



2024/2046

30.7.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2046

of 29 July 2024

amending Implementing Regulation (EU) 2017/2470 as regards the specific labelling requirements for the novel food partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)

(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 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) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) as an authorised novel food.
- (4) Commission Implementing Regulation (EU) 2023/2851 ⁽³⁾ authorised the placing on the market of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) as a novel food for use in a number of foods for the general population.
- (5) On 6 February 2024, the company Evergrain LLC ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the specific labelling requirements of the novel food 'Partially hydrolysed protein from spent barley and rice'. The applicant requested to change the specific labelling requirements, in particular the designation of the novel food to 'Hydrolysed protein from barley and rice'.

⁽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) 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 (OJ L, 2023/2851, 21.12.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2851/oj).

- (6) The original labelling requirement referred to 'Partially hydrolysed protein from spent barley and rice'. The applicant considers that the change of the designation is necessary because the word 'partially' is not a well-defined term, in particular to the average consumer, who will not know to what extent the protein is hydrolysed, especially as compared to other plant proteins. The applicant further indicates that the word 'spent' is not used for other authorised novel proteins which are processed in a similar manner, and therefore considers that this may create confusion if utilised for this novel food. Furthermore, the applicant also indicates that when barley and rice feedstocks are processed, the first step is to remove the starch which is the same as the process used for any other plant proteins.
- (7) The Commission considers that the requested update of the Union list concerning the change of the specific labelling requirements, in particular the designation of the novel food 'Partially hydrolysed protein from spent barley and rice' as proposed by the applicant, is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. Based on the justification provided by the applicant, the Commission is of the view that the word 'spent' may be omitted from the designation of the novel food for labelling purposes. However, the Commission does not agree with the removal of the word 'partially' from the designation of the novel food. In accordance with the rules on labelling, in particular Article 10(2), point (g), of Regulation (EU) 2015/2283 specific labelling requirements should not mislead the consumer. Furthermore, pursuant to Article 7 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽⁴⁾, food information should not be misleading, particularly as to the characteristics of the food and, among others things, its properties and composition. Taking into account that the degree of hydrolysis of the novel food is 1-7 %, the Commission considers that the word 'partially' should be maintained in the designation of the novel food. In addition, if the applicant would like to further inform the consumer about the degree of hydrolysis, it may voluntarily indicate it on the label of the product in accordance with Article 36 of Regulation (EU) No 1169/2011. Therefore, the designation of the novel food on the labelling of the foodstuffs containing it should be 'Partially hydrolysed protein from barley and rice'.
- (8) The information provided in the application gives sufficient grounds to establish that the changes to the specific labelling requirements of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (9) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (10) 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.

⁽⁴⁾ 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>).

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, 29 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) is replaced by the following:

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 (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>)	<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 "Partially hydrolysed protein from barley and rice". In accordance with Article 21 of 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 (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>) 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			
	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			