

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

of **XXX**

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. (FCC-3204) oil

(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. (FCC-3204) oil as an authorised novel food.
- (4) Commission Implementing Regulation (EU) 2021/1326³ authorised the placing on the market of *Schizochytrium* sp. (FCC-3204) oil as a novel food.
- (5) On 22.3 juni 2023, the company Fermentalg ('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. (FCC-3204) oil. The applicant requested to extend the use of the novel food *Schizochytrium* sp. (FCC-3204) oil to protein products, excluding dairy analogues, intended for the general population.

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).

³ 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 (OJ L 288, 11.8.2021, p. 24, ELI: http://data.europa.eu/eli/reg_impl/2021/1326/oj)

- (6) On 23 December 2023, the applicant also made a request to the Commission for the protection of the following proprietary data: taxonomic analysis⁴, viable cell analysis⁵ and certificate of analyses of protein products to which the novel food was added⁶.
- (7) On 15 February 2024, the Commission requested the European Food Safety Authority ('the Authority') requesting it to provide a scientific opinion on the change of conditions of use of *Schizochytrium* sp. (FCC-3204) oil as a novel food.
- (8) On 24 September 2024, the Authority adopted its scientific opinion on the 'Safety of an extension of use of oil from *Schizochytrium limacinum* (strain FCC-3204) as a novel food pursuant to Regulation (EU) 2015/2283'⁷ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (9) In its scientific opinion, the Authority concluded that the novel food, *Schizochytrium* sp. (FCC-3204) oil, is safe under the new intended use.
- (10) 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. (FCC-3204) oil are in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (11) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on taxonomic analysis, viable cell analysis and certificate of analyses of protein products to which the novel food was added, without which it could not have assessed the novel food and reached its conclusion.
- (12) 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)(b) of Regulation (EU) 2015/2283.
- (13) The applicant declared that it held proprietary and exclusive rights of reference to the taxonomic analysis, viable cell analysis and certificate of analyses of protein products to which the novel food was added, at the time it submitted the application, and that third parties cannot lawfully access, use or refer to those data.
- (14) The Commission assessed all the information provided by the applicant and considered that it has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the taxonomic analysis, viable cell analysis and certificate of analyses of protein products to which the novel food was added 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. (FCC-3204) oil for use in protein products, excluding dairy analogues, on the market within the Union during a period of five years from the entry into force of this Regulation.
- (15) 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 their application is based on legally obtained information supporting such an authorisation.

⁴ Annex 3 – under Section 3.2 'Identity of the NF'

⁵ Annex 35 – under Section 3.3 'Production process'

⁶ Annex 51 – under Section 3.4 'Compositional data'

⁷ EFSA Journal. 2024;22:e9043.

- (16) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (17) 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 Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

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,

For the Commission
The President
Ursula VON DER LEYEN