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EN

ANNEX

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for *Clostridium butyricum* TO-A 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
<i>Clostridium butyricum</i> TO-A	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be ' <i>Clostridium butyricum</i> TO-A'.		Authorised on [...][<i>OP please insert the date dd.mm.yyyy - 20th day following its publication</i>]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Food supplements as defined in Directive 2002/46/EC	<p>1.0×10⁸ CFU/day for children from 3 to < 10 years</p> <p>2.0×10⁸ CFU/day for adolescents from 10 to < 14 years</p> <p>2.8×10⁸ CFU/day for adolescents from 14 to < 18 years</p> <p>3.2×10⁸ CFU/day for adults, excluding pregnant and lactating women</p>			
			The labelling of food supplements containing <i>Clostridium butyricum</i> TO-A shall bear a statement that the food supplements should not be consumed by infants and children under 4 years of age/children under 7 years of age/children under 11 years of age/children and adolescents under 18 years of age		Applicant: TOA Biopharma Co. Ltd., 2-1-11, Sasazuka, Shibuya, Tokyo, Japan. During the period of data protection, the novel food <i>Schizochytrium</i> sp. (ATCC-20889) oil is authorised for placing on the market within the Union only by TOA Biopharma Co. Ltd., unless a subsequent applicant obtains authorisation for the novel

					<p>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 TOA Biopharma Co. Ltd.</p> <p>End date of the date protection: [...]<i>[OP please insert the date dd.mm.yyyy – after 5 years]</i></p>
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(1) 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
<i>Clostridium butyricum</i> TO-A	<p>Description/Definition: The novel food is produced by anaerobic fermentation of <i>Clostridium butyricum</i> TO-A, which is harvested by centrifugation, dried and mixed with potato starch.</p> <p>Characteristics/criteria: <i>C. butyricum</i> TO-A: $1\text{--}7 \times 10^9$ CFU/g Moisture: < 5% Coliforms: < 10 CFU/g TAMC: $\leq 1 \times 10^3$ CFU/g TYMC: $\leq 1 \times 10^2$ CFU/g <i>Salmonella</i> spp.: not detected in 25 g</p> <p>Abbreviations: CFU, colony forming units; TAMC, total aerobic microbial count; TYMC, total yeast and mould count.</p>