

## 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**

(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 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.
- (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) On 8 December 2021, the company DSM Nutritional Products ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for an amendment of the conditions of use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA. The applicant requested to extend the use of *Schizochytrium* sp. oil rich in DHA and EPA to fish analogues and meat analogues at levels 300 mg/100 g and 300 mg/100 g respectively, intended for the general population.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

<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).

<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).

<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).

<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).

- (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 European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The requested extension of use will result in intakes of *Schizochytrium* sp. oil rich in DHA and EPA which, combined with the intakes from the currently authorised uses of the novel food, are comparable with the intakes assessed by the Authority <sup>(6)</sup> as safe and which supported the authorisation of an extension of use of *Schizochytrium* sp. oil rich in DHA and EPA by Implementing Decision (EU) 2015/546. Therefore, it is appropriate to amend the conditions of use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA by extending its use to fish analogues and meat analogues.
- (8) The information provided in the application gives sufficient grounds to establish that the changes to the conditions of use 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, 4 August 2022.

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

---

<sup>(6)</sup> 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).

In Table 1 (Authorised novel foods) 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	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Schizochytrium sp. oil rich in DHA and EPA	<i>Specified food category</i>	<i>Maximum levels of DHA and EPA combined</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "DHA and EPA-rich oil from the microalgae <i>Schizochytrium sp.</i> "		
	Food supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women	3 000 mg/day			
	Food supplements as defined in Directive 2002/46/EC for pregnant and lactating women	450 mg/day			
	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			
	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			
	Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013				
	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				
	Bakery products (breads, rolls and sweet biscuits)	500 mg/100 g			
	Breakfast cereals				
Cooking fats	360 mg/100 g				

Dairy analogues, except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products (excluding drinks)			
Dairy products except milk-based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, <i>fromage frais</i> and yoghurt products; excluding drinks)			
Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 g			
Cereal/nutrition bars	500 mg/100 g			
Spreadable fats and dressings	600 mg/100 g			
Fish analogues	300 mg/100 g			
Meat analogues	300 mg/100 g			