COMMISSION DECISION

of 12 December 2008

authorising the placing on the market of arachidonic acid-rich oil from *Mortierella alpina* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2008) 8080)

(Only the English text is authentic)

(2008/968/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,

Whereas:

(1) On 18 June 1999 the company Abbott Laboratories (now Suntory Limited, Japan) made a request to the competent authorities of the Netherlands to place arachidonic acid-rich oil from *Mortierella alpina* on the market as a novel food ingredient.

(2) On 19 October 2005 the competent food assessment body of the Netherlands issued its initial assessment report. In that report it came to the conclusion that arachidonic acid-rich oil from *Mortierella alpina* can safely be used in infant formulae and formulae for premature infants.

(3) The Commission forwarded the initial assessment report to all Member States on 17 November 2005.

(4) 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.

(5) Therefore the European Food Safety Authority (EFSA) was consulted on 26 June 2007.

(6) On 10 July 2008 EFSA adopted the 'Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety of "fungal oil from *Mortierella alpina*".'

(7) In the opinion the EFSA came to the conclusion that the fungal oil from *Mortierella alpina* is a safe source of arachidonic acid to be used in infant formulae and follow-on formulae.

(8) Annex I and Annex II to Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC [2] specify the rules for the addition of long chain (20 and 22 carbon atoms) poly-unsaturated fatty acids and in particular of arachidonic acid to infant formulae and follow-on formulae.

(9) On the basis of the scientific assessment, it is established that fungal oil from *Mortierella alpina* complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(10) 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

Fungal oil from *Mortierella alpina* as specified in the Annex may be placed on the market in the Community as a novel food ingredient to be used in infant formulae and follow-on formulae as defined in Article 2 of Directive 2006/141/EC and in formulae for premature infants.

The addition of fungal oil from *Mortierella alpina* to infant formulae and follow-on formulae shall be limited by its content of arachidonic acid according to the rules specified in Annex I, 5.7 and in Annex II, 4.7 to Directive 2006/141/EC. Its use in formulae for premature infants shall be in accordance with the provisions of Council Directive 89/398/EEC [3] of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.

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

[2] OJ L 401, 30.12.2006, p. 1.

[3] OJ L 186, 30.6.1989, p. 27.

Article 2

The designation of the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'oil from *Mortierella alpina*'.

Article 3

This Decision is addressed to Beverage & Food Company, Suntory Limited, 2-4-1 Shibakoen Minato-ku, Tokyo, Japan.

Done at Brussels, 12 December 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

SPECIFICATIONS OF ARACHIDONIC ACID-RICH OIL FROM *MORTIERELLA ALPINA*

Description

The clear yellow arachidonic acid-rich oil is obtained by fermentation of the fungus *Mortierella alpina* using soy flour and soy oil as substrates.

Specifications of arachidonic acid-rich oil from *Mortierella alpina*

Arachidonic acid	≥ 40 %
Peroxide value	≤ 5 meq/kg
Acid value	≤ 0,2 mg KOH/g
Anisidin value	≤ 20
Free fatty acids	≤ 0,2 %
Unsaponifiable matter	≤ 1 %
Colour (Lovibond 50,8 mm cell) yellow	≤ 50
Colour (Lovibond 50,8 mm cell) red	≤ 10