EN

ANNEX

(1) In Table 1 (Authorised novel foods) the following entry is inserted: [*OP, please insert in the EN version 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
	Specified food category	**Maximum levels**	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘beta-nicotinamide mononucleotide (β-NMN)’ or ‘beta-nicotinamide mononucleotide’ 2. The labelling of food supplements containing the novel food shall bear a statement that the food supplements should be consumed by adults only, excluding 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. Applicant: EffePharm (Shanghai) Ltd., Bld 4, No.1, Mid Wangdong Rd, Shanghai, China. During the period of data protection, the novel food beta-nicotinamide mononucleotide (β-NMN) is authorised for placing on the market within the Union only by EffePharm (Shanghai) Ltd., unless a subsequent applicant obtains authorisation for the novel food
Beta-nicotinamide mononucleotide (β-NMN)	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	300 mg per day, corresponding to an equimolar amount of 109.7 mg nicotinamide per day			

					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 EffePharm (Shanghai) 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: [*OP, please insert in the EN version in alphabetical order*.]

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Authorised Novel Food	Specifications
Beta-nicotinamide mononucleotide (β-NMN)	**Description/Definition:** β-NMN is an odourless, white to off-white crystalline powder with a chemical purity of more than 99% and is highly soluble in water. The novel food is s produced through chemical synthesis via reaction of nicotinamide riboside chloride with trimethyl phosphate and phosphorus oxychloride, then hydrolysing and purifying the intermediate compound to obtain the final ingredient. **Identity and composition:** Chemical (IUPAC) name 3-Carbamoyl-1-[5-O-(hydroxyphosphinato)-β-D-ribofuranosyl]pyridinium or [(2R,3S,4R,5R)-5-(3-carbamoylpyridin-1-ium-1-yl)-3,4-dihydroxyoxolan-2-yl]methyl dihydrogen phosphate Synonyms, trade names, abbreviations: Beta-nicotinamide mononucleotide; beta-NMN; β-NMN; nicotinamide ribonucleoside 5′-phosphate; β-nicotinamide riboside monophosphate; 3-(aminocarbonyl)-1-(5-O-phosphonato-beta-D-ribofuranosyl)pyridinium CAS number: 1094-61-7 Molecular formula: $C_{11}H_{15}N_2O_8P$ Molecular weight: 334.221 g/mol Assay (%, on a dry basis): 99.00–102.00 Purity (%): ≥ 99.0 Water (%): ≤ 1.0 **Specific optical rotation** (about 5% aqueous solution, w/v) (°): −49° to −51° **Residual solvents:** Ethyl acetate (mg/kg): ≤ 50 Ethanol (mg/kg): ≤ 100

	Trimethyl phosphate (mg/kg): ≤ 0.5 Phosphorus oxychloride (%): ≤ 0.002 **Heavy metals:** Arsenic (mg/kg): ≤ 0.05 **Microbiological parameters** TAMC: ≤ 1000 (CFU/g) TYMC: ≤ 100 (CFU/g) *Salmonella* in 25 g: Not detected *Escherichia coli* in 10 g: Not detected Coagulase positive staphylococci in 10 g: Not detected Coliforms (MPN/g): < 0.92 CFU: colony forming units; TAMC: total aerobic microbial count; TYMC: total yeast and mould count; MPN: most probable number