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

of **XXX**

**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<sup>1</sup>, 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) 2017/2470<sup>2</sup> 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 DHA and 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<sup>3</sup>, *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.

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

<sup>2</sup> 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](http://data.europa.eu/eli/reg_impl/2017/2470/oj)).

<sup>3</sup> 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>).

- (5) Commission Implementing Decision (EU) 2015/546<sup>4</sup> amended the conditions of use of *Schizochytrium* sp. oil rich in DHA and EPA. In particular, the use of *Schizochytrium* sp. oil rich in DHA and EPA has been extended to additional foods, namely, food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council<sup>5</sup>.
- (6) Commission Implementing Regulation (EU) 2022/1365<sup>6</sup> amended the conditions of use of *Schizochytrium* sp. oil rich in DHA and EPA. The applicant requested to extend the use of *Schizochytrium* sp. oil rich in DHA and EPA has been extended to additional foods, namely, fish analogues and meat analogues at levels 300 mg/100 g and 300 mg/100 g respectively, intended for the general population.
- (7) 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 change the level of docosahexaenoic acid (DHA) from the current authorised level of equal or greater than 22,5% to equal or greater than 15,0%.
- (8) 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 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. This revision of the existing specifications for *Schizochytrium* sp. oil rich in DHA and EPA concerns change of one parameter in the specifications, minimum level of DHA, while other parameters of the specifications remain identical. The change is related to an optimization of fermentation nutrients and manufacturing conditions. The resulting decrease of the level of DHA in the product was intended and expected, and was the result of production improvements and optimization, mainly due to the minor adjustments in the fermentation phase, while other processing steps remain the same. This change of the specifications of *Schizochytrium* sp. oil rich in DHA and EPA does not affect the safety of the novel food.
- (9) The information provided in the application 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.
- (10) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

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<sup>4</sup> Commission Implementing Decision (EU) 2015/546 of 31 March 2015 authorising an extension of use of DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 90, 2.4.2015, p. 11, ELI: [http://data.europa.eu/eli/dec\\_impl/2015/546/oj](http://data.europa.eu/eli/dec_impl/2015/546/oj)).

<sup>5</sup> 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>).

<sup>6</sup> Commission Implementing Regulation (EU) 2022/1365 of 4 August 2022 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA (OJ L 205, 5.8.2022, p. 230, ELI: [http://data.europa.eu/eli/reg\\_impl/2022/1365/oj](http://data.europa.eu/eli/reg_impl/2022/1365/oj)).

(11) 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,

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