COMMISSION IMPLEMENTING REGULATION (EU) 2021/1326

of 10 August 2021

authorising the placing on the market of *Schizochytrium* sp. (FCC-3204) 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 of the European Parliament and of the Council 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) On 23 January 2019, the company Fermentalg ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 for an extension of use of the novel food *Schizochytrium* sp. oil. The applicant requested to extend the use of *Schizochytrium* sp. oil to infant formula and follow-on formula intended for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]). The strain of *Schizochytrium* sp. used by the applicant and concerned by that application is specified as strain FCC-3204.

(4) On 15 April 2019, the applicant submitted another application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 requesting to change the conditions of use of the novel food *Schizochytrium* sp. oil. The applicant requested to increase the maximum level of *Schizochytrium* sp. oil in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]) for the adult population, excluding pregnant and lactating women. The strain of *Schizochytrium* sp. used by the applicant and concerned by that application is the same strain FCC-3204 as above.

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 13 May 2019, requesting it to provide a scientific opinion by carrying out an assessment for an extension of the use of *Schizochytrium* sp. oil as a novel food in infant formula and follow-on formula.

(6) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the Authority on 10 July 2019, requesting it to provide a scientific opinion by carrying out an assessment for the change of the conditions of use of *Schizochytrium* sp. oil as a novel food in food supplements.

([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]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

([4]) 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) On 24 November 2020, the Authority adopted its scientific opinions on the 'Safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in infant and follow-on formula as a novel food pursuant to Regulation (EU) 2015/2283' ([5]) and 'Safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in food supplements as a novel food pursuant to Regulation (EU) 2015/2283' ([6]). These opinions are in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(8) In these opinions, the Authority confirmed that the strain FCC-3204 belongs to the species *Schizochytrium limacinum*, which was attributed the qualified presumption of safety ('QPS') status and included in 2020 in the list of QPS-recommended biological agents intentionally added to food or feed ([7]).

(9) The Authority concluded that *Schizochytrium* sp. oil produced from the strain FCC-3204, belonging to the species *Schizochytrium limacinum*, is safe under the proposed conditions of use in infant formula and in follow-on formula and at the maximum level of 1 g/day in food supplements.

(10) With regard to the application concerning the food supplements, the Authority considered that the data provided by the applicant were not sufficient to conclude on the safety of the novel food at the proposed uses (3 g DHA/day in food supplements for adults, excluding pregnant and lactating women). However, the Authority in its 2012 scientific opinion on the 'Tolerable Upper Intake Level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA)' ([8]) concluded that supplemental intakes of DHA alone up to about 1 g/day do not raise safety concerns for the general population. In line with the conclusions made by the Authority, and taking into account the Member States views, the Commission is of the view that this authorisation should concern general population above 3 years of age.

(11) A labelling requirement should be provided in order to properly inform the consumers that the food supplements containing *Schizochytrium* sp. (FCC-3204) oil should not be consumed by infants and children under 3 years of age.

(12) Data submitted by the applicant did not allow for a conclusion on the safety of oil produced from other strains of the *Schizochytrium* microalgae genus. Therefore, the opinions of the Authority do not give sufficient grounds to establish that oil produced from other strains of *Schizochytrium* microalgae genus when used in infant formula and follow-on formula and with increased levels in food supplements fulfil the requirements of Article 12(1) of Regulation (EU) 2015/2283.

(13) Following the Authority's opinions and taking into account that authorised *Schizochytrium* sp. oil for which an extension of use was requested is neither species-specific nor strain-specific, it is therefore necessary to authorise the placing on the market of oil from strain FCC-3204 of *Schizochytrium* sp. under the assessed conditions of use, and not an extension of use of oil from all strains of the *Schizochytrium* genus as requested by the applicant.

(14) Regulation (EU) 2017/2470 should therefore be amended accordingly.

(15) 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. *Schizochytrium* sp. (FCC-3204) oil as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

([5]) *EFSA Journal* 2021;19(1):6344.
([6]) *EFSA Journal* 2021;19(1):6345.
([7]) EFSA BIOHAZ Panel, 2020. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 11: suitability of taxonomic units notified to EFSA until September 2019. *EFSA Journal* 2020;18(2):5965, 57 pp.
([8]) *EFSA Journal* 2012;10(7):2815.

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, 10 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	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.".		
Schizochytrium sp. (FCC-3204) oil	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
	Food supplements as defined in Directive 2002/46/EC for the general population above 3 years of age	1 g/day	The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil shall bear a statement that they should not be consumed by infants and children under 3 years of age.'		

(2) in Table 2 (Specifications), the following entry is inserted:

'Authorised Novel Food	Specifications
Schizochytrium sp. (FCC-3204) oil	**Description/Definition:** The novel food is an oil produced from the strain FCC-3204 of the microalgae *Schizochytrium* sp. **Composition:** Acid value: ≤ 0,5 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1,0 % Docosahexaenoic acid (DHA): ≥ 32,0 % p-anisidine value: ≤ 10'