

# Report of the Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) on a request for initial assessment for marketing of chia (*Salvia hispanica*) seeds in sterilized ready-to-serve meals based on cereal, pseudocereals and/or pulse grains under Regulation (EC) No 258/97 on novel foods and novel food ingredients

## Section of Food Safety and Nutrition

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## Abstract

The company Herba Ricemills S.L.U. requested authorization to market chia (*Salvia hispanica*) seeds in sterilized ready-to-serve meals based on cereal, pseudocereals and/or pulse grains in the European Union. This would be an extension of use of the novel food authorized in 2009, 2013 and 2015.

The AECOSAN Scientific Committee takes the view that, according to the information provided, there is no indication that consumption of chia (*Salvia hispanica*) seeds in ready-to-serve meals based on cereal, pseudocereals and/or pulse grains, under the conditions proposed by the applicant, can produce adverse effects on health. The Committee concludes that the novel food presented for assessment meets the criteria for acceptance laid down by Regulation (EC) No 258/97 concerning novel foods and novel food ingredients (UE, 1997a).

## Key words

Chia seeds, ready-to-serve meals, novel foods.

## 1. Assessment of the novel food

### Introduction

The company Herba Ricemills S.L.U. requested authorization to market chia seed (*Salvia hispanica*) in the European Union as an ingredient in sterilised ready-to-serve meals based on cereal, pseudocereals and/or pulse grains along with vegetables and seasonings. These ready-to-serve meals are intended to be sold at room temperature and have a prolonged shelf life (1 year). The products are ready to eat after brief heating. This request would mean an extension of the uses authorised for this novel food in 2009, 2013 and 2015.

On the basis of Decision 2009/827/EC (EU, 2009) the company Columbus Paradigm Institute S.A. was authorised to place chia seed on the European market as a novel food ingredient in bread products, up to a maximum chia seed content of 5 %. Subsequently, The Chia Company applied to the competent authorities in the United Kingdom for an extension of use of chia seed. Specifically, it asked to be allowed to use up to 10 % chia seed in certain categories of food and to sell pre-packaged chia seed. This extension of use was authorised in accordance with Decision 2013/50/EU (EU, 2013). Subsequently, in 2015, the competent authorities of Ireland authorised an extension of use for Wow Food and Drinks for use in fruit juices and mixtures of fruit juices (15 g/450 ml of juice) (FSAI, 2015).

The applicant has included chia seed (*Salvia hispanica*) in Class 2 “complex novel foods obtained from non-GM sources”, which includes intact microorganisms used as foods, and in Sub-class 2 “the source of the novel food has no history of food use in the Community”. As a result of that classification (2.2) the request file has been dealt with in accordance with Commission Recommendation 97/618/EC, following the guidelines for that category (EU, 1997b).

### Comments

The Scientific Committee agrees with the applicant’s classification of the product as a novel food which had no history of consumption in the European Union prior to 1997.

### I. Specification of the novel food

The specifications of chia seed were laid down in Decisions 2009/827/EC and 2013/50/EU. The letter of authorisation from Ireland’s competent authorities subsequently laid down a series of conditions for authorisation of the use of chia seed in fruit juice and in fruit juice blends.

The chia seed it will use is subject to a notification of its substantial equivalence to seed already authorised in accordance with the assessment report issued by the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN).

### Comments

The Scientific Committee has verified that Herba Ricemills S.L.U. has notified the European Commission of the substantial equivalence of the chia seed it wishes to market to seed already authorised. The specifications laid down in Decisions 2009/827/EC and 2013/50/EU are considered sufficient.

## II. Effects of the production process applied to the novel food

The applicant states that the chia seed it will use has marketing authorisation obtained by means of notification of its substantial equivalence to seed already authorised in the European Union.

Attached are three examples of formulations based on pulses, cereals or both and a diagram is provided showing the different stages of the production of those ready-to-serve meals.

The ready-to-serve meals would be packaged in polymeric material suitable for holding between 125 g and 400 g. The containers can hold individual portions of 125 to 200 g or three or four portions per 300 or 400 g container. The packaging materials (bowls or pouches) of polymeric material (PP/EVOH/PP) are sealed in a modified atmosphere (CO<sub>2</sub>/N<sub>2</sub>, 30:70) using flexible film (PET/OPA/OPP), or dispensed into PET/PETSiOx/OPP doypacks of 134 microns. These materials act as barriers to oxygen and other gases and can withstand the sterilisation process.

The product is heat-treated in order to ensure that it is harmless, at temperatures of over 100 °C for more than 30 minutes. Furthermore, the heat treatment itself is performed in an autoclave at a temperature of 121 °C and at a pressure of around 2 000 millibars for more than 15 minutes in order to ensure a reduction in the microbial load (mainly spores of genera *Clostridium* and *Bacillus*, using *Clostridium botulinum* as a model) of 12D (i.e. a reduction of 10<sup>12</sup> of the initial load), using equivalent time values, F<sub>0</sub>, greater than 7 minutes, which can guarantee reliable sterilisation in the worst-case scenario. In this respect, the applicant provides analytical documentation from an independent laboratory which corroborates the results indicated for a number of products (five samples), and no presence of spores of a different microbial origin is observed.

