

## SUBSTANTIAL EQUIVALENCE OPINION

### Chia Oil

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

Derived from chia seed (*Salvia hispanica*), chia oil is rich in polyunsaturated fatty acids, particularly the omega-3 alpha-linolenic acid and to a less extent the omega-6 linoleic acid. 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 novel chia oil is derived from South American grown chia seed by cold pressing followed by filtration to remove residual solid material before being packaged into food grade containers. The novel chia oil is to be used as a food ingredient in the same manner and at the same use levels as the authorised chia oil.

Having reviewed the information provided by Andean Grain Products Ltd., 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

The composition of the novel chia oil is similar to the comparator in terms of total fat as well as saturated, monounsaturated, polyunsaturated and trans-fat. The profiles of the fatty acids, tocopherols, sterols and inorganic metals are also very similar, with any minor variations considered to be in line with natural variation. The novel chia oil is produced by the cold pressing of chia seeds sourced from South America in accordance with ISO standards and HACCP principles, before being filtered to

remove any residual impurities. The oil is then packaged into nitrogen filled food grade containers and stored at or below 15°C which along with the natural tocopherol content provides a level of oxidative stability.

### **Nutritional Value and Metabolism**

As the novel chia 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 to use the novel chia oil in the same way and at the same use levels as the existing chia oil which will include its use in fats and oils at not more than 10% and in food supplements at no more than 2g per day.

### **Level of Undesirable Substances**

Batch analyses of the novel chia oil demonstrates that levels of heavy metals (arsenic, cadmium, lead and mercury), mycotoxins, hazardous air pollutants, dioxins, furans and PCBs as well microbiological contaminants such as *Staphylococcus aureus*, *Escherichia coli* and *Salmonella* are within regulatory or guideline limits. Allergenicity is not a particular concern since protein is not present at any appreciable level.

### **Conclusions**

The FSAI is satisfied from the information provided by the applicant that chia oil produced by Andean Grain Products 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 EU food 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.