

Summary of the application: *Schizochytrium* sp. oil

Applicant: FERMENTALG, 4 rue Rivière, 33500 Libourne, France

This novel food application refers to a *Schizochytrium* sp. oil rich in DHA already authorized as a novel food on the European Union market, and requests an extension of use to infant and follow-on formulae.

The *Schizochytrium* sp. oil is compliant with the specifications laid down in the Regulation (E) No 2017/2470. The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283. The Novel Food consists in a DHA-rich *Schizochytrium* sp. oil.

Analyses performed on five independent batches showed that 1) the *Schizochytrium* sp. oil is compliant with the specifications of *Schizochytrium* sp. oils already authorized in the European Union (Regulation (EU) 2017/2470), 2) the *Schizochytrium* sp. oil is devoid of any contaminant (microbiological contaminant, heavy metals, solvents, PCB and dioxins, PAH, pesticides, sterols, melamine, 2-MCPD ester and 3-MCPD esters, shellfish poisons), 3) does not present any variability among batches, and 4) is stable under standard conditions of storage for such products (storage under a nitrogen blanket in a closed, light-resistant container under frozen conditions).

It is well known that DHA is devoid of any safety concern in humans. The available toxicity studies have demonstrated a lack of genotoxicity/mutagenicity, as of acute and chronic toxicity. DHA-rich oils from *Schizochytrium* sp. are not associated with any allergenicity. Reproductive and developmental toxicity studies have demonstrated the safe use of such oils for infant and young children. Due to its higher amount in DHA in comparison to other oils, the use of the *Schizochytrium* sp. oil in infant and follow-on formula will lead to the use of a lower amount of oil to meet the requirements in DHA and to a similar intake of DPA n-6. To conclude, the *Schizochytrium* sp. oil is well-characterized and compliant with European Regulations, and notably with the specifications of *Schizochytrium* sp. DHA-rich oils presented in Regulation (EU) 2017/2470. Moreover, as for other DHA-rich oil from *Schizochytrium* sp., the product is totally safe for a use in infant and follow-on formulae.