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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:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Heat-killed <i>Mycobacterium setense manresensis</i>	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘heat-killed <i>Mycobacterium setense manresensis</i> ’. The labelling of food supplements containing the heat-killed <i>Mycobacterium setense manresensis</i> shall bear a statement that they should only be consumed for periods of 14 consecutive days separated by periods of		Authorised on 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:
	Food supplements as defined in Directive 2002/46/EC intended for the general population above the age of 18 years, excluding pregnant and lactating women	200 mg containing $\leq 1 \times 10^5$ heat-killed <i>Mycobacterium setense manresensis</i>			

			at least six months of no consumption	<p>Laboratorio Reig Jofre, S.A., Gran Capitan, 10, 08970 Sant Joan Despi, Barcelona, Spain.</p> <p>During the period of data protection, the novel food heat-killed <i>Mycobacterium setense manresensis</i> is authorised for placing on the market within the Union only by Laboratorio Reig Jofre, 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</p>
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					Regulation (EU) 2015/2283 or with the agreement of Laboratorio Reig Jofre, S.A..
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(2) 'In Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised Novel Food	Specification
Heat-killed <i>Mycobacterium setense manresensis</i>	<p>Description/Definition: Heat-killed <i>Mycobacterium setense manresensis</i> is a white homogeneous powder consisting of food grade mannitol and 0.00025% (w:w), corresponding to $\leq 5.0 \times 10^5$ of heat killed, freeze dried <i>Mycobacterium setense manresensis</i> bacteria.</p> <p>Characteristics/Composition: Moisture : $\leq 1.7 \%$ pH: 4-7 Heat-killed <i>Mycobacterium setense manresensis</i>: 0.00025% (w:w) or ≤ 625 ng/g corresponding to $\leq 5.0 \times 10^5$ bacteria Food grade mannitol : $\geq 99.9\%$ (w:w)</p> <p>Heavy metals: Mercury: ≤ 0.005 mg/kg Arsenic: ≤ 0.1 mg/kg Lead: ≤ 0.05 mg/kg Cadmium: ≤ 0.01 mg/kg</p> <p>Microbiological criteria: Total aerobic microbial count: $\leq 10^3$ CFU/g Total yeast/mold count: $\leq 10^2$ CFU/g <i>Escherichia coli</i>: Negative/10 g</p>

'CFU: Colony Forming Units'