

SUBSTANTIAL EQUIVALENCE OPINION

Chia Oil

The Food Safety Authority of Ireland (FSAI) received an application in March of 2017 from De Wit Speciality Oils of the Netherlands for an opinion on the substantial equivalence of its chia oil (NEWmega™) to chia oil authorised for the EU market by Commission Implementing Decision 2014/890/EU.

The chia seeds from which the oil is derived are grown in Mexico. After harvesting, the Chia seed is cleaned using different sized meshes and a gravity selector to remove plant and other contaminating materials along with magnets to remove any metal. If required, the seeds are dried to ensure a moisture content of no more than 10% and then pressed with a screw press to release the oil. Following cold pressing, the chia oil is filtered before packaging in a nitrogen atmosphere and storage at between -10 °C and 15 °C.

Composition

Batch analysis demonstrates that the composition of De Wit's Chia oil is very similar to the comparator in terms of a range of parameters including acidity, peroxide value, insoluble impurities as well as alpha linolenic acid and linoleic acid.

Parameter	Commission Implementing Decision 2014/890/EU	Novel chia oil
Acidity expressed as oleic acid	≤ 2.0%	≤ 2.0%
Peroxide value	≤ 10.0 meq/kg	≤ 8.0 meq/kg
Insoluble impurities	≤ 0.05%	≤ 0.05%
Alpha linolenic acid	≥ 60%	≥ 60%
Linoleic acid	15.0 – 20.0%	15.0% - 20%

Nutritional Value and Metabolism

The novel chia oil is compositionally 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 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 which includes its use in fats and oils ($\leq 10\%$) and food supplements (≤ 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, *E. coli*, *Salmonella*, *Pseudomonas* and *Staphylococcus Aureus* all are within regulatory or guideline limits.

Conclusions

The FSAI is satisfied from the information provided by the applicant that chia oil marketed by De Wit Speciality Oils of the Netherlands is substantially equivalent in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances to chia oil authorised for the EU market by Commission Implementing Decision 2014/890/EU. The novel chia oil will be designated “Chia oil (*Salvia hispanica*) and its use in supplements will be without prejudice to Directive 2002/46/EC.