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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

authorising the placing on the market of *Schizochytrium* sp. (ATCC-20889) oil as a novel food and amending 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 1852/2001¹, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470² has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes *Schizochytrium* sp. oil as an authorised novel food.
- (4) On 24 May 2023, the company BioPlus Life Sciences ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to change the conditions of use of the novel food *Schizochytrium* sp. oil. The applicant requested to extend the use of the novel food *Schizochytrium* sp. oil to infant formulae and follow-on formulae as defined by Regulation (EU) No 609/2013

¹ OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

of the European Parliament and of the Council³. The strain of *Schizochytrium* sp. concerned by the application is specified as strain ATCC 20889.

- (5) On 30 August 2024, the applicant also made a request to the Commission for the protection of the following proprietary data:
- (6) On 10 October 2023, the Commission requested the European Food Safety Authority ('the Authority') to provide a scientific opinion on the change of the conditions of use of *Schizochytrium* sp. oil as a novel food.
- (7) On 28 November 2024, the Authority adopted its scientific opinion on the 'Safety of oil from *Schizochytrium limacinum* (strain ATCC-20889) for use in infant and follow-on formula as a novel food pursuant to Regulation (EU) 2015/2283'⁴ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority concluded that the oil produced from the strain ATCC-20889 belonging to species *Schizochytrium limacinum*, is safe under the proposed conditions of use.
- (9) The information provided in the application and the Authority's scientific opinion give sufficient grounds to establish that the changes to the conditions of use of *Schizochytrium* sp. (ATCC-20889) oil are in accordance with Article 12(1) of Regulation (EU) 2015/2283 and should be approved.
- (10) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the, without which it could not have assessed the novel food and reached its conclusion.
- (11) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2), point (b), of Regulation (EU) 2015/2283.
- (12) The applicant declared that they held proprietary and exclusive rights of reference to the, at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.
- (13) The Commission assessed all the information provided by the applicant and considers that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore,, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place *Schizochytrium* sp. (ATCC-20889) oil on the market within the Union during a period of five years from the entry into force of this Regulation.
- (14) However, such restriction of the authorisation and the reference to the data contained in the applicant's file for their sole use does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that

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, ELI: <http://data.europa.eu/eli/reg/2013/609/oj>).

⁴ EFSA Journal. 2025;23:e9156.

their application is based on legally obtained information supporting such an authorisation.

- (15) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (16) 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. (ATCC-20889) oil is authorised to be placed on the market within the Union.

Schizochytrium sp. (ATCC-20889) oil shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

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

Article 2

Only the company BioPlus Life Sciences⁵ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from [*the date of entry into force of this Regulation*] [*OP please insert the date*], unless a subsequent applicant obtains an authorisation for the novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of the company BioPlus Life Sciences.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of the company BioPlus Life Sciences.

Article 4

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.

⁵ Address: Pharmed Gardens, Whitefield Road, Bangalore 560048 India

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN