

SUBSTANTIAL EQUIVALENCE OPINION

Chia Seed (*Salvia hispanica*)

The Food Safety Authority of Ireland (FSAI) received an application in January of 2015 from Royal Ingredients Group BV in the Netherlands 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 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 close compositional similarity of their Chia seed with the comparator in terms of dry matter, protein, fat, carbohydrate, dietary fibre and ash. Extensive comparison using data from Commission Decisions and EFSA safety assessments also demonstrates significant similarity between the novel ingredient and authorised comparators with respect to micronutrients such as vitamins and minerals, with any minor differences considered due either to analytical or 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 pre-packaged seed.

Level of Undesirable Substances

The applicant details the chemical treatment of the ground prior to planting and treatments of the growing Chia crop during cultivation with EU approved plant protection products. 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 Royal Ingredients Group BV 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.