

Summary of the application: *Schizochytrium* sp. oil

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The subject of this application is to extend the authorisation of docosahexaenoic acid (DHA)-rich algal oil sourced from the marine microalgae *Schizochytrium* sp. to include strain WZU477 as a novel food ingredient for use in infant and follow-on formulae in the European Union (EU) Union List as an alternative source of fatty acids presently permitted in these products. Progress Biotech BV (Progress Biotech) also proposes to extend the approval of DHA-rich algal oil sourced from *Schizochytrium* sp. to include strain WZU477 as a novel food ingredient for use in fruit/vegetable puree with a maximum DHA content of 100 mg/100 g. No other changes to the existing specifications are proposed.

Currently, Progress Biotech markets a DHA-rich algal oil from *Schizochytrium* sp. strain WZU477 that meets the specification for this material for use in general food products in the EU as stated in the Union List of novel foods. Within this list, it is not approved for use as an ingredient in infant or follow-on formulae. At the present time, only DHA algal oil produced from 2 specific strains of *Schizochytrium* sp. have had the approval extended for use as an ingredient in infant and follow-on formulae. These strains are ATCC PTA-9695 and T18. It should be noted that the basis for approval of oils produced from *Schizochytrium* sp. strains ATCC PTA-9695 and T18 in infant and follow-on formulae was the submission of a 90-day repeat-dose study during the in utero phase. Progress Biotech previously received a favourable opinion from the Committee on Safety Assessment of Novel Foods (VNV Committee) of the Novel Foods Unit establishing substantial equivalence of its DHA rich algal oil in composition and, consequently, nutritional value and metabolism to the reference oils for existing authorised uses. As such, Progress Biotech proposes to extend the authorisation of the DHA-rich algal oil to include a specification for strain WZU477 for use as a novel food ingredient in infant formula and follow-on formulae. Furthermore, the approved uses of *Schizochytrium* sp. oil, which includes DHA-rich algal oil produced by Progress Biotech, was recently amended in the EU Union List to authorize its use in fruit/vegetable puree. Progress Biotech's proposal to amend the EU Union List to include a specification for strain WZU477 is not expected to impact the safety of DHA-rich algal oil when used in fruit/vegetable puree.

Moreover, the DHA-rich algal oil produced by Progress Biotech is intended to be a direct replacement for the currently approved reference oils in infant formulae and follow-on formulae and, as such, the anticipated intakes of the product in question are not expected to be significantly different than the current intakes of the reference oils. Considering the DHA-rich algal oil from *Schizochytrium* sp. strain WZU477 produced by Progress Biotech is substantially equivalent in composition and effect to the reference oils, the safety of the product in question is not expected to be significantly different than that established in the safety studies submitted to support the reference oils. In conclusion, based on the available information, Progress Biotech considers that there is sufficient data to support the approval for an extension of use for DHA-rich algal oil from *Schizochytrium* WZU477 in infant formulae and follow-on formulae.