Safety of chia seeds (salvia hispanica l.) as a novel food for extended uses pursuant to regulation (eu) 2015/2283

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Safety of chia seeds (*Salvia hispanica* L.) as a novel food for extended uses 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 overall safety assessment for chia seeds (*Salvia hispanica* L.) as a novel food (NF) pursuant to Regulation (EU) 2015/2283 in the light of the increasing dietary intake from the growing number of authorised uses in recent years. The safety assessment of this NF is based on data supplied in seven applications, previous safety assessments of chia seeds and information retrieved from an extensive literature search done by EFSA. Since none of the applications addressed the possible formation of process contaminants, the present assessment is limited to those proposed extended uses which do not raise safety concerns regarding the formation of such contaminants. These include the use of whole and ground chia seeds added to chocolate, fruit spreads, fruit desserts, mixed fruit with coconut milk in twin pot, fruit-preparations to underlay a dairy product, fruit-preparations to be mixed with dairy products, confectionary (excluding chewing gums), dairy products and analogues, edible ices, fruit and vegetables products, non-alcoholic beverages and compotes from fruit and/or vegetables and/or with cereals. In addition, this assessment also concerns uses of chia seeds without specific restrictions and precautions regarding their use levels in other foods which usually do not include heat treatment during processing and cooking. Apart from allergenicity, the Panel did not identify any hazard which causes safety concerns. Lacking the basis and need to establish safe maximum intake levels for chia seeds, no exposure assessment was conducted. The Panel concludes that chia seeds are safe under the assessed conditions of use.

Keywords: chia seeds (*Salvia hispanica* L.), novel food, safety, extensions of use

Requestors: European Commission following applications by Parry's Pots Limited (PPL), Sanchis Mira S.A., Zentis GmbH & Co. KG, Majami Sp. z o.o. Sp. k., Naturkost Übelhör GmbH & Co. KG, The Chia Co and Materne SAS

Question numbers: EFSA-Q-2018-00224, EFSA-Q-2018-00344, EFSA-Q-2018-00681, EFSA-Q-2018-00682, EFSA-Q-2018-00683, EFSA-Q-2018-00684, EFSA-Q-2018-00686

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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 an opinion on overall dietary exposure and safety assessment for chia seeds (*Salvia hispanica* L.) as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The assessment of the safety of this NF, which follows the methodology set out in the EFSA Guidance on the preparation and presentation of an application for authorisation of a NF and in the Commission Implementing Regulation (EU) 2017/2469, is based on the data supplied in seven applications: EFSA-Q-2018-00224 (NF2018/0214), EFSA-Q-2018-00344 (NF2018/0183), EFSA-Q-2018-00681 (NF2018/0283), EFSA-Q-2018-00682 (NF2018/0424), EFSA-Q-2018-00683 (NF2018/0469), EFSA-Q-2018-00684 (NF2018/0519) and EFSA-Q-2018-00686 (NF2018/05452), previous safety assessments of chia seeds (EFSA NDA Panel, 2005, 2009), information provided by the EFSA Working Group on Compendium of Botanicals, which are based on extensive literature search and ad hoc search performed by the European Food Safety Authority (EFSA) for scientific literature related to chia seeds and process contaminants.

The NF is chia seeds (*S. hispanica* L.) and is currently authorised in the European Union (EU) in accordance with Regulation (EC) No 258/97, as a NF for a number of uses as listed in Commission Implementing Regulation (EU) 2017/2470 and in accordance with Regulation (EU) 2015/2283 in the following food categories: bread products; baked products; breakfast cereals; fruit, nut and seed mixes; fruit juice and fruit/vegetable blend beverages; pre-packaged chia seed as such; fruit spreads; yoghurt; sterilised ready to eat meals based on cereal grains, pseudocereals and/or pulses.

During the safety assessment of the new uses proposed in these seven applications, the Panel retrieved one study which investigated process contaminants in biscuits for which chia flour was partially substituting wheat flour in the dough, baked at 190°C. The results indicated that different formulations of biscuits containing chia seeds may lead to substantial increase in acrylamide. None of the applications addressed and considered the formation of process contaminants in foods with added chia seeds when such foods undergo thermal processing and/or cooking procedures. In the absence of information that addresses such possible formation of a process contaminant, the safety of those proposed uses is not assessed in this opinion and will be subject of a separate assessment.

The present assessment is therefore focused on proposed extended uses that do not raise safety concerns regarding the formation of acrylamide (because such foods are usually not subject to thermal processing or cooking procedures and/or are considered not to be among the relevant contributors of this process contaminant to the overall human exposure). Thus, this assessment concerns the safety of whole and ground chia seeds without specified maximum use levels when added to chocolate, fruit spreads, fruit desserts, mixed fruit with coconut milk in twin pot, fruit-preparations to underlay a dairy product, fruit-preparations to be mixed with dairy products, confectionary (excluding chewing gums), dairy products and analogues, edible ices, fruit and vegetables products, non-alcoholic beverages and compotes from fruit and/or vegetables and/or with cereals. In addition, this assessment also concerns uses of chia seeds without specific restrictions and precautions regarding their use levels in other foods which usually do not include heat treatment during processing and cooking.

