

SUBSTANTIAL EQUIVALENCE OPINION

DHA-Rich Oil

SUMMARY

The Food Safety Authority of Ireland (FSAI) received an application in February of 2014 from a UK company, New Horizons Global Ltd. for an opinion on the substantial equivalence of its DHA-rich algal oil (V-Pure[®]) derived from *Schizochytrium sp.* to another DHA-rich algal oil (derived from a related *Schizochytrium sp.*) 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 V-Pure[®] is substantially equivalent to the authorised DHA-rich algal oil 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 acid) found in certain fish species including tuna and salmon. 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 in microscopic algae (microalgae) found in marine and freshwater systems.

In recent years, 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.* 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.

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

Composition

Based on a number of parameters including genetics, morphological characteristics and fatty acid profiles, the applicant demonstrates that the *Schizochytrium sp.* (NHG S-002) used to produce V-Pure[®] is closely related to that which produces the EU-authorized DHA-rich oil. Microalgae are grown in fermentation vessels and the novel DHA-rich oil is extracted and processed using standard procedures. After refinement of the oil that includes de-gumming and bleaching, antioxidants are added to ensure oxidative stability and the oil is packaged under nitrogen in phenolic-lined containers. Fermentation, oil extraction and refinement are all carried out in ISO accredited facilities that operate to good manufacturing process standards and HACCP principles.

The applicant employs routine quality control procedures and analysis of the finished product to ensure compliance with product specifications which are in line with those for the authorised oil as set out in Annex I of Commission Decision 2003/427/EC.

Nutritional Value and Metabolism

V-Pure[®] 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 DHA-rich oil, 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, pesticides, dioxins, PAHs or microbiological contaminants are within regulatory or guideline limits. Erucic acid is not present while allergenicity is not a concern since protein is not detectable at any significant level.

Conclusions

The FSAI is satisfied from the information provided that the DHA-rich algal oil from *Schizochytrium sp.* (NHG S-002) is substantially equivalent in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances to DHA-rich algal oil from a 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.