

## Novel food: Schizochytrium oil

*Published by AGRINFO on 15 Apr 2025; Revised 07 Aug 2025*

### EU authorises two strains of Schizochytrium oil as novel foods

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 July 2025, the European Union (EU) authorised the use of oil produced from *Schizochytrium limacinum* strain ATCC-20889 as a novel food for use in infant/follow-on formula.

This follows the authorisation in April 2025 of new conditions of use for oil produced from *Schizochytrium* sp. strain FCC-3204 in protein products (excluding dairy analogues).

Over the next 5 years, only the companies that applied for these authorisations are permitted to market these novel foods in the EU. Other companies wishing to market these foods must seek permission from the relevant company or apply for EU authorisation.

### Impacted products

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

### What is changing?

The EU has authorised new conditions of use for the novel food *Schizochytrium* sp. (FCC-3204) oil in protein products intended for the general population, excluding dairy analogues (products using plant-based ingredients that mimic dairy products). It has also authorised an additional strain of *Schizochytrium limacinum* (ATCC-20889) as a novel food for use in infant/follow-on formula.

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

Only the companies that applied for these authorisations 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.

## Why?

The European Food Safety Authority has concluded that the novel food *Schizochytrium* FCC-3204 oil is safe when used in protein products intended for the general population, excluding dairy analogues ([EFSA 2024](#)), and has provided a positive safety evaluation of *S. limacinum* strain ATCC-20889 ([EFSA 2025](#)).

## Timeline

The use of *Schizochytrium* (FCC-3204) oil in protein products is permitted from **1 May 2025**. The use of *S. limacinum* (ATCC-20889) oil in infant/follow-on formula is permitted from **18 August 2025**.

## Background

This Regulation updates 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 (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 (EU) [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

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

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

Visit the [AGRINFO website](#) to view the latest AGRINFO Update newsletters and [search](#) the database.

## Table & Figures

Table 1 <i>Schizochytrium</i> strains authorised as novel foods				
Strain	Authorised uses	Applicant company	Exclusivity period	Labelling requirements
FCC-3204	<ul style="list-style-type: none"> <li>Protein products (excluding dairy analogues)</li> <li>Infant and follow-on formula*</li> <li>Food supplements (&gt;3 years)*</li> </ul>	Fermentalg	1 May 2025 to 1 May 2030	"Oil from the microalgae <i>Schizochytrium</i> sp."
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> "
<p>* Uses previously authorised under Regulation 2021/1326.</p> <div>  <b>AGRINFO</b>  <a href="http://www.agrininfo.eu">www.agrininfo.eu</a> </div>				

Source: Regulations [2025/688](#) and [2025/1515](#)

**Disclaimer:** Under no circumstances shall COLEAD be liable for any loss, damage, liability or expense incurred or suffered that is claimed to have resulted from the use of information

*available on this website or any link to external sites. The use of the website is at the user's sole risk and responsibility. This information platform was created and maintained with the financial support of the European Union. Its contents do not, however, reflect the views of the European Union.*