

Latest novel food authorisations – April 2024

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EU authorises several novel foods

Commission Implementing Regulations:

(EU) [2024/1037](#) 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

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

(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 and amending Implementing Regulation (EU) 2017/2470

(EU) [2024/1048](#) 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

(EU) [2024/1052](#) authorising the placing on the market of calcidiol monohydrate 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*)
- calcidiol monohydrate as a form of vitamin D.

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)
- protein concentrate from water lentil (ABC Kroos BV)
- calcidiol monohydrate as a form of vitamin D (DSM Nutritional Products Ltd).

These novel foods will be included in the [Union list of novel foods](#) (Regulation (EU) [2017/2470](#)). Calcidiol monohydrate will also be included in the list of vitamin and mineral substances (Directive [2002/46/EC](#), Annex II) in order to allow its use as a source of vitamin D in food supplements ([G/TBT/N/EU/1082](#)).

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

These novel foods may be placed on the market from **30 April 2024** (**1 May 2024** for calcidiol monohydrate). The applicant companies' data protection rights end on 30 April 2029 (1 May 2029 for calcidiol monohydrate).

Recommended Actions

Comments on the proposal to include calcidiol monohydrate in the list of vitamin and mineral substances that may be used in the manufacture of food supplements can be submitted via the [National TBT notification authority](#) of the country concerned to the [EU TBT Enquiry Point](#) until **6 October 2024**.

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 16 May 2018, DSM Nutritional Products Ltd submitted an application to place calcidiol monohydrate on the EU market as a novel food and a form of vitamin D.

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.

Resources

EFSA (2021) [Safety of calcidiol monohydrate produced by chemical synthesis as a novel food pursuant to Regulation \(EU\) 2015/2283](#). EFSA Journal, 19(6): 6660.

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.

EFSA (2024) [Scientific and technical assistance to the evaluation of the safety of calcidiol monohydrate as a novel food](#). EFSA Journal, 22(1): e8520.

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

Regulation (EU) [2024/1052](#) authorising the placing on the market of calcidiol monohydrate as a novel food

[Draft](#) Commission Regulation as regards calcidiol monohydrate used in the manufacture of food supplements

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