

Andreas Klepsch
European Commission
DG SANCO
Brussels B-1049

29 April 2013

Ref NFU 795

Dear Mr Klepsch

DRAFT Initial Opinion: DHA and EPA-rich algal oil from *Schizochytrium sp* (Extension of use)

On 19 November 2012 the UK Competent Authority accepted an application from DSM Nutritional Products to extend the use of their novel food, docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) rich algal oil, in accordance with Article 4 of Regulation (EC) 258/97.

This oil was evaluated in 2011 for use in the EU as a novel food ingredient and there were no objections to the initial assessment report that the UK transmitted to the Commission on 9 December 2011 (ref NFU 786, attached). The UK wrote to the applicant confirming the authorisation of the oil for a range of uses on 6 July 2012.

The new application follows the publication of two positive EFSA opinions in 2012 which establish a cause and effect relationship between dietary intake of EPA and DHA and the reduction of blood pressure and blood triglycerides. These opinions have resulted in approved health claims¹ which, due to the doses of DHA and EPA required, are likely to be restricted to high dose food supplements.

¹ Expected early 2013

The Advisory Committee on Novel Foods and Processes (ACNFP) has reviewed this new application and noted that the only change is an increase in the amount of algal oil in food supplements from 250 mg DHA+EPA per day to a maximum of 3000 mg per day. In all other respects the Committee's 2011 opinion applies to this request.²

In its 2011 opinion, the intake of the oil was estimated using data from the UK National Diet and Nutrition Survey data. This indicated that male teenagers potentially have the greatest high level (97.5th percentile) intake of DHA and EPA from fortified foods at 1.72g per day.

These estimates did not include intake from food supplements but, in the event that high level consumers of fortified foods also consumed high dose supplements providing the maximum proposed dose of 3000mg/day, this would result in a maximum consumption of DHA and EPA of 4.72g/day. The ACNFP noted that this combined estimate is below 5g/day, a level of intake that EFSA do not regard to cause safety concerns (EFSA 2012³) and accepted that this provides sufficient reassurance of the safety of this extension of use.

The 5g/day figure applies specifically to adults but the ACNFP accepted that high dose food supplements will not be targeted at children, as EFSA has established a cause and effect relationship between high dietary intake of EPA and DHA and the reduction of blood pressure and blood triglycerides, which are not relevant to younger age groups.

In view of the ACNFP's advice, the UK Competent Authority considers that this algal oil, at levels of up to 3000 mg EPA and DHA per day in food supplements, and not exceeding the maximum use levels previously described for other foods, meets the criteria for acceptance of a novel food defined in Article 3(1) of regulation 258/97.

I have also attached a copy of the specification for this oil, which was included in my letter of 6 July 2012 that authorised the use of this oil.

² A copy of this opinion is available at <http://www.food.gov.uk/multimedia/pdfs/inopdhamartek.pdf>

³ <http://www.efsa.europa.eu/en/efsajournal/pub/2815.htm>

Yours sincerely

by email

Dr Chris Jones
UK Competent Authority

**SPECIFICATION OF DHA (DOCOSAHEXAENOIC ACID) AND EPA
(EICOSAPENTAENOIC ACID)-RICH OIL FROM MICROALGAE *SCHIZOCHYTRIUM SP.***

Test	Specification
Acid value	Not more than 0.5 mg KOH/g
Peroxide value (PV)	Not more than 5.0 meq/kg oil
Moisture and volatiles	Not more than 0.05%
Unsaponifiables	Not more than 4.5%
Trans-fatty acids	Not more than 1%
DHA content	Not less than 22.5%
EPA content	Not less than 10%