

Summary of the application: Schizochytrium sp. DHA-rich oil

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This application requests an extension of use for the authorized DHA-rich oil from Schizochytrium sp. to obtain the authorization to use such oils in food supplements up to 3000 mg/day. This application is related to all Schizochytrium sp. oils compliant with the specifications laid down in the Regulation (EU) 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. compliant with the Regulation (EU) 2017/2470. 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. Many clinical trials have examined the efficacy and safety of high DHA intakes (> 3g/day) in humans, without reporting any safety concerns. This is in agreement with the previous opinion on EFSA on the tolerable upper intake levels of EPA, DHA and DPA published in 2012, in which EFSA mentioned that daily intakes of EPA and DHA up to 5 g/day were devoid of any safety concern.

To conclude, DHA-rich oils from Schizochytrium sp. are well-characterized and are now widely consumed in Europe. The use of DHA up to 3 g/day is not associated with any safety concern. The authorized maximum level of DHA from Schizochytrium sp. should be therefore increase from 250 mg/day to 3000 mg/day.