COMMISSION IMPLEMENTING REGULATION (EU) 2019/1686

of 8 October 2019

authorising the extension of use of bovine milk basic whey protein isolate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission 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 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list 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]) establishing a Union list of authorised novel foods was adopted.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.

(4) Commission Implementing Regulation (EU) 2018/1632 ([3]) authorised the placing on the market of bovine milk basic whey protein isolate as a novel food under Regulation (EU) 2015/2283 and amended the Union list of authorised novel foods.

([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]) Commission Implementing Regulation (EU) 2018/1632 of 30 October 2018 authorising the placing on the market of bovine milk basic whey protein isolate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 272, 31.10.2018, p. 23).

(5) On 10 October 2018 the company Armor Protéines S.A.S made a request to the Commission for the extension of use of the bovine milk basic whey protein isolate within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The requested changes concern the use of the bovine milk basic whey protein isolate in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]) and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([5]) for infants up to 12 months.

(6) On 24 January 2019, the Commission consulted the European Food Safety Authority ('the Authority'), asking it to carry out an additional assessment for the extension of use of the bovine milk basic whey protein isolate as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(7) On 14 March 2019, the Authority adopted its scientific opinion 'Safety of whey basic protein isolate for extended uses in foods for special medical purposes and food supplements for infants pursuant to Regulation (EU) 2015/2283' ([6]). That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(8) That scientific opinion gave sufficient grounds to establish that bovine milk basic whey protein isolate, in the proposed extended uses and use levels in foods for special medical purposes, and in food supplements for infants up to 12 months, complies with Article 12(1) of Regulation (EU) 2015/2283. The Authority in that opinion concluded that the extended uses would not increase the potential intake of the novel food compared to that assessed in its 2018 Opinion ([7]). It is therefore appropriate to amend the Union list of authorised novel foods to include this extension of uses in the authorised uses of the bovine milk basic whey protein isolate.

(9) 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. The entry in the Union list of authorised novel foods, established under Implementing Regulation (EU) 2017/2470, referring to the substance bovine milk basic whey protein isolate shall be amended as specified in the Annex to this Regulation.

2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

3. The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 609/2013 and of Directive 2002/46/EC.

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

([4]) 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).

([5]) 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).

([6]) *EFSA Journal* 2019; 17(4):5659.

([7]) *EFSA Journal* 2018; 16(7):5360.

Article 3

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, 8 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) In Table 1 (Authorised novel foods), the entry on 'Bovine milk basic whey protein isolate' 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
	Specified food category	**Maximum levels**			
Bovine milk basic whey protein isolate	Infant formulae as defined in Regulation (EU) No 609/2013 Follow-on formulae as defined in Regulation (EU) No 609/2013 Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013 Foods for special medical purposes as defined in Regulation (EU) No 609/2013 Food Supplements as defined in Directive 2002/46/EC	30 mg/100 g (powder) 3,9 mg/100 mL (reconstituted) 30 mg/100 g (powder) 4,2 mg/100 mL (reconstituted) 300 mg/day 30 mg/100 g (powder formula for infants during the first months of life until the introduction of appropriate complementary feeding) 3,9 mg/100 mL (reconstituted formula for infants during the first months of life until the introduction of appropriate complementary feeding) 30 mg/100 g (powder formula for infants when appropriate complementary feeding is introduced) 4,2 mg/100 mL (reconstituted formula for infants when appropriate complementary feeding is introduced) 58 mg/day for young children 380 mg/day for children and adolescents from 3 to 18 years of age 610 mg/day for adults 25 mg/day for infants 58 mg/day for young children 250 mg/day for children and adolescents from 3 to 18 years of age 610 mg/day for adults	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Milk whey protein isolate". Food supplements containing bovine milk basic whey protein isolate shall bear the following statement: "This food supplement should not be consumed by infants/children/adolescents under the age of one/three/eighteen (*) years" (*) Depending on the age group the food supplement is intended for.		Authorised on 20 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Armor Protéines S.A.S., 19 bis, rue de la Libération 35460 Saint-Brice-en- Coglès, France. During the period of data protection the novel food bovine milk basic whey protein isolate is authorised for placing on the market within the Union only by Armor Protéines S.A.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 Armor Protéines S.A.S. End date of the data protection: 20 November 2023.'

(2) in Table 2 (Specifications), the entry on 'Bovine milk basic whey protein isolate' is replaced by the following:

'Authorised Novel Food	Specification
Bovine milk basic whey protein isolate	**Description** Bovine milk basic whey protein isolate is a yellowish grey powder obtained from bovine skimmed milk via a series of isolation and purification steps. **Characteristics/Composition** Total protein (w/weight of product): ≥ 90 % Lactoferrin (w/weight of product): 25-75 % Lactoperoxidase (w/weight of product): 10-40 % Other proteins (w/weight of product): ≤ 30 % TGF-β2: 12-18 mg/100 g Moisture: ≤ 6,0 % pH (5 % solution w/v): 5,5 – 7,6 Lactose: ≤ 3,0 % Fat: ≤ 4,5 % Ash: ≤ 3,5 % Iron: ≤ 25 mg/100 g **Heavy Metals** Lead: < 0,1 mg/kg Cadmium: < 0,2 mg/kg Mercury: < 0,6 mg/kg Arsenic: < 0,1 mg/kg **Microbiological criteria:** Aerobic mesophilic count: ≤ 10 000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Escherichia coli*: Negative/g Coagulase positive *Staphylococci*: Negative/g *Salmonella*: Negative/25 g *Listeria*: Negative/25 g *Cronobacter* spp.: Negative/25 g Moulds: ≤ 50 CFU/g Yeasts: ≤ 50 CFU/g

CFU: Colony Forming Units'