REGULATED PRODUCTS SAFETY ASSESSMENT

# Assessment on the Change of Conditions of Use of the Novel Food, Partially Defatted Chia Seed (*Salvia Hispanica* L.) Powder With a High Fibre Content (RP2158)

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Keywords: Regulated Products, Safety assessment, Novel foods

https://doi.org/10.46756/001c.129209

FSA Research and Evidence

Functional Products Trading Arica S.A./BENEXIA, Chile ("the applicant") submitted a novel food application for the authorisation of the change in the conditions of use of partially defatted chia seed powder with a high fibre content as a novel food to each nation of Great Britain in December 2023.

The novel food is manufactured by cold press extraction of chia seeds to partially remove the seed oil. The pressed chia seeds are then ground into a powder with a particle size ≤ 400 µm and a fibre content ≥ 50%.

Partially defatted chia seed powder with a high fibre content is currently authorised as a novel food in the UK and EU under assimilated Regulation (EU) 2017/2470. This new application is for a change in the conditions of use seeking to extend the intended use of defatted chia seed powder with a high fibre content within the food categories: fine bakery wares; processed fruit and vegetables; bread; pasta; and protein products. The assessment is limited to food products within these additional food categories which are subject to thermal processing and have a high moisture content.

This novel food had its application for authorisation assessed by the European Food Safety Authority (EFSA) which was published in April 2023. The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have reviewed the information available, including the EFSA opinion, and confirmed that partially defatted chia seed powder with a high fibre content is safe under the intended changes in the conditions of use. The anticipated intake levels and intended use in food were not considered to be nutritionally disadvantageous.

This assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication


# 1. Introduction

In accordance with assimilated Regulation (EU) 2015/2283 on novel foods, the application RP2158, for the change in the conditions of use of partially defatted chia seed powder with a high fibre content as a novel food, has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the risk assessments of the European Food Safety Authority (EFSA) in respect of authorisations for regulated food and feed products. Since the end of the transition period, the FSA and FSS have adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

To ensure our regulatory systems are risk proportionate, and resources are used effectively, the FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA risk assessment opinion, to inform this assessment.

The FSA and FSS have evaluated the published EFSA risk assessment on the novel food and confirmed that this is appropriate for GB risk analysis. Consideration has been given to the processes undertaken to ensure the EFSA opinion is robust and whether there are any aspects that would require further review, such as specific issues for the countries of GB. The result of the assessment is that there is sufficient evidence of safety to conclude without requiring further risk assessment at this time.

This assessment represents the opinion of the FSA and FSS.

# 2. Details of other Regulators Opinions

The applicant, Functional Products Trading Arica S.A./BENEXIA (Chile), is seeking authorisation for the change in the conditions of use of partially defatted chia seed powder with a high fibre content as novel food.

The first novel food application was submitted by the applicant in April 2018 and received a positive EFSA opinion which was published in May 2019 (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA),

2019b). The novel food is currently authorised in GB (and listed in assimilated Regulation (EU) 2017/2470) for use in the following food categories: confectionary, fruit juices as defined by assimilated Directive 2001/112/EC and vegetable juices, fruit nectars as defined by assimilated Directive 2001/112/EC and vegetable nectars, flavoured drinks, and food supplements. This was implemented in UK law through assimilated Regulation (EU) 2017/2470.

The safety of the changes in the conditions of use of partially defatted chia seed powder with a high fibre content (Functional Products Trading Arica S.A./BENEXIA, Chile) was assessed by EFSA and a positive opinion was published in April 2023 (EFSA NDA Panel, 2023). This opinion has been reviewed by the FSA and FSS risk assessors.

## 2.1. Methodology applied in the EFSA Opinion

EFSA conducted the assessment of the novel food in accordance with the procedure as outlined in the EFSA scientific opinion 'Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1)' (EFSA NDA Panel, 2021) and Commission Implementing Regulation (EU) 2017/2469.

Under Article 3(4) of Commission Implementing Regulation (EU) 2017/2469, it may not be necessary for the applicant to provide all the data required under Article 5 of this Regulation when a novel food application seeks to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food. Verifiable justification explaining that the intended changes do not affect the results of the existing safety assessment is provided by the applicant. Given that the novel food is identical to the one reviewed in the previous assessment, this new safety assessment has focused on the impact of the intended changes of use for novel food.