In 2009, the Panel expressed the uncertainty related to the potential allergenicity of chia seeds and noted the cross-reactivity of sera from patients known to be allergic to peanuts and sesame. Since then, the available information from two case studies (García Jiménez et al., 2015; and Tomas-Pérez et al., 2018) indicates that allergic reactions upon consumption of chia seeds may occur.

In addition to previous safety assessments of chia seeds (EFSA NDA Panel, 2005, 2009) and based on the information provided in the applications that are subject of the present assessment, as well as the ones retrieved from the extensive literature search regarding composition, stability, history of consumption, toxicological and human data regarding whole and ground chia seeds, the Panel did not identify any other hazard which causes safety concerns.

In the absence of such hazard and thus, lacking the basis and need to establish safe maximum intake levels for chia seeds, no exposure assessment was conducted.

The Panel concludes that 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

Chia seeds (*Salvia hispanica* L.) are authorised, in accordance with Regulation (EC) No 258/97[1], as a novel food for a number of uses as listed in Commission Implementing Regulation (EU) 2017/2470[2] establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283[3]. The authorised uses of chia seeds include the following food categories: bread products, baked products, breakfast cereals, fruit, nut and seed mixes, fruit juice and fruit/vegetable blend beverages, pre-packaged chia seed as such, fruit spreads, yoghurt, sterilised ready to eat meals based on cereal grains, pseudocereals and/or pulses.

The first authorisation for placing on the Union market of chia seeds as a novel food to be used in bread products was given by Commission Decision 2009/827/EC[4] following the European Food Safety Authority's Opinion (EFSA NDA Panel, 2009) on safety of chia seeds (*Salvia hispanica* L.) as a novel food. Subsequent authorisations of extension of use of chia seeds received under Article 4 of Regulation (EC) No 258/97 were based on risk assessments carried out by the Member States national authorities with no objections having been raised by the other Member States.

On 12 September 2017, the company Sanchis Mira S.A. submitted a request to the competent authority of Spain in accordance with Article 4 of Regulation (EC) No 258/97 for an extension of use of chia seeds in additional food category, namely, chocolate with a maximum content of 3% chia seeds.

On 25 September 2017, the competent authority of Spain forwarded to the Commission its initial assessment report, in which it has been concluded that the extension of use and proposed maximum use level of chia seeds met the criteria for novel food set out in Article (3) of Regulation (EC) No 258/97.

On 17 October 2017, the Commission forwarded the initial assessment report to the other Member States. One Member State raised objections, questioning the overall safety of the novel food in light of the 2009 EFSA NDA Panel assessment as a result of the increasing dietary intake of chia seeds from the growing number of authorised uses. The objecting MS underlined that while individual uses, including the proposed use in chocolate at 3%, may be safe, there is a need to assess the overall dietary intake from all authorised uses since 2009 including the current request for the extension of use and if necessary, revise the 2009 EFSA NDA Panel safety assessment.

Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283. The application also meets the requirements laid down in Regulation (EU) 2015/2283.

In addition to the above request (NF 2018/0183), the Commission has received through its novel food e-submission portal the following requests for the authorisation of the extension of use of chia seeds within the meaning of Article 10 of Regulation (EU) 2015/2283:

- Extension of use in chocolate to a maximum of 10% (NF 2018/0183 and NF 2018/0469);
- Increasing the maximum levels in fruit spreads, from the currently authorised level of 1.0% to a maximum of 10% (NF 2018/0283 and NF 2018/0214);
- Extension of use in fruit desserts at maximum level of 2.5% (NF 2018/0283);
- Extension of use in mixed fruit with coconut milk for a twin pot at maximum level of 6% (NF 2018/0283);
- Extension of use in fruit-preparations to underlay a dairy product at maximum level of 6% (NF 2018/0283);

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

[2] 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).

[3] 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).

[4] Commission Decision 2009/827/EC of 13 October 2009 authorising the placing on the market of Chia seed (*Salvia hispanica*) as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 294, 11.11.2009, p. 14).

