

SUBSTANTIAL EQUIVALENCE OPINION

Chia Seed (*Salvia hispanica*)

The Food Safety Authority of Ireland (FSAI) received a joint application in August of 2014 from Duria Global GmbH & Co. KG of Kreuzau in Germany and Medina Vasquez SRL of Santa Cruz in Bolivia for an opinion on the substantial equivalence of their Chia seed (*Salvia hispanica*) to Chia seed already on the EU market as a novel food. The comparator Chia seed on the EU market was authorised to the Chia Company in Australia by Commission Implementing Decision 2013/50/EU.

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

Composition

The applicants sent three product batches to an independent laboratory for compositional and nutritional analysis. Relatively minor differences between the novel and authorised Chia seed were identified in the levels of macro and micro nutrients which can be attributed to natural variation experienced by plants growing in different geographical areas with differing climate patterns and other factors. The compositional data recorded related to dry matter, protein, fat (saturated and unsaturated), carbohydrate, fibre and ash, as well as a number of vitamins and minerals.

Nutritional Value and Metabolism

The novel Chia seed and the authorised comparator contain similar levels of the main macro and micro nutrients 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 novel Chia seed is naturally grown to organic standards which means without the use of chemicals in the form of pesticides or fertilizers during production or processing and therefore detailed chemical residue analysis has not been carried out. Regardless, the applicants carry out regular screening for pesticide contaminants as part of the quality control process.

Data relating to microbial contaminants (mycotoxins, yeasts, *Staphylococci*, *Bacilli*, *Salmonella*, *E. Coli* and *Listeria*) as well as heavy metals (arsenic, cadmium, lead and mercury) are provided and are similar to those for the comparator seed. The applicant will ensure that monitoring for these contaminants will continue as part of the quality control system.

Conclusions

The FSAI is satisfied from the information provided that Chia seed marketed by Duria Global GmbH & Co. KG and Medina Vasquez SRL is substantially equivalent to Chia seed already on the EU market and authorised to the Chia Company in Australia by 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 15g.