The novel food was already assessed and authorised under Commission Implementing Regulation (EU) 2017/2470. This resulted in the inclusion of defatted chia seed on the permitted list of novel foods in the EU and UK. As the identity of the novel food and its production process remain unchanged, the conclusions drawn from the information provided in the original application on the identity of the novel food; the production process; the compositional information, stability and specification; absorption, distribution, metabolism and excretion (ADME); the toxicity and the allergenicity, would not be affected by the proposed change in condition of use. Therefore, this information was not provided or reviewed as part of the assessment.

The FSA and FSS agree with the view that the changes in the conditions of use do not alter the previous assessment of the novel food composition and specification, or the conclusion that no safety concerns have been identified. As such, the focus of this review has been the impact of the changes to the conditions of use to extend the uses in the following food categories: fine bakery wares; processed fruit and vegetables; bread; pasta; and protein products.

## 2.1.1. Identity of the novel food

The novel food is partially defatted chia seed powder with a particle size ≤ 400 µm and a fibre content ≥ 50% (EFSA NDA Panel, 2023).

The identity of the novel food is not changed in this application to modify the conditions of use of partially defatted chia seed powder with a high fibre content. The FSA and FSS considered that no further assessment on the identity of the novel food was necessary.

## 2.1.2. Production process

No changes have been made to the novel food production process in this application.

In the original assessment, EFSA concluded that the data provided on the novel food production process was sufficient and did not give rise to any safety concerns (EFSA NDA Panel, 2019b). The FSA and FSS agreed with this conclusion, and the changes to the conditions of use sought in this application do not change this opinion.

No further assessment on the production process was considered necessary by the FSA and FSS.

## 2.1.3. Compositional information and specification

The novel food is primarily composed of dietary fibre (≥ 50%), protein (≥ 24%) and fat (≤ 12%), and has moisture content of ≤ 9% (EFSA NDA Panel, 2023).

Analytical data on the composition of the novel food, along with the chemical contaminants and the microbiological quality, was reviewed in the original assessment. EFSA concluded that this data did not give rise to any safety concerns (EFSA NDA Panel, 2019b). The FSA and FSS agreed with EFSA's conclusion, and the changes to the conditions of use sought in this application do not change this opinion.

No additional compositional data was provided in this application (EFSA NDA Panel, 2023).

The FSA and FSS considered that no further assessment on the composition of the novel food was necessary.

The oxidative stability of the novel food was assessed in the original assessment. EFSA concluded that the data provided did not give rise to any safety concerns (EFSA NDA Panel, 2019b). The FSA and FSS agreed with EFSA's conclusion, and the changes to the conditions of use sought in this application do not change this opinion.

No additional oxidative stability data was provided for either the novel food or the novel food as an ingredient in the intended food categories (EFSA NDA Panel, 2023).

The FSA and FSS considered that no further assessment on the oxidative stability of the novel food was necessary.

As the new uses include food subject to thermal processing, consideration was given to the potential to impact the formation of process contaminants such as acrylamide. A previous study reported that partially replacing wheat flour with chia flour as a dough ingredient in biscuits, followed by baking at 190°C, may lead to a substantial increase in levels of acrylamide (EFSA NDA Panel, 2019a; Mesıas et al., 2016). Using bread as a food category, an investigation was conducted to evaluate the impact of the novel food on the formation of process contaminants during thermal processing (EFSA NDA Panel, 2023).

Three batches of novel food from different geographical regions (Bolivia or Mexico) and different years of harvest (2018, 2019 or 2020), and one batch of wheat flour (Spain – control), were used in the prepare bread dough. In total, twenty-one loaves composed of wheat and different contents of novel food (0%, 5% or 10%) were prepared under different cooking conditions (210°C or 220°C for 20 min, or 210°C for 25 min). The acrylamide content was determined in triplicate by liquid chromatography – tandem mass spectrometry (LC-MS/MS). The furan and methylfuran content were determined in triplicate by headspace gas chromatography – mass spectrometry (HS-GC/MS). The moisture content was determined by drying the bread. The results are summarised in Table 1.

