

Article 4 Request

Regulation (EU) 2015/2283

Recipient Member State: Ireland, Food Safety Authority of Ireland (FSAI)

Name of the Foods: 'DHA and EPA ethyl esters oil from *Schizochytrium* sp. microalga'

Date: 14/12/2022

Description of the food

The food in question is an oil rich in docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) ethyl esters from the microalgae *Schizochytrium* sp. strain ATCC PTA-10208.

The manufacturing process starts with the production in a closed fermentation process of a crude oil containing DHA and EPA omega-3 fatty acids in the triglyceride form from *Schizochytrium* sp. strain ATCC PTA-10208. This crude oil further undergoes transesterification and purifications steps that results in an oil which is rich in DHA and EPA ethyl esters. The minimum DHA and EPA ethyl esters content is 450 mg/g and 150 mg/g, respectively.

The oil is intended to be used in food supplements for the general population including pregnant and lactating women.

Novel or Not Novel

The FSAI considers that 'DHA and EPA ethyl esters oil from *Schizochytrium* sp. microalga' is a **novel food**.

Reasons why the food is novel

'*Schizochytrium* sp. oil rich in DHA and EPA' is an authorised novel food as per the Union List. This oil is almost entirely composed of triglycerides (EFSA, 2014), therefore, the *Schizochytrium* sp. oil rich in DHA and EPA ethyl esters proposed here is outside the specifications of the authorised novel food in the Union List and therefore must be authorised before placing on the market.

Appropriate novel food category

This novel food falls in either Category (ii) – “Food consisting of, isolated from or produced from microorganisms, fungi or algae” or Category (vi) – “Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae”.