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Safety of chia seeds (*Salvia hispanica* L.) powders, as novel foods, 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 chia seeds (*Salvia hispanica* L.) powders as novel foods (NFs) pursuant to Regulation (EU) 2015/2283. The NFs are partially defatted chia seed powders, obtained by extrusion of whole seeds of *S. hispanica* L. with the main differences between two powders in particle sizes and the content of some macronutrients. The information provided on the production processes, composition, batch-to-batch variability, stability and specifications of the NFs is sufficient and does not raise safety concerns. The applicant proposed to market the NFs as food supplements and as ingredients in a variety of foods. The target population for the NFs is the general population. Noting that no hazard raising safety concerns (except for allergenicity) could be identified from the information available on the source (i.e. chia seeds), the production processes, composition, specifications and proposed uses of the NFs, irrespectively of the maximum use levels at the proposed uses, the Panel considers that intake estimates and additional toxicological data for the NFs are not needed for this assessment. The Panel concludes that the NFs, partially defatted powders of whole chia seeds, are safe under the assessed conditions of use.

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Keywords: chia seeds, partially defatted powders, novel food, safety

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Question numbers: EFSA-Q-2018-00373, EFSA-Q-2018-00685

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Summary

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver a scientific opinion on chia seeds (*Salvia hispanica* L.) powders as novel foods (NFs) pursuant to Regulation (EU) 2015/2283. The assessment of the safety of these NFs, which follows the methodology set out in the EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food and in the Commission Implementing Regulation (EU) 2017/2469, is based on the data supplied in the applications (EFSA-Q-2018-00373 and EFSA-Q-2018-00685), information submitted by the applicant following EFSA requests for supplementary information and additional data identified by the Panel.

The NFs, which are the subjects of this assessment, are partially defatted chia seed powders, obtained by extrusion of whole seeds of *S. hispanica* L. The main differences between the powders are the particle sizes and the content of some macronutrients. The first powder, named by the applicant 'Xia 125', has a particle size below 130 μm and protein content of at least 40%. The second powder, 'Xia 435', has a particle size below 400 μm and dietary fibre content of at least 50%.

The information provided on the production processes, batch-to-batch variability, composition and specifications of the NFs is sufficient and does not raise safety concerns.

The NFs are proposed to be marketed as food supplements (up to 7.5 and 12 g/day, respectively) and as ingredients in a variety of foods. The maximum proposed use levels range from 0.7% to 10% in fortified foods. The target population for the NFs is the general population.

The Panel noted that the fatty acid, amino acid and carbohydrate profiles of the NFs were similar to those of chia seeds. Taking into account the employed production processes and the compositional data available for chia seeds (EFSA NDA Panel, 2009, 2019), the Panel considers the consumption of the NFs not to be nutritionally disadvantageous.

Given the source of the NFs (i.e. chia seeds) and that the manufacturing processes or compositional data do not raise a safety concern, the Panel considers that no toxicological studies, performed with the NFs, are required.

In addition, since no hazard raising safety concerns (except for allergenicity) could be identified from information provided on the production processes, composition, specifications and proposed uses of the NFs, irrespectively of the maximum use levels at the proposed uses, the Panel considers that intake estimates for the NFs are not needed for this assessment.

The Panel considers that the allergenic potential of the NFs is similar to that of chia seeds, because the manufacturing steps employed in the production of the NFs are not expected to modify the allergenic potential of the chia seeds.

The Panel concludes that the NFs, partially defatted powders of whole chia seeds, are safe under the assessed conditions of use.

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1. Introduction

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

On 18 April 2018, the company Access Business Group International LLC submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) N° 2015/2283[1] to place chia seed powder 'Xia 125' on the Union market as a novel food.

On 22 June 2018 and in accordance with Article 29(1)(a) of Regulation (EU) 178/20023, the Commission asked the European Food Safety Authority (EFSA) to provide a scientific opinion by carrying out the safety assessment for chia seeds powder as a NF in the context of Regulation (EU) 2015/2283, by the end of March 2019. In accordance with Article 10 (3) of Regulation (EU) 2015/2283, EFSA shall give its opinion as to whether the update of the Union List referred to in Article 10 (1) is liable to have an effect on human health.

