Official Journal
of the European Union

EN
L series

2023/2851

21.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2851

of 20 December 2023

authorising the placing on the market of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) 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 20 November 2020, the company Evergrain LLC ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) on the Union market as a novel food. The applicant requested for partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) to be used in a number of foods intended for the general population.

(4) On 20 November 2020, the applicant also made a request to the Commission for the protection of proprietary data, namely, report on the protein quality of the novel food ([3]), information on the inactivation of the enzyme in the novel food ([4]), information on the absence of toxigenic potential in the enzyme preparation ([5]), information on the absence of mycotoxins and other secondary metabolites produced by *Aspergillus niger* in the enzyme preparation ([6]), compositional data (certificates of analyses of the novel food batches) ([7]) and the stability study report ([8]).

(5) On 10 June 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) as a novel food.

(6) On 24 May 2023, the Authority adopted its scientific opinion on the 'Safety of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) as a novel food pursuant to Regulation (EU) 2015/2283' ([9]) 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]) Dossier section 2.h.4.1 and Annex F; Gallaher (2019, Vrasidas, 2022).
([4]) Dossier section 2.b.1.2.
([5]) Dossier section 2.b.1.2.
([6]) Dossier section 2.b.1.2.
([7]) Dossier section 2.c.1 and Annex C.
([8]) Dossier section 2.c.2 and Annex D.
([9]) EFSA Journal 2023;21(9):8064.

(7) In its scientific opinion, the Authority concluded that the novel food, partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*), is safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*), 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 report on the protein quality of the novel food, information on the inactivation of the enzyme in the novel food, information on the absence of mycotoxins and other secondary metabolites produced by *Aspergillus niger* in the enzyme preparation, compositional data (certificates of analyses of the novel food batches) and the stability study report 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 report on the protein quality of the novel food, information on the inactivation of the enzyme in the novel food, information on the absence of mycotoxins and other secondary metabolites produced by *Aspergillus niger* in the enzyme preparation, compositional data (certificates of analyses of the novel food batches) and the stability study report, at the time it 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 it has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the report on the protein quality of the novel food, information on the inactivation of the enzyme in the novel food, information on the absence of mycotoxins and other secondary metabolites produced by *Aspergillus niger* in the enzyme preparation, compositional data (certificates of analyses of the novel food batches) and the stability study report should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) 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 partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) and the reference to the data contained in the applicant's file for its 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.

(13) As the source of the novel food comes from barley (*Hordeum vulgare*), which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council [10] as one of a number of substances or products which may cause allergies or intolerances, foods containing the novel food should be appropriately labelled following the requirements laid down in Article 21 of that Regulation.

(14) It is appropriate that the inclusion of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) 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.

[10] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18, ELI: http://data.europa.eu/eli/reg/2011/1169/oj).

(15) Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) 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.

(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. Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) is authorised to be placed on the market within the Union.

Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) 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 Evergrain LLC ([11]) 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 10 January 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 Evergrain LLC.

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 Evergrain LLC.

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, 20 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

([11]) 3205 S. 9th St, St. Louis, Missouri, 63118 USA.

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
"**Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Partially hydrolysed protein from spent barley and rice'. In accordance with Article 21 to Regulation (EU) No 1169/2011.		Authorised on 10 January 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Evergrain LLC, 3205 S. 9th St, St. Louis, Missouri, 63118 USA. During the period of data protection, the novel food partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) is authorised for placing on the market within the Union only by Evergrain LLC, 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 Evergrain LLC. End date of the date protection: 10 January 2029."
	Fried or extruded cereal, seed or root-based products	5 g/100 g			
	Confectionery including chocolate	5 g/100 g			
	Breakfast cereals	5 g/100 g			
	Pastas and rice (or other cereal)-based dishes	8 g/100 g			
	Soups (dry mixture)	50 g/100 g			
	Soups (ready-to-eat)	5 g/100 g			
	Sauces	10 g/100 g			
	Dried sauce preparation	50 g/100 g			
	Meat analogues	15 g/100 g			
	Cereal bars	30 g/100 g			
	Butter and margarine/oil blends	10 g/100 g			
	Milk analogues based ice creams	10 g/100 g			
	Milk analogues	5 g/100 ml			
	Nut/seeds paste/emulsion	15 g/100 g			
	Energy drinks	8 g/100 ml			
	Soft drinks marketed in relation to physical exercise	5 g/100 ml			
	Cola type drinks	5 g/100 g			
	Powdered drink bases	90 g/100 g			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Beverages based on fruit and/or vegetable juices	5 g/100 ml			
	Cream, cheese and yoghurt (non-soy) analogues	10 g/100 g			
	Hummus	10 g/100 g			
	Alcohol-free beer	5 g/100 ml			
	Meal replacement for weight control	30 g/100 g			

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

Authorised Novel Food	Specification
"**Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)**	**Description/Definition:** The novel food is partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*), residues obtained from the solid by-product of beer production that contains 45-70 % spent barley and 30-55 % spent rice. The novel food is produced by enzymatically treating the pasteurised spent barley and rice residues of the mash step of beer production. Several mechanical treatment steps of the partial hydrolysate are employed to obtain the final product. **Characteristics/composition:** Appearance: powder Degree of hydrolysis: 1-7 % Proteins (N x 6,25): 78-90 % Moisture: 2-8 % Carbohydrates: 2-10 % Fat: 0-2 % Ash: 1-8 % **Heavy metals:** Arsenic (mg/kg): ≤ 0,2 Cadmium (mg/kg): ≤ 0,1 Lead (mg/kg): ≤ 0,2 Mercury (mg/kg): ≤ 0,01 **Mycotoxins:** Aflatoxin B1: ≤ 2 µg/kg Sum of aflatoxins (B1, B2, G1, G2): ≤ 4 µg/kg Deoxynivalenol: < 200 µg/kg

	Fumonisins (sum of B1, B2): ≤ 200 µg/kg Ochratoxin A: ≤ 3 µg/kg Zearalenone: ≤ 20 µg/kg Patulin: ≤ 50 µg/kg **Antinutritional factors:** Phytic acid: < 0,25 % **Microbiological criteria:** Total aerobic microbial count (CFU/g): < 10^4 Coliforms (CFU/g): < 100 Total yeast and mould count (CFU/g): < 100 *Salmonella* spp.: Not detected in 25 g Escherichia coli (CFU/g): < 10 Staphylococcus *aureus* (CFU/g): < 10 *Listeria monocytogenes*: Not detected in 25 g *Bacillus cereus* (CFU/g): < 100 CFU: colony forming units"