

ANNEX

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

- (1) the following last column is added in Table 1 (Authorised novel foods):

Data Protection

- (2) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
‘1-Methylnicotinamide chloride	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “1-Methylnicotinamide chloride”. Food supplements containing 1-Methylnicotinamide shall bear the following statement: This food supplement should be consumed by adults only excluding pregnant and lactating women		Authorised on 2 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Pharmena SA, Wolczanska 178, 90 530 Lodz, Poland. During the period of data protection the novel food 1-methylnicotinamide chloride is authorised for placing on the market
	Food Supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women	58 mg/day			

*Status: Point in time view as at 31/01/2020.**Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1123, ANNEX. (See end of Document for details)*

				within the Union only by Pharmena S.A. 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 Pharmena S.A. End date of the data protection: 2 September 2023'.
--	--	--	--	---

(3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
1-Methylnicotinamide chloride	<p>Definition: Chemical name: 3-carbamoyl-1-methylpyridinium chloride Chemical formula: C₇H₉N₂OCl CAS No: 1005-24-9 Molecular weight: 172,61 Da</p> <p>Description 1-Methylnicotinamide chloride is white or off-white, crystalline solid produced by a chemical synthesis process.</p> <p>Characteristics/Composition</p>

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1123, ANNEX. (See end of Document for details)

Appearance: White – off-white, crystalline solid
Purity: $\geq 98,5$ %
Trigonelline: $\leq 0,05$ %
Nicotinic Acid: $\leq 0,10$ %
Nicotinamide: $\leq 0,10$ %
Largest unknown impurity: $\leq 0,05$ %
Sum of unknown impurities: $\leq 0,20$ %
Sum of all impurities: $\leq 0,50$ %
Solubility: soluble in water and methanol. Practically insoluble in 2-propanol and dichloromethane
Moisture: $\leq 0,3$ %
Loss on drying: $\leq 1,0$ %
Residue on ignition: $\leq 0,1$ %
Residual Solvents and Heavy Metals
Methanol: $\leq 0,3$ %
Heavy metals: $\leq 0,002$ %
Microbiological criteria:
Total aerobic microbial count: ≤ 100 CFU/g
Mould/yeast: ≤ 10 CFU/g
Enterobacteriaceae: absence in 1 g
Pseudomonas aeruginosa: absence in 1 g
Staphylococcus aureus: absent in 1 g
CFU: Colony Forming Units'

Status:

Point in time view as at 31/01/2020.

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1123, ANNEX.