



2025/2245

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COMMISSION IMPLEMENTING REGULATION (EU) 2025/2245

of 7 November 2025

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. (ATCC PTA-9695) 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 *Schizochytrium* sp. (ATCC PTA-9695) oil as an authorised novel food.
- (4) Commission Implementing Decision (EU) 2015/545 ⁽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 *Schizochytrium* sp. (ATCC PTA-9695) oil as a novel food to be used in a number of foods. Commission Implementing Regulation (EU) 2019/387 ⁽⁵⁾ 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/EC of the European Parliament and of the Council ⁽⁶⁾ 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 children below 3 years of age.

⁽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>).

⁽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>).

- (6) Commission Implementing Regulation (EU) 2021/1326⁽⁷⁾ 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. The Commission considers that the requested update of the Union list concerning the change of the conditions of use of *Schizochytrium* sp. (ATCC PTA-9695) oil proposed by the applicant, 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 increase to 1 g DHA/day in food supplements for the general population above 3 years of age does not affect safety and the conclusions of the Authority that supported the authorisation of *Schizochytrium* sp. (FCC-3204) oil by Regulation (EU) 2021/1326 for use in food supplements for the general population above 3 years of age at maximum level of 1 g DHA/day apply to this proposed increase. These conclusions took into consideration the Authority's scientific opinion on the 'Tolerable Upper Intake Level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA)'⁽⁹⁾ in which the Authority concluded that supplemental intakes of DHA alone up to about 1 g/day do not raise safety concerns for the general population. Taking into account those considerations, the proposed change of the conditions 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 for the general population above 3 years of age.
- (7) The information provided in the application and the Authority's opinions on 'Safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in food supplements as a novel food pursuant to Regulation (EU) 2015/2283'⁽¹⁰⁾ and 'Tolerable Upper Intake Level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA)' give 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.
- (8) 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 about the uses of food supplements containing *Schizochytrium* sp. (ATCC PTA-9695) oil.
- (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.

⁽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).

⁽⁹⁾ EFSA Journal 2012;10(7):2815.

⁽¹⁰⁾ EFSA Journal 2021;19(1):6345.

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, 7 November 2025.

For the Commission
The President
Ursula VON DER LEYEN

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for *Schizochytrium* sp. (ATCC PTA-9695) oil is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Schizochytrium sp. (ATCC PTA-9695) oil	Specified food category	Maximum levels of DHA	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the microalgae Schizochytrium sp.". 2. The labelling of food supplements containing more than 250 mg DHA/day shall bear a statement that they should not be consumed by children under 3 years of age.'		
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g			
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g			
	Spreadable fats and dressings	600 mg/100 g			
	Breakfast cereals	500 mg/100 g			
	Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for the general population			
		1 g DHA/day for the general population excluding infants and young children			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal			
	Milk-based drinks and similar products intended for young children	200 mg/100 g			
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014					

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Bakery products (breads, rolls, and sweet biscuits)	200 mg/100 g			
	Cereal bars	500 mg/100 g			
	Cooking fats	360 mg/100 g			
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 g			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	200 mg/100 g			
	Fruit/vegetable puree	100 mg/100 g			