# 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 (Text with EEA relevance)

## 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

(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)] was adopted, which establishes a Union list of authorised novel foods.

(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 updating the Union list.

(4) Commission Implementing Decision (EU) No 463/2014[(3)] authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council[(4)] concerning novel food and novel food ingredients, the placing on the market of oil containing docosahexaenoic acid ('DHA') from the micro algae *Schizochytrium* sp. as a novel food ingredient to be used in certain foods, foods intended for use in energy restricted diets for weight reduction, dietary foods for special medical purposes, other foods for particular nutritional uses as defined in Directive 2009/39/EC of the European Parliament and of the Council[(5)] (excluding infant and follow on formulae) and food supplements.

(5) Commission Implementing Decision (EU) 2015/545[(6)] authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of oil containing

docosahexaenoic acid ('DHA') from another strain of the micro algae *Schizochytrium* sp. (ATCC PTA 9695), as a novel food ingredient to be used in certain foods, including infant and follow on formulae and processed cereal-based foods and baby foods for infants and young children.

(6) On 21 November 2016, the company Mara Renewables Corporation made a request to the competent authority of the United Kingdom for an extension of use of oil produced from a different strain of the micro algae *Schizochytrium* sp. (strain T18) within the meaning of point (d) of Article 1(2) of Regulation (EC) No 258/97. The application requested to use oil from this *Schizochytrium* sp. strain T18 for all foods authorised by Implementing Decisions (EU) No 463/2014 and (EU) 2015/545, and extend its use to fruit and vegetable purees.

(7) On 10 January 2017, the company Mara Renewables Corporation notified the Commission that it placed the novel food ingredient 'oil from *Schizochytrium* sp.' produced with strain T18 on the Union market pursuant to Article 5 of Regulation (EC) No 258/97. The company intended to use this novel food ingredient in all previously authorised foods under Implementing Decision (EU) No 463/2014.

(8) On 22 September 2017, the company Nutraveris notified the Commission that it placed the novel food ingredient 'oil from *Schizochytrium* sp.' produced with strain T18 on the Union market pursuant to Article 5 of Regulation (EC) No 258/97. The company intended to use this novel food ingredient in all previously authorised foods under Implementing Decisions (EU) No 463/2014 and (EU) 2015/545.

(9) On 23 October 2017, the company BASF notified the Commission that it placed the novel food ingredient 'oil from *Schizochytrium* sp.' produced with strain T18 on the Union market pursuant to Article 5 of Regulation (EC) No 258/97. The company intended to use this novel food ingredient in all previously authorised foods under Implementing Decisions (EU) No 463/2014 and (EU) 2015/545.

(10) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.

(11) While the request for an extension of use of oil from the micro-algae species *Schizochytrium* sp. strain T18 was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

(12) On 6 October 2017, the competent authority of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that the extension of use of oil from strain T18 of the micro-algae *Schizochytrium* sp. meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(13) On 7 October 2017, the Commission forwarded the initial assessment report to the other Member States. Comments were made by the other Member States within the 60-day

period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 which confirmed the conclusions of the initial assessment.

(14) The initial report conclusions give sufficient grounds to establish that the extension of use of oil from strain T18 of the micro-algae *Schizochytrium* sp. complies with Article 12(1) of Regulation (EU) 2015/2283.

(15) Regulation (EU) No 1308/2013 of the European Parliament and Council[7] establishing a common organisation of the markets in agricultural products lays down requirements for agricultural products, in particular on milk and milk products. The extension of use of DHA-rich oil from the micro-algae *Schizochytrium* sp. strain T18 should be authorised without prejudice to that Regulation.

(16) Directive 2002/46/EC of the European Parliament and of the Council[8] lays down requirements on food supplements. The extension of use of oil from the micro-algae species *Schizochytrium* sp. strain T18 should be authorised without prejudice to that Directive.

(17) Regulation (EU) No 609/2013 of the European Parliament and of the Council[9] lays down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The extension of use of oil from the micro-algae species *Schizochytrium* sp. strain T18 should be authorised without prejudice to that Regulation.

(18) 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 entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to oil from the micro-algae species *Schizochytrium* sp. (T18) shall be amended as specified in the Annex to this Regulation.

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.

The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 1308/2013, Directive 2002/46/EC and Regulation (EU) No 609/2013.

*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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1032. (See end of Document for details)*

Done at Brussels, 20 July 2018.

*For the Commission*

*The President*

Jean-Claude JUNCKER