

COMMISSION IMPLEMENTING DECISION

of 14 July 2014

on authorising the placing on the market of 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 and repealing Decisions 2003/427/EC and 2009/778/EC

(notified under document C(2014) 4670)

(Only the English text is authentic)

(2014/463/EU)

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) The specification of oil from micro-algae *Schizochytrium* sp. has been laid down and its placing on the market has been authorised in several foods at certain maximum use levels by Commission Decision 2003/427/EC ⁽²⁾. The first extension of uses of oil from micro-algae *Schizochytrium* sp. has been granted by Commission Decision 2009/778/EC ⁽³⁾.
- (2) On 16 January 2013, the company DSM Nutritional Products made a request to the competent authorities of the United Kingdom for extension of uses of oil from micro-algae *Schizochytrium* sp. as a novel food ingredient. DSM Nutritional Products has acquired company Martek Biosciences, who was the addressee of the previous decisions, by contract dated 30 June 2012.
- (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 uses 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. In particular, objections that concerned elevated intake levels of docosahexaenoic acid (DHA) were raised. In accordance with Article 7(1) of Regulation (EC) No 258/97 a Commission Implementing Decision should be made that takes into account the objections raised. The applicant consequently modified the request concerning the maximum amount of DHA in food supplements. This change and additional explanations provided by the applicant alleviated the concerns to the satisfaction of Member States and the Commission.
- (6) Directive 2002/46/EC of the European Parliament and of the Council ⁽⁴⁾ lays down requirements on food supplements. Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽⁵⁾ lays down requirements on the addition of vitamins and minerals and of certain other substances to foods. Directive 2009/39/EC of the European Parliament and of the Council ⁽⁶⁾ lays down requirements on foodstuffs intended for particular nutritional uses. Commission Directive 96/8/EC ⁽⁷⁾ lays down requirements on foods intended for use in energy-restricted diets for weight reduction. The use of oil from the micro-algae *Schizochytrium* sp. should be authorised without prejudice to the requirements of those legislations.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ Commission Decision 2003/427/EC 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 (OJ L 144, 12.6.2003, p. 13).⁽³⁾ Commission Decision 2009/778/EC 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 (OJ L 278, 23.10.2009, p. 56).⁽⁴⁾ 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).⁽⁵⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).⁽⁶⁾ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21).⁽⁷⁾ Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).

- (7) For reasons of legal clarity Decisions 2003/427/EC and 2009/778/EC should be repealed and replaced by this Decision.
- (8) Notifications of the placing on the market of an ingredient substantially equivalent to the algal oil as authorised by Decisions 2003/427/EC and 2009/778/EC, which have been submitted to the Commission in accordance with Article 5 of Regulation (EC) No 258/97 remain valid.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

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 uses defined and at the maximum levels established in the Annex II without prejudice to the provisions of Directive 2002/46/EC, Regulation (EC) No 1925/2006, Directive 2009/39/EC and Directive 96/8/EC.

Article 2

The designation of oil from the micro-algae *Schizochytrium* sp. authorised by this Decision on the labelling of the food-stuffs containing it shall be 'oil from the micro-algae *Schizochytrium* sp.'.

Article 3

Decisions 2003/427/EC and 2009/778/EC are hereby repealed.

Article 4

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

Done at Brussels, 14 July 2014.

For the Commission
Tonio BORG
Member of the Commission

ANNEX I

SPECIFICATION OF 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 32,0 %

ANNEX II

AUTHORISED USES OF OIL FROM THE MICRO-ALGAE *SCHIZOCHYTRIUM* SP.

Food category	Maximum use level of DHA
Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g
Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g
Spreadable fat and dressings	600 mg/100 g
Breakfast cereals	500 mg/100 g
Food supplements	250 mg DHA per day as recommended by the manufacturer for normal population 450 mg DHA per day as recommended by the manufacturer for pregnant and lactating women
Foods intended for use in energy-restricted diets for weight reduction as defined in Directive 96/8/EC	250 mg per meal replacement
Other foods for particular nutritional uses as defined in Directive 2009/39/EC excluding infant and follow on formulae	200 mg/100 g
Dietary foods for special medical purposes	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Bakery products (breads and rolls), sweet biscuits	200 mg/100 g
Cereal bars	500 mg/100 g
Cooking fats	360 mg/100 g
Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml