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COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and of the specific labelling requirement of the novel food *Schizochytrium* sp. (ATCC PTA-9695) oil

(Text with EEA relevance)

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(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 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 *Schizochytrium* sp. (ATCC PTA-9695) oil as an authorised novel food.
- (4) Commission Implementing Decision (EU) 2015/545³ authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council⁴, the placing on the market of *Schizochytrium* sp. (ATCC PTA-9695) oil as a novel food to be used

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 Decision (EU) 2015/545 of 31 March 2015 authorising the placing on the market of oil from the micro-algae *Schizochytrium* sp. (ATCC PTA-9695) 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. 7, ELI: http://data.europa.eu/eli/dec_impl/2015/545/oj).

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, ELI: <http://data.europa.eu/eli/reg/1997/258/oj>)

in a number of foods. Commission Implementing Regulation (EU) 2019/387⁵ authorised an extension of use of the novel food.

- (5) On 4 March 2025, the company DSM Nutritional Products Europe Ltd. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to change the conditions of use of the novel food *Schizochytrium* sp. (ATCC PTA-9695) oil. The applicant requested to increase the maximum level of DHA in food supplements as defined in Directive 2002/46/EC⁶ from a maximum of 250 mg DHA/day for the general population and 450 mg DHA/day for pregnant and lactating women to a maximum of 1 g DHA/day for the general population above 3 years of age, including pregnant and lactating women, while maintaining 250 mg DHA/day in food supplements for the general population below 3 years of age.
- (6) Commission Implementing Regulation (EU) 2021/1326⁷ authorised placing on the market as a novel food of another *Schizochytrium* sp. oil produced from a different strain, FCC-3204. On the basis of positive opinion of the European Food Safety Authority ('the Authority')⁸, *Schizochytrium* sp. (FCC-3204) oil was authorised for use in food supplements as defined in Directive 2002/46/EC for the general population above 3 years of age at the maximum levels of DHA of 1 g/day.
- (7) The Commission considers that the requested update of the Union list is 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 proposed change of the conditions of use of the novel food does not change the safety considerations that supported the authorisation of *Schizochytrium* sp. (FCC-3204) oil by Regulation (EU) 2021/1326 for use in food supplements and it does not either pose any safety concern. Taking into account those considerations, the proposed extension of use complies with Article 12(1) of Regulation (EU) 2015/2283. Therefore, it is appropriate to amend the conditions of use of the novel food *Schizochytrium* sp. (ATCC PTA-9695) oil by increasing the maximum use levels of DHA in food supplements.
- (8) The information provided in the application gives sufficient grounds to establish that the changes to the conditions of use of *Schizochytrium* sp. (ATCC PTA-9695) oil are in accordance with Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (9) It is appropriate that the inclusion of *Schizochytrium* sp. (ATCC PTA-9695) oil as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In line with the conditions of use of food supplements containing *Schizochytrium* sp. (ATCC PTA-9695) oil as proposed by the applicant, it is necessary to inform the consumers in that regard by appropriate labelling

⁵ Commission Implementing Regulation (EU) 2019/387 of 11 March 2019 authorising an extension of use of *Schizochytrium* sp. (ATCC PTA-9695) oil as a novel food and the change of the designation and of the specific labelling requirement of *Schizochytrium* sp. (ATCC PTA-9695) oil under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 70, 12.3.2019, p. 17, ELI: http://data.europa.eu/eli/reg_impl/2019/387/oj).

⁶ 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>).

⁷ Commission Implementing Regulation (EU) 2021/1326 of 10 August 2021 authorising the placing on the market of *Schizochytrium* sp. (FCC-3204) oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 288, 11.8.2021, p. 24, ELI: http://data.europa.eu/eli/reg_impl/2021/1326/oj).

⁸ Safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in food supplements as a novel food pursuant to Regulation (EU) 2015/2283 (EFSA Journal 2021;19(1):6345).

about the uses of food supplements containing *Schizochytrium* sp. (ATCC PTA-9695) oil.

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