

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

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EU authorises 3-Fucosyllactose produced from *E. coli* K-12 DH1 as a novel food

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

The European Commission has authorised a new source of 3-Fucosyllactose produced from *Escherichia coli* K-12 DH1 as a novel food.

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 with pH < 5), total diet replacement for weight control, food supplements

What is changing?

The EU has 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. It can be used as an ingredient in processed cereal-based foods, milk-based drinks, foods for special medical purposes, and food supplements.

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.

Timeline

The 5-year period of Glycom's exclusive right to put this novel food on the market begins on 9 November 2023.

End date of the data protection: 12 November 2028.

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](#) (Union list of novel foods)

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

Sources

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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