

## Latest novel food authorisations – April 2024

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### EU authorises several novel foods

Commission Implementing Regulation (EU) [2024/1037](#) of 9 April 2024 authorising the placing on the market of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food and amending Implementing Regulation (EU) 2017/2470

Commission Implementing Regulation (EU) [2024/1046](#) of 9 April 2024 authorising the placing on the market of beta-glucan from *Euglena gracilis* microalgae as a novel food and amending Implementing Regulation (EU) 2017/247

Commission Implementing Regulation (EU) [2024/1047](#) of 9 April 2024 authorising the placing on the market of 3'-Sialyllactose sodium salt produced using a derivative strain of *Escherichia coli* W (ATCC 9637) as a novel food and amending Implementing Regulation (EU) 2017/2470

Commission Implementing Regulation (EU) [2024/1048](#) of 9 April 2024 authorising the placing on the market of protein concentrate from *Lemna gibba* and *Lemna minor* as a novel food and amending Implementing Regulation (EU) 2017/2470

### Update

The EU has authorised the sale of the following novel foods on its market:

- a monosodium salt of L-5-methyltetrahydrofolic acid
- beta-glucan from *Euglena gracilis* microalgae (paramylon)
- a 3'-sialyllactose sodium salt obtained by microbial fermentation using *Escherichia coli* NEO3
- a protein concentrate from water lentil (*Lemna gibba* and *Lemna minor*).

### Impacted products

Milk products (pasteurised, sterilised, UHT), unflavoured and flavoured fermented milk products, flavoured beverages, cereal bars, infant formula, follow-on formula, processed cereal-based food and baby food, milk-based drinks and similar products, diet replacement foods (for weight control), special medical foods, food supplements (except for young children)

## What is changing?

The EU has authorised placing on the market the following novel foods:

- a monosodium salt of L-5-methyltetrahydrofolic acid (company applicant: Merck & Cie KmG)
- beta-glucan from *Euglena gracilis* microalgae (Kemin Foods L.C.)
- a 3'-sialyllactose sodium salt from *Escherichia coli* NEO3 (Kyowa Hakko Bio Co., Ltd)
- calceol monohydrate from water lentil (DSM Nutritional Products Ltd).

These novel foods will be included in the [Union list of novel foods](#) (Regulation (EU) [2017/2470](#)). Only the company that applied for authorisation may sell the respective novel food on the EU market over the next 5 years, unless they allow other companies to sell it, or if another company obtains a novel food authorisation without reference to the scientific data used by the original applicant, which is data protected.

## Why?

The European Food Safety Authority (EFSA), in its scientific opinions ([2023a](#), [2023b](#), [2023c](#), [2023d](#)), concluded that these novel foods are safe under the applicants' proposed conditions of use.

## Timeline

The novel foods may be placed on the market from **30 April 2024**. The applicant companies data protection rights end on 30 April 2029.

## Background

Only novel foods authorised and included in the [Union list of novel foods](#) may be placed on the market within the EU (Regulation [2015/2283](#)).

On 28 December 2018, ABC Kroos BV submitted an application to place protein concentrate from water lentil (*Lemna gibba* and *Lemna minor*) on the EU market.

On 15 August 2019, Kemin Foods L.C. submitted an application to place beta-glucan from *Euglena gracilis* microalgae (paramylon) on the EU market.

On 12 November 2020, Merck & Cie KmG submitted its application for authorisation to place the monosodium salt of L-5-methyltetrahydrofolic acid on the EU market as a novel food and a source of bioavailable folate.

On 25 March 2021, Kyowa Hakko Bio Co., Ltd submitted its application for authorisation to place the 3'-sialyllactose (3'-SL) sodium salt, obtained by microbial fermentation using *Escherichia coli* NEO3, on the EU market.

## Resources

EFSA (2023a) [Safety of water lentil protein concentrate from a mixture of \*Lemna gibba\* and \*Lemna minor\* as a novel food pursuant to Regulation \(EU\) 2015/2283](#). EFSA Journal, 21(4): 7903.

EFSA (2023b) [Safety of paramylon as a novel food pursuant to Regulation \(EU\) 2015/2283](#). EFSA Journal, 21(5): 7995.

EFSA (2023c) [Safety of 6'-sialyllactose \(6'-SL\) sodium salt produced by a derivative strain \(\*Escherichia coli\* NEO6\) of \*E. coli\* W \(ATCC 9637\) as a Novel Food pursuant to Regulation \(EU\) 2015/2283](#). EFSA Journal, 21(9): 8224.

EFSA (2023d) [Safety of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food pursuant to Regulation \(EU\) 2015/2283 and the bioavailability of folate from this source in the context of Directive 2002/46/EC, Regulation \(EU\) No 609/2013 and Regulation \(EC\) No 1925/2006](#). EFSA Journal, 21(11): e8417.

European Commission: [Union list of novel foods](#)

Commission Implementing Regulation (EU) [2017/2470](#) (Union list of novel foods)

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

## Sources

Regulation (EU) [2024/1037](#) authorising the placing on the market of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food

Regulation (EU) [2024/1046](#) authorising the placing on the market of beta-glucan from *Euglena gracilis* microalgae as a novel food

Regulation (EU) [2024/1047](#) authorising the placing on the market of 3'-Sialyllactose sodium salt produced using a derivative strain of *Escherichia coli* W (ATCC 9637) as a novel food

Regulation (EU) [2024/1048](#) authorising the placing on the market of protein concentrate from *Lemna gibba* and *Lemna minor* as a novel food

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