- Extension of use in fruit-preparations to be mixed with dairy products at maximum level of 6% (NF 2018/0283);
- Extension of use in confectionary, excluding chewing gums, at a maximum level of 10% (NF 2018/0424 and NF 2018/0519);
- Extension of use in dairy products and analogues at a maximum level of 10% (NF 2018/0519);
- Extension of use in edible ices at a maximum level of 10% (NF 2018/0519);
- Extension of use in fruit and vegetables products at a maximum level of 10% (NF 2018/0519);
- Extension of use in cereal and cereal products at a maximum level of 10% (NF 2018/0519);
- Extension of use in bakery wares at a maximum level of 10% (NF 2018/0519);
- Extension of use in herbs, spices, seasonings, soups and broths, sauces, salads and savoury based sandwich spreads and protein products at a maximum level of 10% (NF 2018/0519);
- Extension of use in total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013[5], foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014[6] at a maximum level of 10% (NF 2018/0519);
- Extension of use in non-alcoholic beverages at a maximum level of 10% (NF 2018/0519);
- Extension of use in ready-to-eat savouries and snacks at a maximum level of 10% (NF 2018/0519);
- Extension of use in desserts at a maximum level of 10% (NF 2018/0519);
- Extension of use in compotes from fruit and/or vegetables and/or with cereals at maximum level of 2% (NF 2018/0542).

In light of the above, an overall dietary exposure and safety assessment of chia seeds is necessary to update the 2009 EFSA NDA Panel opinion so as to ensure that the currently authorised uses together with the prospective extensions of use mentioned above comply with the requirements of Article 7 of Regulation (EU) 2015/2283 and to underpin the above extension of uses in line with the requirements of Article 10 of the same Regulation.

On 16 July 2018 and in accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission asked EFSA to provide a scientific opinion on the above listed extensions of use of chia seeds (*Salvia hispanica* L.) as a novel food.

In addition, in accordance with Article 29(1) of Regulation (EC) No 178/2002[7], the Commission asked EFSA to evaluate whether the safety of chia seeds as a novel food is still in accordance with the requirements of Article 7 of Regulation (EU) 2015/2283, taking into account the overall, cumulative intakes of chia seeds from all authorised uses and including the above extension of use.

In its opinion, EFSA should, if possible, pronounce as to whether the overall exposure, safety, and history of consumption of chia as a novel food in Europe and as a traditional food in third countries would support its indiscriminate uses in foods much in a similar manner that other European staple foods are used.

2. Data and methodologies

2.1. Data

The safety assessment of this novel food (NF) is based on data supplied in the applications (EFSA-Q-2018-00224, EFSA-Q-2018-00344, EFSA-Q-2018-00681, EFSA-Q-2018-00682, EFSA-Q-2018-00683, EFSA-Q-2018-00684 and EFSA-Q-2018-00686), previous safety assessments of chia seeds (EFSA NDA Panel, 2005, 2009), information provided by the EFSA Working Group on Compendium of Botanicals and an ad hoc literature search performed by EFSA.

[5] Regulation (EC) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

[6] Commission Implementing Regulation (EC) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food.

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

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in Commission Implementing Regulation (EU) 2017/2469[8].

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[9]. 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 support the safety of the proposed NF.

None of the NF applications under this mandate included 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 Commission Implementing Regulation (EU) 2017/2469.

The information provided by the EFSA Working Group on Compendium of Botanicals is based on an extensive literature search on chia seeds (*S. hispanica* L.) using the following scientific databases: 'Scopus', 'Pubmed', 'Scifinder' and 'Web of Science'. This provided the basis for identifying scientific evidence available in peer-reviewed scientific papers in relation to substances contained in chia seeds of potential concerns, toxicological data and studies reporting adverse health outcomes in humans.

In addition, EFSA searched ad hoc for scientific literature related to chia seeds and process contaminants.

This assessment concerns only the risk 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 chia seeds with regard to any claimed benefit.

3. Assessment

3.1. Introduction

This mandate refers to the safety of the NF chia seeds (*S. hispanica* L.), which has been already assessed by EFSA NDA Panel (2009) and authorised in the EU under the conditions of use as specified in the Union list of novel foods (Commission Implementing Regulation (EU) 2018/1023).

This assessment aims to answer (I) whether the extended uses of chia seeds proposed by the applicants are safe for human consumption and (II) whether chia seeds can be safely consumed by the European consumers without specific precautions and restrictions which would differ from other foods on the European market.

From an ad hoc literature search regarding chia seeds and process contaminants, EFSA retrieved one study on wheat-based biscuits (Mesias et al., 2016), which reported that partial replacement of wheat flour by chia flour as dough ingredient (10%, 15% and 20% chia flour, respectively) and baking at 190°C resulted in increased formation of the process contaminant acrylamide compared to the control. None of the applications for the proposed extended uses addressed and considered the potential formation of processing contaminants in foods with added chia seeds when such foods undergo thermal processing or cooking procedures.

One of the proposed extended uses of chia seeds concerns their use in bakery wares at a maximum level of 10% (NF 2018/0519). The Panel considers that baking normally implies heat treatment above 120°C, temperatures at which acrylamide may be formed. The Panel notes that also other proposed extended uses may include heat treatment during processing or cooking procedures at temperatures which may result in the formation of relevant levels of process contaminants such as acrylamide. In the absence of information that addresses such possible formation of a process

[8] 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.

