COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of nonapeptide-pentapeptide mixture 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[1], 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[2] has established a Union list of novel foods.

(3) On 18 March 2023, the company Caregen Co., Ltd ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place nonapeptide-pentapeptide mixture on the Union market as a novel food. The applicant requested the nonapeptide-pentapeptide mixture to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[3], at levels not exceeding 30 mg/day for the general adult population, excluding pregnant and lactating women.

(4) On 18 March 2023, the applicant also made a request to the Commission for the protection of the proprietary scientific studies and data, namely, identity of the novel

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

[2] 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).

[3] 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).

food[4], compositional data[5], absorption, distribution, metabolism and excretion information[6], and toxicological information[7].

(5) On 14 November 2023, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of nonapeptide-pentapeptide mixture as a novel food.

(6) On 17 April 2026, the Authority adopted its scientific opinion "Safety of nonapeptide-pentapeptide mixture as a novel food pursuant to Regulation (EU) 2015/2283[8]" in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority did not establish the safety of nonapeptide-pentapeptide mixture used in food supplements intended for adults, excluding pregnant and lactating women at the maximum dose of 30 mg/day as proposed by the

---

4 Annex 2a - Peptide sequence analysis Method.pdf; Annex 2b - Peptide sequence raw data_R.pdf; Annex 2c - Certificate of Standard_Adiporin.pdf; Annex 2d - Certificate of Standard_Deobetide.pdf; Annex 2e - Third party confirmation Adiporin sequence.pdf; Annex 2f - Third party confirmation Deobetide sequence.pdf; Annex 2j - Corn-extracted Pentapeptide.pdf; Annex 2k - Corn-extracted Nonapeptide.pdf; Annex 2l - Third party laboratory - peptide synthesis - Quality certificate.pdf; Annex 2m - Manufacturing Process - Third-party peptide synthesis.pdf; Annex 2n - Study Report _ Identity_Purity Comparison to 3rd-Party Standards.pdf; Annex 2o - COA_Adiporin - Reference standard.pdf; Annex 2p - COA_Deobetide - Reference standard.pdf; Annex 2q - COA_Adiporin_new_1.pdf; Annex 2r - COA_Adiporin_new_2.pdf; Annex 2s - COA_Adiporin_new_3.pdf; Annex 2t - COA_Adiporin_new_4.pdf; Annex 2u - COA_Adiporin_new_5.pdf; Annex 2v - COA_Deobetide_new_1.pdf; Annex 2w - COA_Deobetide_new_2.pdf; Annex 2x - COA_Deobetide_new_3.pdf; Annex 2y - COA_Deobetide_new_4.pdf; Annex 2z - COA_Deobetide_new_5.pd; Annex 2aa - Study Report _ Enantiomeric purity.pdf; Annex 10 - Water solubility of Deglusterol.pdf; Annex 10a - Water Solubility of Individual Peptides - 1 batch.pdf; Annex 10b - Water Solubility of Individual Peptides - 4 batch.pdf.

5 Annex 6a1 - Method Validation Protocol Nona.pdf; Annex 6a2 - Method Validation Report Nona.pdf; Annex 6a3_updated - Method Validation Protocol Penta.pdf; Annex 6a4_updated - Method Validation Report Penta.pdf; Annex 6a6 - Method Validation Report HBTU HOBt.pdf; Annex 6a7 - Method Validation Protocol SOCl2 Fmoc.pdf; Annex 6a8 - Method Validation Report SOCl2 Fmoc.pdf; Annex 6a9 - Method Validation Protocol DIEAThioanisole.pdf; Annex 6a10 - Method Validation Report DIEAThioanisole.pdf; Annex 6a11 - Method Validation Protocol Piperidine.pdf; Annex 6a12 - Method Validation Report Piperidine.pdf; Annex 6a13 - Method Validation Protocol EDT.pdf; Annex 6a14 - Method Validation Report EDT.pdf; Annex 6a15 - Method Validation Protocol Residual solvents.pdf; Annex 6a16 - Method Validation Report Residual solvents.pdf; Annex 6a17 - Method Validation Protocol TFA.pdf; Annex 6a18 - Method Validation Report TFA.pdf; Annex 6a19 - Styrol Analysis Method Validation Protocol.pdf; Annex 6a20 - Styrol Analysis Method Validation Report.pdf; Annex 6a21 - Divinylbenzene Analysis Method Validation Protocol.pdf; Annex 6a22 - Divinylbenzene Analysis Method Validation Report.pdf; Annex 12 - Stability in food.pdf; Annex 13 - Stability Test Method.pdf; Annex 16 - Proximate Analysis.pdf.

6 Annex 15 - In vitro digestion of Nona + Penta.pdf; Annex 15b - CoA Penta.pdf.

7 Annex 17 - Bacterial reverse mutation test_signed.pdf; Annex 18 - Chromosome aberration test_signed.pdf; Annex 19 - In vitro micronucleus.pdf; Annex 20 New - In vivo micronucleus test_revised report.pdf; Annex 21 - Acute respiratory_signed.pdf; Annex 22 - Acute CNS_signed.pdf; Annex 23 - Acute oral toxicity rats_signed.pdf; Annex 24 - Acute oral toxicity dogs_signed.pdf; Annex 25 - Acute cardiovascular_signed.pdf; Annex 26a - Subchronic Rats_signatured.pdf; Annex 26b - HCD_Clinical chemistry.pdf; Annex 26c - HCD_Hematology.pdf; Annex 27a - Subchronic Dogs.pdf; Annex 27b - Subchronic Dogs Dose Range Finding.pdf; Annex 28_updated - Clinical Study.pdf.

8 *EFSA Journal*. 2026;24:e10098 https://doi.org/10.2903/j.efsa.2026.10098

applicant because the intake would exceed the level which is considered safe (0,2 mg/kg bw per day). However, the Authority concluded that the nonapeptide-pentapeptide mixture is safe for adults, excluding pregnant and lactating women when added to food supplements at a maximum daily dose of 14 mg, which corresponds to the safe level of intake for an adult person with a default body weight of 70 kg. Therefore, the scientific opinion gives sufficient grounds to establish that nonapeptide-pentapeptide mixture, when used in food supplements as defined in Directive 2002/46/EC at levels not exceeding 14 mg/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, compositional data, absorption, distribution, metabolism and excretion information, and toxicological information 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, compositional data, absorption, distribution, metabolism and excretion information, and toxicological information should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place nonapeptide-pentapeptide mixture 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 nonapeptide-pentapeptide mixture 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) It is appropriate that the inclusion of nonapeptide-pentapeptide mixture 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.

(13) Nonapeptide-pentapeptide mixture 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.

(14) 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. Nonapeptide-pentapeptide mixture is authorised to be placed on the market within the Union.

   Nonapeptide-pentapeptide mixture 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 Caregen Co., Ltd [9] 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 Caregen Co., Ltd.

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 applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Caregen Co., Ltd.

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

[9] 16-27 LS-ro 91beon-gil, Dongan-gu, Angang-si Gyeonggi-do, 14119, South Korea.