

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the additional labelling requirements 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 1852/2001¹, and in particular Article 12(1) 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) 2017/2470² 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 Regulation (EU) 2022/966³ authorised the placing on the market of *Calanus finmarchicus* oil for use in food supplements as defined in Directive 2002/46/EC⁴, excluding food supplements for infants and young children, up to a

¹ OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

³ 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 (OJ L 166, 22.6.2022, p. 125, ELI: http://data.europa.eu/eli/reg_impl/2022/966/oj).

⁴ 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, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

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maximum level of 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, and up to a maximum level of 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.

- (5) On 16 December 2024, 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 conditions of use of the novel food '*Calanus finmarchicus* oil'. The applicant proposed to change the conditions of use with regard to astaxanthin esters to a maximum level of 0.9 g/day (\leq 0.25% astaxanthin esters resulting in \leq 2.25 mg astaxanthin per day) for children from 3 to less than 10 years of age, and to a maximum level of 2.2 g/day (\leq 0.25% astaxanthin esters, resulting in \leq 5.5 mg astaxanthin per day) for adolescents from 10 to less than 14 years of age. The applicant also proposed to increase the maximum level of astaxanthin esters for the general population older than 14 years of age to 3.1 g/day (\leq 0.25% astaxanthin esters resulting in \leq 7.75 mg astaxanthin per day). Finally, the applicant requested to amend the additional labelling requirements, as the statement indicating that food supplements containing *Calanus finmarchicus* oil should not be consumed by children younger than 14 years if the ingredient contains \geq 0.1% astaxanthin is no longer appropriate.
- (6) The Commission considers that the requested update of the Union list of *Calanus finmarchicus* oil concerning the changes in its conditions of use for children from 3 to less than 10 years of age, for adolescents from 10 to less than 14 years of age and for the general population older than 14 years of age are 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 proposed increase in the astaxanthin esters in oil from *Calanus finmarchicus* is expected to result in intakes of astaxanthin which, in combination with the intake of astaxanthin from the normal diet, are not expected to exceed, in any population group, the acceptable daily intake of 0,2 mg of astaxanthin/kg body weight established by the Authority⁵.
- (7) It is therefore appropriate to amend the conditions of use of the novel food *Calanus finmarchicus* oil, as proposed by the applicant.
- (8) It is also appropriate to amend the labelling requirements of *Calanus finmarchicus* oil, in line with the proposed conditions of use, as the statement indicating that food supplements containing *Calanus finmarchicus* oil should not be consumed by children younger than 14 years if the ingredient contains \geq 0.1% astaxanthin does no longer apply.
- (9) The information provided in the application gives sufficient grounds to establish that the changes to the conditions of use and to the specific labelling requirements 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.

⁵ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.5993>

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- (10) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (11) 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.
- (12) 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.

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,

For the Commission
The President
Ursula VON DER LEYEN