Acrylamide is a product of the Maillard reaction, where amino acids, usually asparagine and glutamine, react with reducing sugars (Mottram et al., 2002; Stadler et al., 2002). The free asparagine and glutamine content for each batch of the novel food and the wheat flour was determined in triplicate by ion chromatography – ultra-violet/visible spectrometry (IC-UV/Vis). There were no significant differences in the asparagine content in any batch of the novel food compared to the wheat flour. The glutamine content was below the limit of quantification (LOQ) (0.005 g/100 g) in all batches of the novel food.

Control bread samples (wheat flour only) had a higher acrylamide content than bread containing 5% or 10% novel food, despite the similar asparagine content in both the novel food and the wheat flour. The control bread samples also had a lower moisture content after baking compared to the bread made with the novel food.

Previously, Galluzo *et al.* (2021) investigated the formation of acrylamide in bread baked at 200°C for 20 minutes with different percentages of chia seeds (2%, 5%, 7% and 10%). No significant differences were reported in the acrylamide levels between wheat bread with up to 10% chia seeds and wheat bread without chia seeds.

Munoz *et al.* (2012) reported that the mucilage from chia seeds has a high water-binding capacity. The bread made with the 5% and 10% novel food had a higher water retention compared to the control (Table 1).

Sadd and Hamlet (2005) observed that low moisture content promotes acrylamide formation. The moisture levels in the bread crust are a key factor contributing towards increased acrylamide formation. When the moisture levels decrease significantly during baking, the temperature of the crust approaches oven temperature. Other studies have demonstrated that relatively higher moisture contents reduce the acrylamide content in foods (Ahrne et al., 2007; Clesarova et al., 2006).

The FSA/FSS agrees with the EFSA's conclusion that the higher retention of water in baked products such as bread appears to reduce acrylamide formation during thermal processing (Clesarova et al., 2006; EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015; Sadd & Hamlet, 2005).

Furans and methylfurans are volatile compounds that form during thermal processing of foods. Ascorbic acid, carbohydrates, amino acids, unsaturated fatty acids and carotenoids are all precursors for the formation of these contaminants (EFSA CONTAM, 2017; Moro et al., 2012).

Furan levels up to 8.6 µg/kg were found in bread containing 5% novel food. Although higher than the control samples in this study, these levels are lower than the average levels found in bread and rolls, raw pasta, breakfast cereals or fine bakery wares (16 – 30 µg/kg) (EFSA CONTAM, 2017). For 2-methylfuran, the levels in some samples of bread containing 5% novel food were higher than the control levels. By contrast, 3-methylfuran levels were below the limit of quantification in all samples.

Based on these results, foods containing up to 10% novel food which are subject to thermal processing are not expected to contribute to elevated production of acrylamide, furan or methylfurans compared to similar products without the novel food.

Table 1. The mean levels of process contaminants in bread containing 5% and 10% novel food

| Parameter | Control 1<br>210°C<br>20 mins | 5% NF<br>210°C<br>20 mins | 10% NF<br>210°C<br>20 mins | Control 2<br>220°C<br>20 mins | 5% NF<br>220°C<br>20 mins | 10% NF<br>220°C<br>20 mins | Control 3<br>210°C<br>25 mins | 5% NF<br>210°C<br>25 mins | 10% NF<br>210°C<br>25 mins |
|---|---|---|---|---|---|---|---|---|---|
| Moisture (%) | 29.2 | 30.8 | 32.5 | 28.7 | 31.4 | 32.7 | 27.7 | 29.2 | 33.5 |
| Acrylamide (µg/kg) | 46.6 | 35.6 * | 31.6 | 52.3 | 31.2 | 28.9 | 51.2 | 38.4 * | 34.2 |
| Furan (µg/kg) | < 5 | 5.6 * | < 5 | < 5 | 5.3 * | < 5 | < 5 | 6.8 * | < 5 |
| 2-methylfuran (µg/kg) | < 5 | 7.0 | < 5 | < 5.7 ** | 9.3 | < 5 | < 6.3 ** | 10.1 | < 5 |
| 3-methylfuran (µg/kg) | < 5 | < 5 | < 5 | < 5 | < 5 | < 5 | < 5 | < 5 | < 5 |

