5
		210°C/25 min	28.8	43.6	< 5	15.1	< 5
	#3	210°C/20 min	31.7	< 30	6.9	< 5	< 5
		220°C/20 min	29.8	24.4	6.2	< 5	< 5
		210°C/25 min	29.6	< 30	8.6	< 5	< 5
10	#1	210°C/20 min	30.9	35.9	< 5	< 5	< 5
		220°C/20 min	32.1	27.5	< 5	< 5	< 5
		210°C/25 min	33.6	37	< 5	< 6.3	< 5
	#2	210°C/20 min	34	25.7	< 5	< 5	< 5
		220°C/20 min	32.8	30.3	< 5	< 5	< 5
		210°C/25 min	32.2	33.1	< 5	< 5	< 5
	#3	210°C/20 min	32.7	25.2	< 5	< 5	< 5
		220°C/20 min	33.2	28.8	< 5	< 5	< 5
		210°C/25 min	34.8	32.4	< 5	< 5	< 5

[7] Analysed in semi-dry bread and expressed as μg/kg ready to eat bread.

Previously, Galluzzo et al. (2021) investigated the formation of acrylamide in bread with added chia seeds in various percentages (2%, 5%, 7% and 10%) baked for 20 min at 200°C. Their findings indicate no significant increase in acrylamide values in bread with added chia seeds compared to control samples (wheat bread).

A recent study retrieved by EFSA (Mesías et al., 2023), examined acrylamide formation as well as the content of the precursors – asparagine and reducing sugars – in whole and ground chia seeds under different roasting conditions (160–200°C/5–30 min). Highest concentration of acrylamide was seen in ground chia seeds and highest content (9-fold higher) was seen after 15 min of roasting at 180°C. The authors hypothesised that the grinding of the chia seeds exposes the acrylamide-forming compounds from the inner part of the seeds, making them more accessible to the Maillard reaction, indicating that grinding and the particle size of chia seeds are important factors for acrylamide formation. However, the Panel notes that only one batch of chia seeds and no comparator were used in this study, and it concerns acrylamide formation in chia seeds (whole and grounded) only, without addition in different food matrices.

In the study submitted by the applicant, the presence of the NF led to higher water retention in the bread prepared with the NF than in the control bread. Available literature data indicate that the absorption of water by chia mucilage may be as high as 27 times of its weight (Muñoz et al., 2012). Thus, the initial moisture of about 40% in the doughs decreased slightly to around 30–35% in the baked products. The examined bread products containing the NF in the applicant's study had a less crunchy crust compared to control bread. The high moisture content after baking may have contributed towards lower total acrylamide levels in the final products containing the NF. A tendency of an increased water absorption and kneading time in bread with added 5% chia flour was reported previously by Iglesias-Puig and Haros (2013).

Previous findings by Sadd and Hamlet (2005) indicate that low moisture promotes acrylamide formation and that the crust moisture is a key factor contributing towards increased acrylamide formation. The authors indicate that the temperature of the crust approaches oven temperature as soon as the moisture level reduces significantly, which makes the products with a higher crust-to-crumb ratio more susceptible to acrylamide formation. Other studies also demonstrate that moisture and water activity influence the rate of acrylamide formation and that high humidity during baking reduced the acrylamide content in baked foods (Ciesarová et al., 2006; Ahrné et al., 2007).

Furan and methylfurans are volatile compounds formed in food during thermal processing (EFSA CONTAM Panel, 2017). The most important precursors for furan formation in food include ascorbic acid, carbohydrates, amino acids, unsaturated fatty acids and carotenoids (Moro et al., 2012; EFSA CONTAM Panel, 2017). The current study reported furan content of up to 8.6 μg/kg in a bread sample containing 5% NF, which is higher than the control samples but below the average levels of 16–30 μg/kg found in the corresponding food group (bread and rolls, raw pasta, breakfast cereals, fine bakery wares) (EFSA CONTAM Panel, 2017). Chia seeds are a source of unsaturated fatty acids. The NF is a defatted powder of chia seeds. The current data suggest that the remaining lipid content in the NF does not lead to a furan formation proportional to the NF content than what occurs in refined wheat flour.

In addition, the study indicated 2-methylfuran concentrations in some of the 5% NF bread formulations higher than in control samples, whereas the 3-methylfuran concentrations were lower than 5 μg/kg (LOQ) in each of the formulations. It was found earlier (Märk et al., 2006) that polyunsaturated fatty acids, such as linoleic and linolenic acid and their corresponding triglycerides, act as potent precursors in furan and methylfuran formation in the headspace of model systems under dry roasting conditions, with 10–20% attributed to methylated furan derivatives. Considering the lipid content of the NF of about 12%, the findings of Märk et al. (2006) could help explain the 2-methylfuran levels found in bread with 5% NF.

