

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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
	Specified food category	Maximum levels of DHA			
<i>Schizochytrium</i> sp. (ATCC-20889) oil	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 [...] [<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.</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>

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

’.

(1) in Table 2 (Specifications), the following entry is inserted: [OP, please insert in the EN version in alphabetical order.]

,

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: $\leq 0.05\%$ Unsaponifiables: $\leq 4.5\%$ Trans-fatty acids: $\leq 1.0\%$ Docosahexaenoic acid (DHA): $\geq 32\%$ p-anisidine value: ≤ 10</p>