

SUBSTANTIAL EQUIVALENCE OPINION

Chia Seed (*Salvia hispanica*)

The Food Safety Authority of Ireland (FSAI) received a joint application in July of 2016 from Chosen Agrifoods Bolivia SRL, Sesajal S.A. de C.V. of Mexico and Aregare B.V. in the Netherlands for an opinion on the substantial equivalence of their chia seed (*Salvia hispanica* L.) to chia seed already authorised as a novel food on the EU market. The novel chia seed is compared to chia seed authorised for the EU market by Commission Decision 2009/827/EC and Commission Implementing Decision 2013/50/EU.

Organic chia seed is cultivated on various farms located in the Santa Cruz region of Bolivia and collected by Chosen Agrifoods. Sesajal S.A. de C.V. purchases the cleaned and graded seed from Chosen Agrifoods for export to the EU and acceptance by Aregare B.V. in the Netherlands. The organic method of cultivation of the chia seed ensures minimal exposure to chemical fertilizers or plant protection products while traceability, safety and quality control systems take effect soon after harvesting.

Composition

The applicant demonstrates, through batch test results, that the composition of the novel Chia seed is substantially equivalent to the authorised comparator in terms of dry matter, protein, fat, carbohydrate, dietary fibre and ash. Any differences observed in these parameters are relatively minor and can be explained by natural variation.

Nutritional Value and Metabolism

The novel chia seed and the authorised comparator are compositionally very similar and therefore the nutritional value and metabolism of both products would not be expected to differ.

Intended Uses

The novel chia seed is to be used in the same food categories that are set out in Commission Decision 2009/827/EC and Commission Implementing Decision 2013/50/EU and includes bread products ($\leq 5\%$), baked products ($\leq 10\%$), breakfast

cereals ($\leq 10\%$), fruit, nut and seed mixes ($\leq 10\%$) and pre-packaged seed ($\leq 15\text{g/day}$).

Level of Undesirable Substances

Satisfactory results are provided for seed batches tested for the presence of the heavy metals; arsenic, cadmium, mercury and lead. Results are also provided in relation to sample analysis relating to microbial contaminants (mycotoxins, yeasts/moulds, *Staphylococcus coagulans*, *Bacillus cereus*, *Salmonella*, *E. coli* and *Clostridium perfringens*).

Conclusions

The FSAI is satisfied from the information provided that chia seed produced and marketed by Chosen Agrifoods Bolivia SRL, Sesajal S.A. de C.V. of Mexico and Aregare B.V. in the Netherlands is substantially equivalent to chia seed authorised for the EU market by Commission Decision 2009/827/EC and Commission Implementing Decision 2013/50/EU. The designation of the novel ingredient in foodstuffs will be “Chia (*Salvia hispanica*) seeds” in accordance with Article 2 of Commission Implementing Decision 2013/50/EU. When sold in pre-packaged form, the consumer will be informed through the label that the daily intake of chia seed should not exceed 15 g per day.