

# 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) [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

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)'

Visit the [AGRINFO website](#) to view the latest AGRINFO Update newsletters and [search](#) the database.

**Disclaimer:** *Under no circumstances shall COLEAD be liable for any loss, damage, liability or expense incurred or suffered that is claimed to have resulted from the use of information available on this website or any link to external sites. The use of the website is at the user's sole risk and responsibility. This information platform was created and maintained with the financial*

*support of the European Union. Its contents do not, however, reflect the views of the European Union.*