

## SUBSTANTIAL EQUIVALENCE OPINION

### Chia Oil

The Food Safety Authority of Ireland (FSAI) received an application in October of 2015 from Negocios Europa Limited (trading as AgroBolivia) in the UK for an opinion on the substantial equivalence of its chia seed oil to chia oil produced by Functional Products Trading S.A. of Chile and authorised for the EU market by Commission Implementing Decision 2014/890/EU.

Chia oil, derived from chia seeds (*Salvia hispanica*), is a rich source of polyunsaturated fatty acids, primarily the omega-3 alpha-linolenic acid and to a less extent the omega-6 linoleic acid among others. Chia oil is novel and is categorised under *Article 1.2(e)* of the novel food Regulation (EC) No. 258/97 as “*foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use*”.

The applicant produces chia seed oil by the cold pressing of EU-authorised chia seed sourced in Bolivia followed by filtration to remove residual waxes and solid materials. The chia seed oil is to be used in fats and oils as well as in food supplements in accordance with Annex II of Commission Implementing Decision 2014/890/EU and shall be designated as “Chia oil (*Salvia hispanica*)” on the labelling of foodstuffs containing it.

Having reviewed the information provided by AgroBolivia, the FSAI is satisfied that the novel ingredient is substantially equivalent to chia oil already on the EU market in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances as set out in *Article 3.4* of the novel food Regulation EC No 258/97.

#### Composition

Batch analyses demonstrate that the composition of AgroBolivia’s chia seed oil is similar to the comparator chia oil in terms of physical-sensorial parameters, total fat, saturated, monounsaturated, polyunsaturated and trans fat, fatty acid profiles, peroxides and tocopherols. Any minor differences detected are in line with natural variation.

The novel chia seed oil is produced by cold pressing of chia seeds according to HACCP principles followed by filtration to remove solid material before being packaged into food grade containers.

### **Nutritional Value and Metabolism**

As the novel chia seed oil is compositionally very similar to the comparator chia oil already on the EU market, it is reasonable to conclude that it will also be similar in terms of nutritional value and metabolism.

### **Intended Uses**

The applicant intends placing the novel chia oil on the EU market in the same food categories and at the same use levels as the existing chia oil as specified in Commission Implementing Decision 2014/890/EU which specifies its use in fats and oils at not more than 10% and in food supplements at not more than 2g per day.

### **Level of Undesirable Substances**

The applicant provides results from analysis of AgroBolivia's chia oil which demonstrates that levels of heavy metals (lead, cadmium, arsenic and mercury), aflatoxins, pesticides, dioxins, furans, PCB and microbiological contaminants such as *Escherichia coli*, *Salmonella*, *Staphylococci* and *Bacillus cereus* are within acceptable limits. As protein is not present at any appreciable level, allergenicity is not a particular concern.

### **Conclusions**

The FSAI is satisfied from the information provided by the applicant that AgroBolivia's chia seed oil is substantially equivalent to chia oil already on the EU market in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances. The novel chia oil will be subject to the same general and specific legislation that currently governs the marketing and use of seed oils on the EU market and shall be designated as "Chia oil (*Salvia hispanica*)" on the labelling of foodstuffs containing it.