Novel food: 3-Fucosyllactose from E. coli K-12 DH1

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EU corrects novel food authorisation for 3-Fucosyllactose produced from E. coli K-12 DH1

Commission Implementing Regulation (EU) 2025/1549 of 30 July 2025 correcting Implementing Regulations (EU) 2023/2210 as regards the conditions of use of the novel foods 3-Fucosyllactose produced by a derivative strain of Escherichia coli K-12 DH1

Commission Implementing Regulation (EU) 2023/2210 of 20 October 2023 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of Escherichia coli K-12 DH1 as a novel food and amending Implementing Regulation (EU) 2017/2470

Update

In 2023, the European Commission authorised a new source of 3-Fucosyllactose produced from *Escherichia coli* K-12 DH1 as a novel food.

When authorising this novel food, the Commission omitted to include foods for special medical purposes intended for infants and young children. Annex 1 of Regulation 2023/2210 has now been modified to correct this error.

Impacted products

Unflavoured, pasteurised, and sterilised (including UHT) milk products, fermented milk-based products (including heat-treated), cereal bars, milk-based drinks, foods for special medical purposes, beverages (flavoured drinks excluding pH <5), total diet replacement for weight control, food supplements, foods for special medical purposes intended for infants and young children

What is changing?

In 2023, the European Union (EU) authorised 3-Fucosyllactose produced with a derivative strain of *E. coli* (K-12 DH1) as a novel food that may be sold on the EU market for use as an ingredient in processed cereal-based foods, milk-based drinks, foods for special medical purposes, and food supplements (Regulation 2023/2210).

In July 2025, Annex I to Regulation 2023/2210 was modified to include foods for special medical purposes intended for infants and young children, with a maximin level of 1.75 g/l in the final product ready for use.

Only the company that applied for the authorisation, Glycom A/S, is authorised to sell this novel food on the EU market over the next 5 years, unless Glycom permits it, or if another company obtains a novel food authorisation for 3-Fucosyllactose produced with a derivative strain of *E. coli* (K-12 DH1) without reference to scientific data protected by Glycom.

Why?

The original authorisation in 2023 erroneously omitted foods for special medical purposes intended for infants and young children.

Timeline

The use of this novel food in foods for special medical purposes intended for infants and young children is permitted from **19 August 2025**.

Background

This Regulation updates the Annex to Implementing Regulation (EU) 2017/2470 which lists authorised novel foods (see the Union list of novel foods).

Resources

European Commission: Union list of novel foods

Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods

Regulation (EU) 2015/2283 on novel foods

Sources

Commission Implementing Regulation (EU) 2025/1549 as regards the conditions of use of the novel foods 3-Fucosyllactose produced by a derivative strain of Escherichia coli K-12 DH1

Commission Implementing Regulation (EU) 2023/2210 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of Escherichia coli K-12 DH1

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