NF = novel food

Process contaminant levels reported for 5% NF and 10% NF are mean values derived from the analysis of three independent batches of NF

* Upper bound limit used to determine mean where any reported value < LOQ

** Analytical laboratory reports that when interferences are observed in the analysis of furans, the LOQ is raised

The novel food is also intended to be used in plant-based meat analogues. Published data reports that high-moisture thermo-extrusion, a widely used production process for these types of food products, can reduce the production of acrylamide. This is due to the relatively high moisture content in the food and the moderate temperatures during the manufacturing process (Akdogan, 1999). Using this procedure, plant-based meat analogues contain 50 – 80% moisture content (Cheftel et al., 1992; Isobe & Noguchi, 1987; Wild et al., 2014).

EFSA concluded that the data provided was sufficient to address the concerns regarding the production of process contaminants in the intended food categories subjected to heat treatment (EFSA NDA Panel, 2023).

The FSA and FSS have reviewed this information and agreed with this conclusion. No further assessment on the production of the process contaminants was considered necessary.

The specification of the novel food, as authorised in assimilated Commission Regulation (EU) 2017/2470, is summarised in Table 2.

Table 2. Specification of the novel food

| Parameter | Specification | Method of analysis |
|---|---|---|
| Foreign matter | ≤ 0.1 % | Internal method |
| Particle size | ≤ 400 µm | Laser scattering |
| Moisture | ≤ 9% | ISO 711 |
| Protein | ≥ 24 % | Kjeldahl method |
| Fat | ≤ 12 % | Soxhlet extraction |
| Fibre | ≥ 50% | AOAC 991.43 |
| Arsenic | ≤ 0.1 ppm | AOAC 986.15 |
| Cadmium | ≤ 0.1 ppm | AOAC 986.15 |
| Lead | ≤ 0.1 ppm | AOAC 986.15 |
| Mercury | ≤ 0.1 ppm | AOAC 971.21 |
| Total aflatoxins | ≤ 4 ppb | LC-MS/MS |
| Ochratoxin A | ≤ 1 ppb | LC-MS/MS |
| Total plate count | ≤ 10,000 CFU/g | ISO 4833 |
| Yeasts | ≤ 500 CFU/g | ISO 21527 |
| Moulds | ≤ 500 CFU/g | ISO 21527 |
| *Staphylococcus aureus* | ≤ 10 CFU/g | ISO 6888-1 |
| Coliforms | < 100 MPN/g | ISO 4831 |
| Enterobacteriaceae | ≤ 100 CFU/g | ISO 21528-2 |
| *Bacillus cereus* | ≤ 50 CFU/g | ISO 7932 |
| *Escherichia coli* | < 10 MPN/g * | ISO 7251 |
| *Listeria monocytogenes* | Absence in 1 g * | ISO 11290-1 |

| Parameter | Specification | Method of analysis |
|---|---|---|
| *Salmonella* | Absence in 25 g | ISO 6579 |

AOAC = Association of Official Agricultural Chemists; CFU = colony forming unit; ISO = International Organisation for Standardisation; LC-MS/MS = liquid chromatography – tandem mass spectrometry; MPN = most probable number; ppb = parts per billion; ppm = parts per million

* The specification for *Listeria monocytogenes* ('Absence/g') and *Escherichia coli* ('< 10 MPN/g') in assimilated Commission Regulation (EU) 2017/2470 is incorrect. To ensure compliance with assimilated Regulation (EC) 2073/2005 and the methods of analysis used, the specification for *Listeria monocytogenes* should be reported as 'not detected in 25 g' and *Escherichia coli* as 'not detected in 10 g (EFSA NDA Panel, 2023).

This specification is unchanged from the original assessment and the FSA and FSS agree that further review is not needed.

## 2.1.4. History of use

The novel food is produced from chia (*S. hispanica* L.) seeds. Chia is a summer annual herbaceous plant which is a member of the Lamiaceae plant family. The plant is native to Central and South America (Mexico, Argentina and Bolivia) where there is a long history of traditional food use by the indigenous South American populations. There is also a more recent documented history of use for chia in the USA, Canada, Australia and the EU (EFSA NDA Panel, 2023).

