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EN

ANNEX

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for *Schizochytrium* sp. (ATCC-20889) oil 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>Schizochytrium</i> sp. (ATCC-20889) oil	Specified food category	Maximum levels of DHA			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae <i>Schizochytrium</i> sp.'		<p>Authorised on [...] [OP please insert the date 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.</p> <p>Applicant: BioPlus Life Sciences, Pharmed Gardens, Whitefield Road, Bangalore 560048 India.</p> <p>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 BioPlus Life Sciences, unless a subsequent applicant obtains authorisation for the novel food</p>

					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 BioPlus Life Sciences.
					End date of the date protection: [...][<i>OP please insert the date dd.mm.yyyy – after 5 years</i>]

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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>Schizochytrium</i> sp. (ATCC-20889) oil	<p>Description/Definition: The novel food is an oil produced from the strain ATCC-20889 of the microalgae species <i>Schizochytrium limacinum</i>.</p> <p>Composition: Acid value: ≤ 0.5 mg KOH/g Peroxide value (PV): ≤ 5.0 meq/kg oil Moisture and volatiles: ≤ 0.05% Unsaponifiables: ≤ 4.5% Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32 % p-anisidine value: ≤ 10</p>