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 (Text with EEA relevance)

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

(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 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) On 22 August 2016, the company Armor Protéines S.A.S. (‘the Applicant’) made a request to the competent authority of Ireland to place bovine milk basic whey protein isolate obtained from skimmed bovine milk through a series of purification steps, on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council[(3)]. The application seeks to have bovine milk basic whey protein isolate used in infant and follow-on formulae, in total diet replacement foods for weight control and in foods for special medical purposes, and in food supplements.

(5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food

ingredients, and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.

(6) While the request for placing bovine milk basic whey protein isolate on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

(7) On 27 June 2017, the competent authority of Ireland issued its initial assessment report. In that report, it concluded that bovine milk basic whey protein isolate meets the criteria for a novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 4 July 2017, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to the safety of bovine milk basic whey protein isolate for infants, and the toxicological relevance of the results in a 6-week developmental toxicity study in juvenile rats[(4)].

(9) In view of the objections raised by the other Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 11 December 2017, asking it to carry out an additional assessment for bovine milk basic whey protein isolate as a novel food ingredient in accordance with Regulation (EC) No 258/97.

(10) In a subsequent application submitted on 3 January 2018, the Applicant made a request to the Commission for protection of proprietary data for a number of studies submitted in support of the application, namely two human clinical studies with a bovine milk basic whey protein isolate[(5)(6)], an *in vitro* bacterial reverse mutation assay[(7)], an *in vitro* mammalian cell micronucleus test[(8)], a 90-day oral toxicity study in rats[(9)], a 6-week developmental toxicity study in juvenile rats, and the electrophoresis analysis of bovine milk basic whey protein isolate[(10)].

(11) On 27 June 2018, the Authority adopted 'Scientific Opinion on the safety of bovine milk basic whey protein isolate as a novel food pursuant to Regulation (EU) 2015/2283'[(11)]. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(12) That opinion gives sufficient grounds to establish that bovine milk basic whey protein isolate, in the proposed uses and use levels when used as an ingredient in infant and follow-on formulae, in total diet replacement foods for weight control, in foods for special medical purposes, and in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.

(13) In its opinion on bovine milk basic whey protein isolate, the Authority considered that the data from the 90-day oral toxicity study in rats served as a basis to establish a reference point and to assess whether the margin of exposure in relation to the proposed maximum intake of the novel food by humans is sufficient. Therefore, it is considered that the conclusions on the safety of bovine milk basic whey protein isolate could not have been reached without the data from the report of this study.

(14) Following receipt of the Authority's opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary claim over the 90-day oral toxicity in rats study report, and to clarify their claim to an exclusive right of reference to this study, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.

(15) The Applicant also declared to hold proprietary and exclusive rights of reference to the study under national law at the time the application was submitted, and that therefore third parties could not lawfully access or use this study. The Commission has assessed all the information provided by the Applicant and considers that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.

(16) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the 90-day oral toxicity study in rats contained in the Applicant's file, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.

(17) However, restricting the authorisation of this novel food and of the reference to the 90-day oral toxicity study in rats contained in the Applicant's file for the sole use of the Applicant does not prevent other 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 the authorisation under this Regulation.

(18) As the source of the novel food comes from milk, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council[(12)] as one of a number of substances or products which cause allergies or intolerances, foods and food supplements containing bovine milk basic whey protein isolate should be appropriately labelled following the requirements of Article 21 of that Regulation.

(19) Directive 2002/46/EC of the European Parliament and of the Council[(13)] lays down requirements on food supplements. The use of bovine milk basic whey protein isolate should be authorised without prejudice to that Directive.

(20) Regulation (EU) No 609/2013 of the European Parliament and of the Council[(14)] lays down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The use of bovine milk basic whey protein isolate should be authorised without prejudice to that Regulation.

(21) 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 basic whey protein isolate as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2 For a period of five years from the date of entry into force of this Regulation only the initial Applicant:

— Company: Armor Protéines S.A.S.

— Address: Armor Protéines S.A.S., 19 bis, rue de la Libération 35460 Saint-Brice-en-Coglès, France;

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Armor Protéines S.A.S.

3 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.

4 The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 1169/2011, to the provisions of Directive 2002/46/EC, and to the provisions of Regulation (EU) No 609/2013.

Article 2

The study contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the Applicant as fulfilling the requirements 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 Armor Protéines S.A.S.

Article 3

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

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, 30 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

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

(1) the following last column is added in Table 1 (Authorised novel foods):

Data Protection

(2) the following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

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 children/ adolescents under the age of three/ eighteen (*) years (*) Depending on the age group		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
	Infant formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 3,9 mg/100 mL (reconstituted)			
	Follow-on formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 4,2 mg/100 mL (reconstituted)			
	Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	300 mg/day			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	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			

	Food Supplements as defined in Directive 2002/46/EC	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 food supplement is intended for.	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.’

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

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’

(**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 (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, (OJ L 43, 14.2.1997, p. 1).

(**4**) Spézia (2012).

(**5**) Armor Protéines (2013).

(**6**) Schmitt & Mireaux (2008).

(**7**) Sire, G. (2012a).

(**8**) Sire, G. (2012b).

(**9**) Silvano (2012).

(**10**) Armor Protéines (2017).

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

(**12**) 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).

(**13**) 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).

(**14**) 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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1632.