On 16 July 2018, another request from the same applicant has been submitted, to place chia seed powder 'Xia 435' on the Union market as a novel food. Consequently, on 22 October, the Commission asked EFSA to also provide a scientific opinion for this NF, by the end of July 2019.

2. Data and methodologies

2.1. Data

The safety assessment of these NFs is based on data supplied in the applications (EFSA-Q-2018-00373 and EFSA-Q-2018-00685), information submitted by the applicant following EFSA requests for supplementary information and additional data identified by the Panel.

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[2].

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.[3] As indicated in this guidance, it is the duty of the applicant to provide all available (proprietary, confidential and published) scientific data, including both data in favour and not in favour to supporting the safety of the proposed NF.

Both NF applications did not include a request for protection of proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283.

2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications 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.

This assessment concerns only risk that might be associated with consumption of the NFs under the proposed conditions of use and is not an assessment of the efficacy of chia seed powders 'Xia 125' and 'Xia 435' with regard to any claimed benefit.

3. Assessment

3.1. Introduction

This assessment refers to partially defatted chia seed powders, obtained by extrusion of whole seeds of *Salvia hispanica* L. The main differences between the powders in the two requests are the

[1] Regulation (EU) 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] 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.*

[3] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArdle H, Naska A, Neuhäuser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Siani A, Sjödin A, Stern M, Tomé D, Vinceti M, Willatts P, Engel K-H, Marchelli R, Pöting A, Poulsen M, Salminen S, Schlatter J, Arcella D, Gelbmann W, de Sesmaisons-Lecarré A, Verhagen H and van Loveren H, 2016. Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4594, 24 pp. https://doi.org/10.2903/j.efsa.2016.4594

particle sizes and the content of some macronutrients. The NFs have been marketed outside the European Union (EU) under the trade names of 'Xia 125' and 'Xia 435'. The applicant proposes to market the NFs as food supplements and to use them as an ingredient in various foods. The target population is the general population.

3.2. Identity of the NFs

The NF, named by the applicant 'Xia Powder 125', is a fine and dispersible powder, with a protein content of at least 40% and particle sizes of less than 130 μm. 'Xia Powder 435' is a fine powder with a fibre content of at least 50% and particle sizes of less than 400 μm. Both are obtained from partially defatted chia seeds (*S. hispanica* L.).

3.3. Production process

The manufacturing process of the NFs comprises of three main steps: defatting and grinding of the chia seeds, followed by densimetric classification. In the first step, cleaned seeds are pressed (< 45°C) to partially remove the oil. After cooling to ambient temperature (< 30°C), the pressed seeds are ground and particles are separated into two groups: those below 130 μm for ('Xia powder 125') and those between 130 and 435 μm (for 'Xia powder 435'). Final steps include packaging and storage.

The cultivation of chia (*S. hispanica* L.) follows Good Agricultural Practice (GAP) and the manufacturing processes of the chia seed powders are conducted in accordance with Good Manufacturing Practice (GMP). They are also compliant with FSSC 22000 and a Hazard Analysis and Critical Control Points (HACCP) principles.

No processing aids or solvents are used during the manufacturing processes.

The Panel considers that the production processes are sufficiently described and do not raise safety concerns.

3.4. Compositional data

In order to confirm that the manufacturing process is reproducible and adequate to produce a product with certain characteristics on a commercial scale, the applicant provided batch-to-batch analysis of several independent batches for both NFs, where physico-chemical-sensorial parameters were measured, as well as the occurrence of microbiological and chemical contaminants. All results were obtained in an accredited laboratory, using validated methods; the respective limits of detection (LODs) and quantification (LOQs) have been reported.

Key characteristics of 'Xia 125' are particle size below 130 μm, the content of: proteins above 40%, fat below 17% and dietary fibre below 22% (Tables 1a and 2a).

Key characteristics of 'Xia 435' and also key differences in comparison to 'Xia 125' are particle size below 400 μm, the content of: proteins above 21%, fat below 12% and dietary fibre above 60% (Tables 1b and 2b).

