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*Status: Point in time view as at 12/12/2008.*

*Changes to legislation: There are currently no known outstanding effects for the 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). (See end of Document for details)*

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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)

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<sup>(1)</sup>, 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*”.’

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- (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<sup>(2)</sup> specify the rules for the addition of long chain (20 and 22 carbon atoms) polyunsaturated 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<sup>(3)</sup> of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.

*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*

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## 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	$\geq 40 \%$
Peroxide value	$\leq 5$ meq/kg
Acid value	$\leq 0,2$ mg KOH/g
Anisidin value	$\leq 20$
Free fatty acids	$\leq 0,2 \%$
Unsaponifiable matter	$\leq 1 \%$
Colour (Lovibond 50,8 mm cell) yellow	$\leq 50$
Colour (Lovibond 50,8 mm cell) red	$\leq 10$

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- (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.

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