

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
	Specified food category	Maximum levels			
‘1-Methylnicotinamide chloride			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			

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*Status: This is the original version (as it was originally adopted).*

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

Authorised Novel Food	Specification
<b>1-Methylnicotinamide chloride</b>	<p><b>Definition:</b>            Chemical name: 3-carbamoyl-1-methylpyridinium chloride            Chemical formula: C<sub>7</sub>H<sub>9</sub>N<sub>2</sub>OCl            CAS No: 1005-24-9            Molecular weight: 172,61 Da</p> <p><b>Description</b>            1-Methylnicotinamide chloride is white or off-white, crystalline solid produced by a chemical synthesis process.</p> <p><b>Characteristics/Composition</b></p>

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:  $\leq 100$  CFU/g  
Mould/yeast:  $\leq 10$  CFU/g  
Enterobacteriaceae: absence in 1 g  
*Pseudomonas aeruginosa*: absence in 1 g  
*Staphylococcus aureus*: absent in 1 g  
CFU: Colony Forming Units'

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