SUBSTANTIAL EQUIVALENCE OPINION

Chia Seed (Salvia hispanica)

The Food Safety Authority of Ireland (FSAI) received an application in July of 2015 from Sun & Seed Ltd. in the UK 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 the possible uses extended by Commission Implementing Decision 2013/50/EU. The novel Chia seed will be grown in Bolivia in South America and will generally conform to the compositional parameters set out in Annex I of Commission Implementing Decision 2013/50/EU. The production process meets organic standards and so chemical fertilizers or pesticides are not used during production or processing. The intended uses and labelling of the novel Chia seed will be the same as for the authorised comparator.

Composition

A variety of compositional parameters were determined for separate batches of the novel Chia seed. The results demonstrate a high level of similarity between the novel and authorised Chia seed in terms of dry matter, protein, fat, carbohydrate, dietary fibre and ash. Micronutrient content including vitamins, minerals, amino acids and fatty acid profiles are also very similar.

Nutritional Value and Metabolism

The novel Chia seed and the authorised comparator contain similar levels of the main macro and micro 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 up to 10% in baked products, breakfast cereals, fruit/nut/seed mixes as well as pre-packaged seed that carry a recommendation that no more than 15g/day is consumed.

Level of Undesirable Substances

The novel Chia seed is grown in Bolivia and produced to organic standards without the use of chemical fertilizers or synthetic pesticides/herbicides. The applicant provides analytical results that demonstrate the absence of Dioxins and PCB-congeners. The results of analysis for the presence of contaminants including heavy metals (arsenic, cadmium, lead and mercury), mycotoxins and ochratoxin A do not raise any concerns. The level of microbiological contaminants such as yeasts, moulds, coliforms, *Bacillus cereus*, *Staphylococcus aureus* and *Salmonella* spp. are all within community safety parameters.

Conclusions

The FSAI is satisfied from the information provided by Sun & Seed Ltd. that Chia seed intended to be marketed by Sun & Seed 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 prepackaged form, the consumer will be informed through the label that the daily intake of Chia seed should not exceed 15 g per day.