# 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)

## 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,

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/109. (See end of Document for details)*

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** | ***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 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 | | | |