

## Novel food: Schizochytrium oil

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

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

### What is changing and why?

The European Union (EU) has authorised new conditions of use for the novel food *Schizochytrium* (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 a 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 sought these authorisations.


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 have provided 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.

### 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**.

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.

## Tables & 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> "
* Uses previously authorised under Regulation 2021/1326. <div>    <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.