[9] 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

contaminant in the applications for the proposed extended uses, the safety of the following proposed uses is not evaluated in this opinion and will be subject of separate assessments:

- Extension of use in bakery wares at a maximum level of 10% (NF 2018/0519);
- Extension of use in cereal and cereal products at a maximum level of 10% (NF 2018/0519);
- Extension of use in herbs, spices, seasonings, soups and broths, sauces, salads and savoury based sandwich spreads and protein products at a maximum level of 10% (NF 2018/0519);
- Extension of use in total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013, foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 (NF 2018/0519) at a maximum level of 10% (NF 2018/0519);
- Extension of use in ready-to-eat savouries and snacks at a maximum level of 10% (NF 2018/0519);
- Extension of use in desserts at a maximum level of 10% (NF 2018/0519).

The present assessment is therefore focused on proposed extended uses that do not raise safety concerns regarding the formation of acrylamide (because such foods are usually not subject to thermal processing or cooking procedures and/or are considered not to be among the relevant contributors of this process contaminant to the overall human exposure (EFSA CONTAM Panel, 2015)). Thus, this assessment concerns the safety of whole and ground chia seeds including such following proposed uses in foods:

- Extension of use in chocolate to a maximum of 10% (NF 2018/0183 and NF 2018/0469);
- Increasing the maximum levels in fruit spreads, from the currently authorised level of 1.0% to a maximum of 10% (NF 2018/0283 and NF 2018/0214);
- Extension of use in fruit desserts at maximum level of 2.5% (NF 2018/0283);
- Extension of use in mixed fruit with coconut milk for a twin pot at maximum level of 6% (NF 2018/0283);
- Extension of use in fruit-preparations to underlay a dairy product at maximum level of 6% (NF 2018/0283);
- Extension of use in fruit-preparations to be mixed with dairy products at maximum level of 6% (NF 2018/0283);
- Extension of use in confectionary, excluding chewing gums, at a maximum level of 10% (NF 2018/0424 and NF 2018/0519);
- Extension of use in dairy products and analogues at a maximum level of 10% (NF 2018/0519);
- Extension of use in edible ices at a maximum level of 10% (NF 2018/0519);
- Extension of use in fruit and vegetables products at a maximum level of 10% (NF 2018/0519);
- Extension of use in non-alcoholic beverages at a maximum level of 10% (NF 2018/0519);
- Extension of use in compotes from fruit and/or vegetables and/or with cereals at maximum level of 2% (NF 2018/0542).

3.2. Identity of the NF

The NF is seeds obtained from chia (*S. hispanica* L.) a summer annual herbaceous plant belonging to the Labiatae family (EFSA NDA Panel, 2009).

3.3. Production process

The chia seeds are imported from producing countries of South and Central America, Africa and Australia. The cultivation and the processing of the chia seeds as raw material described in the submitted applications for the extended uses do not differ from those assessed in the context of the EFSA NDA Panel Opinion from 2009.

The production processes of the NF as a raw material follow conventional agricultural practices and are in compliance with Hazard Analysis Critical Control Points (HACCP) principles, when the NF is processed.

3.4. Compositional data

In the EFSA NDA Panel opinion from 2009, compositional data of chia seeds were based on analytical data from several batches from Bolivia, Peru and Australia. Samples had been analysed regarding proximate parameters (dry matter, protein, oil, crude fibre and ash) and fatty acids. Further

analyses had been carried out on the contents of minerals and vitamins, on carbohydrates, the amino acid profile and the fatty acid profile (EFSA NDA Panel, 2009).

After the EFSA NDA Panel opinion (2009), additional studies have become available which aimed to further characterise chia seeds. De Falco et al. (2017), among others, gave an overview of compositional data of chia seeds. They have been reported to contain a broad spectrum of tocopherols, phytosterols, carotenoids, flavonoids and polyphenolic compounds. Examples of phenolic acids and flavonoids are shown in Table 1.

Regarding the total phenolic content, the highest amount was found in a study by Martinez-Cruz and Paredes-Lopez (2014) (1.6 ± 0.2 mg GAE[10]/g of chia seeds). The authors compared this amount with the concentrations of total phenolic compounds in other foods of plant origin, such as raspberry (1.1 mg GAE/g), strawberry (1.6 mg GAE/g), banana (0.9 mg GAE/g), pink guava (1.3 mg GAE/g), mango (0.6 mg GAE/g), peach (0.8 mg GAE/g), papaya (0.6 mg GAE/g) and pineapple (0.02 mg GAE/g).