A stability study was carried out on a sterilised ready-to-serve meal containing chia seed (1.5 %). The meal was kept at 5 °C (control), 25 °C (up to 3 months) and 38 °C (up to 6 months) and the residual oxygen, colour, pH and total titratable acidity (TTA) were checked and a sensory assessment of the product performed. The changes observed were considered small and insignificant.

### Comments

The Scientific Committee considers the sterilisation by heat treatment applied to be traditional for this type of product and appropriate from the point of view of microbiological food safety. Furthermore, the microbiological checks, based on periodic microbiological sampling and on monitoring compliance with the temperature, pressure and time parameters at each stage of heat treatment, can be considered adequate.

## III. History of the organism used as the source of the food

The applicant refers to the EFSA report which revised the history of chia seed use (EFSA, 2009) and to the recognition of its seeds' substantial equivalence to those already authorised. Furthermore, in other sections it describes the use of these seeds in their countries of origin and in other countries.

### Comments

The Scientific Committee believes that the use of chia seed in food is widespread in South America and that it has increased significantly in other countries.

## **IX. Anticipated intake/extent of use of the novel food**

The chia seed is intended to be marketed as an ingredient in sterilised ready-to-serve meals based on cereal, pseudocereals and/or pulse grains at a concentration of no more than 5 %.

In order to estimate the consumption of chia seed via ready-to-serve meals, the applicant has taken account of the report on food production, industry, distribution and consumption in Spain by Mercasa, a public company of the State Industrial Holding Company (SEPI) and the Spanish Ministry of Agriculture, Fisheries, Food and the Environment (Mercasa, 2016).

According to that report, total consumption of ready-to-serve meals in 2015 stood at 12.9 kilograms/person/year of the total consumption of ready-to-serve meals, 9.3 % was consumed as preserved vegetables, pulses and pasta, which would mean that 1.2 kg of that type of ready-to-serve meal was consumed per person per year.

If we take this scenario and assume that the formulation includes the maximum permitted chia seed content (5 % of weight), chia seed consumption would amount to 60 g of chia seed per year or 0.16 g per day.

At European level, an expected average consumption of ready-to-serve meals is provided of 12.1 kg/year in 2017, calculated by a company (Statista, 2017).

As an alternative, an estimate has been made based on the daily intake of a ready-to-serve meal of 200 g containing 5 % chia seed, which would be equivalent to an intake of 10 g of chia seed per day.

### **Comments**

Surveys of food intake do not provide data on the consumption of pulses, cereals or pseudocereals in the form of ready-to-serve meals. Given the limited information available on the consumption of ready-to-serve meals, the Scientific Committee considers the applicant's estimates of intake to be appropriate. Consumption estimated on the basis of the average consumption of ready-to-serve meals per person may not be representative of the high-consumption population groups (independent adults and young people and single-family households). Therefore, in order to cover a more extreme scenario, the Committee considers it more appropriate to estimate intake on the basis of the consumption of a daily dish of 200 g containing 5 % chia seed.

However, it is considered unlikely that a consumer would choose a ready-to-serve meal containing chia seed every day or choose a product from each category containing chia seed from amongst the wide of variety of products currently available.

## **XI. Nutritional information on the novel food**

The applicant states that Chia seeds are notable for their protein, fibre, carbohydrate and fat content, particularly omega-3 fatty acids. It states that the use of chia seeds in sterilised ready-to-serve meals based on cereal, pseudocereals and/or pulse grains will not pose any nutritional disadvantage for consumers but rather will improve the nutritional quality of ready-to-serve meals.

The results are included of the analysis of different components (protein, amino acid profile,

fibre, carbohydrates, fat, fatty acid profile, vitamins A, C, E and B and minerals) in three batches of chia seeds of Herba Ricemills S.L.U.

### Comments

The Scientific Committee believes that the use of chia seed in ready-to-serve meals based on cereal, pseudocereals and/or pulse grains will not pose any nutritional disadvantage for consumers. In any case, no nutrition or health claims can be made other than those authorised under Regulation (EC) No 1924/2006 (EU, 2006).

## XII. Microbiological information on the novel food

The results are included of the analysis of moulds and yeasts, *S. aureus*, Coliforms, *Salmonella* spp., *Enterobacteriae* and *Bacillus cereus* in three batches of chia seed of Herba Ricemills S.L.U.

The level of the ochratoxin A detected in one sample is below the maximum limit laid down for cereals. Likewise, the levels of the aflatoxin B1 detected in two samples are below those laid down for oilseeds.

### Comments

The Scientific Committee considers the information on the absence of pathogenic microorganisms in chia seed to be sufficient, and would point out that, if its marketing as an ingredient in ready-to-serve meals is authorised, the product must comply with all of the food legislation applicable to it and, once the product is on the market, the operator must ensure that undesirable microorganisms are absent or are present at levels below the maximum limits laid down.

