SUBSTANTIAL EQUIVALENCE OPINION

Chia Seed (Salvia hispanica)

The Food Safety Authority of Ireland (FSAI) received an application in February of 2015 from Sesajal S.A. de CV of Mexico and Intra Europa Mf UG of Germany 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 Mexico 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 comparators 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 constituents 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

Though the original dossier listed the application of a "sealant" to the ground prior to planting, that step has been discontinued by the applicant. Pesticides, herbicides or synthetic fertilisers are not applied in crop production, though certain pesticide analysis is still carried out on the final product. The production company has a food safety management system in place which incorporates HACCP principles. Harvesting and processing are all carried out mechanically with quality control checks carried out after processing and prior to packaging.

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.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Chia seed marketed by Sesajal S.A. de CV and Intra Europa Mf UG 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 prepackaged form, the consumer will be informed through the label that the daily intake of Chia seed should not exceed 15 g per day.