

COMMISSION IMPLEMENTING DECISION (EU) 2015/546**of 31 March 2015****authorising an extension of use of DHA and EPA-rich 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***(notified under document C(2015) 2083)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 6 July 2012, the competent authorities of the United Kingdom authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of docosahexaenoic acid (DHA) and eicosapentaenoic (EPA)-rich oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient to be used in certain foods.
- (2) On 19 November 2012, the company DSM Nutritional Products made a request to the competent authorities of the United Kingdom for extension of use of DHA and EPA-rich oil from micro-algae *Schizochytrium* sp. as a novel food ingredient.
- (3) On 29 April 2013, the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that the extension of use of this algal oil meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.
- (4) On 9 July 2013, the Commission forwarded the initial assessment report to the other Member States.
- (5) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.
- (6) On 25 March 2014, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment of the extension of use of DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient in accordance with Regulation (EC) No 258/97.
- (7) On 18 September 2014, EFSA adopted a scientific opinion on the extension of use for DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient ⁽²⁾, concluding that it is safe under the proposed uses and use levels.
- (8) That opinion gives sufficient grounds to establish that DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. in the proposed uses and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (9) Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ lays down requirements on food supplements. The use of DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. should be authorised without prejudice to the requirements of that legislation.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal 2014; 12(10):3843.⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

HAS ADOPTED THIS DECISION:

Article 1

DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the use defined and at the maximum level established in Annex II without prejudice to the provisions of Directive 2002/46/EC.

Article 2

The designation of DHA- and EPA-rich oil from the micro-algae *Schizochytrium* sp. authorised by this Decision on the labelling of the foodstuffs containing it shall be 'DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp.'.

Article 3

This Decision is addressed to DSM Nutritional Products, 6480 Dobbin Road, Columbia, MD 21045, USA.

Done at Brussels, 31 March 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

**Specification of DHA (docosahexanoic acid) and EPA (eicosapentaenoic acid)-rich oil from the micro-algae
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 1,0 %
DHA content	Not less than 22,5 %
EPA content	Not less than 10 %

ANNEX II

**Authorised uses of DHA (docosahexanoic acid) and EPA (eicosapentaenoic acid)-rich oil from the micro-algae
Schizochytrium sp.**

Food category	Maximum use level of DHA and EPA (mg/day)
Food supplements	3 000 mg as recommended by the manufacturer for adult population excluding pregnant and lactating women