



2024/1046

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COMMISSION IMPLEMENTING REGULATION (EU) 2024/1046

of 9 April 2024

**authorising the placing on the market of beta-glucan from *Euglena gracilis* microalgae 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 15 August 2019, the company Kemin Foods L.C. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place beta-glucan from *Euglena gracilis* microalgae (paramylon) on the Union market as a novel food. The applicant requested for beta-glucan from *Euglena gracilis* microalgae (paramylon) to be used in a number of foods as follows: cereal bars, total diet replacement for weight control as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽³⁾, food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁴⁾, yoghurt, yoghurt drinks, beverages based on fruit and/or vegetable juices, soft drinks and meal replacements for weight control (as drinks). Subsequently, on 25 January 2024, the applicant modified the initial request in the application on the use of beta-glucan from *Euglena gracilis* microalgae to exclude use in yoghurt, yoghurt drinks, beverages based on fruit and/or vegetable juices, soft drinks and meal replacements for weight control (as drinks). The applicant also modified the initial request in the application on the use of beta-glucan from *Euglena gracilis* microalgae in food supplements to exclude infants and children under three years of age.

⁽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⁾ 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⁾ 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, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

- (4) On 15 August 2019, the applicant also made a request to the Commission for the protection of proprietary data, namely, *in vitro* fermentation studies ⁽⁵⁾, a bacterial reverse mutation test ⁽⁶⁾, an *in vivo* micronucleus test ⁽⁷⁾, an acute toxicity study in rats ⁽⁸⁾, a 14-day dietary toxicity/palatability study in rats ⁽⁹⁾, a 90-day toxicity studies in rats ⁽¹⁰⁾, a 90-day clinical trial ⁽¹¹⁾, a particle size analysis ⁽¹²⁾, the characterization and comparison of paramylon to yeast products ⁽¹³⁾, a study on the effect of mechanical grinding on paramylon structure and particle size ⁽¹⁴⁾, stability reports ⁽¹⁵⁾, a mammalian erythrocyte micronucleus test ⁽¹⁶⁾ and a repeated dose (90-day) oral toxicity study in rats ⁽¹⁷⁾.
- (5) On 23 April 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of beta-glucan from *Euglena gracilis* microalgae as a novel food.
- (6) On 28 March 2023, the Authority adopted its scientific opinion on the 'Safety of paramylon as a novel food pursuant to Regulation (EU) 2015/2283' ⁽¹⁸⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that the novel food, beta-glucan from *Euglena gracilis* microalgae, is safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that beta-glucan from *Euglena gracilis* microalgae, 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.
- (8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the compositional data (particle size analysis, the study on the effect of mechanical grinding on paramylon structure and particle size (Annex D), stability reports (Annex E), a transmission electron microscopy report (Annex D), a 90-day subchronic toxicity study (Annex I, Eurofins Advinus Limited, 2020, unpublished) without which it could not have assessed the novel food and reached its conclusion.
- (9) 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.
- (10) The applicant declared that it held proprietary and exclusive rights of reference to the particle size analysis, the study on the effect of mechanical grinding on paramylon structure and particle size (Annex D), stability reports (Annex E), a transmission electron microscopy report (Annex D) and repeated dose (90-day) oral toxicity study in rats (Annex I, Eurofins Advinus Limited, 2020, unpublished), at the time it submitted the application, and that third parties cannot lawfully access, use or refer to those data.

⁽⁵⁾ Kemin Corporation (2016)

⁽⁶⁾ Product Safety Labs (2015a)

⁽⁷⁾ Product Safety Labs (2015b)

⁽⁸⁾ Product Safety Labs (2014)

⁽⁹⁾ Product Safety Labs (2015c)

⁽¹⁰⁾ Product Safety Labs (2015d)

⁽¹¹⁾ Kemin Foods (2019)

⁽¹²⁾ CoAs Particle Size in Annex D (Product Batch Data and Analytical Methods)

⁽¹³⁾ Annex D – Kemin (2017)

⁽¹⁴⁾ Annex D – Kemin Foods (2021)

⁽¹⁵⁾ Stability Accelerated Long-term, Stability_Capsule, Stability_Retort, pH Stability report in Annex E (Stability reports)

