

SUBSTANTIAL EQUIVALENCE OPINION

DHA-Rich Algal Oil

SUMMARY

The Food Safety Authority of Ireland (FSAI) received an application in November of 2014 from Runke Bioengineering (Fujian) Co. Ltd of China for an opinion on the substantial equivalence of its DHA-rich algal oil derived from *Schizochytrium* sp. STRK-SSP01 to another DHA-rich algal oil derived from a related *Schizochytrium* sp. (ATCC20888). The comparator DHA-rich oil was authorised for the EU market by Commission Implementing Decision 2014/463/EU.

Having reviewed the information provided by the applicant, the FSAI is satisfied that DHA-rich algal oil produced by Runke Bioengineering 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 previously been authorised as novel food for the EU market and are now considered 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 by Commission Decision 2009/778/EC. Commission Implementing Decision 2014/463/EU authorised another extension of use of DHA-rich algal oil from *Schizochytrium* sp. and was addressed to DSM Nutritional Products which had acquired Martek Biosciences Corporation.

Runke Bioengineering Co. Ltd produces DHA-rich oil by heterotrophic fermentation using the micro-algae *Schizochytrium* sp. STRK-SSP01 under controlled conditions. *Schizochytrium* sp. STRK-SSP01 has been scientifically shown by the applicant to be closely related to *Schizochytrium* sp. ATCC20888 which is used to produce the comparator algal oil. Fermentation is carried out in the dark under controlled conditions using a carbon-based substrate. Extraction and refinement of the DHA-rich oil utilises standard procedures that involve permitted solvents and is performed to good manufacturing standards while observing HACCP principles. Quality checks are maintained at all stages of the production process and the stability of the DHA-rich oil is enhanced by the addition of natural tocopherol.

The applicant seeks an opinion on the substantial equivalence of their novel DHA-rich algal oil from *Schizochytrium* sp. (STRK-SSP01) to the DHA rich oil already authorised for the EU market by Commission Implementing Decision 2014/463/EU.

Composition

The novel ingredient is identical to the comparator algal oil in terms of acid value, peroxide value, moisture and volatiles, unsaponifiables trans-fatty acids and minimum DHA content as set out in Annex I of Commission Implementing Decision 2014/463/EU. Laboratory analysis of the novel ingredient and commercially available samples of the authorised comparator demonstrated a close similarity in the fatty acid profiles. Minimal amounts of carbohydrate and protein were detected in the novel ingredient.

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 foods categories and at the same use levels as the comparator DHA-rich oil which are set out in Annex II of Commission Implementing Decision 2014/463/EU.

Level of Undesirable Substances

Fermentation and subsequent refinement of the oil is carried out under aseptic conditions, with regular microbiological checks carried out, including the final product. The applicant provides data which demonstrates the absence of heavy metals (arsenic, cadmium, copper, lead and mercury) and a range of solvents. Additional analysis for the presence of environmental toxins like PCBs and marine biotoxins is provided by the applicant and are satisfactory.

Conclusions

The FSAI is satisfied from the information provided that DHA-rich algal oil from *Schizochytrium* sp. (STRK-SSP01) 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 “Oil from the micro-algae *Schizochytrium* sp.” shall be displayed in the list of ingredients on food products containing the novel ingredient.