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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

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Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**	**Data protection**
Nonapeptide-pentapeptide mixture	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of food supplements containing it shall be ‘nonapeptide-pentapeptide mixture (1)’. The labelling of food supplements containing ‘nonapeptide-pentapeptide mixture’ shall bear a statement that they should not be consumed by persons under 18 years of age, and pregnant and lactating women.		Authorised on […][*OP, please insert the date dd.mm.yyyy - 20th day following its publication*]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Food supplements as defined in Directive 2002/46/EC, for the general adult population, excluding pregnant and lactating women.	14 mg/day			

					Applicant: " Caregen Co., Ltd ", 16-27 LS-ro 91beon-gil, Dongan-gu, Angang-si Gyeonggi-do, 14119, South Korea . During the period of data protection, the novel food nonapeptide-pentapeptide mixture is authorised for placing on the market within the Union only by "Caregen Co., Ltd" unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of

					Regulation (EU) 2015/2283 or with the agreement of "Caregen Co., Ltd". End date of the data protection: […][*OP please insert the date dd.mm.yyyy – after 5 years*].

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(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:
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Authorised novel food	Specification
Nonapeptide-pentapeptide mixture	**Description:** The novel food is a powdered mixture of two peptides (Nonapeptide: lysine-glycine-serine-alanine-threonine-glycine-tryptophan-methionine-alanine and Pentapeptide: leucine-lysine-threonine-arginine-asparagine) in an approximately 1:1 ratio. The two peptides are independently produced by solid-phase chemical synthesis and then mixed with resistant maltodextrin in a ratio of 1:99. **Characteristics/Composition** Sum of Nonapeptide and Pentapeptide: ≥95% Nonapeptide assay[1] (%): 45–55% Pentapeptide assay[1] (%): 45–55% Moisture: ≤5 % **Residual solvents** N,N-Dimethylformamide: ≤0.004 mg/kg tert-Butyl methyl ether: ≤100 mg/kg Methylene chloride (Dichloromethane): ≤0.002 mg/kg Acetonitrile: ≤200 mg/kg Trifluoroacetic acid (TFA): ≤250 mg/kg Methyl alcohol: ≤10 mg/kg

[1] Assay refers to the quantitative determination of peptide content in the test sample calculated against defined concentrations of the peptide reference standards for the generation of a calibration curve to calculate the peptide content of samples of the same peptide, i.e., the actual amount of peptide present in the sample.

	Processing Aids 2-(1H-benzotriazol-1-yl)-1,1,3,3- tetramethyluronium hexafluorophosphate (HBTU): <1.2 mg/kg Hydroxybenzotriazole (HOBt): <0.7 mg/kg Fluorenylmethyloxycarbonyl (fmoc) : < 2 mg/kg Thionyl chloride: < 0.6 mg Piperidine: < 1.9 mg/kg N,N-Diisopropylethylamine (DIEA) : < 4.8 mg/kg 1,2-Ethanedithiol (EDT): < 3.6 mg/kg Thioanisole: < 4.2 mg/kg **Heavy Metals** Arsenic: ≤0.02 mg/kg **Microbiological criteria** Total plate count: <100 CFU[2]/g Total Coliforms: Not detected in 25g Salmonella spp.: Not detected in 25g Yeast and mould: <100 CFU/g

[2] CFU = colony forming units