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 (Text with EEA relevance)

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

(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 (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 in the Union of oil from the micro-algae *Schizochytrium* sp. (ATCC PTA-9695) 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. (ATCC PTA-9695) oil within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of *Schizochytrium* sp. (ATCC PTA-9695) 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 for extension of use of *Schizochytrium* sp. (T18) oil by Implementing Regulation (EU) 2018/1032 to fruit and vegetable purees 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) On 10 September 2018, the company DSM Nutritional Products Europe also made a request to the Commission to authorise the change of the designation and of the specific labelling requirement for *Schizochytrium* sp. (ATCC PTA-9695) oil within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requests the deletion of the mention of the strain '(ATCC PTA 9695)' from the designation of the novel food as listed in the Union list and from the labelling of foods containing it.

(9) The Applicant considers that the change of the designation and the labelling requirements for *Schizochytrium* sp. (ATCC PTA-9695) oil is necessary because the indication of the strain '(ATCC PTA-9695)' on the labelling of foods containing *Schizochytrium* sp. (ATCC PTA-9695) oil is not understandable nor relevant for consumers.

(10) There are four oils from *Schizochytrium* sp. currently authorised and listed in the Union list of novel foods. However, *Schizochytrium* sp. (ATCC PTA-9695) oil is the only one for which the strain must be specified on the label. Therefore, the change of the designation and labelling of *Schizochytrium* sp. (ATCC PTA-9695) oil will ensure consistency in the designation and labelling of all oils from *Schizochytrium* sp. authorised as novel foods without having a negative impact on human health and consumer interests.

(11) Considering the removal of the mention of the strain '(ATCC PTA 9695)' from the designation of the novel food and of the specific labelling requirement for *Schizochytrium* sp. (ATCC PTA-9695) oil, the wording '(ATCC PTA 9695)' should be included in the specifications as it is necessary for a proper identification of the novel food. Therefore, the specifications of the entry '*Schizochytrium* sp. (ATCC PTA-9695) oil' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 should be amended accordingly.

(12) 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. (ATCC PTA-9695) oil, the change of the designation and of the specific labelling requirement for *Schizochytrium* sp. (ATCC PTA-9695) oil and the subsequent updating of the Union list are not liable to have an effect on human health.

(13) 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

1 The entry in the Union list of authorised novel foods, established under Implementing Regulation (EU) 2017/2470, referring to the substance *Schizochytrium* sp. (ATCC PTA-9695) oil shall be amended as specified in the Annex to this Regulation.

2 The entry in the Union list referred to in paragraph 1 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, 11 March 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/387. (See end of Document for details)*

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) The entry for '*Schizochytrium* sp. (ATCC PTA-9695) oil' in Table 1 (Authorised novel foods) 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. (ATCC PTA-9695) oil**	***Specified food category***	***Maximum levels of DHA***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae *Schizochytrium* 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 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 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		