Commission Implementing Regulation (EU) 2018/1647 of 31 October 2018 authorising the placing on the market of egg membrane hydrolysate 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) 2018/1647

of 31 October 2018

authorising the placing on the market of egg membrane hydrolysate 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 5 August 2016, the company Biova, LLC (‘the Applicant’) made a request to the competent authority of Denmark to place egg membrane hydrolysate 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 egg membrane hydrolysate to be used in food supplements for the general adult population.

(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.

(6) While the request for placing egg membrane hydrolysate 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 7 June 2017, the competent authority of Denmark issued its initial assessment report. In that report, it concluded that egg membrane hydrolysate meets the criteria for a novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 12 June 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 manufacturing process, composition, toxicological data and potential drug interaction between the novel food and medication taken by people with joint pain.

(9) In a subsequent application submitted on 5 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 detailed manufacturing process description, the Generally Recognized as Safe (GRAS) Status of BiovaFlex. Expert Panel Report[(4)], an analysis of solubilized egg shell membrane using Radioallergosorbent Test Inhibition[(5)], quantitative egg allergen test results[(6)], an *in vitro* mammalian cell micronucleus assay in TK6 cells[(7)], an acute oral toxicity study[(8)], a bacterial reverse mutation assay[(8)], a human clinical safety and efficacy pilot[(9)], guinea pig sensitization (Buehler) study[(10)], and a haematology and blood biochemistry data and study report[(11)].

(10) The Commission consulted the European Food Safety Authority ('the Authority') on 20 April 2018, asking it to carry out an additional assessment for egg membrane hydrolysate as a novel food in accordance with Regulation (EU) 2015/2283.

(11) On 27 June 2018, the Authority adopted 'Scientific Opinion on the safety of egg membrane hydrolysate as a novel food pursuant to Regulation (EU) 2015/2283'[(12)]. This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(12) That opinion gives sufficient grounds to establish that egg membrane hydrolysate, in the proposed uses and use levels when used as an ingredient in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.

(13) In its opinion on egg membrane hydrolysate as a novel food, the Authority considered that the data on the manufacturing process served as a basis to assess the safety of egg membrane hydrolysate. Therefore, the Authority considers that the conclusions on the safety of egg membrane hydrolysate, could not have been arrived at without the data from the unpublished report of this process.

(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 studies and to clarify their claim to an exclusive right of reference to those studies, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1647. (See end of Document for details)*

(15) The Applicant also declared to hold proprietary and exclusive rights to the studies under national law at the time the application was submitted, and that therefore third parties could not lawfully access or use those studies. 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 detailed manufacturing process description 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 detailed manufacturing process description 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 eggs, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council[(13)] as one of a number of substances or products which cause allergies or intolerances, food supplements containing egg membrane hydrolysate 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[(14)] lays down requirements on food supplements. The use of egg membrane hydrolysate should be authorised without prejudice to that Directive.

(20) 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 Egg membrane hydrolysate 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: Biova, LLC

Address: 5800 Merle Hay Rd, Suite 14 PO Box 394 Johnston 50131, Iowa USA;

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 Biova, LLC.

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.

4 The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

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 Biova, LLC.

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, 31 October 2018.

For the Commission

The President

Jean-Claude JUNCKER