Table 1a: Batch-to-batch analysis of 'Xia 125'

Parameter (unit)	Product analyses for 'Xia Powder 125'				
	Batch No				
	125/20/2017	125/21/2017	125/22/2017	125/24/2017	125/26/2017
Physico-chemical-sensorial parameters					
Colour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Foreign matter (%)	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10
Particle size (μm)	D99 ≤ 105	D99 ≤ 113	D99 ≤ 125	D99 ≤ 125	D99 ≤ 122
Moisture (%)	7.2	7.9	7.03	7.18	6.7
Protein (%)	> 40	> 40	44.8	44.8	> 40
Fat (%)	< 17	< 17	6.7	14.3	< 17
Dietary fibre (%)	21.1	21.3	20.3	20.4	< 30

Parameter (unit)	Product analyses for 'Xia Powder 125'				
	Batch No				
	125/20/2017	125/21/2017	125/22/2017	125/24/2017	125/26/2017
Contaminants					
Cadmium (mg/kg)	< 0.01[(a)]	< 0.01[(a)]	< 0.01[(a)]	< 0.01[(a)]	< 0.01[(a)]
Arsenic (mg/kg)	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]
Lead (mg/kg)	< 0.05[(a)]	< 0.05[(a)]	< 0.02[(a)]	< 0.02[(a)]	< 0.02[(a)]
Mercury (mg/kg)	< 0.1[(a)]	< 0.1[(a)]	< 0.02[(a)]	< 0.02[(a)]	< 0.1[(a)]
Total aflatoxin (μg/kg)	< 0.2[(a)]	< 0.2[(a)]	< 0.2[(a)]	< 0.2[(a)]	< 0.2[(a)]
Ochratoxin A (μg/kg)	< 0.5[(b)]	< 0.5[(b)]	< 0.5[(b)]	< 0.5[(b)]	< 0.5[(b)]
Microbiology					
Total plate count (CFU/g)	5,000	1,800	3,500	5,500	3,500
Moulds (CFU/g)	< 10	< 10	< 10	< 10	< 10
Yeast (CFU/g)	< 10	< 10	< 10	< 10	< 10
Enterobacteriaceae (CFU/g)	< 10	< 10	< 100	< 10	< 10
Coliforms (MPN/g)	< 3	< 3	< 100	< 10	< 3
Salmonella (Absence/25 g)	Absence	Absence	Absence	Absence	Absence
Escherichia coli (MPN/g)	< 10	< 10	< 10	< 10	< 10
Staphylococcus aureus (CFU/g)	< 10	< 10	< 10	< 10	< 10
Bacillus cereus (CFU/g)	< 10	< 10	< 50	< 10	< 10
Listeria monocytogenes (Absence/g)	Absence	Absence	Absence	Absence	Absence

CFU: colony forming units; MPN: Most Probable Number.
(a): for each lot of raw material.
(b): values based on analyses for seeds belonging to the same harvest campaign.

Table 1b: Batch-to-batch analysis of 'Xia 435'

Parameter (unit)	Product analyses for 'Xia Powder 435'				
	Batch No				
	435/21/2018	435/22/2018	435/23/2018	435/25/2018	435/26/2018
Physico-chemical-sensorial parameters					
Colour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Foreign matter (%)	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10
Particle size average (μm)	< 400	< 400	< 400	< 400	< 400
Moisture (%)	7.2	7.6	7.1	7.3	6.8
Protein (%)	24.0	24.0	24.0	24.0	24.0
Fat (%)	< 12	< 12	7.2	< 12	< 12
Dietary fibre (%)	> 50.0	> 50.0	> 50.0	> 50.0	> 50.0
Contaminants					
Cadmium (mg/kg)	< 0.01[(a)]	< 0.01[(a)]	< 0.01[(a)]	< 0.01[(a)]	< 0.01[(a)]
Arsenic (mg/kg)	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]
Lead (mg/kg)	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]	< 0.05[(a)]
Mercury (mg/kg)	< 0.1[(a)]	< 0.1[(a)]	< 0.1[(a)]	< 0.1[(a)]	< 0.1[(a)]
Total aflatoxins (μg/kg)	< 0.2	< 0.2	< 0.2	< 0.2	< 0.2
Ochratoxin A (μg/kg)	< 0.5[(b)]	< 0.5[(b)]	< 0.5[(b)]	< 0.5[(b)]	< 0.5[(b)]

