

COMMISSION IMPLEMENTING REGULATION (EU) 2023/6**of 3 January 2023****authorising the placing on the market of pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia 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 12 December 2019, the company MycoTechnology, Inc. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia, on the Union market as a novel food. The applicant requested for the fermented pea and rice protein to be used in bakery wares, breads, rolls, croutons, pizza, breakfast cereals, cereal bars, fruit- and vegetable- based drinks, ready-to-mix beverage powders, cocoa and chocolate confectionary, dairy analogues and non-dairy meal replacements for weight control, fermented milk-based products, pasta-based products, meat preparations and meat products, soups (ready-to eat) and soup concentrates or powders, salads, meat analogues, milk-based drinks, and single meal replacements for weight control, intended for the general population.
- (4) On 12 December 2019, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data submitted in support of the application, namely, the detailed production process description ⁽³⁾ and the compositional analyses of the novel food ⁽⁴⁾.
- (5) On 22 April 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of pea and rice protein fermented by *Lentinula edodes* mycelia as a novel food.
- (6) On 28 February 2022, the Authority adopted its scientific opinion on the 'Safety of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia 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.

⁽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⁾ MycoTechnology, Inc. (2020, unpublished).

⁽⁴⁾ MycoTechnology, Inc. (2020 and 2021, unpublished).

⁽⁵⁾ EFSA Journal 2022;20(4):7205.

- (7) In its scientific opinion, the Authority concluded that pea and rice protein fermented by *Lentinula edodes* mycelia is safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that the fermented pea and rice protein, when used in bakery wares, breads, rolls, croutons, pizza, breakfast cereals, cereal bars, fruit- and vegetable- based drinks, ready-to-mix beverage powders, cocoa and chocolate confectionary, dairy analogues and non-dairy meal replacements for weight control, fermented milk-based products, pasta-based products, meat preparations and meat products, soups (ready-to eat) and soup concentrates or powders, salads, meat analogues, milk-based drinks, and single meal replacements for weight control, intended for the general population, 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 scientific studies and data from the detailed production process description and the compositional analyses of the novel food, contained in the applicant's file, 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 their proprietary claim over those scientific studies and data 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 they held proprietary and exclusive rights of reference to the scientific studies and data on the detailed production process description and the compositional analyses of the novel food at the time they submitted the application and that third parties cannot lawfully access, use or refer to those data.
- (11) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific studies and data on the detailed production process description and the compositional analyses of the novel food should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place pea and rice protein fermented by *Lentinula edodes* mycelia on the market within the Union during a period of five years from the entry into force of this Regulation.
- (12) However, restricting the authorisation of the novel food and the reference to the scientific studies and data contained in the applicant's file for the sole 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 pea and rice protein fermented by *Lentinula edodes* mycelia 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.
- (14) Pea and rice protein fermented by *Lentinula edodes* mycelia 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) Pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia is authorised to be placed on the market within the Union.

Pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia 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 MycoTechnology, Inc. ⁽⁶⁾ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 24 January 2023, 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 MycoTechnology, Inc.

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 MycoTechnology, Inc..

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, 3 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ Address: 18250 E. 40th Avenue, Suite 50, Aurora, 80011 Colorado, United States.

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			
'Pea and rice protein fermented by <i>Lentinula edodes</i> (Shiitake mushroom) mycelia	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Pea and rice protein fermented by Shiitake mushroom mycelia".		<p>Authorised on 24.1.2023. This inclusion is based on proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: MycoTechnology, Inc., 18250 E. 40th Avenue, Suite 50, Aurora, 80011 Colorado, United States. During the period of data protection, the novel food pea and rice protein fermented by <i>Lentinula edodes</i> (Shiitake mushroom) mycelia is authorised for placing on the market within the Union only by MycoTechnology, Inc. unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of MycoTechnology, Inc.</p> <p>End date of the data protection: 24.1.2028.'</p>			
	Bakery wares, breads, rolls, croutons, pizza	5 g/100 g						
	Breakfast cereals and cereal bars	33 g/100 g						
	Fruit- and vegetable-based drinks	20 g/100 ml						
	Ready-to-mix beverage powders	93 g/100 g						
	Cocoa and chocolate confectionary	7 g/100 g						
	Dairy analogues and non-dairy meal replacements for weight control	11 g/100 g						
	Fermented milk-based products	5 g/100 g						
	Pasta-based products	15 g/100 g						
	Meat preparations and meat products	14 g/100 g						
	Soups (ready-to-eat) and soup concentrates or powders	3 g/100 g						
	Salads	26 g/100 g						
	Meat analogues	40 g/100 g						
	Milk-based drinks	1 g/100 g						
Single meal replacements for weight control	1 g/100 g							

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

Authorised Novel Food	Specification
<p>'Pea and rice protein fermented by <i>Lentinula edodes</i> (Shiitake mushroom) mycelia</p>	<p>Description: The novel food is produced from the fermentation of a mixture of 65 % pea and 35 % rice protein concentrates by the mycelia of the Shiitake mushroom (<i>Lentinula edodes</i>) followed by heat treatment to terminate the fermentation and a series of drying steps to form a powder.</p> <p>Characteristics/Composition: Protein (% dry weight, N x 6,25): ≥ 75,0 Moisture: ≤ 7,0 Total fat (% dry weight): ≤ 10,0 Ash (% dry weight): ≤ 10,0 Carbohydrates (% by calculation): ≤ 15,0</p> <p>Mycotoxins: Aflatoxin B1 (µg/kg): < 1,0 Aflatoxin B2 (µg/kg): < 1,0 Aflatoxin G1 (µg/kg): < 1,0 Aflatoxin G2 (µg/kg): < 1,0 Aflatoxin total (B1+B2+G1+G2) (µg/kg): < 3,0</p> <p>Heavy metals: Arsenic (µg/g): < 0,1 Cadmium (µg/g): < 0,1 Lead (µg/g): < 0,3 Mercury (µg/g): < 0,1</p> <p>Microbiological criteria: Total aerobic microbial count: < 1 000 CFU/g Total yeast/moulds count: < 100 CFU/g Coliforms: ≤ 10 CFU/g <i>Salmonella</i> spp.: Absent in 25 g <i>Escherichia coli</i>: < 10 CFU/g <i>Listeria monocytogenes</i>: Absent in 25 g *CFU: Colony Forming Units'</p>