This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.
COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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 was adopted, which establishes a Union list of authorised novel foods.

(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. The application requests for bovine milk basic whey protein isolate to be used in infant and follow-on formulae, in total diet replacement foods for weight control, and 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, 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.

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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.

On 27 June 2017, the competent authority of Ireland issued its initial assessment report. In that report, it came to the conclusion 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.

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 sub-chronic oral toxicity study in juvenile rats.

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.

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 a human clinical study with a bovine milk basic whey protein isolate, a human clinical study with a bovine milk basic whey protein isolate, an in vitro bacterial reverse mutation assay study, an in vitro mammalian cell micronucleus test study, a 90-day oral toxicity study in rats, the sub-chronic oral toxicity study in juvenile rats, and the electrophoresis analysis of bovine milk basic whey protein isolate.

On 26 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". That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

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.

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

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11. EFSA Journal, 2018; ….
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 the 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 of Regulation (EU) 2015/2283.

(15) The applicant also declared that, at the time the application was submitted, they held proprietary and exclusive rights of reference to the study under national law and that therefore third parties could not lawfully access or use this study. The Commission assessed all the information provided by the applicant and considered 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 as one of substances or products causing allergies or intolerances, food supplements containing bovine milk basic whey protein isolate should be appropriately labelled following the requirements of Article 21 of that Regulation.


(20) Regulation (EU) No 609/2013 of the European Parliament and of the Council lays down requirements on food intended for infants and young children, food for special

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medical purposes, and total diet replacement for weight control. The use of 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 applicant:
   • Company: Armor Protéines S.A.S.
   • Address: 19 bis, rue de la Libération 35460 Saint-Brice-en-Coglès, 35460 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 to this Regulation or with the agreement of Armor Protéines S.A.S.

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


Article 2

A 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 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,

For the Commission
The President
Jean-Claude JUNCKER