Novel food: 3-Fucosyllactose produced by a derivative strain of E. coli BL21 (DE3)

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EU amends specifications for the novel food 3-Fucosyllactose produced by a derivative strain of E. coli BL21 (DE3)

Commission Implementing Regulation (EU) 2025/1537 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food '3-Fucosyllactose produced by a derivative strain of Escherichia coli BL21 (DE3)'

Update

The European Commission is increasing the permitted maximum levels of the novel food 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3). This novel food was first authorised under Regulation 2023/52.

Impacted products

Infant formula, follow-on formula, processed cereal-based foods, milk-based drinks, foods for special medical purposes, food supplements

What is changing?

The European Union (EU) has amended the conditions of use of *E. coli* BL21 (DE3) in infant and follow-on formula, processed cereal-based foods and baby foods for infants and young children, milk-based drinks, and foods for special medical purposes.

The maximum authorised levels of use for this ingredient have been increased to:

- 1.75 g/l in infant formula (up from 0.9 g/l), follow-on formula (up from 0.9 g/l), and foods for special medical purposes for infants and young children (up from 1.2 g/l)
- 4.0 g/day in food supplements intended for the general population, excluding infants and young children (up from 3.0 g/day).

Only the company that applied for the initial novel food authorisation, Chr. Hansen A/S, is authorised to place the novel food on the EU market until 25 January 2028, unless another

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company obtains a novel food authorisation for 3-Fucosyllactose produced with a derivative strain of *E. coli* BL21(DE3) (without reference to scientific data protected by Chr. Hansen) or with the agreement of Chr. Hansen.

Timeline

The newly approved conditions of use for this novel food apply 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

Commission Implementing Regulation (EU) 2023/52 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of Escherichia coli BL21(DE3) as a novel food

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) 2025/1537 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food '3-Fucosyllactose produced by a derivative strain of Escherichia coli BL21 (DE3)'

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