Table 1: Phenolic acid derivatives and flavonoids from *Salvia hispanica* L. seeds

Chemical constituent	Quantification (μg/g)	Analytical method (Reference)	Quantification in other foods (Reference)
Caffeic acid	27.4	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 50 μg/g in basil to 290 μg/g in thyme (Kivilompolo and Hyotylainen, 2007)
	139–149	HPLC (Ayerza, 2013)	
	30	HPLC (Coelho and de las Mercedes Salas-Mellado, 2014)	
Ferulic acid	Traces (LOD: 0.0004)	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 1 μg/g in rice, whole grain flour to 722 μg/g in hard wheat, whole grain flour (Weidner et al., 1999)
Chlorogenic acid	226–218	HPLC (Ayerza, 2013)	From 174 μg/g in potatoes tubers to 754 μg/g in potato sprouts (Dao and Friedman, 1992)
	4	UPLC (Coelho and de las Mercedes Salas-Mellado, 2014)	
Rosmarinic acid	927	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 910 μg/g in fresh thyme to 829 μg/g in dried thyme (Zheng and Wang, 2001; Wang et al., 2004)
Myricetin	115–121	HPLC (Ayerza, 2013)	From 14 to 142 μg/g in cranberries (Häkkinen et al., 1999)
Quercetin	7–6	HPLC (Ayerza, 2013)	From 74 to 146 μg/g in lingonberries (Häkkinen et al., 1999)
	0.17	UPLC (Coelho and de las, 2014)	
Kaempferol	25–24	HPLC (Ayerza, 2013)	From 19 μg/g in gooseberries to 5 μg/g in strawberries (Häkkinen et al., 1999)
Daidzin	6	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 16 μg/g in soy sprouts to 339 μg/g in soy seeds (Morandi et al., 2005)
Glycitein	0.5	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 2.8 μg/g in soy raw to 19 μg/g in soy flour (Wang and Murphy, 1994; Murphy et al., 1999)
Glycitin	1.4	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 6.3 μg/g in soy raw to 114 μg/g in soy flour (Wang and Murphy, 1994; Murphy et al., 1999)
Genistein	5.1	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 3.5 μg/g in soy sprouts to 20 μg/g in soy seeds (Morandi et al., 2005)
Genistin	3.4	UHPLC (Martinez-Cruz and Paredes-Lopez, 2014)	From 13 μg/g in soy sprouts to 423 μg/g in soy seeds (Morandi et al., 2005)

UHPLC: ultrahigh-performance liquid chromatography; HPLC: high-performance liquid chromatography; LOD: limit of detection

According to a study by Da Silva et al. (2017), the amounts of phytic acid in chia seeds range between 0.96 and 1.16 g/100 g. EFSA (2018) noted the phytic acid content of white and whole wheat flour (about 0.4 g/100 g and 2.2 g/100 g, respectively), and of rye, rice, barley and oat flours (range: 0.45–0.75 g/ 100 g) as reported by Garcia-Estepa et al. (1999). These authors also indicated that the

[10] Gallic acid equivalents.

phytic acid content reported in other studies shows a wide variability depending on flour yield, and flour types (range 0.15–0.32 g/100 g in white flour and 0.96–1.75 g/100 g in whole wheat flour). The authors reported the phytic acid content of brans (wheat brans: 2.5–5.8 g/100 g; oat brans: 2.0 g/100 g; rice bran: 5.8 g/100 g). EFSA also notes the phytate content of wheat and whole wheat flour (0.28 and 0.84 g/100 g, respectively) as reported by OECD in the consensus document on the composition of *Triticum aestivum* (OECD, 2003). Thus, the Panel considers that the content of phytates in chia seeds is comparable to the contents in cereal grains and does not raise a safety concern.

De Souza et al. (2017) investigated the antitryptic activity in chia seeds and reported the chromatographic isolation of a protein fraction with an estimated molecular mass of approximately 14.4 kDa that exhibited trypsin-inhibitory activity. Crude extract obtained from chia seeds presented 60% (13 TIU[11]/mg) of inhibitory activity for trypsin. Guillamon et al. (2008) investigated trypsin inhibitors in different grain legume seeds from different species and cultivars. Trypsin inhibitor content varied among species and cultivars, but in general showed the highest values in soybean (43–84 TIU/mg) and common bean (21–28 TIU/mg).

Another study (Sosa Crespo et al., 2018) retrieved by EFSA, indicated the inhibitory effect of peptide fractions obtained after hydrolysis of chia seeds and flour against enzymes α-amylase and α-glucosidase, responsible for the digestion of carbohydrates.

Overall, the Panel notes that, since the last evaluation by EFSA NDA Panel (2009), the knowledge of the composition of chia seeds has been extended, and no safety concerns were identified.

3.4.1. Stability of the NF under the intended conditions of use

Among the foods for which the use of chia seeds has been already authorised, there are various foods that are subject to heat-treatment in the course of their production (e.g. bread, baked products, breakfast cereals, sterilised ready-to-eat meals based on cereal grains, pseudocereals and/or pulses) or exhibit a low pH (e.g. fruit juice and fruit/vegetable blend beverages, fruit spreads, yoghurt). The authorised uses are summarised in Table 3.

The extensions of use of chia seeds which are subject of this assessment (see Section 3.1) could not only increase levels of some authorised uses, but also represents an extension of the spectrum of foods to which chia seeds could be added.

