

COMMISSION IMPLEMENTING REGULATION (EU) 2022/966**of 21 June 2022****amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use, the specific labelling requirements and specifications of the novel food *Calanus finmarchicus* oil****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes *Calanus finmarchicus* oil as an authorised novel food.
- (4) Commission Implementing Decision (EU) 2017/2353 ⁽³⁾ authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁴⁾, the placing on the market of *Calanus finmarchicus* oil as a novel food ingredient to be used in food supplements intended for the general population.
- (5) On 30 November 2021, the company 'Calanus A/S' ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the specifications, of the conditions of use, and of the specific labelling requirements of the novel food '*Calanus finmarchicus* oil'. The applicant proposed to change the specifications of *Calanus finmarchicus* oil with regard to astaxanthin esters to the level up to 0,25 %. They requested an increased maximum level of up to 0,25 % of astaxanthin esters contained in *Calanus finmarchicus* oil for persons older than fourteen years of age, in addition to the currently authorised maximum level of < 0,1 % of astaxanthin esters in *Calanus finmarchicus* oil for the general population. For food supplements containing the currently authorised level of < 0,1 % astaxanthin esters that are intended for the general population, the applicant proposed reducing the currently authorised use levels of the *Calanus finmarchicus* oil from 2,3 g/day to 1,0 g/day and excluding infants and young children.
- (6) As a consequence of the proposed changes in the specifications *Calanus finmarchicus* oil and the conditions of use of this novel food, the applicant proposed an amendment in its labelling to ensure that consumers only use the food supplements intended for their age group. In addition, in light of the current use of food supplements containing astaxanthin esters in the Union market, the applicant also proposed additional specific labelling to warn consumers not to use *Calanus finmarchicus* oil food supplements, when other food supplements containing astaxanthin esters are consumed on the same day.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ 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 (OJ L 336, 16.12.2017, p. 45).

⁽⁴⁾ 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, 14.2.1997, p. 1).

- (7) The Commission considers that the requested update of the Union list concerning specifications of *Calanus finmarchicus* oil and the resulting changes in its conditions of use for the population groups older than 14 years of age is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The increase in the astaxanthin esters in oil from *Calanus finmarchicus* from < 0,1 % to ≤ 0,25 % in food supplements intended for population groups older than 14 years is expected to result in intakes of astaxanthin esters which, in combination with the intake of astaxanthin from the normal diet, are not expected to exceed the revised Acceptable Daily Intake ('ADI') of 0,2 mg astaxanthin/kg bw, established by the Authority ⁽⁵⁾.
- (8) Furthermore, the Commission considers that the requested update of the Union list concerning the reduction of the currently authorised use levels of *Calanus finmarchicus* oil from 2,3 g/day to 1,0 g/day in food supplements intended for the general population that contain < 0,1 % astaxanthin esters, and the exclusion of infants and young children is also not liable to have an effect on human health and that a safety evaluation by the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The exclusion of infants and young children is justified because the anticipated combined intake of astaxanthin esters from food supplements containing *Calanus finmarchicus* oil with levels of < 0,1 % astaxanthin esters and from the normal diet is expected to exceed the revised Acceptable Daily Intake ('ADI') of 0,2 mg astaxanthin/kg of body weight established by the Authority for these groups of consumers.
- (9) The proposed change to the specifications and conditions of use of *Calanus finmarchicus* oil as regards the astaxanthin esters values are in line with the conclusions of the safety assessment conducted by the Authority on astaxanthin. Therefore, it is appropriate to amend the specifications and the conditions of use of the novel food *Calanus finmarchicus* oil at the proposed astaxanthin esters levels.
- (10) The proposed changes to the labelling requirements of *Calanus finmarchicus* oil are in line with the conclusions of the safety assessment conducted by the Authority on astaxanthin. In addition, the Commission considers appropriate to lay down additional labelling requirement in order to prevent concomitant consumption of astaxanthin food supplements, which is likely to exceed the ADI established by the Authority. Therefore, it is appropriate to include additional labelling requirements for that novel food.
- (11) The information provided in the application gives sufficient grounds to establish that the changes to the conditions of use, the specific labelling requirements and specifications of the novel food *Calanus finmarchicus* oil are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (12) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (13) In order to provide business operators with sufficient time to adjust their practices to comply with the requirements of this Regulation, transitional measures should be laid down as regards food supplements containing *Calanus finmarchicus* oil, which have been lawfully placed on the Union market or dispatched from third countries for the Union, before the date of entry into force of this Regulation.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

⁽⁵⁾ Safety of astaxanthin for its use as a novel food in food supplements; EFSA Journal 2020;18(2):5993.

Article 2

1. *Calanus finmarchicus* oil food supplements which were lawfully placed on the market before the date of entry into force of this Regulation, may be marketed until their date of minimum durability or use by date.
2. *Calanus finmarchicus* oil food supplements which were dispatched from a third country and were on their way to the Union before the date of entry into force of this Regulation and complying with the rules in force before the date of entry into force of this Regulation, may be marketed until their date of minimum durability or use by date.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 June 2022.

For the Commission
The President
Ursula VON DER LEYEN

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the entry for '*Calanus finmarchicus* oil' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
' <i>Calanus finmarchicus</i> oil'	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'oil from <i>Calanus finmarchicus</i> (crustacean)'. 2. The labelling of food supplements containing <i>Calanus finmarchicus</i> oil shall bear a statement that those food supplements should not be consumed: a) if other food supplements containing astaxanthin esters are consumed on the same day. b) by infants and children younger than 3 years. c) by children younger than 14 years, if the ingredient contains $\geq 0,1$ % astaxanthin.'	
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	1,0 g/day ($< 0,1$ % astaxanthin esters, resulting in $< 1,0$ mg astaxanthin per day) for the general population, excluding infants and young children 2,3 g/day (from $0,1$ % to $\leq 0,25$ % astaxanthin esters, resulting in $\leq 5,75$ mg astaxanthin per day) for the general population older than 14 years of age		

(2) in Table 2 (Specifications), the entry for '*Calanus finmarchicus* oil' is replaced by the following:

Authorised Novel Food	Specifications
' <i>Calanus finmarchicus</i> oil'	<p>Description/Definition: The novel food is ruby coloured, slightly viscous oil with a slight shellfish odour extracted from the crustacean (marine zooplankton) <i>Calanus finmarchicus</i>. The ingredient consists primarily of wax esters (> 85 %) with minor amounts of triglycerides and other neutral lipids.</p> <p>Specifications: Water: $< 1,0$ % Wax esters: > 85 % Total fatty acids: > 46 % Eicosapentaenoic acid (EPA): $> 3,0$ %</p>

	Docosahexaenoic acid (DHA): > 4,0 % Total fatty alcohols: > 28 % C20:1 n-9 fatty alcohol: > 9,0 % C22:1 n-11 fatty alcohol: > 12 % Trans fatty acids: < 1,0 % Astaxanthin esters: ≤ 0,25 % Peroxide value (PV): < 3,0 meq. O ₂ /kg'
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