

# Novel food: Schizochytrium oil

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## EU authorises use of novel food Schizochytrium oil in certain protein products

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

The European Union (EU) has authorised the use of the novel food *Schizochytrium* (FCC-3204) oil in protein products, excluding dairy analogues, for the EU market. Over the next 5 years, only the company that applied for authorisation, Fermentalg, is permitted to market these protein products. Other companies wishing to use this novel food in protein products must seek permission from Fermentalg or apply for EU authorisation.

### Impacted products

Protein products, excluding dairy analogues

### What is changing?

The EU has authorised new conditions to use *Schizochytrium* (FCC-3204) oil as a novel food in protein products intended for the general population, excluding dairy analogues (products using plant-based ingredients that mimic dairy products).

Only the company that applied for authorisation, Fermentalg, is authorised to put protein products using *Schizochytrium* oil on the EU market over the next 5 years, unless Fermentalg permits it, or if another company obtains a novel food authorisation for this use without reference to scientific data protected by Fermentalg.

*Schizochytrium* (FCC-3204) oil was already authorised (Regulation [2021/1326](#)) to be used in:

- infant formula and follow-on formula
- food supplements for the general population above 3 years of age.

## 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](#)).

## Timeline

Fermentalg's 5-year period of exclusive right to put this novel food on the EU market begins on **30 April 2025** and ends on 30 April 2030.

## 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.

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

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

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