Considering the uses subject of this assessment and the composition of chia seeds, the Panel has no safety concerns regarding the stability of the NF.

3.5. Specifications

The specifications of chia seeds are described in the Union list of novel foods (Commission Implementing Regulation (EU) 2017/2470) and are summarised in Table 2.

Table 2: Specifications of chia seeds (*Salvia hispanica*)

Parameter	Range
Dry matter	90–97%
Protein	15–26%
Fat	18–39%
Carbohydrate	18–43%
Crude fibre	18–43%
Ash	3–7%

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

3.6.1. History of use of the NF

There is a documented history of use of chia seeds in third countries (mainly in Latin America), dating back hundreds of years. Also, information was provided on the consumption of chia seeds in countries such as USA, Canada, Australia, New Zealand, Japan and South Korea; in some of them, the consumption dates to the year 2000 (EFSA NDA Panel, 2009).

[11] Trypsin inhibitor units.

Since their first authorisation in 2009, there has also been a history of use of chia seeds in the EU (Table 3).

Table 3: Authorised use of chia seeds and products 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
	Pre-packed 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, pseudocereal grains and/or pulses	5% whole chia seeds
Chia oil from *Salvia hispanica*	Fats and oils	10%
	Pure chia oil	2 g/day
	Food Supplements as defined in Directive 2002/46/EC	2 g/day

According to the CBI report (2017), the import of chia seeds in Europe reached 16,182 t in 2016, indicating an average annual increase of 27% (in volume) since 2012. The four top countries regarding the import of chia seeds are Germany (with a market share of 40%), Netherlands (18%), Spain (12%) and UK (8%).

3.7. Uses and use levels and anticipated intake

3.7.1. Target population

The target population for the consumption of the NF is the general population.

3.7.2. Uses and use levels

The proposed extensions of use of chia seeds are listed in Section 1.1.

Those proposed extended uses included in this assessment, are indicated in Section 3.1 and concern the use of chia seeds in chocolate, fruit spreads, fruit desserts, mixed fruit with coconut milk in twin pot, fruit-preparations to underlay a dairy product, fruit-preparations to be mixed with dairy products, confectionary (excluding chewing gums), dairy products and analogues, edible ices, fruit and vegetables products, non-alcoholic beverages, and compotes from fruit and/or vegetables and/or with cereals. In order to address the terms of reference regarding the overall safety of chia seeds, this assessment considers the use of chia seeds added to these food groups without the proposed maximum use levels or other specific restrictions or precautions.

For the same reason (to assess the overall safety of chia seeds), this assessment also considers the use of chia seeds without specific restrictions and precautions regarding their use levels in other foods, which are usually not subject to thermal processing or cooking procedures.

3.7.3. Anticipated intake of the novel food

The Panel notes that no hazard, which raises safety concerns (except for allergenicity), could be identified from the information provided on chia seeds by the applicants (previous and present applications) or the information retrieved by EFSA through the extensive literature search.

In the absence of such hazard and thus, lacking the basis and need to establish safe maximum intake levels for chia seeds, the Panel considers that exposure assessment for chia seeds does not provide meaningful information for this assessment.

3.8. Nutritional information

Based on the compositional data, animal studies and the history of use, the Panel considered that chia seeds are unlikely to be nutritionally disadvantageous to the consumer under the proposed conditions of use, i.e. 5% of chia seeds in bread (EFSA NDA Panel, 2009).

Since then, the knowledge of the composition of chia seeds has been extended and the Panel has no concern regarding nutritionally disadvantageous effects resulting from the consumption of chia seeds.

3.9. Toxicological information

The applicants referred to a publication, which summarises the results of four toxicological studies with chia seeds (Shu-Qin et al., 2013). These studies were conducted according to the National Standards of the People's Republic of China for the toxicological assessment of food (GB15193.3-2003). It is not indicated whether the studies were conducted in compliance with Good Laboratory Practice (GLP) and, based on the short description and limited data presented, the Panel cannot assess whether the protocols applied were in line with the respective OECD test guidelines.

An acetone extract of chia seeds was tested for induction of gene mutations using the plate incorporation method and only four *Salmonella* Typhimurium tester strains (TA97, TA98, TA100 and TA102). No increase in the number of revertant colonies was observed at dose levels up to 5 mg/plate in the absence and presence of a metabolic activation system when compared with the solvent control.

In an *in vivo* micronucleus test using bone marrow, chia seeds ground into a powder, which was passed through a sieve and suspended in maize oil, was used as test material. After oral administration twice within 24 h at dose levels up to 7.5 g/kg body weight (bw) to Kunming mice (n = 5/sex per group), no increase in the frequency of micronucleated polychromatic erythrocytes (PCE) compared with the control group (which received maize oil) and no cytotoxicity of the test material was observed.

