

SUBSTANTIAL EQUIVALENCE OPINION

Arachidonic acid-rich oil derived from *Mortierella alpina* FJRK-MA01

The Food Safety Authority of Ireland (FSAI) received an application in October of 2016 from Runke Bioengineering (Fujian) Co., Ltd. of China for an opinion on the substantial equivalence of its arachidonic acid-rich oil produced through fermentation with *Mortierella alpina* (strain FJRK-MA01). The novel ingredient is compared with the same ingredient already authorised in 2011 to Cargill Inc. MN, USA c/o Cargill Research and Development Centre Europe, Vilvoorde, Belgium.

The novel oil is extracted from a non-GM strain of the fungus *Mortierella alpina* and is rich in arachidonic acid, a long chain polyunsaturated fatty acid of 20 carbon atoms, with 4 double bonds at C5, C8, C11 and C14. It is produced in accordance with HACCP principles and to GMP standards for use as an ingredient in infant and follow on formula and formula for premature babies, similar to the authorised comparator. The applicant considers the ingredient to be novel and fall within the category of “*foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae*” as set out in Article 1.2(d) of the novel food Regulation EC No. 258/97.

Composition

The arachidonic acid-rich oil is a yellow to light orange-coloured oil extracted from a non-GMO strain of *Mortierella alpina* (FJRK-MA01). The fungal strain is grown in a pure culture heterotrophic fermentation process and the biomass recovered from the fermentation broth before being dried. Crude oil is then extracted and further processed to yield an oil with high levels of arachidonic acid. After antioxidants are added to maintain stability, the oil is filtered and packaged in airtight containers. Compositional comparison of the specifications for the novel oil with those for the authorised comparator outlined in the authorisation letter of the Competent Authorities of the Netherlands in 2011 demonstrates the similarity of both oils. The applicant demonstrates that the novel ingredient is stable for at least 12 months when stored in a cool dry place under inert gas.

Specifications of the novel arachidonic acid-rich oil and the authorised comparator

Parameter	Authorised Oil	Novel oil
Arachidonic acid	≥ 40 %	≥38%
Free fatty acids	≤0.45%	≤0.45%
Trans fatty acids	≤0.5%	≤0.5%
Unsaponifiable matter	≤1.5% w/w	≤1.5% w/w
Moisture	≤0.5%	≤0.1%
Peroxide value	≤ 2 meq/kg	≤ 2 meq/kg
Acid value	≤ 1.0 mg KOH/g	≤1.0 mg KOH/g

Nutritional Value and Metabolism

The arachidonic acid content and overall fatty acid profile of the novel ingredient and its authorised counterpart are very similar; therefore the nutritional value and metabolism would not be expected to differ.

Intended Uses

The novel oil is intended to supplement the arachidonic acid content of infant formula, follow on formula and formula for premature babies. In accordance with the authorised comparator, the addition of the novel oil to infant formulae and follow-on formulae shall not exceed the fat content for arachidonic acid as referred to point 5.7 of Annex I and point 4.7 of Annex II to Directive 2006/141/EC. The use of *Mortierella alpina* oil in formulae for premature infants shall comply with the provisions of Directive 89/398/EEC as amended.

Level of Undesirable Substances

Batch analyses demonstrate that heavy metals including lead, cadmium, mercury and arsenic among others comply with specifications and are within regulatory limits. Hexane is the solvent used to extract the oil from the biomass but it is not detected in the end product. Checks for other potential contaminants included benzo(a)pyrene, dioxins, dioxin-like PCBs

and non-dioxin-like PCBs, pesticide residues, acrylamide and mycotoxins, with no concerns identified.

Conclusions

The FSAI is satisfied from the information provided by the applicant that arachidonic acid-rich oil derived from *Mortierella alpina* (strain FJRK-MA01) by Runke Bioengineering (Fujian) Co., Ltd. of China is substantially equivalent to the arachidonic acid-rich oil already authorised in 2011 for the EU market to Cargill Inc. MN, USA c/o Cargill Research and Development Centre Europe, Vilvoorde, Belgium. The novel ingredient will be subject to the same conditions of general and specific legislation governing the marketing and use of the comparator. The designation of the novel ingredient in foodstuff containing it shall be '*Mortierella alpina* oil' in line with the authorised comparator. The addition of *Mortierella alpina* oil to infant formulae and follow-on formulae shall not exceed the fat content for arachidonic acid as referred to in point 5.7 of Annex I and point 4.7 of Annex II to Directive 2006/141/EC. The use of *Mortierella alpina* oil in formulae for premature infants shall comply with the provisions of Directive 89/398/EEC as amended.