

Andreas Klepsch
European Commission
DG SANCO
Brussels B-1049

29 April 2013

Reference NFU 796

Dear Mr Klepsch

Draft Initial Opinion: DHA-rich algal oil from *Schizochytrium* sp (Second Extension of use)

On 16 January the UK Competent Authority accepted an application from DSM Nutritional Products to extend the use of their novel food, docosahexaenoic acid (DHA) rich algal oil, in accordance with Article 4 of Regulation (EC) 258/97.

This oil was evaluated in 2003¹ for use in the EU as a novel food ingredient and the company successfully sought an extension of the use in 2009.²

This application is to bring the use categories into line with their DHA and EPA rich oil which is produced from the same algal source and was approved as a novel food in July 2012. The application includes an increased use level in food supplements, which is in line with the company's parallel request for the DHA and EPA rich oil to be added to supplements at levels providing up to 3000 mg DHA and EPA per day. The UK's initial opinion on the latter request was also sent to the European Commission on 29 April (ref NFU 795).

¹ Commission Decision of 5 June 2003 authorising the placing on the market of oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (2003/427/EC)

² Commission Decision of 22 October 2009 concerning the extension of uses of algal oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (2009/778/EC)

Both applications follow the publication of two 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 claims³ which, due to the level of DHA and EPA required, are likely to be restricted to high dose food supplements.

The ACNFP's 2011 opinion for the DHA and EPA rich oil⁴ assessed the estimated intake of the oil using data from the UK National Diet and Nutrition Survey data and the results are also applicable to this oil. This estimate 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. This estimate applies equally to the present application for the extension of use of the DHA rich oil, which would bring its uses in line with that of the second oil.

This intake assessment did not consider intake from food supplements. 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 of 4.72g/day. When assessing the DHA and EPA oil 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 2012⁵) 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 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 the 2003 Commission Decision,

³ Expected early 2013

⁴ A copy of this opinion is available at <http://www.food.gov.uk/multimedia/pdfs/inopdhamartek.pdf>

⁵ <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) 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 32%