Table 3. Current authorisation for food use of chia seeds under assimilated Regulation (EU) 2017/2470

| Food Category Name | Maximum Use Level |
|---|---|
| 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 vegetable 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 | |

Table 4. Current authorisation for food use of chia seed oil under assimilated Regulation (EU) 2017/2470

| Food Category Name | Maximum Use Level |
|---|---|
| Fats and oils | 10 % |
| Pure chia oil | 2 g/day |
| Food Supplements * | 2 g/day |

* Food Supplements as defined in the Food Supplements (England) Regulations 2003/1387, the Food Supplements (Wales) Regulations 2003/1719 and the Food Supplements (Scotland) Regulations 2003/278

The safe use of chia seeds has been established in the EU (EFSA NDA Panel, 2009; EFSA NDA Panel, 2019b, EFSA NDA Panel, 2019a). Chia seeds and oil are both authorised under assimilated Regulation (EU) 2017/2470 under specific conditions of use and maximum use levels in a variety of food categories (Tables 3 and 4).

The novel food is currently authorised under assimilated Regulation (EU) 2017/2470 for use in several food categories not subject to heat treatment (Table 5) including confectionary, fruit and vegetable juices, fruit and vegetable nectars, flavoured drinks and food supplements for infants and young children.

Table 5. Current authorisation for the food use of the novel food under assimilated Regulation (EU) 2017/2470

| Food Category Name | Maximum Use Level |
|---|---|
| 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 |

* Food Supplements as defined in the Food Supplements (England) Regulations 2003/1387, the Food Supplements (Wales) Regulations 2003/1719 and the Food Supplements (Scotland) Regulations 2003/278, for infants and children (under 3 years)

The novel food has been placed on the market in the USA, Canada, Latin America, Asia and Australia. In these geographical regions, there are no restrictions on the food categories where the novel food can be used as a food ingredient (EFSA NDA Panel, 2023).

## 2.1.5. Proposed use and intake

The target population is the general population.

The novel food is already authorised for use in food categories which are not subjected to thermal processing. The intended changes in the conditions of use of the novel food include food categories with a relatively high moisture content that are subject to thermal processing (e.g., cakes 15 – 30% moisture; pastry 11 – 15% moisture).

The intended food categories and maximum use levels are listed in Table 6.

Table 6. Food Categories and Maximum Use Levels of the novel food

| Food Category Name | Food products | Maximum Use Level (g/100g) |
|---|---|---|
| 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 * | 10 |

* 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'.

In the previous assessment for chia seeds, no hazard was identified that required an exposure assessment (EFSA NDA Panel, 2019a).

The novel food is partially defatted chia seed powder with a high fibre content. No hazards were identified based on the production process, composition, specification and proposed uses for the novel food. For these reasons, an intake assessment on the changes in the conditions of use for the novel food was not required (EFSA NDA Panel, 2023).

The FSA and FSS agreed with this conclusion and no further assessment on the proposed use and intake was necessary.

## 2.1.6. Absorption, Distribution, Metabolism and Excretion (ADME)

No information was provided in the original assessment (EFSA NDA Panel, 2019b) or in this application to change the conditions of use of the novel food (EFSA NDA Panel, 2023).

The FSA and FSS considered that no further assessment was necessary given the nature of the novel food.

## 2.1.7. Nutritional information

Nutritional analysis of five independent batches of the novel food confirmed that partially defatted chia seed powder with a high fibre content is mainly composed of dietary fibre (~ 63%), protein (~ 24%), fat (~ 8%), water (~ 5%) and ash (~ 5%) (EFSA NDA Panel, 2023).

The fatty acid, amino acid and carbohydrate profiles of the novel food are similar to chia seeds (EFSA NDA Panel, 2019a).

EFSA concluded that consumption of the novel food under the intended changes in the conditions use is not expected to be nutritionally disadvantageous for consumers (EFSA NDA Panel, 2023).

