

SUBSTANTIAL EQUIVALENCE OPINION

Chia Seed (*Salvia hispanica*)

The Food Safety Authority of Ireland (FSAI) received an application in April of 2016 from Seitenbacher GmbH & Co. of Germany for an opinion on the substantial equivalence of its chia seed (*Salvia hispanica* L.) 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 is organically grown and harvested by a US company in South America and generally conforms 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 comparators.

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. Additional comparison also demonstrates significant similarity between the novel ingredient and authorised comparator with respect to select vitamins and minerals as well as saturated and unsaturated fat profiles. Only minor differences are evident 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 Commission Decision 2009/827/EC and Annex II of Commission Implementing Decision 2013/50/EU which include bread products, baked products, breakfast cereals, fruit, nut and seed mixes and pre-packaged seed.

Level of Undesirable Substances

The novel chia seed is organically grown in South America without the application of chemicals during crop production or processing. However, analysis for the presence of pesticide residues carried out on the final product confirms the absence of pesticide residues. Batch analysis data relating to microbial contaminants (mycotoxins, yeasts/moulds, *Bacillus cereus*, *Salmonella*, *Enterobacteriaceae*, *Staph. aureus*, Coliforms and Enterobacteriaceae) as well as heavy metals (arsenic, cadmium, mercury and lead) 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 to be marketed by Seitenbacher GmbH & Co. of Germany 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.