

## Summary of the application: EPA-rich oil from *Phaeodactylum tricornerutum*

Applicant: Simris Alg AB, Herrestadsvägen 24A, 276 50 Hammenhög, Sweden

Simris Alg AB (Simris) wishes to market an eicosapentaenoic (EPA)-rich oil, derived from the microalgae *Phaeodactylum tricornerutum*, as an ingredient for use in food supplements intended to be consumed by the general population in the European Union (EU). *Phaeodactylum tricornerutum* is a naturally occurring algae found throughout marine and freshwater environments. EPA-rich oil from *Phaeodactylum tricornerutum*, manufactured by Simris (Simris EPA oil), does not have a significant history of consumption in the EU prior to May 1997, and under Regulation (EU) 2015/2283 concerning novel foods should therefore be considered as novel. The present application was originally submitted under Regulation (EC) No 258/97. In recent years, *Schizochytrium* sp.-derived docosahexaenoic (DHA)-rich oils have been the subject of several Novel Food applications in the EU submitted under Regulation (EC) No 258/97. The algal oil produced by Simris differs from the currently authorised oils in that: (a) it is produced from the microalgae *Phaeodactylum tricornerutum* rather than from existing sources e.g. *Schizochytrium* sp. or *Ulkenia* sp. (or *Crypthecodinium cohnii*), and; (b) the predominant polyunsaturated fatty acid (PUFA) present in the oil is EPA rather than DHA. DHA is also present in Simris EPA oil but to a lesser extent than in the oils currently on the market. Simris EPA oil is intended to be used in food supplements only in a blend with DHA-rich oil. Simris EPA oil is obtained by supercritical fluid oil extraction of freeze-dried *Phaeodactylum tricornerutum* grown in closed glass tube systems in greenhouses exposed to sunlight. The extraction process is common in the production of food grade oils and aromatic compounds, and the overall manufacturing process is very similar to those used in the production of vegetable oils already on the market. A range of characteristics of the EPA-rich oil derived from *Phaeodactylum tricornerutum* were assessed in five different production batches of oil. Analytical data have been provided confirming the composition of Simris EPA oil. All levels of contaminants are confirmed analytically to be in compliance with current regulatory controls in the EU. The stability of Simris EPA oil is expected to be consistent with other structurally similar marine and algal oils. The EPA-rich oil will be used in a blend for various supplements, including 'Simris® Algae Omega-3', and 'Simris® Algae Omega-3 for Athletes' (which are both intended for use in the general population). These supplements contain EPA and DHA from algal oils, blended with flaxseed oil including ALA. The recommended daily dose of the blended oil when taken as a supplement is 2g/day in capsule form, giving a combined daily intake of DHA and EPA of 250 mg. There has been several previous safety evaluations of similar algal oils, including those produced from *Schizochytrium* sp., *Ulkenia* sp. and *Odontella aurita*. Several studies, including in mammals, support the safety of *Phaeodactylum tricornerutum*. The Joint Research Centre (JRC) of the EU has evaluated the possibility of using a range of microalgae, including *Phaeodactylum tricornerutum*, for food production, and concluded that *Phaeodactylum tricornerutum* is non-toxic and lacks the capability to produce toxins. *Phaeodactylum tricornerutum* is also extensively used in aquaculture as feed for fish and seafood intended for human consumption. In particular, it is used for molluscs and crustaceans in their early growth stages, when the larvae are particularly sensitive to potential toxins. In summary, it is reasonable to conclude that Simris EPA oil can be considered a safe and suitable source of EPA under the proposed conditions of use in food supplements in the EU. The suggested designation of the EPA oil on the labelling of the foodstuffs containing it shall be 'EPA-rich oil from *Phaeodactylum tricornerutum* algae'.