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

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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)'

What is changing and why?

The European Union (EU) 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.

The conditions of use have been amended for *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).

These conditions of use apply only to the company Chr. Hansen A/S, which applied for the initial authorisation.

Timeline

The newly approved conditions of use for this novel food apply from **19 August 2025**.

For more information see the full record on the AGRINFO website – where you can also view the latest AGRINFO Update newsletters and search the database.

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