

Letter dated:  
19 December 2011

From:  
Ministry of Health, Welfare and Sport  
Postbus 20350  
2500 EJ The Hague  
Netherlands

To:  
Cargill Research and Development Centre Europe  
attn. Ms Juliana Martinez Sanchez  
Scientific and Regulatory Affairs Manager EMEA  
Global Food Research/Scientific and Regulatory Affairs  
Havenstraat 84  
B-1800 Vilvoorde  
Belgium

**Subject:** Arachidonic acid-rich oil from the fungus *Mortierella alpina*  
**Ref.:** VGP/3097620  
**Case No** 3097618

Dear Ms Sanchez,

In a letter dated 2 November 2009, a request as provided for in Article 4(1) of Regulation (EC) 258/97 ("the Regulation") was addressed on behalf of your company to the Ministry of Health, Welfare and Sport. This request asked for permission to place on the market for the first time an arachidonic acid-rich oil from the fungus *Mortierella alpina* ("*Mortierella alpina* oil"). In this connection, I would like to inform you as follows.

Your request has been assessed in accordance with the procedure described in Article 6 of the Regulation. The initial assessment was undertaken by the Novel Foods Unit (*Bureau Nieuwe Voedingsmiddelen – BNV*) of the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen - CBG*), and revealed that no additional assessment as referred to in Article 6(3) of the Regulation is required. Furthermore, no Member State has presented a reasoned objection as referred to in Article 6(4) of the Regulation. There are thus no objections to *Mortierella alpina* oil being introduced onto the market.

I am therefore able to inform you that you are permitted to place *Mortierella alpina* oil on the market. This notification will be published in the Netherlands Government Gazette (*Staatscourant*) (see attachment) and brought to the attention of the European Commission.

In this connection, I assume that when foods containing this oil are sold on the market, this ingredient will be shown on the labelling as "*Mortierella alpina* oil".

As a matter of form, I would draw your attention to the fact that, when selling *Mortierella alpina* oil on the market, all applicable legislation must be complied with. This includes the labelling requirements under the Commodities Act (Labelling of Foods) Decree (*Warenwetbesluit etikettering van levensmiddelen*) and Article 8 of the Regulation.

I hope that the above information will be sufficient for your purposes.

Yours sincerely,

On behalf of the Minister for Health, Welfare and Sport

pp. (signature)

M. Sonnema

Head of the Directorate of Nutrition, Health Protection and Prevention

# Ministry of Health, Welfare and Sport

Ref. VGP /3097618

Official notice from the Minister for Health, Welfare and Sport of 19 December 2011 concerning approval for the placing on the market of arachidonic acid-rich oil from the fungus *Mortierella alpina*

Date: 19 December 2011

The Minister for Health, Welfare and Sport,

Having examined the request of 2 November 2009 from Cargill Inc. MN, USA c/o Cargill Research and Development Centre Europe, Vilvoorde, Belgium;

Having examined the report No 2011-01 BNV of 7 April 2011 from the Novel Foods Unit (*Bureau Nieuwe Voedingsmiddelen – BNV*) of the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen - CBG*) concerning the initial assessment as provided for in Article 6(3) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43/1997);

Having regard to Article 4(1) and (2) of Regulation (EC) No 258/97 and Article 3(1) of the Commodities Act (Novel Foods) Decree (*Warenwetbesluit Nieuwe voedingsmiddelen*),

ISSUES THE FOLLOWING NOTICE.

## Article 1

In this Notice,

- a) "*Mortierella alpina* oil" means oil from the fungus *Mortierella alpina* as referred to in the Annex;
- b) "Directive 2006/141/EC" means Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401/2006);
- c) "Directive 89/398/EEC" means Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ L 186/1989).

## Article 2

Cargill Inc. MN, USA c/o Cargill Research and Development Centre Europe, Vilvoorde, Belgium, shall be permitted to introduce *Mortierella alpina* oil onto the market as a food ingredient for use in:

- a) infant formulae and follow-on formulae as referred to in Directive 2006/141/EC;

b) formulae for premature infants.

This Notice shall be published in the Government Gazette (*Staatscourant*).

On behalf of the Minister for Health, Welfare and Sport

pp. (signature)

M. Sonnema

Head of the Directorate of Nutrition, Health Protection and Prevention

## ANNEX

### Specifications and use of *Mortierella alpina* oil

#### Description

The fungus *Mortierella alpina* is cultivated in a suitable liquid with sunflower oil as a source of fatty acids. The oil is then isolated from the biomass and, following purification, has a clear yellow colour.

#### Specifications

|                       |   |
|-----------------------|---|
| Arachidonic acid      | $\geq 40\%$ by weight of the total fatty acid content           |
| Free fatty acids      | $\leq 0.45\%$ of the total fatty acid content ( <i>area %</i> ) |
| Trans fatty acids     | $\leq 0.5\%$ of the total fatty acid content ( <i>area %</i> )  |
| Unsaponifiable matter | $\leq 1.5\%$ w/w  |
| Moisture              | $\leq 0.5\%$  |
| Peroxide value        | $\leq 2.0$ meq/kg   |
| Acid value            | $\leq 1.0$ KOH/g  |

#### Use

The addition of *Mortierella alpina* oil to infant formulae and follow-on formulae shall not exceed the fat content for arachidonic acid as referred to in Annex I point 5.7 and Annex II point 4.7 to Directive 2006/141/EC. The use of *Mortierella alpina* oil in formulae for premature infants shall comply with the provisions of Directive 89/398/EEC.