No statistically significant increase in the rate of abnormal sperms was observed after administration of the same test material to male Kunming mice (n = 5/group) at dose levels up to 7.5 g/kg bw.

In an acute oral toxicity study with Kunming mice (n = 10/sex), no adverse effects were identified after administration of chia seed powder (mixed with maize oil) at a dose of 22.5 g/kg bw.

The Panel considers that the available toxicological studies do not indicate a safety concern.

3.9.1. Human data

After the EFSA NDA Panel opinion in 2009, a number of human studies have been conducted on chia seeds, primarily investigating putative beneficial effects resulting from their consumption.

The applicants provided eight articles on human studies (Nieman et al., 2009, 2012; Vuksan et al., 2010, 2017a; Illian et al., 2011; Guevara-Cruz et al., 2012; Jin et al., 2012; Ho et al., 2013) and three reviews (Ulbricht et al., 2009; Ali et al., 2012; Teoh et al., 2018). EFSA retrieved six additional human studies in literature search (Brissette et al., 2013; Toscano et al., 2014, 2015; Nieman et al., 2015; Ayaz et al., 2017; Vuksan et al., 2017b) and three review articles (De Souza Ferreira et al., 2015; Parker et al., 2018; Grancieri et al., 2019).

The highest amounts of chia seeds were used in a single-blinded, placebo-controlled study by Nieman et al. (2009), in amounts of 50 g/day for 12 weeks with 76 adults. This study included endpoints such as serum lipoproteins, serum glucose, blood pressure, plasma cytokines and serum CRP (C-reactive protein). In addition, symptom logs consisted of measures of digestive health (constipation, heartburn, bloating, diarrhoea and nausea), sickness (fever, cough, sore throat, stuffy nose, runny nose and headache) and overall well-being. The same endpoints were also studied by Nieman et al. (2012) among 56 postmenopausal women consuming 25 g chia seeds or control (poppy) seeds in their randomised controlled trial for 10 weeks.

Other studies had a duration of up to half a year (Brissette et al., 2013; Vuksan et al., 2017a) with the number of participants ranging from 10 (Jin et al., 2012) to 77 (Vuksan et al., 2017a) and average dose levels of 30 g/day. Some of these studies, although not primarily designed to assess the safety of

chia seeds, reported safety-related parameters such as anthropometrics (body mass and composition), blood pressure, clinical chemistry (urea, creatinine, alanine transaminase (ALT), serum lipid profile, serum glucose and lactate, serum cortisol, inflammation markers) and haematology parameters (complete blood counts, prothrombin time). Also, adverse events that were reported by symptom logs consisting of measures of digestive health (constipation, heartburn, bloating, diarrhoea and nausea), hunger levels and energy levels (morning, afternoon and evening), sickness (fever, cough, sore throat, stuffy nose, runny nose and headache), pain (joint, muscle and back), allergies, dry eyes, fingernail growth, stress level, focus/concentration and overall well-being (Nieman et al., 2009, 2012, 2015; Jin et al., 2012; Brissette et al., 2013; Toscano et al., 2014, 2015; Vuksan et al., 2017a).

The Panel notes that the human studies provided by the applicants and those found by an extensive literature search were primarily designed to investigate putative beneficial effects at intakes up to 50 g per day and addressed only a limited number of safety-relevant endpoints such as blood pressure, standard clinical chemistry and some haematology parameters. 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.

3.10. Allergenicity

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, two case reports were identified in the available literature, both cases within the EU (Spain).

García Jiménez et al. (2015) described the first case of an immunoglobulin E (IgE)-mediated anaphylactic reaction induced by chia seeds. A few days after starting to consume chia seeds, a 54-year-old male patient experienced the following symptoms: pruritus in his mouth, followed by generalised urticaria, facial angioedema, shortness of breath, and dizziness. The authors identified known water-soluble and liposoluble allergens which include lectin, an elongation factor, and an 11S globulin as well as three additional undescribed allergens.

Tomas-Pérez et al. (2018) reported another case of IgE-mediated reaction with an atypical clinical manifestation (i.e. eczema and dermatitis) induced by chia seeds. A 46-year-old male patient complained of eczematous and itchy lesions on his hands after the introduction of chia seeds in his diet. A skin prick testing with chia seed extract was found positive. The authors identified allergens of molecular weights of around 60, 30, 15 and 10 kDa as responsible for sensitisation, and argued that allergens with 10 kDa could be lipid transfer proteins (LTPs) because they were proven to be resistant both to heat and pepsin digestion.

There is no information available on the prevalence of chia seeds allergy. The information available indicates that allergic reactions upon consumption of chia seeds may occur.

4. Discussion

This assessment concerns the safety of chia seeds for the general population under extended uses. These include the use of chia seeds without specific restriction or precaution in chocolate, fruit spreads, fruit desserts, mixed fruit with coconut milk in twin pot, fruit-preparations to underlay a dairy product, fruit-preparations to be mixed with dairy products, confectionary (excluding chewing gums), dairy products and analogues, edible ices, fruit and vegetables products, non-alcoholic beverages, and compotes from fruit and/or vegetables and/or with cereals. The assessment also takes into account the use of chia seeds without specific restrictions or precautions regarding their use for other foods which are usually not subject to thermal processing or cooking procedures.

