

COMMISSION DECISION

of 24 October 2006

authorising the placing on the market of 'maize-germ oil high in unsaponifiable matter' as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2006) 4980)

(Only the French text is authentic)

(2006/723/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 24 October 2001 the company Laboratoires Pharmascience (now Laboratoires Expanscience) made a request to the competent authorities of France to place 'maize-germ oil high in unsaponifiable matter' on the market as a novel food ingredient.
- (2) On 8 January 2002 the competent authorities of France forwarded their initial assessment report to the Commission. The report came to the conclusion that maize-germ oil high in unsaponifiable matter proposed as a food ingredient at a daily intake of 2 g per day would make it possible to supplement vitamin E intake and also concluded that the levels of phytosterol were not sufficient to reduce cholesterolaemia.
- (3) The Commission forwarded the initial assessment report to all Member States on 18 February 2002.
- (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) The European Food Safety Authority (EFSA) was therefore consulted on 30 January 2004.
- (6) On 6 December 2005, EFSA adopted the 'Opinion of the Scientific Panel on Dietetic Products, Nutrition and

Allergies on a request from the Commission related to maize-germ oil high in unsaponifiable matter as a novel food ingredient'.

- (7) The opinion came to the conclusion that the proposed use level of 2 g per day of 'maize-germ oil high in unsaponifiable matter' was safe.
- (8) It is recognised that 'maize-germ oil high in unsaponifiable matter' at the intended use level of 2 g per day is a safe source of Vitamin E. For labelling and presentation 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 ⁽²⁾ applies.
- (9) On the basis of the scientific assessment, it is established that 'maize-germ oil high in unsaponifiable matter' 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

'Maize-germ oil high in unsaponifiable matter', as specified in the Annex may be placed on the market in the Community as a novel food ingredient for use in food supplements.

Article 2

The maximum amount of 'maize-germ oil high in unsaponifiable matter' present in a portion recommended for daily consumption by the manufacturer shall be 2 g.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 183, 12.7.2002, p. 51. Directive as amended by Commission Directive 2006/37/EC (OJ L 94, 1.4.2006, p. 32).

Article 3

The designation of the novel food ingredient shall be 'maize-germ oil extract'.

Article 4

This Decision is addressed to Laboratoires Expanscience, Siège Social, 10, Avenue de l'Arche, F-92419 Courbevoie Cedex.

Done at Brussels, 24 October 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Specifications of 'maize-germ oil high in unsaponifiable matter'

DESCRIPTION

'Maize-germ oil high in unsaponifiable matter' is produced by vacuum distillation and it is different from refined maize-germ oil in the concentration of the unsaponifiable fraction (1,2 g in refined maize-germ oil and 10 g in 'maize-germ oil high in unsaponifiable matter').

SPECIFICATIONS

<i>Unsaponifiable matter</i>	> 9 g/100 g
<i>Tocopherols</i>	≥ 1,3 g/100 g
α-tocopherol (%)	10-25 %
β-tocopherol (%)	< 3 %
γ-tocopherol (%)	68-89 %
δ-tocopherol (%)	< 7 %
<i>Sterols, triterpenic alcohols, methylsterols</i>	> 6,5g/100 g
<i>Fatty acids in tryglycerides</i>	
palmitic acid	10-20 %
stearic acid	< 3,3 %
oleic acid	20-42,2 %
linoleic acid	34-65,6 %
linolenic acid	< 2 %
<i>Acid value</i>	≤ 6 mg KOH/g
<i>Peroxide value</i>	≤ 10 mEq O ₂ /kg
<i>Iron (Fe)</i>	< 1 500 µg/kg
<i>Copper (Cu)</i>	< 100 µg/kg
<i>Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene</i>	< 2 µg/kg

Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'maize-germ oil high in unsaponifiable matter'.