

Safety Assessment of Chia Seed (Extension of use)

Name of Applicant: Chia Love Ltd

Contact person(s): Mr Oliver J Dickinson

Novel Food Classification: 1.2.(e)

Introduction

An application to extend the food categories that can deliver chia seed within the EU was submitted to the Food Safety Authority of Ireland (FSAI) by Chia Love Ltd of the UK in accordance with *Article 4* of the novel food Regulation (EC) No. 258/97. The application was accepted by the FSAI on November 19th of 2014.

Chia seed has been approved as a novel food in the EU since 2009 by Commission Decision 2009/827/EC and the number of food categories to which it can be added was extended in 2013 by Commission Implementing Decision 2013/50/EU. Currently, chia seed is approved for use in baked products, breakfast cereals, fruit, nut and seed mixes and as 100% packaged seed. The applicant initially requested an ‘extension of use’ to market chia seed in fruit juice, fruit juice blends and other non-alcoholic beverages. However, following discussion with the applicant, this has been reduced to fruit juice and fruit juice blends with no reference to “other non-alcoholic beverages”.

The applicant considers chia seed to be novel based on *Article 1.2(e)* of the novel food Regulation (EC) No 258/97: “foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating and breeding practices and which have a history of safe food use.” The application dossier was prepared pursuant to Commission Recommendation 97/618/EC and in order to assess wholesomeness chia seed is placed in class 2.2: “Complex novel food from a non- GM source”, “The source of the novel food has no history of food use in the Community”.

I. Specification of the novel food

The chia seed to be used by the applicant was authorised for the EU market by virtue of a substantial equivalence opinion provided by the German Authorities in 2010 (No 147: http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf).

Therefore, the specifications of the chia seed are already deemed equivalent to previously authorised chia seed and do not require further evaluation. The applicant intends to add up to 15g of whole mashed chia seed and ground chia seed to 450 mL containers of fruit juice and fruit juice blends.

II. Effect of the production process applied to the novel food

Organic chia seed is produced through standard planting and harvesting procedures with weed control and seed cleaning achieved mechanically. A number of sampling steps are included in the process to ensure seed quality and safety. The applicant claims that the results from pesticide analysis of chia seed indicate that levels are in accordance with the requirements for pesticide residue levels of the German Association for Organic Production and Trade. The chia seed (whole mashed or ground chia seeds) are pre-hydrated in water prior to adding to the juice of choice. Pasteurisation steps and microbiological analyses of samples of the seed, fruit juice and the final product ensure a high level of confidence in the safety of the production process and the final product with respect to the risk posed by the potential proliferation of spoilage or pathogenic microorganisms.

III. Source Organism History

Chia (*Salvia hispanica*) is a summer annual herbaceous plant belonging to the *Labiatae* family. The applicant states chia has been consumed for thousands of years, historically constituting a significant component of the diet of Aztecs and the Mayans in Central and South America. Currently, chia is grown commercially in Latin America and Australia and is consumed in many countries around the world, some contained in beverages. In recent years within the EU, chia has become a popular food ingredient in a number of food categories by virtue of two novel food authorisations and numerous substantial equivalence opinions. The chia seed to be used by the applicant in beverages is already authorised for the EU market through a substantial equivalence opinion provided by the German Authorities in 2010.

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

Chia seed is already authorised for use in a number of food categories in the EU including baked products, breakfast cereals, fruit, nut and seed mixes and pre-packaged chia seed. The applicant wishes to extend the use of chia seed to include ground and whole mashed chia seeds in fruit juice and fruit juice blends and plans to launch in the UK and Germany only. However, if this extension of use application is successful the product could potentially be marketed in all EU Member States without any additional authorisation. The applicant quotes data from the UK Soft Drinks Report of 2013 (not supplied) which reveals that 17.6 litres of fruit juice were consumed per person in 2012. Based on these figures, incorporation of 15g of chia seed in 450 ml of a juice drink corresponds to an estimated intake of 587g of chia seed per person over a 12 month period. This translates to 1.61g chia seed per day which would leave sufficient scope for the consumption of chia seed through other sources and still be within the recommended upper intake level of 15g per day. The estimated consumption level of chia seed in beverages is likely to be an over-estimation since there are a variety of fruit juices on the market and only a limited number of people are likely to consume Chia Love every day. Although the applicant

outlines trends in intakes of various juice drinks from 2006, there is no reason to believe that actual intakes will deviate significantly from 2012 values.

On the basis that target markets would be different, the applicant did not conduct a cumulative assessment of intakes from existing and proposed dietary sources of chia seed. However, cumulative assessments can lead to an overestimation of intakes as they generally consider high level consumers for each food category which reflects a worst-case scenario.

