SUBSTANTIAL EQUIVALENCE OPINION

Chia Seed (Salvia hispanica)

The Food Safety Authority of Ireland (FSAI) received an application in April of 2015 from Chia Freyval Co. Ltd. of Ireland for an opinion on the substantial equivalence of its Chia seed (*Salvia hispanica*) to Chia seed already authorised as a novel food on the EU market. The comparator Chia seed on the EU market was authorised by Commission Decision 2009/827/EC and Commission Implementing Decision 2013/50/EU.

The novel Chia seed will be grown in Argentina and Bolivia and will generally conform to the compositional parameters set out in Annex I of Commission Implementing Decision 2013/50/EU. The intended uses and labelling of the novel Chia seed will be the same as for the authorised comparator.

Composition

The applicant provides data demonstrating the compositional similarity of their Chia seed with the comparator in terms of dry matter, protein, fat, carbohydrate, dietary fibre and ash. Extensive comparison also demonstrates significant similarity between the novel ingredient and authorised comparator with respect to micronutrients such as vitamins and minerals as well as amino acid and fatty acid profiles. Only minor differences can be observed and these are in line with natural variation.

Nutritional Value and Metabolism

The novel Chia seed and the authorised comparator contain similar amounts of the major and minor nutritional components 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 EU at similar levels and in the same food categories set out in Annex II of Commission Implementing Decision 2013/50/EU which includes baked products, breakfast cereals, fruit/nut/seed mixes and prepackaged seed.

Level of Undesirable Substances

The Chia seed is grown in Argentina and Bolivia without the application of chemicals during crop production or processing and in accordance with an *ad-hoc* quality management system. However, extensive pesticide analysis carried out on the final product by the applicant ensures the absence of chemical residues. Batch analysis data relating to microbial contaminants (mycotoxins, yeasts/moulds, *Bacillus cereus, Salmonella, E. Coli, Staphylococci, Listeria* and *clostridia*) as well as heavy metals (arsenic, cadmium, lead and mercury) and pesticides are provided and do not identify any cause for concern.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Chia seed marketed by Chia Freyval Co. Ltd. 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 this 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.