This assessment does not address the safety of chia seeds when added to foods other than those covered by the preceding paragraph which may undergo heat treatment during processing and/or cooking procedures at temperatures which may result to the formation of relevant levels of the process contaminants, such as acrylamide. In the absence of sufficient information regarding the formation of this process contaminant in heated foods with added chia seeds, the safety of those proposed extended uses is subject of separate assessments.

The composition of chia seeds on proximate parameters (dry matter, protein, oil, crude fibre and ash) and fatty acids was assessed by the Panel in the EFSA opinion in 2009. Data on the contents of

minerals and vitamins, carbohydrates, amino- and fatty acid profiles, total polyphenols, tannins and rosmarinic acid and contaminants, such as heavy metals and mycotoxins were also assessed. Since 2009, several new studies have become available which provide further information on the presence of tocopherols, phytosterols, carotenoids, flavonoids and polyphenolic compounds but also antinutrients, such as phytates and some enzyme inhibitors in chia seeds. The Panel considers that their occurrence in chia seeds does not raise any safety concern.

Since the first authorisation for placing of chia seeds on the Union market as a NF in 2010, the safety of chia seeds for extensions of use was assessed several times by the Member States which did not identify any hazard which may pose a risk for the consumers.

For the present assessment, the Panel took into account previous safety assessments (EFSA NDA Panel, 2005, 2009), the information presented in seven applications, the history of consumption since 2010, and the information gathered from an extensive literature search designed to identify hazards related to chia seeds, toxicological and human studies.

Chia seeds have been consumed in North and South America, Australia, New Zealand and Asian countries as Japan, South Korea and other countries. The history of use in countries as USA, Canada and Australia extends nowadays to up to approximately 20 years, while its consumption in Europe reaches over a decade now. The Panel considers that the history of use of chia seeds supports the safety assessment of the NF.

The Panel considers that the limited available toxicological studies do not indicate safety concerns.

Available human trials with intake levels of up to 50 g of chia seeds per day 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. The Panel notes that no adverse events related to the consumption of chia seeds were reported, noting however the inherent limitations of such human studies for their use in this safety assessment.

In 2009, the Panel expressed the uncertainty related to the potential allergenicity of chia and noted the cross-reactivity of sera from patients known to be allergic to peanuts and sesame. Since then, the available 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.

The Panel notes that no other hazard causing safety concerns has been identified on the basis of the available information on composition, stability, history of consumption, toxicological and human data regarding whole and ground chia seeds.

The Panel considers that an exposure estimate for chia seeds does not provide meaningful information for safety assessment.

5. Conclusions

The Panel concludes that chia seeds are safe under the assessed conditions of use.

Steps taken by EFSA

1) Letter from the European Commission to the European Food Safety Authority with the request to carry out an overall dietary exposure and safety assessment for chia seeds (*Salvia hispanica* L.) as a novel food. Ref. Ares(2018)3762383, dated 16 July 2018 and subsequent amendments Ref. Ares(2018)4459892, dated 30 August 2018 and Ref. Ares (2018)5097094, dated 04 October 2018.
2) On 16 July 2018, EFSA received a valid application from the European Commission on extension of use of chia seeds as NF, which was submitted by SANCHIS MIRA S.A. and the scientific evaluation procedure started.
3) On 09 October 2018, EFSA received four valid applications from the European Commission on extension of use of chia seeds as NF, which were submitted by Zentis GmbH & Co. KG, by Majami Sp. z o.o. Sp. k., by Naturkost Übelhör GmbH & Co. KG and by The Chia Co and the scientific evaluation procedures started.
4) On 16 November 2018, EFSA received two valid applications from the European Commission on extension of use of chia seeds as NF, which were submitted by Parry's Pots Limited (PPL), and by Materne SAS and the scientific evaluation procedures started.
5) During its meeting on 14 March 2019, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of chia seeds (*Salvia hispanica* L.) as a NF for extended uses pursuant to Regulation (EU) 2015/2283.

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Abbreviations

ALT	alanine transaminase
bw	body weight
CBI	The Centre for the Promotion of Imports from developing countries
CRP	C-reactive protein
GAE	Gallic acid equivalents
GLP	Good Laboratory Practice
HACCP	Hazard Analysis and Critical Control Points
HPLC	high-performance liquid chromatography
IgE	immunoglobulin E
LOD	limit of detection
LTP	lipid transfer protein
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food
OECD	Organisation for Economic Cooperation and Development
PCE	Micronucleated polychromatic erythrocytes
TIU	trypsin inhibitory activity
UHPLC	ultrahigh-performance liquid chromatography