

COMMISSION DECISION

of 27 June 2008

authorising the placing on the market of refined echium oil as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

*(notified under document number C(2008) 3049)***(Only the English text is authentic)**

(2008/558/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 11 August 2006 the company Croda Chemicals Ltd. made a request to the competent authorities of the United Kingdom to place refined echium oil on the market as a novel food ingredient.

(2) On 12 July 2007 the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that refined echium oil is safe for human consumption at the proposed uses.

(3) The Commission forwarded the initial assessment report to all Member States on 1 August 2007.

(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) On 10 January 2008 in his response to the comments and objections, the applicant agreed to amend the specifications of the refined echium oil and to restrict its uses as requested by some Member States.

(6) Refined echium oil complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(7) 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

Refined echium oil as specified in Annex I, hereinafter called the product, may be placed on the market in the Community as a novel food ingredient for the uses and under the conditions specified in Annex II.

Article 2

The designation on the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'refined echium oil'.

Article 3

This Decision is addressed to Croda Chemicals Europe Ltd, Oak Road, Clough Road, Hull, East Yorkshire, HU6 7PH, United Kingdom.

Done at Brussels, 27 June 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽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).

ANNEX I

Specifications of refined echium oil**Description**

Echium oil is the pale yellow product obtained by refining oil extracted from the seeds of *Echium plantagineum*.

Specifications

Test	Specification
Stearidonic acid content	Not less than 10 % w/w of total fatty acids
Trans fatty acids	Not more than 2 % (w/w of total fatty acids)
Acid value	Not more than 0,6 mg KOH/g
Peroxide value	Not more than 5 meq O ₂ /kg
Unsaponifiable content	Not more than 2 %
Protein content (total nitrogen)	Not more than 20 µg/mL
Pyrrolizidine alkaloids	Not detectable with a detection limit 4 µg/kg

ANNEX II

Uses of refined Echium oil

Use group	Maximum level of stearidonic acid (STA)
Milk-based products and drinkable yoghurt products delivered in a single dose	250 mg/100 g; 75 mg/100 g for drinks
Cheese preparations	750 mg/100 g
Spreadable fat and dressings	750 mg/100 g
Breakfast cereals	625 mg/100 g
Food supplements	500 mg/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	250 mg/meal replacement