Parameter (unit)	Product analyses for 'Xia Powder 435'				
	Batch No				
	435/21/2018	435/22/2018	435/23/2018	435/25/2018	435/26/2018
Microbiology					
Total plate count (CFU/g)	1,250	6,000	2,500	4,000	3,000
Moulds (CFU/g)	< 10	< 10	< 10	< 10	< 10
Yeast (CFU/g)	< 10	< 10	< 10	< 10	< 10
Enterobacteriaceae (CFU/g)	< 10	< 10	< 10	< 10	< 10
Coliforms (MPN/g)	< 3	< 3	< 3	< 3	< 3
Salmonella (Absence/25 g	Absence	Absence	Absence	Absence	Absence
Escherichia coli (MPN/g)	< 10	< 10	< 10	< 10	< 10
Staphylococcus aureus (CFU/g)	< 10	< 10	< 10	< 10	< 10
Bacillus cereus (CFU/g)	< 50	< 50	< 50	< 50	< 50
Listeria monocytogenes (Absence/g)	Absence	Absence	Absence	Absence	Absence

CFU: colony forming units; MPN: Most Probable Number.
(a): for each lot of raw material.
(b): values based on analyses for seeds belonging to the same harvest campaign.

Table 2a: Batch-to-batch proximate analyses of 'Xia 125'

Parameter (unit)	Product analyses for 'Xia Powder 125'					Method
	Batch No					
	1	2	3	125/22	125/23	
Moisture (%)	6.7	6.5	6.5	6.8	–	ISO 6496:1999
Protein (%)	45.15	44.89	44.81	–	–	ISO 5983-2:2009
Ash (%)	7.82	7.96	7.74	–	–	AOAC 923.03 2000
Fat (%)	13.9	12.9	12.8	16.7	16.4	AOAC 920.39 2000
Dietary fibre (%)	–	–	–	20.3	19.2	AOAC 985.29 2012

Table 2b: Batch-to-batch proximate analyses of 'Xia 435'

Parameter (unit)	Product analyses for 'Xia Powder 435'									Method
	Batch No									
	1	2	3	4	435/20	435/21	435/22	435/23	435/24	
Moisture (%)	6.0	5.2	5.5	5.7	–	6.0	7.6	7.1	–	ISO 6496:1999
Protein (%)	24.12	25.15	27.93	21.66	21.06	–	–	–	–	ISO 5983-2:2009
Ash (%)	5.29	5.8	6.2	5.4	–	–	–	–	5.2	AOAC 923.03 2000
Fat (%)	7.48	8.8	8.2	6.1	–	–	–	7.2	–	AOAC 920.39 2000
Dietary fibre (%)	–	–	–	–	62.7	62.8	63.3	62.5	62.9	AOAC 985.29 2012

In addition to the parameters shown in the above tables, the applicant provided information about identities and quantities of pesticide residues in five independent batches of both NFs. For all batches, results were below detection levels of the method(s) used (data not shown here), except in one batch of 'Xia 125' and one batch of 'Xia 435', in which residue levels of pirimiphos-methyl were 0.085 mg/kg and 0.21 mg/kg, respectively.

The Panel notes that current legislation on pesticides[4] gives maximum residue levels (MRLs) for pirimiphos-methyl in raw materials, with MRL for category 'buckwheat and other pseudocereals' of 0.5 mg/kg.

Also, dioxins, dioxin-like polychlorinated biphenyls (dl-PCBs) and furans were measured in five independent batches, showing values below limits of detection and quantification (0.03 BEQ[5] ng/kg and 0.09 BEQ ng/kg, respectively) for the method used (data not shown here).

