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## COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

### **authorising the placing on the market of egg membrane collagen peptides as a novel food and amending 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<sup>1</sup>, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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<sup>2</sup> has established a Union list of novel foods.
- (3) On 7 September 2022, the company Eggnovo SL ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place egg membrane collagen peptides on the Union market as a novel food. The applicant requested for the egg membrane collagen peptides to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council<sup>3</sup>, at levels not exceeding 500mg/day for the general adult population, excluding pregnant and lactating women.
- (4) On 7 September 2022, the applicant also made a request to the Commission for the protection of the proprietary scientific studies and data, namely, identity of the novel

<sup>1</sup> OJ L 327, 11.12.2015, p. 1. ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>

<sup>2</sup> 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, ELI: [http://data.europa.eu/eli/reg\\_impl/2017/2470/oj](http://data.europa.eu/eli/reg_impl/2017/2470/oj)).

<sup>3</sup> 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, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

Feltkode ændret

food<sup>4</sup>, production process<sup>5</sup>, compositional data<sup>6</sup>, absorption, distribution, metabolism and excretion information<sup>7</sup>, toxicological information<sup>8</sup>, and allergenicity<sup>9</sup>.

- (5) On 29 February 2024, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of egg membrane collagen peptides as a novel food.
- (6) On 29 September 2025, the Authority adopted its scientific opinion "Safety of egg membrane collagen peptides as a novel food pursuant to Regulation (EU) 2015/2283<sup>10</sup>" in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that egg membrane collagen peptides is safe under the proposed conditions of use for the proposed target population. Therefore, that scientific opinion gives sufficient grounds to establish that egg membrane collagen peptides, when used in food supplements as defined in Directive 2002/46/EC at levels not exceeding 500mg/day for the general adult population, excluding pregnant and lactating women, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on analytical reports for the identity of the novel food, production process, and allergenicity without which it could not have assessed the novel food and reached its conclusion.
- (9) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data at the time they submitted the application.
- (10) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific evidence and data, namely, identity of the novel food, production process, and allergenicity should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place egg membrane collagen peptides on the market within the Union during a period of five years from the entry into force of this Regulation.
- (11) However, restricting the authorisation of egg membrane collagen peptides and the reference to the scientific evidence and data contained in the applicant's file for the sole use by them does not prevent subsequent 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 such an authorisation.
- (12) 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<sup>11</sup> as

<sup>4</sup> Identity of the Novel Food.

<sup>5</sup> The production process\_v4; 01\_Flowchart; Mass balance; EA\_report\_external; EA\_report\_internal; Met\_HPLC-SEC\_report; MW\_report.

<sup>6</sup> Compositional data; Compositional data Internal analysis results Pept1-Pept5; Compositional data External analysis results Pept1-Pept5\_22; Amino acid composition; Compositional data Technical report shelf-life study; Heavy metalsPept1-Pept5\_22; Accelerated shelf-life study certificates.

<sup>7</sup> Original report\_In vitro absorption study of Ovomet.

<sup>8</sup> Cytotoxicity study.

<sup>9</sup> Allergenicity certificate of analysis; Sequence similarity report\_enzyme.

<sup>10</sup> EFSA Journal. 2025;23:e9709. (<https://doi.org/10.2903/j.efsa.2025.9709>)

one of a number of substances or products which cause allergies or intolerances, food supplements containing egg membrane collagen peptides– should be appropriately labelled following the requirements of Article 21 of that Regulation.

- (13) Directive 2002/46/EC of the European Parliament and of the Council lays down requirements on food supplements. The use of egg membrane collagen peptides hydrolysate should be authorised without prejudice to that Directive.
- (14) It is appropriate that the inclusion of egg membrane collagen peptides as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (15) Egg membrane collagen peptides should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (16) 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 collagen peptides is authorised to be placed on the market within the Union.

Egg membrane collagen peptides shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

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

#### *Article 2*

Only the company Eggново SL<sup>12</sup> is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from [*the date of entry into force of this Regulation*] [*OP please insert the date*], unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Eggново SL.

#### *Article 3*

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent

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<sup>11</sup> 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).

<sup>12</sup> Av. de los Tilos nº5, 31132, Villatuerta, Spain.

applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Eggnovo SL.

*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*