

SCHEDULE 3

Regulation 2

Authorisation of *Schizochytrium* sp. (WZU477) oil as a novel food

1. In Table 1 (authorised novel foods), after the entry for “*Schizochytrium* sp. (T18) oil”, insert the following entry—

<p>“<i>Schizochytrium</i> sp. (WZU477) oil</p>	<p>Specified food category</p> <p>Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013</p>	<p>Maximum levels of DHA</p> <p>In accordance with Regulation (EU) No 609/2013</p>	<p>The designation of the novel food on the labelling of the foodstuffs containing it is “Oil from the microalgae <i>Schizochytrium</i> sp.”.</p>	<p>Included in the list on 30 June 2022.</p> <p>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: Progress Biotech BV, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den IJssel, the Netherlands.</p> <p>During the period of data protection, <i>Schizochytrium</i> sp. (WZU477) oil is authorised for placing on the market within Wales only by Progress Biotech BV 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</p>
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Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

					<p>Progress Biotech BV.</p> <p>The data protection ends at the end of 29 June 2027."</p>
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2. In Table 2 (specifications), after the entry for “*Schizochytrium* sp. (T18) oil”, insert the following entry—

<p>“<i>Schizochytrium</i> sp. (WZU477) oil</p>	<p>Description/Definition:</p> <p>The novel food is an oil produced from the strain WZU477 of the microalgae <i>Schizochytrium</i> sp.</p> <p>Composition:</p> <p>Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g</p> <p>Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil</p> <p>Moisture and volatiles: ≤ 0.05 %</p> <p>Unsaponifiables: ≤ 4.5 %</p> <p>Trans-fatty acids: ≤ 1.0 %</p> <p>Docosahexaenoic acid (DHA): ≥ 32.0 %</p> <p>P-anisidine value: ≤ 10””.</p>
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