⁽¹⁶⁾ Annex I – Eurofins Advinus Limited, 2019

⁽¹⁷⁾ Annex I – Eurofins Advinus Limited, 2020

⁽¹⁸⁾ EFSA Journal 2023;21(5):7995

- (11) 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 particle size analysis, the study on the effect of mechanical grinding on paramylon structure and particle size (Annex D), the stability reports (Annex E), the transmission electron microscopy report (Annex D) and the repeated dose (90-day) oral toxicity study in rats (Annex I, Eurofins Advinus Limited, 2020, unpublished) should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place beta-glucan from *Euglena gracilis* microalgae on the market within the Union during a period of 5 years from the entry into force of this Regulation.
- (12) However, restricting the authorisation of beta-glucan from *Euglena gracilis* microalgae and the reference to the relevant data contained in the applicant's file to the exclusive use by them 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.
- (13) It is appropriate that the inclusion of beta-glucan from *Euglena gracilis* microalgae 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. In this regard, in line with the conditions of use of food supplements containing beta-glucan from *Euglena gracilis* microalgae as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers by appropriate labelling about the uses of food supplements containing beta-glucan from *Euglena gracilis* microalgae.
- (14) Beta-glucan from *Euglena gracilis* microalgae should 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.
- (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. Beta-glucan from *Euglena gracilis* microalgae is authorised to be placed on the market within the Union.

Beta-glucan from *Euglena gracilis* microalgae 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 Kemin Foods L.C. ⁽¹⁹⁾ 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 30 April 2024, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Kemin Foods L.C.

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 five years from the date of entry into force of this Regulation without the agreement of Kemin Foods L.C.

⁽¹⁹⁾ 1900 Scott Avenue Des Moines, IA 50317, United States.

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.

Done at Brussels, 9 April 2024.

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
	<i>Specified food category</i>	<i>Maximum levels</i>			
Beta-glucan from <i>Euglena gracilis</i> microalgae	Cereal bars	670 mg/100 g	The designation of the novel food on the labelling of the foodstuffs containing it shall be “beta-glucan from <i>Euglena gracilis</i> microalgae”.		<p>Authorised on 30 April 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Kemin Foods L.C., 1900 Scott Avenue Des Moines, IA 50317, United States. During the period of data protection, the novel food beta-glucan from <i>Euglena gracilis</i> microalgae is authorised for placing on the market within the Union only by Kemin Foods L.C., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Kemin Foods L.C.</p> <p>End date of the date protection 30 April 2029.’</p>
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	600 mg/day			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	<p>100 mg/day for children from 3 to 9 years of age</p> <p>150 mg/day for children from 10 to 17 years of age</p> <p>200 mg/day for adults</p>			
			<p>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “beta-glucan from <i>Euglena gracilis</i> microalgae”.</p> <p>2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by persons above 3 years of age/above 9 years of age/adults, depending on the age group the product is intended for</p>		

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

Authorised Novel Food	Specification
Beta-glucan from <i>Euglena gracilis</i> microalgae	<p>Description/Definition: The novel food, beta-glucan from <i>Euglena gracilis</i> microalgae (paramylon), is a linear, unbranched beta-1,3-D-glucan polymer derived from the non-GM microalga <i>Euglena gracilis</i>. The novel food is produced by fermentation, followed by pH adjustment and homogenization to release the beta-glucan granules. The granules are isolated by decanting and washing, and subsequently, acidified and filtered. After drying, the product is milled. The process includes conditions such as an alkaline pH and heat-killing step of the microalga to ensure the absence of viable <i>Euglena gracilis</i> cells in the novel food.</p> <p>Characteristics/composition: Appearance: cream white powder Beta-glucan (*): (%) ≥ 95 Moisture (%): ≤ 6 Ash (%): ≤ 1</p> <p>Heavy metals: Lead (mg/kg): ≤ 0,5 Cadmium (mg/kg): ≤ 0,5 Mercury (mg/kg): ≤ 0,05 Arsenic (mg/kg): ≤ 0,02</p> <p>Microbiological criteria: Total aerobic microbial count (CFU/g): ≤ 3 000 Total yeast and mould count (CFU/g): ≤ 100 Coliforms (MPN/g): ≤ 30 <i>Escherichia coli</i>: Not detected in 10 g <i>Staphylococcus aureus</i>: Not detected in 10 g <i>Salmonella</i> spp.: Not detected in 25 g <i>Listeria monocytogenes</i>: Not detected in 25 g</p>
CFU: colony forming units, MPN: most probable number. (*) Expressed as total dietary fibre.'	