

Dr Rodney Gray
DSM Nutritional Lipids
(a Division of DSM Nutritional Products LLC)

NFU 786

6 July 2012

DHA AND EPA RICH OIL FROM THE MICROALGAE SCHIZOCHYTRIUM

Dear Rodney

I am writing to inform you of the outcome of your application made to the UK for the pre-market assessment of DHA and EPA rich oil from the microalgae *Schizochytrium* in accordance with Articles 4 and 6 of Regulation (EC) 258/97.

On 31 January 2011 you, on behalf of Martek Bioscience, made a request to the Food Standards Agency, the designated competent food assessment body in the UK, to place DHA and EPA rich oil from the microalgae *Schizochytrium* on the market as a novel food ingredient.

On 9 December the Food Standards Agency issued its initial assessment report, having obtained expert advice from the Advisory Committee on Novel Foods and Processes (ACNFP), the committee that advises the Agency on all novel food issues. This report concluded that DHA and EPA rich oil from the microalgae *Schizochytrium* meets the criteria for acceptance of a novel food, as defined in Article 3(1) of the Regulation.

The Commission forwarded this initial assessment report to all Member States on 15 December. Within the 60 day period laid down in Article 6(4) of the Regulation no reasoned objections to the marketing of this product were presented by the Commission or the Member States, but certain points of

clarification were requested by the German, French, Belgian, Spanish and Greek authorities. These related to:

- (a) Proposed use levels; a failure to take into account background levels of exposure, intake by different age groups and a lack of an EU-wide intake assessment.
- (b) Stability in food products which are subjected to heat during processing.
- (c) Information in relation to the antioxidants used and whether the specification of the high oleic acid sunflower oil is produced in accordance with Codex Standards 210/1999 (as amended).

The Food Standards Agency has considered your responses that were submitted on 15 June 2012 and which we are forwarding to the German, French, Belgian, Spanish and Greek authorities.

- (a) You indicated that the questions that relate to use levels are a generic issue which apply to all sources of DHA and EPA and you note that the European Food Safety Authority is currently conducting an extensive review of omega-3 fatty acids in the diet. As this review is likely to take account both of intake from all dietary sources and any differences in consumption across EU Member States, we agree that any measures which result from this review will address this issue across the board and not apply solely to this novel ingredient.
- (b) You advised that the peroxide value for your oil provides the necessary reassurance that the antioxidants present are functioning correctly and that any unstable product would be unpalatable, You also note that previous novel food authorisations for omega-3 rich algal oils, include a requirement for all food products containing oil from *Schizochytrium* to demonstrate oxidative stability by appropriate and recognised international test methodology (e.g. AOAC). You have advised that you regard this statement to similarly apply to this new oil.

- (c) You indicated that the antioxidants which are added to this oil are approved under regulation (EC) 1333/2008 and that, typically, these are ascorbyl palmitate and tocopherols. You also noted that all your omega-3 rich algal oils are packaged under nitrogen and in opaque packaging with low oxygen permeability.

Therefore on the basis of the initial assessment report it is established that DHA and EPA rich oil from the microalgae *Schizochytrium* complies with the criteria laid down in Article 3(1) of Regulation (EC) 258/97. When marketing this product I would draw your attention to the ACNFP's advice concerning possible effects of high dose of DHA and EPA on gestation. The ACNFP also recommended that this be taken into account when monitoring possible adverse events following the widespread introduction of this novel oil into the diet.

DSM Nutritional Products LLC may therefore place DHA and EPA rich oil from the microalgae *Schizochytrium* on the market in accordance with the conditions in this letter. This letter will be published on the Food Standards Agency website and a copy will be forwarded to the Commission for transmission to all other Member States and general publication as appropriate.

Yours sincerely

Chris Jones

Dr Chris Jones

For the 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%

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

Food Category	Maximum Use-Level of DHA + EPA (mg/100 g) unless otherwise stated
Food Supplements	250 mg per daily dose as recommended by the manufacturer for normal population; 450 mg per daily dose as recommended by the manufacturer for pregnant and lactating women
Dietary foods for special medical purposes	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Foods intended for use in energy-restricted diets for weight reduction	250 mg per meal replacement
Other foods for particular nutritional uses (PARNUTS), as defined in Directive 2009/39/EC excluding infant and follow on formula	200 mg/100 g
Bakery Products, Breads and Rolls, Sweet Biscuits	200 mg/100 g
Breakfast Cereals	500 mg/100 g
Cooking Fats	360 mg/100 g
Dairy Analogues (except drinks)	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products (excluding drinks)
Dairy Products (except milk-based drinks)	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)
Non-alcoholic Beverages (including dairy analogue and milk-based drinks)	80 mg/100 g

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

Food Category	Maximum Use-Level of DHA + EPA (mg/100 g) unless otherwise stated
Cereal/Nutrition Bars	500 mg/100 g
Spreadable Fats and Dressings	600 mg/100 g

Note: All food products containing DHA and EPA-rich oil from *Schizochytrium* sp. should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC).

Name: DHA and EPA-rich oil from *Schizochytrium* sp.