Based on the results from the study provided by the applicant it can be concluded that the addition of 5–10% of the NF to food subjected to thermal processing, such as bread, does not contribute to an elevated production of acrylamide, furan and methylfurans compared to similar products without the NF.

In addition, the applicant provided data on the acrylamide formation following heat treatment in a pasta product containing the NF. The result showed an acrylamide content of < 30 μg/kg, which is within the range for acrylamide levels found in different varieties of pasta products (0–84 μg/kg) reported by health authorities in various countries. However, this data is of limited relevance since only one test item and no control samples were used.

For the NF proposed uses in plant-based meat analogues, the applicant referred to published data indicating that food processing techniques such as high-moisture thermo-extrusion help mitigate the

production of acrylamide due to the relatively high moisture content in the food and to the moderate temperatures applied in such process (Akdogan, 1999). High-moisture extrusion is one of the most widely used techniques in the production of plant-based meat analogues. This technique allows development of meat-like fibrous texture from plant proteins and the resulting meat analogue contains 50–80% moisture (Isobe and Noguchi, 1987; Cheftel et al., 1992; Wild et al., 2014). Therefore, similarly to bread and pasta, plant-based meat analogues have a high humidity, which helps mitigate acrylamide formation when subjected to home cooking.

The Panel considers that the data provided sufficient information with respect to the stability of the NF and addressed the concerns regarding the production of process contaminants in the proposed food categories subject to heat treatment.

3.4. Specifications

The specifications of the NF, as authorised in Commission Implementing Regulation (EU) 2020/500[8] are indicated in Table 2.

Table 2: Specifications of the NF

Description: The novel food is a partially defatted chia seed (*Salvia hispanica* L.) powder with a high fibre content obtained by pressing and grinding of the whole seeds of ***Salvia hispanica* L.**	
Parameter	**Specification**
Physical–sensorial	
Foreign matter	0.1%
Particle size	≤ 400 μm
Chemical composition	
Moisture	≤ 9.0%
Protein	≥ 24.0%
Fat	≤ 12%
Fibre	≥ 50%
Microbiological criteria	
Total plate count	≤ 10 000 CFU/g
Yeasts	≤ 500 CFU/g
Mould	≤ 500 CFU/g
Staphylococcus aureus	≤ 10 CFU/g
Coliforms	< 100 MPN/g
Enterobacteriaceae	≤ 100 CFU/g
Bacillus cereus	≤ 50 CFU/g
Escherichia coli	< 10 MPN/g
Listeria monocytogenes	Absence/g
Salmonella spp.	Absence in 25 g
Heavy metals	
Arsenic	≤ 0.1 ppm
Cadmium	≤ 0.1 ppm
Lead	≤ 0.1 ppm
Mercury	≤ 0.1 ppm
Mycotoxins	
Total aflatoxins	≤ 4 ppb
Ochratoxin	≤ 1 ppb

CFU: colony forming units; ppm: parts per million; ppb: parts per billion; MPN: Most probable number.

[8] Commission Implementing Regulation (EU) 2020/500 of 6 April 2020 authorising the placing on the market of partially defatted chia seed (Salvia hispanica) powders as novel foods under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 109, 7.4.2020, p. 2–7).

The Panel notes the incorrect reporting of the specification for *Listeria monocytogenes* ('Absence/g') and *Escherichia coli* ('< 10 MPN/g') as authorised in the Commission Implementing Regulation (EU) 2020/500 and included in the Union List of NFs. In order to ensure compliance with the Regulation (EC) 2073/2005[9] and the methods of analysis used, the Panel notes that the specification for *Listeria monocytogenes* should be reported as 'not detected in 25 g' and *Escherichia coli* as 'not detected in 10 g'.

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

3.5.1. History of use of the source

The NF is produced from chia seeds (*S. hispanica* L.), a summer annual herbaceous plant belonging to the Lamiaceae family, native to Central and South America (Mexico, Argentina and Bolivia).

The plant has a long history of use both by the native South American civilisations as well as a documented history of use in modern civilisations (USA, Canada, Australia, EU). Safety of use of chia seeds has been established previously (EFSA NDA Panel, 2009, 2019a,b), and chia seeds and oil have been included in the Union list of NFs (Regulation 2017/2470) and are authorised on the EU market under specific conditions of use and use levels in a variety of food categories (Table 3).