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

3.4.1. Stability

The applicant conducted stability tests upon storage of different batches of the NFs at room temperature (20–25°C) and 60% of relative humidity, over periods up to 15 and 16 months, respectively. Monitored parameters were: peroxide index, moisture (only for 'Xia 125') and microbial growth (Tables 3a and 3b).

Table 3a: Stability test of 'Xia 125'

Parameter (unit)	DMC	Batch No			
		125/19/2016	125/15/2016	125/09/2016	125/04/2016
Physicochemical parameters					
Time (months)	0	6	7	12	16
Peroxide index (mEq/kg)	< 0.80*	0.2*	1.41	1.18	1.16
Moisture (%)	7.57	6.2	5.5	5.7	7.2
Microbiological contaminants					
Yeast and moulds (CFU/g)	< 10	< 10	< 10	< 10	< 10
Total Plate Count (CFU/g)	< 10,000	630	< 250	2,300	< 250
Enterobacteriaceae (CFU/g)	< 10	< 10	< 10	< 10	< 10

DMC: defatted milled chia, intermediate product before grinding.
*: Different methods were used with different LOQs.

Table 3b: Stability test of 'Xia 435'

Parameter (unit)	DMC	Batch No			
		435/19/2016	435/09/2016	435/07/2016	435/03/2016
Physicochemical parameters					
Time (months)	0	6	12	13	15
Peroxide index (mEq/kg)	< 0.80	2.29	1.50	1.09	1.39
Microbiological contaminants					
Yeast and moulds (CFU/g)	< 10	< 10	< 10	< 10	< 10
Total Plate Count (CFU/g)	< 10,000	440	< 250	< 10	380
Enterobacteriaceae (CFU/g)	< 10	< 10	< 10	< 10	< 10

DMC: defatted milled chia, intermediate product before grinding.

The Panel notes that the applicant used four different batches of the NFs for analyses at the different time points, i.e. one batch for each time point. Therefore, the data provided regarding stability are of very limited relevance. The data provided on the peroxide index (0.2–2.29 mEq/kg) did not show a clear dependence on the duration of storage. However, even the highest value detected (after 6 months for 'Xia 435') was low and thus indicated the oxidative stability of the NF.

3.5. Specifications

Product specifications provided by the applicant are reported in Tables 4a and 4b.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
[5] BEQ: Bioanalytical Equivalents.

Table 4a: Specifications for 'Xia 125' as provided by the applicant

Parameter	Specification (Unit)	Method
Physical–sensorial		
Particle size	≤ 130 (μm)	Laser diffraction
Foreign matter	≤ 0.1 (%)	Internal method
Colour	Shades of beige to brown	Visual
Chemical		
Moisture	≤ 9.0 (%)	ISO 711
Protein	≥ 40.0 (%)	Kjeldahl
Fat	≤ 17 (%)	Soxhlet
Fibre	≤ 30 (%)	AOAC 991.43
Microbiology		
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/g	ISO 11290-1
Salmonella	Absence (0/25 g)	ISO 6579
Contaminants		
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

CFU: colony forming units.

Table 4b: Specifications for 'Xia 435' as provided by the applicant

Parameter	Specification (Unit)	Method
Physical–sensorial		
Particle size	≤ 400 (μm)	Laser diffraction
Foreign matter	≤ 0.1 (%)	Internal method
Colour	Shades of beige to brown	Visual
Chemical		
Moisture	≤ 9.0 (%)	ISO 711
Protein	≥ 24.0 (%)	Kjeldahl
Fat	≤ 12 (%)	Soxhlet
Fibre	≥ 50 (%)	AOAC 991.43
Microbiology		
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

Parameter	Specification (Unit)	Method
Escherichia coli	< 10 MPN/g	ISO 7251
Listeria monocytogenes	Absence/g	ISO 11290-1
Salmonella	Absence (0/25 g)	ISO 6579
Contaminants		
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

CFU: colony forming units.

The Panel considers that the information provided on the specifications and the batch-to-batch variabilities of the NFs 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 NFs are manufactured from the chia seeds (*S. hispanica* L.), a summer annual herbaceous plant belonging to the Labiatae family (EFSA NDA Panel, 2009, 2019).