The applicant shows that the sterilisation process undergone by ready-to-serve meals is effective and that it has a hazard analysis and critical control points (HACCP) system ensuring the desired levels of harmlessness and quality. The Committee considers that the inclusion of up to 5 % chia seed in these meals does not increase the microbiological risk evading control under the HACCP system.

## XIII. Toxicological information on the novel food

As in the case of previous extensions of use of chia seed, the applicant is not providing results of toxicological tests. The applicant states that, to date, there has been no evidence of allergies, anti-nutritional effects or toxic effects caused by the consumption of chia seeds in the United States, Canada or Australia.

### Comments

The Scientific Committee considered the harmlessness of the novel food to have been demonstrated, and that it is not altered by the novel use as an ingredient in ready-to-serve meals based on cereal, pseudocereals and/or pulse grains. The previous and current use of chia seed in the countries of the European Union and outside of it can be seen as evidence of its safety. Furthermore, a bibliographical search from 2009 (the year of publication of the EFSA scientific

opinion) to the present has been carried out and no toxicological studies have been found. There are, however, intervention studies which use chia seed in greater quantities than those used by the applicant and which do not reveal signs of toxicity (25 g in Nieman et al. (2009); 30 g in Vuksan et al. (2017); etc.).

With regard to allergenicity, the Scientific Committee has found that there has been a recent case of anaphylaxis caused by consumption of chia seed (García-Jiménez et al., 2015). However, the Committee concludes that the existence of one single recorded case of anaphylaxis from chia seed following prolonged use indicates that its allergenicity is insignificant. Furthermore, the indication “chia seed (*Salvia hispanica*)” on the product’s labelling will enable any consumers allergic to other seeds to avoid consuming it.

## Conclusions of the Scientific Committee

The Scientific Committee takes the view that, according to the information provided, there is no indication that consumption of chia (*Salvia hispanica*) seeds in ready-to-serve meals based on cereal, pseudocereals and/or pulse grains, under the conditions proposed by the applicant, can produce adverse effects on health, and that the novel food presented for assessment meets the criteria for acceptance laid down by Regulation (EC) No 258/97 concerning novel foods and novel food ingredients.

## References

- EFSA (2009). European Food Safety Authority. Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission on the safety of ‘Chia seed (*Salvia hispanica*) and ground whole Chía seed’ as a food ingredient. *The EFSA Journal*, 996, pp: 1-26.
- EU (1997a). Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43 of 14 February 1997, pp: 1-6.
- EU (1997b). Commission Recommendation 97/618/CE of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 253 of 16 September 1997, pp: 1-36.
- EU (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404 of 30 December 2006, pp: 9-25.
- EU (2009). 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 of 11 November 2009, pp: 14-15.
- EU (2013). Commission Implementing Decision 2013/50/EU of 22 January 2013 authorising an extension of use of chia (*Salvia hispanica*) seed as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 21 of 24 January 2013, pp: 34-35.
- FSAI (2015). Food Safety Authority of Ireland. Request for extension of use of chia seed in the context of Regulation (EC) No 258/97 on novel foods, to include certain non-alcoholic drinks. 18 September 2015.
- García Jiménez, S., Pastor Vargas, C., de las Heras, M., Sanz Maroto, A., Vivanco, F. and Sastre, J. (2015). Allergen characterization of Chia Seeds (*Salvia hispanica*), a new allergenic food. *Journal of Investigational Allergology and Clinical Immunology*, 25 (1), pp: 55-82.
- MERCASA (2016). Mercados Centrales de Abastecimiento, S.A. Alimentación en España 2016. Producción.

- Industria. Distribución. Consumo. Available at: [http://www.mercasa-ediciones.es/alimentacion\\_2016/pdfs/Alimentacion\\_en\\_Espana\\_web\\_2016\\_150px.pdf](http://www.mercasa-ediciones.es/alimentacion_2016/pdfs/Alimentacion_en_Espana_web_2016_150px.pdf) [accessed 21-04-16].
- Nieman, D.C., Cayeaam, E.J., Austina, M.D., Henson, D.A., McAnulty, S.R. and Jin, F. (2009). Chia seed does not promote weight loss or alter disease risk factors in overweight adults. *Nutrition Research*, 29, pp: 414-418.
- Statista (2017). Statista GmbH. Ready Meals. Available at: <https://www.statista.com/outlook/40080100/102/ready-meals/europe#market-arpc> [accessed 21-04-16].
- Vuksan, V., Jenkins, A.L., Brissette, C., Choleva, L., Jovanovski, E., Gibbs, A.L., Bazinet, R.P., Au-Yeung, F., Zurbau, A., Ho, H.V.T., Duvnjak, L., Sievenpiper, J.L., Josse, R.G. and Hanna, A. (2017). Salba-chia (*Salvia hispanica* L.) in the treatment of overweight and obese patients with type 2 diabetes: A double-blind randomized controlled trial. *Nutrition, Metabolism & Cardiovascular Diseases*, 27, pp: 138-146.