Commission Implementing Regulation (EU) 2018/991 of 12 July 2018 authorising the placing on the market of hen egg white lysozyme 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) 2018/991

of 12 July 2018

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(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)] 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 updating the Union list.

(4) On 31 August 2016, the company DSM Nutritional Products Ltd, United Kingdom, made a request to the competent authority of Ireland to place hen egg white lysozyme hydrolysate on the Union market as a novel food 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 requests for hen egg white lysozyme hydrolysate to be used in food supplements and other food categories, in particular, in non-alcoholic beverages.

(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 hen egg white lysozyme 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 12 May 2017, the competent authority of Ireland issued its initial assessment report. In that report it came to the conclusion that hen egg white lysozyme hydrolysate meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 31 May 2017, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by the 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 insufficient information on intended uses and exposure assessment, toxicological data, product specification and production process.

(9) In view of the objections raised by the other Member States, in particular the insufficient exposure assessment on the potential combined intake from all possible proposed uses the applicant modified the request with regard to the food categories by limiting the use of the novel food only to food supplements. The changes in the proposed uses of the novel food and additional explanations by the applicant alleviated the concerns regarding compliance with Article 7 of Regulation (EU) 2015/2283 to the satisfaction of the Member States and the Commission.

(10) Those explanations give sufficient grounds to establish that hen egg white lysozyme 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.

(11) Directive 2002/46/EC of the European Parliament and of the Council[(4)] lays down requirements on food supplements. The use of hen egg white lysozyme hydrolysate should be authorised without prejudice to that Directive.

(12) 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 Hen egg white lysozyme hydrolysate as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283.

2 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.

3 The authorisation provided for in this Article shall be without prejudice to the provisions 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, 12 July 2018.

For the Commission

The President

Jean-Claude JUNCKER