



2024/2049

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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2049

of 30 July 2024

authorising the placing on the market of *Schizochytrium limacinum* (TKD-1) 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 1852/2001⁽¹⁾, and in particular Article 12(1) 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) 2017/2470⁽²⁾ has established a Union list of novel foods.
- (3) On 17 December 2020, the company ATK Biotech Co., Ltd.⁽³⁾ ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place *Schizochytrium* sp. (TKD-1) oil on the Union market as a novel food. The applicant requested for the novel food to be authorised for use in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council⁽⁴⁾. The strain of *Schizochytrium* sp. used by the applicant and concerned by this application is specified as strain TKD-1.
- (4) On 21 April 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of *Schizochytrium* sp. (TKD-1) oil as a novel food.
- (5) On 26 October 2023, the Authority adopted its scientific opinion on the 'Safety of oil from *Schizochytrium limacinum* (strain TKD-1) for use in infant and follow-on formula as a novel food pursuant to Regulation (EU) 2015/2283'⁽⁵⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.

⁽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⁾ At the moment of the submission of the application the name of the applicant was TK Biohealth Co., Ltd. By letter on 11 April 2024 the applicant, formerly known as Jiangsu Tiankai Biotechnology Co., Ltd. and TK Biohealth Co., Ltd. informed the Commission that they moved their production site and renamed their company into ATK Biotech Co., Ltd.

⁽⁴⁾ 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>).

⁽⁵⁾ EFSA Journal. 2023;21:e8414.

- (6) In its scientific opinion, the Authority concluded that the novel food, oil produced from the strain TKD-1 belonging to species *Schizochytrium limacinum*, is safe under the proposed conditions of use. The Authority noted that the proposed use levels are in accordance with Regulation (EU) No 609/2013 and its supplementing Regulation (EU) 2016/127⁽⁶⁾. The Authority also noted that the available evidence indicates that the source organism (*Schizochytrium* sp., strain TKD-1) belongs to the species *Schizochytrium limacinum*. In its opinion, the Authority further noted that the source organism which is assessed in the application is *Schizochytrium limacinum* (strain TKD-1) and not the generic *Schizochytrium* sp. Therefore, that scientific opinion gives sufficient grounds to establish that *Schizochytrium limacinum* (TKD-1) oil, when used under the proposed conditions of use, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (7) It is appropriate that the inclusion of *Schizochytrium limacinum* (TKD-1) oil as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (8) *Schizochytrium limacinum* (TKD-1) oil should therefore be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (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. *Schizochytrium limacinum* (TKD-1) oil is authorised to be placed on the market within the Union.

Schizochytrium limacinum (TKD-1) 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

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, 30 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1, ELI: http://data.europa.eu/eli/reg_del/2016/127/oj).

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
“Schizochytrium limacinum (TKD-1) oil	<i>Specified food category</i>	<i>Maximum levels of DHA</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Oil from the microalgae <i>Schizochytrium limacinum</i> ’.”		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

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

Authorised Novel Food	Specification
“Schizochytrium limacinum (TKD-1) oil	<p>Description/Definition: The novel food is an oil produced from the strain TKD-1 of the microalgae species <i>Schizochytrium limacinum</i>.</p> <p>Composition: DHA content: ≥ 35,0 % Acid value: ≤ 0,5 mg KOH/g Peroxide value: ≤ 5,0 meq/kg Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 3,5 % Trans-fatty acids: ≤ 2,0 % Free fatty acids: ≤ 0,4 % <i>p</i>-Anisidine value: ≤ 10”</p>