

## SUBSTANTIAL EQUIVALENCE OPINION

### Chia Oil

The Food Safety Authority of Ireland (FSAI) received an application in October of 2015 from Valensa International in the USA for an opinion on the substantial equivalence of its chia oil (ChiaGold<sup>®</sup>) to chia oil authorised for the EU market by Commission Implementing Decision 2014/890/EU. Chia oil is derived from chia seeds (*Salvia hispanica L*) and is considered novel in line with *Article 1.2(e)* of the novel food Regulation EC No. 258/97; “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 chia seeds from which the oil is derived are grown in Australia, Mexico, Bolivia, Nicaragua, Guatemala and Argentina. The oil is extracted by supercritical carbon dioxide extraction in a US facility under USFDA cGMP conditions. The addition of antioxidants to prevent oxidation of unsaturated fatty acids helps the oil to have a shelf life of 24 months under ambient temperature.

#### Composition

Batch analysis results demonstrate that the composition of the novel chia oil is similar to the comparator in terms of acidity expressed as oleic acid ( $\leq 2\%$ ), peroxide value ( $\leq 10$  meq/kg), insoluble impurities ( $\leq 0.05\%$ ), alpha linolenic acid ( $\geq 60\%$ ) and linoleic acid of 15-20%. Similar to the authorised chia oil, ChiaGold<sup>®</sup> also comprises lower levels of saturated fatty acids including oleic, palmitic and stearic acid.

#### Nutritional Value and Metabolism

The novel chia oil is compositionally and nutritionally very similar to the comparator chia oil already on the EU market and therefore it is reasonable to conclude that it will also be similar in terms of 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 which includes its use in fats and oils ( $\leq 10\%$ ) and in food supplements ( $\leq 2$  g/day).

### **Level of Undesirable Substances**

The results of batch analysis for the presence of heavy metals (lead, cadmium, arsenic and mercury), mycotoxins, pesticides, dioxins, PAHs, PCBs do not give any cause for concern. Microbiological contaminants such as yeast/moulds, coliforms including *E. coli*, *Salmonella*, *Pseudomonas* and *Staphylococcus* all are within regulatory or guideline limits and allergenicity is not a concern since protein is not detected.

### **Conclusions**

The FSAI is satisfied from the information provided by the applicant that chia oil produced by Valensa International 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.