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ANNEX

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

(1) the entry for ‘nicotinamide riboside chloride’ in Table 1 (Authorised novel foods) is replaced by the following:

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			
Nicotinamide riboside chloride	Food supplements as defined in Directive 2002/46/EC	300 mg/day for adult population, excluding pregnant and lactating women 230 mg/day for pregnant and lactating women	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “nicotinamide riboside chloride”		Authorised on 20 February 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: ChromaDex Inc., 10900 Wilshire Boulevard Suite 600, Los Angeles, CA 90024 USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by ChromaDex Inc. unless a subsequent applicant obtains authorisation for that 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 ChromaDex Inc. End date of the data protection: 20 February 2025.

	Foods for special medical purposes as defined by Regulation (EU) No 609/2013 for adult population, excluding pregnant and lactating women	500 mg/day	<p>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be “nicotinamide riboside chloride”</p> <p>2. The labelling of foodstuffs containing the novel food shall bear a statement that those foods should not be consumed by persons under 18 years of age and pregnant and lactating women.</p>		
	Total diet replacement for weight control as defined by Regulation (EU) No 609/2013 for adult population, excluding pregnant and lactating women	500 mg/day			
	Meal replacement products for the adult population, excluding pregnant and lactating women	300 mg/day			
	Nutritional drink mixes for the adult population, excluding pregnant and lactating women	300 mg/day			

(2) the entry for ‘nicotinamide riboside chloride’ in Table 2 (Specifications) is replaced by the following:

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Authorised Novel Food	Specification
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<p>Nicotinamide riboside chloride</p>	<p>Description/Definition: The novel food is a synthetic form of nicotinamide riboside. The novel food contains ≥ 90 % nicotinamide riboside chloride, predominantly in its β form, the remaining components being residual solvents, reaction by-products and degradation products.</p> <p>Nicotinamide riboside chloride: CAS number: 23111-00-4 EC number: 807-820-5 IUPAC name: 1-[(2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]pyridin-1-ium-3-carboxamide;chloride Chemical formula: C₁₁H₁₅N₂O₅Cl Molecular weight: 290,7 g/mol</p> <p>Characteristics/Composition: Colour: White to light brown Form: Powder Identification: Conforms by NMR (nuclear magnetic resonance) Nicotinamide riboside chloride: ≥ 90 % Water content: ≤ 2 %</p> <p>Residual solvents: Acetone: $\leq 5\ 000$ mg/kg Methanol: $\leq 1\ 000$ mg/kg Acetonitrile: ≤ 50 mg/kg Methyl tert-butyl ether: ≤ 500 mg/kg</p> <p>Reaction by-products: Methyl acetate: $\leq 1\ 000$ mg/kg Acetamide: ≤ 27 mg/kg Acetic acid: $\leq 5\ 000$ mg/kg</p> <p>Heavy metals: Arsenic: ≤ 1 mg/kg</p>
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	<p>Mercury*: $\leq 0,1$ mg/kg Cadmium*: ≤ 1 mg/kg Lead*: $\leq 0,5$ mg/kg</p> <p>Microbiological criteria: Total Plate Count: $\leq 1\ 000$ CFU/g Yeast and Mould: ≤ 100 CFU/g <i>Escherichia coli</i>: Absence in 10 g</p> <p>CFU: colony forming units * only for foods for special medical purposes, total diet replacement for weight control, meal replacement products and nutritional drink mixes</p>
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