

SUBSTANTIAL EQUIVALENCE OPINION

DHA-Rich Algal Oil

SUMMARY

The Food Safety Authority of Ireland (FSAI) received an application in July of 2014 from French company Fermentalg for an opinion on the substantial equivalence of its DHA-rich algal oil derived from *Schizochytrium sp.* FCC-1324 to another DHA-rich algal oil (derived from a related *Schizochytrium sp.* ATCC20888) authorised for the EU market by Commission Decisions 2003/427/EC and 2009/778/EC.

Having reviewed the information provided by the applicant, the FSAI is satisfied that DHA-rich algal oil produced by Fermentalg is substantially equivalent to the authorised comparator 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.

Introduction

Docosahexaenoic Acid (DHA) is an Omega 3 fatty acid (long-chained poly-unsaturated fatty acids) with an empirical formula of $C_{22}H_{32}O_2$. Fish oils rich in omega-3 fatty acids have long been considered to have an important nutritional role in human growth and development. Much of the DHA found in fish oils originates from microscopic algae (microalgae) found in marine and freshwater systems.

DHA-rich oils harvested directly from microalgae grown in contained fermentation vessels have been authorised as novel food for the EU market and are now a sustainable alternative to fish oils. Commission Decision 2003/427/EC authorised the placing on the market of DHA-rich algal oil isolated from *Schizochytrium sp.* (ATCC20888) in a range of foods. This authorisation was addressed to Martek Biosciences Corporation and the range of foods in which the novel ingredient could be used was extended in 2009 by Commission Decision 2009/778/EC.

The Fermentalg DHA-rich oil is produced by fermentation with the wild-type heterotrophic micro-algae *Schizochytrium sp.* FCC-1324. The applicant has demonstrated that this strain is closely related to the Martek *Schizochytrium sp.* ATCC20888 with the help of a scientific expert who looked at the fatty acid and pigmentation profiles as well as morphogenetic, taxonomic and phylogenetic data.

Fermentation is carried out under light in controlled conditions using a carbon-based substrate. Extraction and refinement of the DHA-rich oil involves standard procedures that do not involve solvent use.

This application seeks an opinion on the substantial equivalence of their novel DHA-rich oil from *Schizochytrium sp.* (FCC-1324) to the DHA rich oil already authorised for the EU market by Commission Decisions 2003/427/EC and 2009/778/EC.

Composition

The novel ingredient is identical to the comparator algal oil in terms of acid value, peroxide value, trans-fatty acid and is very similar when comparing DHA content, unsaponifiables, moisture and volatiles. The applicant analysed the fatty acid profile of their product and found it to be very similar to that of the authorised DHA-rich oil while carbohydrate and protein were not detected.

Nutritional Value and Metabolism

The novel ingredient is compositionally very similar to the authorised DHA-rich oil and therefore it is reasonable to conclude that both oils will be similar in terms of nutritional value and metabolism.

Intended Uses

The applicant intends placing the novel ingredient on the EU market in the same food categories and at the same use levels as the existing comparator DHA-rich oil, the categories of which are set out in Annex 2 of Commission Decisions 2003/427/EC and the Annex to Commission Decision 2009/778/EC.

Level of Undesirable Substances

The applicant provides data which demonstrates that levels of heavy metals (arsenic, copper, iron, lead and mercury among others), microbiological contaminants (yeast, moulds, *E. coli*, *Salmonellae* and *S. aureus*) are within regulatory or guideline limits. Additional analysis for the presence of pesticides, PCBs, dioxin and marine biotoxins is provided. Allergenicity is not a concern since protein is not detectable to any significant level.

Conclusions

The FSAI is satisfied from the information provided that DHA-rich algal oil from *Schizochytrium sp.* (FCC-1324) is substantially equivalent in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances to DHA-rich algal oil from closely related microalgae already on the EU market. The designation of “DHA-rich oil from the micro-algae *Schizochytrium sp.*” or alternately “Oil from the micro-algae *Schizochytrium sp.*” shall be displayed in the list of ingredients on food products containing the novel ingredient.