

COMMISSION IMPLEMENTING REGULATION (EU) 2019/109**of 24 January 2019****authorising an extension of use of *Schizochytrium* sp. 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****(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 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 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⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.
- (4) Commission Implementing Decision 2014/463/EU ⁽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 oil from the microalgae *Schizochytrium* sp. as a novel food to be used in a number of foods.
- (5) Commission Implementing Regulation (EU) 2018/1032 ⁽⁵⁾ extended the authorisation of oil from the microalgae *Schizochytrium* sp. (T18) as a novel food under Regulation (EU) 2015/2283 to fruit/vegetable purees.
- (6) On 10 September 2018, the company DSM Nutritional Products Europe made a request to the Commission to change the conditions of use of the novel food *Schizochytrium* sp. oil within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of *Schizochytrium* sp. oil to fruit and vegetable purees.
- (7) The proposed extension of use of the novel food does not change the safety considerations that supported the authorisation of *Schizochytrium* sp. (T18) oil by Implementing Regulation (EU) 2018/1032 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.
- (8) The Commission did not request an opinion from the European Food Safety Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283, as an extension of use of *Schizochytrium* sp. oil and the subsequent updating of the Union list are not liable to have an effect on human health.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽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).

⁽³⁾ Commission Implementing Decision 2014/463/EU of 14 July 2014 on authorising the placing on the market of 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 and repealing Decisions 2003/427/EC and 2009/778/EC (OJ L 209, 16.7.2014, p. 55).

⁽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).

⁽⁵⁾ Commission Implementing Regulation (EU) 2018/1032 of 20 July 2018 authorising the extension of use of oil from the micro algae *Schizochytrium* sp. 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 185, 23.7.2018, p. 9).

HAS ADOPTED THIS REGULATION:

Article 1

1. The entry in the Union list of authorised novel foods, established under Implementing Regulation (EU) 2017/2470, referring to the substance *Schizochytrium* sp. oil shall be amended as specified in the Annex to this Regulation.
2. The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

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, 24 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

The entry for 'Schizochytrium sp. oil' in Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470 is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Schizochytrium sp. oil'	<i>Specified food category</i>	<i>Maximum levels of DHA</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the microalgae <i>Schizochytrium</i> sp."	
	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 fat 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 general population		
		450 mg DHA/day for pregnant and lactating women		
	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 foods and baby foods 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 Implementing Regulation (EU) No 828/2014				

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements		
	<i>Specified food category</i>	<i>Maximum levels of DHA</i>				
	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 ml				
	Fruit/vegetable puree	100 mg/100 g				