Commission Implementing Regulation (EU) 2018/1633 of 30 October 2018 authorising the placing on the market of refined shrimp peptide concentrate 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) 2018/1633

of 30 October 2018

authorising the placing on the market of refined shrimp peptide concentrate 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 of the European Parliament and of the Council 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 December 2016, the company Marealis AS ('the Applicant') made a request to the competent authority of Finland to place refined shrimp peptide concentrate produced from the enzymatic hydrolysis of Northern shrimp (*Pandalus borealis*) shells and heads, 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 refined shrimp peptide concentrate 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 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 refined shrimp peptide concentrate 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 8 March 2017, the competent authority of Finland issued its initial assessment report. In that report, it concluded that refined shrimp peptide concentrate meets the criteria for a novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 13 March 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 refined shrimp peptide concentrate for hypo-, normo-, and hyper-tensive consumers due to its putative antihypertensive effects, its potential side effects related to its postulated inhibition of the angiotensin converting enzyme (ACE) and potential cardiac effects, and its potential interactions with medicines used in the treatment of blood pressure disorders.

(9) In view of the objections raised by the other Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 21 September 2017, asking it to carry out an additional assessment for refined shrimp peptide concentrate as novel food ingredient in accordance with Regulation (EC) No 258/97.

(10) On 2 February 2018, the Applicant made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application namely, a de novo peptide synthesis study[(4)], the analytical report of the ACE inhibitory effects study[(5)], an acute oral toxicity study[(6)], an *in vitro* bacterial reverse mutation assay[(7)], a 90-day oral toxicity study[(8)], an assessment study of the antihypertensive effects and safety of the refined shrimp peptide concentrate in healthy humans with mild or moderate hypertension[(9)], and a double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate in dietary supplements in healthy humans with mild or moderate hypertension[(10)]. This request was reiterated by the Applicant in a subsequent application submitted on 29 March 2018.

(11) On 18 April 2018, the Authority adopted 'Scientific Opinion on the safety of shrimp peptide concentrate 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 refined shrimp peptide concentrate, 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, the Authority considered that the data from the 90-day oral toxicity study served as a basis to assess the toxicity profile of refined shrimp peptide concentrate and to establish the related No Observed Adverse Effect Level (NOAEL). The data from the assessment study of the antihypertensive effects and safety of the refined shrimp

peptide concentrate in healthy humans with mild or moderate hypertension, and the data from the double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate dietary supplement in healthy humans with mild or moderate hypertension, served as the basis to establish the safety of the novel food for this category of consumers. Therefore, it is considered that the conclusions on the safety of refined shrimp peptide concentrate, could not have been reached without the data from the unpublished reports of these studies.

(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 study reports, 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. The Applicant also declared to hold proprietary and exclusive rights of reference 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.

(15) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the 90-day oral toxicity study, the assessment study of the antihypertensive effects and safety of the refined shrimp peptide concentrate in healthy humans with mild or moderate hypertension, and the double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate dietary supplement in healthy humans with mild or moderate hypertension, 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.

(16) However, restricting the authorisation of this novel food and of the reference to the 90-day oral toxicity study, to the assessment study of the antihypertensive effects and safety of the refined shrimp peptide concentrate in healthy humans with mild or moderate hypertension, and to the double-blind, placebo-controlled, parallel study on the assessment of anti-hypertensive effect and safety of a the refined shrimp peptide concentrate dietary supplement in healthy humans with mild or moderate hypertension, 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.

(17) As the source of the novel food comes from crustaceans, and may contain traces of fish, of other crustaceans, and of molluscs, which are listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council[12] as substances

or products which cause allergies or intolerances, food supplements containing refined shrimp peptide concentrate should be appropriately labelled following the requirements of Article 21 of that Regulation.

(18) Directive 2002/46/EC of the European Parliament and of the Council[13] lays down requirements on food supplements. The use of refined shrimp peptide concentrate should be authorised without prejudice to that Directive.

(19) 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 Refined shrimp peptide concentrate 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: Marealis AS;

— Address: Stortorget 1, Kystens Hus, 2nd floor, N-9008 Tromsø Postal address: P.O. Box 1065, 9261 Tromsø, Norway;

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 Marealis AS.

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 Directive 2002/46/EC and to the provisions of Regulation (EU) No 1169/2011.

Article 2

The studies 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 (EC) No 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 Marealis AS.

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