The FSA and FSS agreed with this conclusion, and no further assessment on the nutritional information of the novel food was considered necessary.

## 2.1.8. Toxicological information

The production process and the composition of the novel food did not give rise to any safety concerns. On this basis, EFSA concluded that no toxicological studies were required (EFSA NDA Panel, 2023).

The FSA and FSS agreed with this decision and considered that no further toxicological studies on the novel food were necessary.

### 2.1.8.1. Human trials

The digestive tolerance of the novel food was assessed in a randomised, double-blind, placebo-controlled human trial with 48 healthy subjects in four groups (n = 12 for each group) (Gotteland, 2019 [unpublished]). Each group received 3 x 12 g sachet/day of either 100% novel food, 66% novel food + 33% maltodextrin, 66% maltodextrin + 33% novel food or 100% maltodextrin (placebo) for 4 weeks. At the end of the study, moderate changes were observed in the digestive function of subjects consuming the highest dose of the novel food.

The results only provide limited information to support the assessment of the safety of the novel food due to the low number of subjects, the limited number of endpoints, and the short duration of the study (EFSA NDA Panel, 2023).

Published clinical studies examining the effects of chia seeds on haematological and biochemical endpoints in humans were referenced (Alwosais et al., 2021; Da Silva et al., 2020; Medina-Urrutia et al., 2020). These studies were designed to investigate beneficial effects of chia seed or chia seed flour but only addressed a limited number of safety-relevant endpoints, such as standard clinical chemistry, haematology parameters and blood pressure.

No changes in the safety-related parameters and no adverse events related to the consumption of chia seeds were reported in these studies. However, the information from these clinical trials only provides limited support for assessing the safety of the novel food (EFSA NDA Panel, 2023).

The FSA and FSS agreed with this decision and considered that no further human studies on the novel food were necessary.

### 2.1.9. Allergenicity

No allergenicity data was provided for the novel food.

The manufacturing process is unlikely to change the allergenicity of the source of the novel food; therefore, partially defatted chia seed powder with a high fibre content is expected to have similar allergenic potential as chia seeds (EFSA NDA Panel, 2019b, EFSA NDA Panel, 2019a).

Possible cross-reactivity to chia seeds using sera from patients with clinically relevant allergy to peanut and sesame have been reported (EFSA NDA Panel, 2005, EFSA NDA Panel, 2009). In addition, two case reports linked the consumption of chia seeds to an immunoglobulin E (IgE)-mediated anaphylactic reaction (García Jimenez et al., 2015) and IgE-mediated reaction with atypical manifestations (Tomas-Perez et al., 2018).

A recent study (Albunni et al., 2019) investigated the cross-reactivity of storage proteins from chia seeds and observed IgE binding to hazelnut.

EFSA concluded that the novel food may trigger allergic reactions, particularly in consumers with clinically relevant allergy to peanut, sesame or hazelnut.

It was noted that the probable prevalence of food allergy to peanut in the UK is 1.76 % of the adult population (Simpson et al., 2024), and as such the potential cross reactivity for this population is a consideration in the assessment.

The FSA and FSS agreed with the conclusions of EFSA that the changes to the conditions of use sought in this application do not change the opinion on the allergenicity of the novel food (EFSA NDA Panel, 2023).

No further assessment of the allergenicity of the novel food was considered necessary by the FSA and FSS.

# 3. Other Regulators Opinions and Conclusions

The novel food is partially defatted chia seed powder with a high fibre content.

The novel food is currently authorised for use in the GB in a variety of food products which are not subjected to thermal treatment, such as confectionery products, fruit and vegetable juices and nectars, flavoured drinks and food supplements (EFSA NDA Panel, 2019b).

The source of the novel food, chia seeds (*S. hispanica* L.), has previously been assessed (EFSA NDA Panel, 2005, EFSA NDA Panel, 2009; EFSA NDA Panel, 2019b).

The novel food is primarily composed of dietary fibre (≥ 50%), protein (≥ 24%) and fat (≤ 12%), and has moisture content of ≤ 9%.

