Novel food: Schizochytrium oil

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Commission Implementing Regulation (EU) 2025/2245 as regards the conditions of use of the novel food *Schizochytrium* sp. (ATCC PTA-9695) oil

Commission Implementing Regulation (EU) 2025/1515 authorising the placing on the market of *Schizochytrium limacinum* (ATCC-20889) oil as a novel food

Commission Implementing Regulation (EU) 2025/688 as regards the conditions of use of the novel food *Schizochytrium* sp. (FCC-3204) oil

What is changing and why?

The European Union (EU) has authorised the use of the novel food *Schizochytrium* sp. (ATCC PTA-9695) oil in food supplements intended for the general population, allowing increased levels of docosahexaenoic acid (DHA).

This follows the authorisation earlier in 2025 of:

- Schizochytrium limacinum (ATCC-20889) as a novel food for use in infant/follow-on formula
- new conditions of use for the novel food Schizochytrium sp. (FCC-3204) oil in protein products.

Table 1 provides details of the strains, authorised uses, and companies that sought these authorisations.

Timeline

New conditions for use of:

- Schizochytrium sp. (ATCC PTA-9695) oil in food supplements intended for the general population – apply from 30 November 2025
- Schizochytrium sp. (FCC-3204) oil in protein products – apply from 1 May 2025.

The use of *S. limacinum* (ATCC-20889) oil in infant/follow-on formula is permitted from **18 August 2025**.

For more information see the full record on the AGRINFO website – where you can also view the latest AGRINFO Update newsletters and search the database.

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Tables & Figures

Table 1
Schizochytrium strains authorised as novel foods

Strain	Authorised uses	Applicant company	Exclusivity period	Labelling requirements
ATCC PTA-9695	Food supplements • for the general population excluding infants and young children (>3 years), 1 g DHA/day[1] • for children under 3 years, 250 mg DHA/day	DSM Nutritional Products Europe Ltd	No exclusivity period	"Oil from the microalgae *Schizochytrium* sp." and a statement that food supplements containing >250 mg DHA/day should not be consumed by children under 3 years
ATCC-20889	• Infant formula • Follow-on formula	BioPlus Life Sciences	18 Aug 2025 to 18 Aug 2030	"Oil from the microalgae *Schizochytrium limacinum*"
FCC-3204	• Protein products (excluding dairy analogues) • Infant and follow-on formula[2] • Food supplements (>3 years)[2]	Fermentalg	1 May 2025 to 1 May 2030	"Oil from the microalgae *Schizochytrium* sp."

1. DHA, docosahexaenoic acid.
2. Uses previously authorised under Regulation 2021/1326.

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Source: based on Regulations 2025/2245, 2025/1515, 2025/688

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