Table 3: Current authorisation of use of chia seeds and chia seed oil (from the European Union list of novel foods)

Authorised novel food	**Conditions under which the novel food may be used**	
	Specified food category	**Maximum levels**
Chia seeds (*Salvia hispanica* L.)	Bread products	5% (whole or ground chia seeds)
	Baked products	10% whole chia seeds
	Breakfast cereals	10% whole chia seeds
	Sterilised ready to eat meals based on cereal grains, pseudocereal grains and/or pulses	5% whole chia seeds
	Fruit, nut and seed mixes	
	Prepacked chia seed as such	
	Confectionery (including chocolate and chocolate products), excluding chewing gums	
	Dairy products (including yoghurt) and analogues	
	Edible ices	
	Fruit and vegetables products (including fruit spreads, compotes with/without cereals, fruit-preparations to underlay or to be mixed with dairy products, fruit desserts, mixed fruits with coconut milk for a twin pot)	
	Non-alcoholic beverages (including fruit juice and fruit/vegetable blend beverages)	
	Puddings that do not require heat treatment at or above 120°C in their manufacture, processing or preparation	
Chia oil from *S. hispanica* L.	Fats and oils	10%
	Pure chia oil	2 g/day
	Food supplements as defined in Directive 2002/46/EC	2 g/day

3.5.2. History of use of the NF

Following EFSA's safety assessment in 2019 (EFSA NDA Panel, 2019b), the NF has been authorised for use in several food categories not subject to heat treatment and is placed on the EU market. The conditions of use and use levels as provided in the Union list of novel foods (Regulation 2017/2470) are presented in Table 4 below.

[9] Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. OJ L 338, 22.12.2005, p. 1–26.

Table 4: Current authorisation of use of the NF (from the European Union list of novel foods)

Authorised novel food	Conditions under which the novel food may be used	
	Specified food category	**Maximum levels**
Partially defatted chia seeds powder (*Salvia hispanica* L.) with high fibre content	Confectionery	4%
	Fruit juices and vegetable juices	2.5%
	Fruit nectars, vegetable nectars and similar products	4%
	Flavoured drinks	4%
	Food supplements excluding food supplements for infants and young children	12 g/day

In addition to being authorised in the EU market under the abovementioned conditions of use, the NF has been placed on the market of USA, Canada, Latin America, Asia and Australia without restrictions regarding the food categories in which it may be used, including multigrain bread, cereals, pasta, cookies and crackers.

3.6. Proposed uses, use levels and anticipated intake

3.6.1. Target population

The target population proposed by the applicant is the general population.

3.6.2. Proposed uses and use levels

The NF is already included in the Union list of novel foods to be added to several food categories not subjected to thermal processing (see Table 4 in Section 3.5.2). The Panel notes that the current extension of use of the NF is referring to several food categories with relatively high moisture content (e.g. cakes contain 15–30% moisture, and pastry 11–15% moisture) that are subject to thermal processing and does not include products with a low moisture content such as breakfast cereals, crackers, chips, crisps, biscuits etc.

Table 5 below summarises the previously authorised proposed uses and use levels of the NF (EFSA NDA Panel, 2019b) as well as the requested extension of use using the food categories presented in Annex II, Part D of Regulation (EC) No 1333/2008[10] for the purposes of the EFSA Food Additives Intake Model (FAIM).[11]

Table 5: Food categories and maximum use levels of the NF

	Food category	**Products**	**Proposed use levels (g/100 g)**
Previously authorised	Confectionery	05.1 Cocoa and chocolate products 05.2.1 Other confectionery with added sugar 05.2.2 Other confectionery without added sugar	4
	Fruit juices as defined by Directive 2001/112/EC[(a)] and vegetable juices	14.1.2.1 Fruit juices 14.1.2.2 Vegetable juices	2.5
	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	14.1.3 Fruit and vegetable nectars and similar products	4
	Flavoured drinks	14.1.4.1 Flavoured drinks with sugar 14.1.4.2 Flavoured drinks with sweetener	4

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

[11] https://www.efsa.europa.eu/sites/default/files/applications/FAIM-instructions.pdf

	Food category	Products	Proposed use levels (g/100 g)
New proposed food categories	Fine bakery wares	Cakes and pastries	5
	Processed fruit and vegetables	04.2 Processed fruit and vegetables (including vegetable-based dishes)	10
	Bread	07.1 Bread and rolls	10
	Pasta	06.4 Pasta	8
	Protein products	12.9 Protein products, excluding products covered in category 1.8[(b)]	10

(a): Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption. OJ L 10, 12.1.2002, p. 58–66.
(b): Category 1.8 is defined in Annex II Part D of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (*OJ L 354, 31.12.2008, p. 16–33*) '01.8 Dairy analogues, including beverage whiteners'.