The plant is native to Central and South America (Mexico, Argentina and Bolivia) where the seeds were used as food in pre-Columbian civilisations. Information on the use of chia seeds in several non-EU countries including the USA, Canada and Australia, demonstrated history of use as food also in modern societies (EFSA NDA Panel, 2009, 2019). In the last decade, chia seeds and chia oil have started to be consumed also in the EU. According to the Union list of novel foods (2017/2470[6]), the use of chia seeds and oil is authorised under particular conditions and maximum inclusion levels, as shown in Table 5.

Table 5: Authorised use of chia seeds and a product thereof (modified from the 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*)	Bread products	5% (whole or ground chia seeds)
	Baked products	10% whole chia seeds
	Breakfast cereals	10% whole chia seeds
	Fruit, nut and seed mixes	10% whole chia seeds
	Fruit juice and fruit/vegetable blend beverages	15 g/day for addition of whole, mashed or ground chia seeds
	Prepacked chia seed as such	15 g/day whole chia seeds
	Fruit spreads	1% whole chia seeds
	Yoghurt	1.3 g whole chia seeds per 100 g of yoghurt or 4.3 g whole chia seeds per 330 g of yoghurt (portion)
	Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/or pulses	5% whole chia seeds
Chia oil from *S. hispanica*	Fats and oils	10%
	Pure chia oil	2 g/day
	Food Supplements as defined in Directive 2002/46/EC	2 g/day

[6] 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 351/72, 30.12.2017.*

The applicant provided some estimations for import of chia seeds in Europe, based on CBI report (2017) and stated that chia importation increased by 27% (in volume) between 2012 and 2016, reaching 16,182 tonnes of chia seeds in 2016. The four top countries regarding the import of chia seeds are Germany (with a market share of 40%), the Netherlands (18%), Spain (12%) and the UK (8%).

3.6.2. History of use of the NF

The applicant provided information on the regulatory status of 'Xia 125' and 'Xia 435' outside EU. Both products have been authorised as foods in New Zealand, Canada, China, Taiwan and the USA, with the longest history of use in the USA (since the early 2000s). Furthermore, the applicant stated that about 40 t of 'Xia 435' per month are traded worldwide and that both NFs can be found in a variety of products such as multigrain bread, cereals, pasta, cookies and crackers, without recorded negative feedback from consumers.

3.7. Proposed uses and use levels and anticipated intake

3.7.1. Target population

The target population for the consumption of the NF, proposed by the applicant, is the general population.

3.7.2. Proposed uses and use levels

The initial intention of the applicant was to use the NFs as food supplements, but also in a range of various foods including food for weight reduction, food for sporting people, functional drinks and drink mixes, confectionery, yoghurt, snack foods, puddings, breakfast cereals, vegetable-based dishes, bread and bakery premixes, pasta, extruded puffs, food bars, crackers and vegetable beverages.

During a literature search regarding chia seeds and process contaminants, EFSA retrieved one study (Mesias et al., 2016; EFSA NDA Panel, 2019) which reported that partial replacement of wheat flour by chia flour as dough ingredient in biscuits and baking at 190°C may lead to substantial increase in levels of process contaminant – acrylamide. The Panel considered that this concern can also apply to these NFs because partial defatting, as a key production step of the NFs, is most likely neutral regarding the formation of acrylamide. Thus, a request for supplementary information was issued to the applicant on the potential formation of process contaminants which may be formed during processing and production of food (at the level of the manufacturer) and/or when food with added NFs is subject to cooking (heat treatment at the consumer level).

Instead of providing requested information, the applicant decided to withdraw those proposed uses of the NFs which may include above-mentioned heat treatment.

Therefore, the final proposed uses and use levels of the NFs are summarised in Tables 6a and 6b. Food categories are based on categories presented in Annex II, Part D, of Regulation (EC) No 1333/2008[7] and are used for the purposes of EFSA Food Additives Intake Model (FAIM).[8]

The Panel notes that also 'pasta' may be subject to heat-treatment to temperatures above 120°C and potentially could represent a relevant source of acrylamide. Since no data were provided to address the potential formation of acrylamide in pasta, if subject to such heat treatment, the safety of proposed use of the NFs in pasta is not taken into account by this opinion.

