

## Novel food: **Schizochytrium oil**

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EU authorises new conditions of use for *Schizochytrium* oil in food supplements

Commission Implementing Regulation (EU) [2025/2245](#) of 7 November 2025 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. (ATCC PTA-9695) oil

Commission Implementing Regulation (EU) [2025/1515](#) of 28 July 2025 authorising the placing on the market of *Schizochytrium limacinum* (ATCC-20889) oil as a novel food and amending Implementing Regulation (EU) 2017/2470

Commission Implementing Regulation (EU) [2025/688](#) of 9 April 2025 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. (FCC-3204) oil

### Update

In November 2025, the European Union (EU) authorised new conditions of use for oil produced from *Schizochytrium* sp. strain ATCC PTA-9695 in food supplements intended for the general population.

This follows the previous authorisation of oil produced from *Schizochytrium limacinum* strain ATCC-20889 as a novel food for use in infant/follow-on formula (July 2025); and authorisation of new conditions of use for oil produced from *Schizochytrium* sp. strain FCC-3204 in protein products, excluding dairy analogues (April 2025).

### Impacted products

Protein products (excluding dairy analogues), infant nutrition, supplements

### What is changing?

In November 2025, the EU authorised an increase in the maximum level of docosahexaenoic acid (DHA) permitted in food supplements for the general population (above 3 years of age) containing the novel food *Schizochytrium* sp. (ATCC PTA-9695) oil.

Earlier in 2025, the EU authorised:

- *Schizochytrium limacinum* ATCC-20889 as a novel food for use in infant/follow-on formula (Regulation 2025/1515)
- new conditions of use for the novel food *Schizochytrium* sp. FCC-3204 in protein products intended for the general population, excluding dairy analogues (products using plant-based ingredients that mimic dairy products) (Regulation 2025/688).

Table 1 provides details of the strains, authorised uses, and companies that requested authorisation.

Only the companies that applied for the authorisations of *Schizochytrium* sp. FCC-3204 in protein products and *S. limacinum* (ATCC-20889) as a novel food for use in infant/follow-on formula may market these novel foods for the uses authorised for a 5-year period (see Table 1), unless these companies provide permission to others to market, or if another company obtains a novel food authorisation for this use without reference to scientific data protected in the novel food authorisations. There is no exclusivity period for the newly authorised conditions of use for *Schizochytrium* sp. (ATCC PTA-9695) oil.

## Why?

On the basis of earlier evaluations by the European Food Safety Authority (EFSA [2012](#), [2021](#)), the European Commission has concluded that the proposed increased levels of DHA in food supplements do not raise health concerns.

[EFSA \(2025\)](#) provided a positive safety evaluation of *S. limacinum* strain ATCC-20889.

[EFSA \(2024\)](#) concluded that the novel food *Schizochytrium* FCC-3204 oil is safe when used in protein products intended for the general population, excluding dairy analogues.

## 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* (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**.

## Background

These Regulations update the Annex to Regulation [2017/2470](#) which lists authorised novel foods (see the [Union list of novel foods](#)). For further information on the EU novel foods authorisation process, see [Novel foods explained](#).

## Resources

EFSA (2012) [Scientific Opinion on the Tolerable Upper Intake Level of eicosapentaenoic acid \(EPA\), docosahexaenoic acid \(DHA\) and docosapentaenoic acid \(DPA\)](#). EFSA Journal, 10(7): 2815.

EFSA (2021) [Safety of oil from \*Schizochytrium limacinum\* \(strain FCC-3204\) for use in food supplements as a novel food pursuant to Regulation \(EU\) 2015/2283](#). EFSA Journal, 19(1): 6345.

EFSA (2024) [Safety of an extension of use of oil from \*Schizochytrium limacinum\* \(strain FCC-3204\) as a novel food pursuant to Regulation \(EU\) 2015/2283](#). EFSA Journal, 22: e9043.

EFSA (2025) [Safety of oil from \*Schizochytrium limacinum\* \(strain ATCC-20889\) for use in infant and follow-on formula as a novel food pursuant to Regulation \(EU\) 2015/2283](#). EFSA Journal, 23(1): e9156.

Regulation [2021/1326](#) authorising the placing on the market of *Schizochytrium* sp. (FCC-3204) oil as a novel food.

Regulation [2017/2470](#) establishing the Union list of novel foods.

Regulation [2015/2283](#) on novel foods.

## Sources

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

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## Table & Figures

**Table 1**  
*Schizochytrium* strains authorised as novel foods

Strain	Authorised uses	Applicant company	Exclusivity period	Labelling requirements
ATCC PTA-9695	Food supplements <ul style="list-style-type: none"> <li>• for the general population excluding infants and young children (&gt;3 years), 1 g DHA/day<sup>[1]</sup></li> <li>• for children under 3 years, 250 mg DHA/day</li> </ul>	DSM Nutritional Products Europe Ltd	No exclusivity period	“Oil from the microalgae <i>Schizochytrium</i> sp.” and a statement that food supplements containing >250 mg DHA/day should not be consumed by children under 3 years
ATCC-20889	<ul style="list-style-type: none"> <li>• Infant formula</li> <li>• Follow-on formula</li> </ul>	BioPlus Life Sciences	18 Aug 2025 to 18 Aug 2030	“Oil from the microalgae <i>Schizochytrium limacinum</i> ”
FCC-3204	<ul style="list-style-type: none"> <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 <i>Schizochytrium</i> sp.”

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

Source: based on Regulations [2025/2245](#), [2025/1515](#), [2025/688](#)

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