COMMISSION DECISION

of 5 June 2003

authorising the placing on the market of oil rich in DHA (docosahexaenoic acid) 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 number C(2003) 1790)

(Only the English text is authentic)

(2003/427/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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,

Having regard to the request by Martek Biosciences Corporation, formerly OmegaTech GmbH to the competent authorities of the United Kingdom of 13 February 2001 for placing oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium sp.* on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of the United Kingdom,

Whereas:

(1) In their initial assessment report the United Kingdom's competent food assessment body came to the conclusion that DHA-rich oil from the microalgae *Schizochytrium sp.* is safe for human consumption.

(2) The Commission forwarded the initial assessment report to all Member States on 20 June 2002.

(3) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97, reasoned objections to the marketing of the product were raised in accordance with that provision.

(4) In response to the comments and objections raised, OmegaTech GmbH amended the specifications and the applications of the DHA-rich oil. These amendments were discussed with Member States' experts on 21 October 2002.

(5) On the basis of the initial assessment report, it is established that DHA-rich oil from the microalgae *Schizochytrium sp.* complies with the criteria laid down in Article 3(1) of the Regulation.

(6) 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

DHA-rich oil from the microalgae *Schizochytrium sp.* as specified in Annex 1, may be placed on the market in the Community as a novel food ingredient for the uses and at the maximum levels as listed in Annex 2.

Article 2

The designation 'DHA-rich oil from the microalgae *Schizochytrium sp.*' shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.

Article 3

This Decision is addressed to Martek Biosciences Corporation, 6480 Dobbin Road, Columbia, Maryland 21045 USA.

Done at Brussels, 5 June 2003.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

ANNEX 1

SPECIFICATION OF OIL RICH IN DHA (DOCOSAHEXAENOIC ACID) OBTAINED BY HEXANE EXTRACTION OF 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 32,0 %

ANNEX 2

USES OF OIL RICH IN DHA (DOCOSAHEXAENOIC ACID) FROM THE MICROALGAE *SCHIZOCHYTRIUM SP.*

Use group	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	200 mg per daily dose as recommended by the manufacturer
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	200 mg/meal replacement

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