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

[8] https://www.efsa.europa.eu/sites/default/files/applications/FAIM-instructions.pdf and https://dwh.efsa.europa.eu/bi/asp/Main.aspx?rwtrep=FAIM

Table 6a: Proposed uses and use levels of 'Xia 125'

Food category*	Products	Proposed use levels
1.2 Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	Yoghurt	0.7%
1.3 Unflavoured fermented milk products, heat-treated after fermentation		
1.4 Flavoured fermented milk products including heat-treated products		
5 Confectionery	Chocolate, fruit chew/gummy	10%
6.4 Pasta**	Pasta	2.5%
14.1.2 Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Vegetable beverages	2.5%
14.1.3 Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Vegetable beverages	2.5%
14.1.4 Flavoured drinks	Energy drinks, isotonic/sport drinks	3%
17 Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children	Food supplements	7.5 g/day

*: Based on Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives.
**: Not considered in a safety assessment of this scientific opinion, due to a lack of supplementary information regarding formation of process contaminants.

Table 6b: Proposed uses and use levels of 'Xia 435'

Food category*	Products	Proposed use levels
5 Confectionery	Chocolate, fruit chew/gummy	4%
6.4 Pasta**	Pasta	10%
14.1.2 Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Vegetable beverages	2.5%
14.1.3 Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Vegetable beverages	4%
14.1.4 Flavoured drinks	Energy drinks, isotonic/sport drinks	4%
17 Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children	Food supplements	12 g/day

*: Based on Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives.
**: Not considered in a safety assessment of this scientific opinion, due to a lack of supplementary information regarding formation of process contaminants.

The NFs are proposed to replace chia seeds and are not intended to be consumed in addition to chia seeds in products for which seeds are authorised, as stated by the applicant.

3.7.3. Anticipated intake of the novel foods

In EFSA's opinion on chia seeds (2019), the Panel did not identify a hazard which would require an exposure assessment.

Given that the NFs are powders of partially defatted whole chia seeds and that no hazard raising safety concerns (except for allergenicity) could be identified from information provided on the production processes, composition, specifications and proposed uses of the NFs, the Panel considers that intake estimates for the NFs are not needed for this assessment.

3.8. Nutritional information

Nutritional profiles of one batch of both NFs were provided by the applicant, which included parameters such as fatty acid, amino acid and carbohydrate profiles, as well as concentrations of sodium, vitamins, minerals, total polyphenols, antioxidants and dietary fibre (data not shown). The fatty acid profiles showed that relative proportions of polyunsaturated fatty acids in both NFs were more than 80% (with more than 60% of omega-3 fatty acids). Sodium content in 'Xia 125' was 51 mg/kg and 28 mg/kg in 'Xia 435', respectively.

The Panel noted that the fatty acid, amino acid and carbohydrate profiles were similar to those of chia seeds. Taking into account the employed production processes and the compositional data available for chia seeds (EFSA NDA Panel, 2009, 2019), the Panel considers the consumption of the NFs not to be nutritionally disadvantageous.

3.9. Toxicological information

3.9.1. General consideration

The Panel notes that no toxicological studies with the NFs were provided. Instead, the applicant provided toxicological data on chia seeds (data not shown here), referred to previous assessment by EFSA NDA Panel (2005, 2009) and authorisation by the European Commission for use in EU as such or in different food categories.

Given that the NFs are produced from partially defatted whole chia seeds and the manufacturing processes or compositional data do not raise a safety concern, the Panel considers that no additional toxicological studies are required.

3.9.2. Human data

The Panel notes that there are no human studies conducted with the NFs. However, in the opinion on safety of chia seeds (EFSA NDA Panel, 2019), the Panel noted that the available human studies were primarily designed to investigate putative beneficial effects and addressed only a limited number of safety-relevant endpoints such as blood pressure, standard clinical chemistry and some haematology parameters. While considering this and other inherent limitations of such studies for their use in a safety assessment, the Panel noted that no changes were found in the studied safety-related parameters and no adverse events related to the consumption of chia seeds were reported.

