



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 chocolate bars under Regulation (EC) No 258/97 concerning novel foods and novel food ingredients

Section of Food Safety and Nutrition

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Reference number: AECOSAN-2017-006

Report approved by the Section of Food Safety and Nutrition of the Scientific Committee in its plenary session on 20 September 2017

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Abstract

The company Sanchis Mira S.A requested authorisation to market chia (*Salvia hispanica*) seeds in chocolate bars in the European Union. This would be an extension of use of the novel food authorised in 2009, 2013 and 2015.

The Scientific Committee takes the view that, according to the information provided, there is no indication that consumption of chia (*Salvia hispanica*) seeds in chocolate bars, 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, chocolate, novel food.

1. Assessment of the novel food

Introduction

The company Sanchis Mira S.A requested authorisation to market chia (*Salvia hispanica*) seeds in chocolate bars in the European Union. 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 to 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 plants, animals and 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. Specifications 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 juices and mixtures of fruit juices.

The chia seed it will use is marketed by Jules Brochenin SA, which has notified its substantial equivalence to seed already authorised in accordance with the report issued by France’s Directorate-General for Competitiveness, Consumer Affairs and Anti-Fraud.

Comments

The Scientific Committee has verified that Jules Brochenin SA 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 and describes the process for producing the seeds.

The coating of liquid chocolate is received and maintained at 40-50 °C for a maximum of approximately one month and is screened for extraneous matter using magnetic, mesh and rotary filters.

Ingredients (chia seeds or other pre-mixed ingredients) are added to the chocolate at 27-33 °C. When the moulds have been filled it is cooled to 6-14 °C and, once solidified, it is packaged and labelled.

The applicant states that the temperature ranges used do not alter the composition or structure of the novel ingredient.

A stability study was carried out on a formulation of chocolate containing cranberries (15 %) and chia seed (3 %). The chocolate was kept subjected to cycles of 0 to 25 °C for 8 hours per day over 8 months. Four microbiological (mould, yeast, enterobacteriae, *E. coli*, *Salmonella/Shigella* and *S. aureus*) and organoleptic controls were carried out over 12 months and no microbiological contamination or variation in organoleptic characteristics (flavour, odour, colour/appearance and texture) was detected.

Comments

The Scientific Committee considers the manufacturing process employed to be traditional for this type of product and appropriate from the point of view of food safety. Furthermore, the applicant has an adequate system of critical chemical, physical and biological control points.

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

The applicant refers to the requests for marketing of chia seeds and chia seed oil already authorised and to the recognition of the substantial equivalence of the seeds it will use to those already authorised.

Comments

The use of chia seed in food is widespread in South America and has increased significantly in other countries. Furthermore, it has authorisations for use as an ingredient in different foods in the European Union.

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

The chia seed is intended to be marketed as an ingredient in chocolate bars at a concentration of no more than 3 %.

In order to estimate the consumption of chia seeds as an ingredient in chocolate bars, the applicant has taken data from the Comprehensive European Food Consumption Database (EFSA, 2017).

According to that database, the highest consumption of chocolate bars is 200 g/day in Slovenia (95th percentile for acute consumption of chocolate bars for adults).

If we take this scenario and assume that the formulation includes the maximum permitted chia seed content (3 % by weight), chia seed consumption amounts to 6 g of chia seed per year.

Comments

The Scientific Committee considers the estimates of intake made by the applicant to be appropriate.

XI. Nutritional information on the novel food

The applicant states that chia seed will not be used for its health properties and that no claim will be made to that effect, and that it will not replace other foods in the diet in such a way as to pose a nutritional disadvantage.

The results are included of the analysis of different components (protein, fibre, carbohydrates, fat, fatty acid profile, vitamins A, C and E and minerals) in three batches of chia seeds from Jules Brochenin SA and an analysis has been carried out to compare the composition of a chocolate formulation with and without chia seeds.

Comments

The Scientific Committee believes that the use of chia seed in chocolate bars will not pose any nutritional disadvantage for consumers. Given the small proportion of chia seeds added, the nutritional difference between chocolate with chia seeds and chocolate without them is small and cannot be considered significant.

In any case, no nutrition or health claims can be made other than those authorised under Regulation (EC) No 1924/2006.

XII. Microbiological information on the novel food

The results are included of the analysis of moulds and yeasts, *S. aureus*, coliforms, *Salmonella*, *Enterobacteriae* and *Bacillus cereus* in three batches of chia seed from Jules Brochenin SA.

The applicant carried out an analysis of Staphylococcus positive coagulase, *L. monocytogenes*, *Salmonella* and *E. coli* in chia seeds and in a formulation of chocolate containing cranberries and chia seeds, with negative results in both cases.

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 chocolate bars 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 has a hazard analysis and critical control points (HACCP) system in place to

ensure that the desired levels of harmlessness and quality are maintained. The Committee considers that the inclusion of up to 3 % chia seed in chocolate bars 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 does not provide results of toxicological tests and refers to studies included in previous authorisation files. It also provides the results of the analysis of heavy metals, mycotoxins and pesticides in chia seeds carried out by Jules Brochenin SA - in the context of the request for substantial equivalence of its seeds - and also by the applicant.

Comments

The Scientific Committee considers that the harmlessness of the novel food has been sufficiently demonstrated and that it is not altered by the novel use as an ingredient in chocolate bars. 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 European Food Safety Authority's scientific opinion (EFSA, 2009)) 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 one 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 AECOSAN Scientific Committee takes the view that, according to the information provided, there is no indication that consumption of chia (*Salvia hispanica*) seeds in chocolate bars, under the conditions proposed by the applicant, can produce adverse effects on health. The Committee believes 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.

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