



## Novel food: Schizochytrium oil

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

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

Commission Implementing Regulation (EU) <u>2025/688</u> 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 <u>full record</u> on the AGRINFO website – where you can also view the latest <u>AGRINFO Update</u> newsletters and <u>search</u> the database.





## **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 <sup>[1]</sup> 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	<ul> <li>Protein products         (excluding dairy         analogues)</li> <li>Infant and follow-on         formula<sup>[2]</sup></li> <li>Food supplements (&gt;3         years)<sup>[2]</sup></li> </ul>	Fermentalg	1 May 2025 to 1 May 2030	"Oil from the microalgae Schizochytrium sp."
DHA, docosahexaenoic acid.     Uses previously authorised under Regulation 2021/1326.				



Source: based on Regulations <u>2025/2245</u>, <u>2025/1515</u>, <u>2025/688</u>

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