

COMMISSION IMPLEMENTING DECISION (EU) 2017/2353**of 14 December 2017****authorising the placing on the market of oil from *Calanus finmarchicus* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document C(2017) 8426)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 31 January 2011, the Norwegian company Calanus AS made a request to the competent authority of the United Kingdom to place oil from the crustacean (marine zooplankton) *Calanus finmarchicus* harvested in the Norwegian Economic Zone and the Jan Mayen zone on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97.
- (2) On 21 October 2016, the competent authority of the United Kingdom issued its initial assessment report. In that report, it came to the conclusion that oil from *Calanus finmarchicus* meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 8 November 2016, the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97, in particular concerning the insufficient information on production process, storage stability and toxicological data. The additional explanations provided by the applicant alleviated those concerns to the satisfaction of Member States and of the Commission.
- (5) Directive 2002/46/EC of the European Parliament and of the Council ⁽²⁾ lays down requirements for food supplements. The use of oil from *Calanus finmarchicus* should be authorised without prejudice to the provisions of that Directive.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Without prejudice to the provisions of Directive 2002/46/EC, oil from *Calanus finmarchicus* as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient to be used in food supplements at the maximum levels established in Annex II to this Decision.

Article 2

The designation of oil from *Calanus finmarchicus* authorised by this Decision on the labelling of the foodstuffs shall be 'oil from *Calanus finmarchicus* (crustacean)'.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ 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, (OJ L 183, 12.7.2002, p. 51).

Article 3

This Decision is addressed to Calanus AS, Stakkevolly. 65, P.O. Box 2489, 9272 Tromsø, Norway.

Done at Brussels, 14 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

SPECIFICATIONS OF OIL FROM CALANUS FINMARCHICUS

Description: The novel food is ruby coloured, slightly viscous oil with a slight shellfish odour extracted from the crustacean (marine zooplankton) *Calanus finmarchicus*. The ingredient consists primarily of wax esters (> 85 %) with minor amounts of triglycerides and other neutral lipids.

Specifications

Parameter	Specifications values
Water	< 1 %
Wax esters	> 85 %
Total fatty acids	> 46 %
Eicosapentaenoic acid (EPA)	> 3 %
Docosahexaenoic acid (DHA)	> 4 %
Total fatty alcohols	> 28 %
C20:1 n-9 fatty alcohol	> 9 %
C22:1 n-11 fatty alcohol	> 12 %
Trans fatty acids	< 1 %
Astaxanthin esters	< 0,1 %
Peroxide value	< 3 meq. O ₂ /kg

ANNEX II

AUTHORISED USES OF OIL FROM *CALANUS FINMARCHICUS*

Food category	Maximum level
Food supplements as defined in Directive 2002/46/EC	2,3 g/day