

SCHEDULE 3

Regulation 3

Authorisation of *Schizochytrium* sp. (WZU477) oil

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>Specific food category Infant formula and follow-on formula as defined in Regulation (EU) 609/2013</p>	<p>Maximum levels of DHA In accordance with Regulation (EU) 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. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Progress Biotech BV of Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den IJssel, the Netherlands. During the period of data protection, the novel food <i>Schizochytrium</i> sp. (WZU477) oil is authorised for placing on the market within Scotland only by Progress Biotech BV unless a subsequent applicant obtains authorisation for the novel food without</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Status: This is the original version (as it was originally made).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.

				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 Progress Biotech BV. The data protection will expire at the end of 29 June 2027.”
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2. In Table 2 (specifications), after the entry for *Schizochytrium sp.* (T18) oil insert the following entry—

<p>“<i>Schizochytrium sp.</i> (WZU477) oil</p>	<p>Description/Definition:</p> <p>The novel food is an oil produced from the strain WZU477 of the microalgae <i>Schizochytrium sp.</i></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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