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)

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.

(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.

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/1686. (See end of Document for details)*

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
Bovine milk basic whey protein isolate	**Specified food category**	**Maximum levels**	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		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
	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)			