# Latest novel food authorisations – April 2024

*Published by AGRINFO on 18 Apr 2024*

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)
- calcidiol 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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