

THE LATEST ON EU AGRI-FOOD POLICIES IMPACTING LOW-INCOME & MIDDLE-INCOME COUNTRIES

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

Published by AGRINFO on 11 Jan 2023; Revised 06 Aug 2025

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

Commission Implementing Regulation (EU) <u>2025/1537</u> 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) <u>2017/2470</u> which lists authorised novel foods (see the <u>Union list of novel foods</u>).

Resources

Commission Implementing Regulation (EU) <u>2023/52</u> 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) <u>2025/1537</u> 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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