The presence of chia seed powder in foods which undergo thermal processing could lead to increased formation of acrylamide. A study was conducted to evaluate the formation of process contaminants in bread containing the novel food. The asparagine and glutamine concentrations (precursors for acrylamide formation) in the novel food were analysed and found to be comparable to those in wheat flour (control). However, the levels of acrylamide in bread containing either 5% or 10% novel food were lower than the control. This difference was attributed to the relatively high moisture content of the bread containing the novel food. The mucilage content of the novel food increases the absorption and retention of water in the bread which appears to reduce acrylamide formation during thermal processing (Clesarova et al., 2006; EFSA CONTAM Panel, 2015; Sadd & Hamlet, 2005).

The assessment of the change in the conditions of use of the novel food is limited to food products within the additional food categories which are subject to thermal processing and have a high moisture content, e.g. fine bakery wares; processed fruit and vegetables; bread; pasta; and protein products. The moisture content in these products is sufficient to limit the formation of acrylamide during thermal processing of the food.

Consumption of the novel food may trigger allergic reactions, particularly in consumers with clinically recognised allergy to peanut, sesame or hazelnut.

# 4. Uncertainties and Limitations

No specific uncertainties were flagged in the assessment by EFSA. The FSA and FSS did not identify further uncertainties to be considered for this assessment.

# 5. FSA-FSS conclusion for GB assessment

The application has been evaluated in line with 'Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of assimilated Regulation (EU) 2015/2083 (EFSA NDA Panel, 2016), and assimilated Regulation (EU) 2017/2469, for purposes of the GB assessment.

The conclusions of the EFSA opinion (EFSA NDA Panel, 2023), which have been reviewed in detail by the FSA and FSS for the purposes of the GB assessment, are considered appropriate and consistent within the uncertainties and limitations identified by EFSA.

# 6. Outcome of the assessment

The FSA and FSS has reviewed the applicant's dossier, supporting documentation, and most notably the EFSA opinion (EFSA NDA Panel, 2023), and consider that there is sufficient evidence to conclude the assessment of the changes in the condition of use of partially defatted chia seed powder with a high fibre content without obtaining further information or conducting a further risk assessment.

The FSA and FSS could not have completed the assessment of the novel food under the intended conditions of use without the following data claimed as proprietary by the applicant:

1. the study on the formation of process contaminants and the related certificates of analysis
2. the human digestive tolerance study

The FSA and FSS conclude that partially defatted chia seed powder with a high fibre content is safe under the proposed conditions of use. The anticipated intake levels and the proposed use in food is not considered to be nutritionally disadvantageous.

In making this assessment, the FSA and FSS were able to rely on sufficient scientific evidence to make a conclusion on safety with no further questions to the applicant, and therefore no further risk assessment activities are necessary.

Sufficient evidence was available in the literature to give the FSA and FSS confidence about the safety of this novel food, for example, where other national food safety authorities had positively assessed the application using the same risk assessment guidance and core legal requirements which apply in GB.

Applicants provided sufficient relevant information as requested by the FSA and FSS.

The FSA and FSS review did not find any issues of divergence from the EFSA guidance (EFSA NDA Panel, 2021) or mutual approaches or new scientific issues for consideration.

There were no other specific issues that would require an assessment for the UK or the nations of the UK.

# Abbreviations

| Abbreviation | Definition |
|---|---|
| ACNFP | Advisory Committee on Novel Foods and Processes |
| AOAC | Association of Official Agricultural Chemists |
| CONTAM | Panel on Contaminants in the Food Chain |
| CFU | Colony forming unit |
| EFSA | European Food Safety Agency |
| EU | European Union |
| FSA | Food Standards Agency |
| FSS | Food Standards Scotland |
| GB | Great Britain |
| HS-GC/MS | Headspace gas chromatography – mass spectrometry |
| IgE | Immunoglobulin E |
| IC-UV/Vis | Ion chromatography – ultra-violet/visible spectrometry |
| ISO | International Organisation for Standardisation |
| LOQ | Limit of quantification |
| LC-MS/MS | Liquid chromatography – tandem mass spectrometry |
| MPN | Most probable number |
| NDA | Panel on Dietetic Products Nutrition and Allergies |
| ppb | Parts per billion |
| ppm | Parts per million |

Published: February 28, 2025 GMT.

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