3.6.3. Anticipated intake of the NF

Considering that no hazard has been identified based on the production process, composition, specifications and proposed uses of the NF, the Panel considers that intake estimates are not needed for this assessment on the extension of use of the NF.

3.7. Nutritional information

The applicant provided a nutritional analysis of five batches of the NF. The analyses show that the NF is mainly composed of dietary fibre (~ 63%), protein (~ 24%), fat (~ 8%), water (~ 5%) and ash (~ 5%). Previously, the Panel noted that the fatty acid, amino acid and carbohydrate profiles of the NF were similar to those of chia seeds (EFSA NDA Panel, 2019b).

The Panel considers that, with regards to the compositional data of the NF and the proposed changes in the conditions of use, its consumption is not nutritionally disadvantageous.

3.8. Toxicological information

The Panel considers that no toxicological studies are required on the NF given that the production process and the composition of the NF do not raise a safety concern.

3.8.1. Human data

The applicant provided one human study using the NF as a test substance (Unpublished report, 2019). The study was a randomised, double-blind, placebo-controlled human trial with 48 healthy subjects randomised into four groups (n = 12 for each group). Each group was receiving a 3 × 12 g sachet/day of either 100% NF, 66% NF + 33% maltodextrin, 66% maltodextrin +33% NF or 100% maltodextrin (placebo) for 4 weeks. The daily intake of the NF was 0, 12, 24 or 36 g/day. The study addressed the digestive tolerance of the NF and the appearance of digestive symptoms in healthy subjects via an online survey. Overall, the study observed moderate changes in the digestive function, mainly in subjects consuming 100% NF, equal to 36 g/day, exhibiting increased borborygmi and flatus, incomplete evacuation and hard stools in the first week of the study.

Considering the low number of subjects, limited number of endpoints as well as the short duration of the study, the Panel considers the study of limited value for the safety assessment of the NF.

In addition to the human studies reported in the previous assessment on chia seeds (EFSA NDA Panel, 2019a), the applicant refers to three recent clinical studies examining the effects of chia seeds on haematological and biochemical endpoints in humans. These studies are summarised in Table 6 below.

Table 6: Summary of recent publicly available human data on chia seeds

Reference	Study design	Study population	Duration of study	Doses; route of administration if relevant	Safety-related parameters investigated
Da Silva et al. (2020)	Double-blinded, randomised, placebo controlled	30 children (5–10 years old)	75 days	25 g/day grounded chia seeds or corn starch placebo. Oral administration	Biochemical parameters (homocysteine, ALT, AST, GGT, CRP, thiobarbituric acid reactive substances, fibrinogens, proinflammatory factors (TNF-α, NF-κb, [IL]-6, and vitamin E, TC and fractions, TGs, glucose, insulin and a complete blood count evaluation)
Alwosais et al. (2021)	Randomised, controlled study	42 adults with type 2 diabetes mellitus	12 weeks	40 g/day chia seeds or no supplementation. Oral administration	Biochemical parameters (glucose, HDL, cholesterol, TGs, LDL, HbA1c, CRP, insulin); Blood pressure
Medina-Urrutia et al. (2020)	Non-controlled study	25 patients with non-alcoholic fatty liver disease	8 weeks	25 g/day milled chia seeds Oral administration	Biochemical parameters (glucose, TC, HDL, TGs, ALT, AST, GGT, uric acid, LDL, free fatty acids); Computed tomography (liver: spleen attenuation ratio and visceral abdominal fat)

ALT: alanine aminotransferase; AST: aspartate aminotransferase; GGT: gamma-glutamyl transferase; CRP: C reactive protein; TNF-α: tumour necrosis factor α; NF-κB: nuclear factor κB; IL-6: interleukin 6; TC: total cholesterol; TGs: triglycerides; HDL: high-density lipoproteins; LDL: low-density lipoproteins; HbA1c: haemoglobin A1c.

The Panel notes that the human studies performed with chia seeds or chia seed flour were primarily designed to investigate putative beneficial effects and addressed only a limited number of safety-relevant endpoints such as standard clinical chemistry, haematology parameters and blood pressure. The Panel notes that no changes were found in the studied safety-related parameters and no adverse events related to the consumption of chia seeds were reported. The Panel notes, however, the inherent limitations of such human studies for their use in this safety assessment.

3.9. Allergenicity

The Panel notes that no allergenicity data were provided for the NF. However, since the manufacturing process is unlikely to change the allergenic potential of the NF, the Panel considers it as similar to the allergenic potential of chia seeds used as source material (EFSA NDA Panel, 2019a,b).