3.10. Allergenicity

No data on allergenicity was provided on the NFs. However, the Panel considers that the allergenic potential of the NFs is similar to that of chia seeds because the manufacturing steps employed in the production of the NFs are not expected to modify the allergenic potential of the chia seeds.

In 2009, the Panel noted the cross-reactivity of sera from subjects allergic to peanuts and sesame and reiterated its earlier opinion from 2005 that it was not possible to predict the potential allergenicity of chia seeds. Since then, the available information from two case reports (García et al., 2015; Tomas-Pérez et al., 2018) indicates that allergic reactions upon consumption of chia seeds may occur (EFSA NDA Panel, 2019).

4. Discussion

The NFs 'Xia 125' and 'Xia 435' are powders obtained from partially defatted chia seeds (*S. hispanica* L.), by extrusion. The main differences between these two NFs are in particle size and in the content of some macronutrients. The source of the NF (chia seeds) was already assessed by EFSA NDA Panel (2005, 2009, 2019).

Noting that no hazard raising safety concerns (except for allergenicity) could be identified from the information available on the source (i.e. chia seeds), the production processes, composition, specifications and proposed uses of the NFs, irrespectively of the maximum use levels at the proposed uses, the Panel considers that intake estimates for the NFs are not needed for this assessment.

The intention of the applicant is to market the NFs to the general population as an ingredient in a variety of foods, as well as food supplements.

Although the provided toxicological and human data, which do not raise safety concerns, regard chia seeds and not the NFs, the Panel considers these studies pertinent for this assessment.

5. Conclusions

The Panel concludes that the NFs, partially defatted powders of whole chia seeds, are safe under the assessed conditions of use.

Steps taken by EFSA

1) On 22 June 2018, EFSA received a letter from the European Commission with the request for a scientific opinion on Chia seeds powder as a novel food (Ref. Ares(2018)3311207). Valid application on 'Xia Powder 125, a partially defatted chia seed powder', which was submitted by the company Access Business Group International LCC, was made available to EFSA through the Commission e-submission portal (NF 2018/0381) and the scientific evaluation procedure was initiated.
2) On 26 July 2018 and 17 September 2018, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
3) On 03 August 2018 and 25 September, additional information was provided by the applicant and the scientific evaluation was restarted.
4) On 22 October 2018, EFSA received a letter from the European Commission with the request for a scientific opinion on another Chia seeds powder as a novel food (Ref. Ares(2018) 6038595. Valid application on 'Xia Powder 435', which was submitted by the same company Access Business Group International LCC, was made available to EFSA through the Commission e-submission portal (NF 2018/0522) and the scientific evaluation procedure started. EFSA decided to evaluate both NFs under the same scientific opinion.
5) On 09 November 2018, EFSA requested the applicant to provide additional information to accompany the application of 'Xia Powder 435' and the scientific evaluation was suspended.
6) On 14 November 2018, additional information was provided by the applicant and the scientific evaluation was restarted.
7) On 13 March 2019, EFSA requested the applicant to provide final additional information for both NFs to accompany the application and the scientific evaluation was suspended.
8) On 24 April 2019, additional information was provided by the applicant and the scientific evaluation was restarted.
9) During its meeting on 15 May 2019, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of chia seeds (*Salvia hispanica* L.) powders as a NF pursuant to Regulation (EU) 2015/2283.

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Abbreviations

AOAC	Association of official analytical chemists
BEQ	Bioanalytical equivalents
CBI	The Centre for the Promotion of Imports from developing countries
CFU	colony forming units
dl-PCB	dioxin-like polychlorinated biphenyl
DMC	defatted milled chia
FAIM	Food Additives Intake Model
FSSC	Food Safety System Certification
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
ISO	International Organization for Standardization
LC-MS/MS	liquid chromatography with tandem spectroscopy
LLC	limited liability company
LOD	limit of detection
LOQ	limit of quantification
MPN	Most Probable Number
MRL	maximum residue level
NDA	EFSA Panel on Nutrition, Novel foods and Food Allergens
NF	novel food