X. Information from previous human exposure to the novel food or its source

Chia seed has reportedly been consumed by people of the Aztec and Mayan cultures in Central and South America. In more recent times, chia seed has become popular in various other parts of the world as a purported health food, including the EU, with no adverse effects reported. This fact is reflected in the 2009 EFSA Opinion on the Safety of Chia Seeds: “experience gained from previous and current use of chia seeds for food purposes in non-EU countries can be regarded as supportive evidence of the safety of chia seeds and ground whole Chia seeds”. Beverages containing chia seeds are already on sale outside of the EU at higher concentrations than those proposed in the current application (e.g. 45g Chia seeds in 295ml drink in the North America) without any reports of adverse effects.

XI. Nutritional information on the novel food

The composition and nutritional value of the novel chia seed is addressed by the applicant and as this chia seed is already authorised for the EU market further evaluation is not required. Similarly, fruit juices and fruit juice blends are also on the EU market and there is no reason to believe their nutritional value will be impacted by the addition of chia seed.

XII. Microbiological information on the novel food

The microbiological status of the chia seed in this application compares favourably to other authorised chia seed and the applicant commits to ensuring that appropriate quality measures are in place to maintain that standard. Microbiological checks are carried out at numerous points in the production process on both the chia seeds and the fruit juice/fruit juice blends as well as the final product which is a mix of whole mashed and ground chia seeds with fruit juice or fruit juice blends. Of significant importance is the withholding of a sample bottle from each batch which is maintained in controlled conditions and monitored until the expiry date of that batch. Microbiological control as well as appropriate storage and handling are especially important criteria of this application since the chia seed are to be consumed in fruit juices and fruit juice blends which would naturally favour the proliferation of spoilage and/or pathogenic microorganisms in uncontrolled situations.

XIII. Toxicological information on the novel food

The applicant acknowledges that while there is limited toxicological data on chia seeds, experience gained from previous and current use of the seeds in the EU and non-EU countries can be regarded as supportive evidence of the safety of chia seeds. Previous assessments of chia seed by EU Member State Authorities and EFSA, as well as human studies presented by the applicant have not identified any toxicological risks associated with the consumption of chia seed. In essence, neither the toxicological safety of the authorised chia seed or the fruit juice or fruit juice blends is in question. The novelty of this application lies in the mix of fruit juice or fruit juice blends with chia seed, with the primary risk being of a microbiological nature.

Allergenicity

The inclusion of chia seed in food products does not require specific allergen labelling within the EU. As per the labelling requirement in Commission Implementing Decision 2013/50/EU, beverages containing chia seed will indicate the presence of seed as “Chia (*Salvia hispanica*) seeds”. The beverages will be marketed in transparent containers and the applicant also commits to monitoring any reported cases of allergic reactions to chia seed through contact with allergy groups in the UK and USA.

Choking Hazard

The applicant acknowledges that the addition of chia seed to a beverage may be perceived as a choking hazard for some individuals. However, the chia seed to be added will be either mashed whole seed or ground seed with the result that the chia seed/juice mixes will not be very different to existing fruit juice and smoothies which contain solid portions of fruit. Any risk of a choking hazard associated with the rapid hydration of a hygroscopic material (for example the non-starch polysaccharide Konjac) will be negated by the pre-hydration of seeds prior to their addition to the juice or juice blend. Hydrated chia seeds are soft and form a jelly like outer coating which acts as a form of lubricant and may actually make them easier to swallow. Chia seed drinks are available in North America with up to 45g of chia seed in a 295ml drink (3 times that proposed by the applicant) and there have been no reported adverse events. The hydrated chia seed will be evident in the transparent juice containers and labelling will also indicate the presence of chia seed. While the choking risk due to chia seed/juice mixes is not considered a concern for juveniles and adults, it may be prudent to consider whether the texture and consistency of such drinks could be an issue for younger children.

Conclusions

Chia Love Ltd proposes to extend the food categories that can deliver chia seed in the EU through the addition of whole mashed or ground chia seed to fruit juice and fruit juice blends at up to 15% w/v. The chia seed source to be used is already authorised for the EU market and therefore a detailed evaluation is not required. In addition, fruit juices and fruit juice blends are already commonplace on the EU market which means the focus of the evaluation is on the mix of chia seed and fruit juice or fruit juice blends. The production process involves a number of pasteurisation steps which,

along with microbiological monitoring provides assurance that the risk of proliferation of spoilage and pathogenic microorganisms will be minimised. It is evident that the consumption of chia seed through the beverages specified by the applicant will not add significantly to the daily intake of chia seed among consumers, but will likely provide an alternative source of chia seed. Similar to orange juice containing bits of the orange, the consistency and texture of fruit juice and fruit juice blends with added chia seed may not be attractive to some people. However, the presence of pre-hydrated chia seed in these beverages is not considered to pose a risk for choking for the reasons discussed earlier in this report. In any case, the transparent containers and labelling will enable consumers to identify the presence of chia seed in the beverage.

Recommendation

The Food Safety Authority of Ireland has not identified any safety concerns associated with the consumption of chia seed contained in fruit juice and fruit juice blends at the intended use levels and therefore considers that it meets the criteria for novel food set out in *Article 3.1.* of the novel food Regulation (EC) No 258/97.