In the 2009 opinion, the Panel noted the possible cross-reactivity of sera from patients allergic to peanuts and sesame and reiterated that it was not possible to predict the potential allergenicity of chia seeds (EFSA NDA Panel, 2005, 2009). Additional information from two case reports (García Jiménez et al., 2015; Tomas-Pérez et al., 2018) indicates that allergic reactions upon consumption of chia seeds may occur.

A recent study (Albunni et al., 2019) extended this information. They investigated cross-reactivity among chia seeds' storage proteins and observed also IgE binding to hazelnut.

The Panel considers it likely that the NF may trigger allergic reactions, in particular in peanut, sesame and hazelnut allergic subjects.

4. Discussion

The NF, which is the subject of the application, is a partially defatted chia seed powder (*S. hispanica* L.) with a high fibre content and an average particle size of < 400 μm. The NF is currently authorised for use in the EU market in a variety of non-heat-treated food products, such as confectionery products, fruit and vegetable juices and nectars, flavoured drinks and food supplements (EFSA NDA Panel, 2019b). The source of the NF, chia seeds (*S. hispanica* L.), has been assessed by EFSA previously (EFSA NDA Panel, 2005, 2009, 2019a).

The NF consists mainly of dietary fibre, proteins and a lesser amount of fat. The target population is the general population.

To address the concern of increased formation of acrylamide in foods with added chia seed powder subjected to thermal processing, the applicant submitted a study on the formation of process contaminants in bread containing the NF. The asparagine and glutamine concentrations (precursors for acrylamide formation) in the NF were analysed and found to be comparable to those in the control (wheat) flour. The results of this study do not indicate an increase in the acrylamide formation in bread containing 5% or 10% added NF. The Panel notes that the higher moisture in the final products due to the increased absorption and retention of water by the mucilage content of the NF may hinder formation of acrylamide by heat treatment of food with relatively high moisture content.

The Panel noted that the current application is limited to the extension of use of the NF in additional food categories that are subject to thermal processing that have a relatively high moisture content, such as cakes, pastries, processed fruits and vegetables, vegetable-based dishes, bread, pasta and protein products. The Panel notes that the moisture content in these products is sufficient to limit the formation of acrylamide during thermal processing of the food (Sadd and Hamlet, 2005; Ciesarová et al., 2006; EFSA CONTAM Panel, 2015).

The Panel considers it likely that the NF may trigger allergic reactions, in particular in peanut, sesame and hazelnut allergic subjects.

5. Conclusions

The Panel concludes that the NF, partially defatted chia seed (*S. hispanica* L.) powder with high fibre content, is safe under the proposed conditions of use.

5.1. Protection of Proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283

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 (study on the formation of process contaminants with related certificates of analysis and human study).

6. Steps taken by EFSA

1) On 23/03/22 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of the change of the conditions of use of partially defatted chia seed (*Salvia hispanica* L.) powder with high fibre content (Ref. Ares (2022)2117103).
2) On 23/03/22, a valid application on the change of the conditions of use of partially defatted chia seed (*Salvia hispanica* L.) powder with high fibre content, which was submitted by Functional Products Trading Arica S.A./BENEXIA, Chile, was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2021/1311) and the scientific evaluation procedure was initiated.
3) On 28/07/2022, 18/10/2022, 12/12/2022 and on 20/01/2023, EFSA requested the applicant to provide additional information and clarifications to accompany the application and the scientific evaluation was suspended.
4) On 27/09/2022, 21/11/2022, 21/12/2022 and on 24/01/2023 additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
5) During its meeting on 27/02/2023 the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of the change of the conditions of use of partially defatted chia seed (*Salvia hispanica* L.) powder with high fibre content as a NF pursuant to Regulation (EU) 2015/2283.

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Abbreviations

ALT	alanine aminotransferase
AST	aspartate aminotransferase
CFU	colony forming units
CONTAM	EFSA Panel on Contaminants in the Food Chain
CRP	C-reactive protein
FAIM	Food Additive Intake Model
GGT	gamma-glutamyl transferase
HbA1c	Haemoglobin A1c
HDL	high-density lipoproteins
HS-GC/MS	headspace-gas chromatography/mass spectrometry
IC-UV/Vis	ion chromatography coupled with UV/visible detector
IL-6	interleukin-6
LC–MS/MS	liquid chromatography tandem mass spectrometry
LDL	low-density lipoproteins
LOQ	limit of quantification
MPN	most probable number
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food
NF-κB	nuclear factor κB
TC	total cholesterol
TG	triglycerides
TNF-α	tumour necrosis factor alpha