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# COMMISSION IMPLEMENTING REGULATION (EU) 2024/2062

## of 30 July 2024

## amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food *Schizochytrium* sp. oil rich in DHA and EPA

**(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 *Schizochytrium* sp. oil rich in docosahexaenoic acid ('DHA') and eicosapentaenoic acid ('EPA') as an authorised novel food.

(4) Pursuant to Article 4(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]), *Schizochytrium* sp. oil rich in DHA and EPA has been authorised to be placed on the market as a novel food to be used in a number of foods.

(5) On 30 January 2024, the company DSM Nutritional Products Ltd. ('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 novel food *Schizochytrium* sp. oil rich in DHA and EPA. The applicant requested to lower the levels of DHA from the current authorised level of equal or greater than 22,5 % to equal or greater than 15,0 %.

(6) The applicant justified the request for the proposed changes in the specifications as relating to an optimisation of fermentation nutrients and manufacturing conditions. The resulting decrease of the levels of DHA in the product was intended and expected, and is the result of production improvements and optimisation, mainly due to minor adjustments in the fermentation phase, while other processing steps remain the same. The applicant also indicated that the requested change of the specifications of *Schizochytrium* sp. oil rich in DHA and EPA does not affect the safety of the novel food.

([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]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel foods ingredients (OJ L 43, 14.2.1997, p. 1, ELI: http://data.europa.eu/eli/reg/1997/258/oj).

(7) The Commission considers that the requested update of the Union list concerning the change of the specifications of *Schizochytrium* sp. oil rich in DHA and EPA as proposed by the applicant 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 requested change of the specifications concerns lower levels of DHA than previously assessed by the Authority [4] as safe. This revision of the specifications for *Schizochytrium* sp. oil rich in DHA and EPA concerns the change of only one parameter, the level of DHA, while the other parameters of the specifications remain unchanged.

(8) The information provided in the application and the Authority's 'Scientific Opinion on the extension of use for DHA and EPA-rich algal oil from *Schizochytrium* sp. as a Novel Food ingredient' gives sufficient grounds to establish that the changes to the specifications of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

(9) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(10) 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*

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, 30 July 2024.

*For the Commission*
*The President*
Ursula VON DER LEYEN

[4] Scientific Opinion on the extension of use for DHA and EPA-rich algal oil from *Schizochytrium* sp. as a Novel Food ingredient (*EFSA Journal* 2014;12(10):3843).

*ANNEX*

In Table 2 (Specifications) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for *Schizochytrium* sp. oil rich in DHA and EPA is replaced by the following:

| Authorised novel food | Specification |
|---|---|
| '***Schizochytrium* sp. oil rich in DHA and EPA** | Acid value: ≤ 0,5 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq/kg oil<br>Oxidative stability: All food products containing *Schizochytrium* sp. oil rich in DHA and EPA should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC)<br>Moisture and volatiles: ≤ 0,05 %<br>Unsaponifiables: ≤ 4,5 %<br>Trans-fatty acids: ≤ 1 %<br>DHA content: ≥ 15 %<br>EPA content: ≥ 10 %' |