COMMISSION IMPLEMENTING REGULATION (EU) 2022/2534

of 21 December 2022

authorising the placing on the market of bovine milk beta-lactoglobulin (*β*-lactoglobulin) 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 22 July 2020, the company Arla Foods Ingredients Group P/S ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place bovine milk beta-lactoglobulin (β-lactoglobulin), isolated from bovine whey under acidic or neutral conditions, on the Union market as a novel food. The applicant requested for bovine milk beta-lactoglobulin to be used in soft drinks marketed in relation to physical exercise, whey powder, milk based drinks and similar products, and in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]) intended for the general population older than three years of age excluding pregnant and lactating women.

(4) On 22 July 2020, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data and submitted in support of the application, namely, a bacterial reverse mutation test ([4]); an in vitro micronucleus assay with human lymphocytes ([5]); a 14-day range-finding oral toxicity study in rodents ([6]); a 90-day oral sub-chronic toxicity study in rodents ([7]); the results of compositional analyses and the analytical certificates for 23 additional batches of the novel food and 20 batches of commercial whey protein isolate ([8]); and, the results of total microbial plate count analyses of the novel food and their certificates ([9]).

(5) On 5 November 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of beta-lactoglobulin as a novel food.

([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]) 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).
([4]) Arla Foods Ingredients Group P/S (2019a, unpublished).
([5]) Arla Foods Ingredients Group P/S (2019b, unpublished).
([6]) Arla Foods Ingredients Group P/S (2019c, unpublished).
([7]) Arla Foods Ingredients Group P/S (2019d, unpublished).
([8]) Arla Foods Ingredients Group P/S (2021 and 2022, unpublished).
([9]) Arla Foods Ingredients Group P/S (2022, unpublished).

(6) On 28 February 2022, the Authority adopted its scientific opinion on the 'Safety of beta-lactoglobulin as a novel food pursuant to Regulation (EU) 2015/2283' ([10]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that bovine milk beta-lactoglobulin is safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that bovine milk beta-lactoglobulin, when used in soft drinks marketed in relation to physical exercise, whey powder, milk based drinks and similar products, and in foods for special medical purposes as defined in Regulation (EU) No 609/2013, intended for the general population older than three years of age excluding pregnant and lactating women, 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 on the bacterial reverse mutation test; the in vitro micronucleus assay with human lymphocytes; the 14-day range-finding oral toxicity study in rodents; the 90-day oral sub-chronic toxicity study in rodents; the results of compositional analyses; and, the analytical certificates for 23 additional batches of the novel food and the 20 batches of commercial whey protein isolate and the results of total microbial plate count analyses of the novel food and their certificates, 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 bacterial reverse mutation test; the in vitro micronucleus assay with human lymphocytes; the 14-day range-finding oral toxicity study in rodents; the 90-day oral sub-chronic toxicity study in rodents; the results of compositional analyses and the analytical certificates for 23 additional batches of the novel food and the 20 batches of commercial whey protein isolate; and, the results of total microbial plate count analyses of the novel food and their certificates, 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 bacterial reverse mutation test; the in vitro micronucleus assay with human lymphocytes; the 14-day range-finding oral toxicity study in rodents; the 90-day oral sub-chronic toxicity study in rodents; the results of compositional analyses and the analytical certificates for 23 additional batches of the novel food and the 20 batches of commercial whey protein isolate; and, the results of total microbial plate count analyses of the novel food and their certificates, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place bovine milk beta-lactoglobulin 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 bovine milk beta-lactoglobulin 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.

([10]) EFSA Journal 2022;20(4):7204.

(13) As the source of the novel food comes from bovine milk, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council [11] as one of a number of substances or products which cause allergies or intolerances, foods containing beta-lactoglobulin, should be appropriately labelled following the requirements of Article 21 of that Regulation.

(14) It is appropriate that the inclusion of bovine milk beta-lactoglobulin 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.

(15) Bovine milk beta-lactoglobulin 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. Bovine milk beta-lactoglobulin (*β*-lactoglobulin) is authorised to be placed on the market within the Union.

Bovine milk beta-lactoglobulin (*β*-lactoglobulin) 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 Arla Foods Ingredients Group P/S [12] 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 11 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 Arla Foods Ingredients Group P/S.

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 5 years from the date of entry into force of this Regulation without the agreement of Arla Foods Ingredients Group P/S.

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*.

[11] 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).

[12] Address: Sønderhøj 10-12, 8260 Viby J, Denmark.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 December 2022.

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
'**Bovine milk beta-lactoglobulin (*β*-lactoglobulin)**	*Specified food category*	*Maximum levels (g NF/100 ml)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'bovine milk beta-lactoglobulin' or 'bovine milk *β*-lactoglobulin'.		Authorised on 11 January 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Arla Foods Ingredients Group P/S, Sønderhøj 10-12, 8260 Viby J, Denmark. During the period of data protection, the novel food beta-lactoglobulin (*β*-lactoglobulin) is authorised for placing on the market within the Union only by Arla Foods Ingredients Group P/S 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 Arla Foods Ingredients Group P/S. End date of the data protection: 11 January 2028.'
	Soft drinks marketed in relation to physical exercise	25			
	Whey powder (reconstituted)	8			
	Milk based drinks and similar products	12			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013 intended for the general population older than 3 years of age, excluding pregnant and lactating women	In accordance with the particular nutritional requirements of the persons for whom the products are intended			

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

Authorised novel food	Specification
'**Bovine milk beta-lactoglobulin (*β*-lactoglobulin)**	**Description:** Beta-lactoglobulin (*β*-lactoglobulin) protein is a white to cream powder produced from bovine whey by a series of steps involving filtration, concentration, crystallisation, re-dissolution (in water), pH adjustment to acidic or neutral pH, re-concentration and drying. CAS number: 9045-23-2 Molecular weight: 36,7 kDa (dimer); 18,3 kDa (monomer) **Characteristics/Composition:** pH (10 % solution): 3,5-8,0 Protein (N x 6,38) (%): ≥ 86,0 Beta-lactoglobulin (% of protein): ≥ 90,0 Lactose (%): ≤ 1,0 Fat (%): ≤ 1,0 Ash (%): ≤ 5,0 Moisture (%): ≤ 5,5 **Heavy Metals**: Cadmium (mg/kg): < 0,2 Lead (mg/kg): < 0,1 Mercury (mg/kg): < 0,01 **Contaminants:** Aflatoxin M1 (µg/kg): < 0,01 **Microbiological criteria:** Total plate count: ≤ 5 000 CFU/g Total yeast/moulds count: ≤ 10 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absent in 25 g *Bacillus cereus*: < 100 CFU/g *Listeria monocytogenes*: Absent in 25 g *Staphylococcus aureus*: < 10 CFU/g Sulfite-reducing clostridia: < 10 CFU/g CFU: Colony Forming Units; kDa: kiloDaltons'