

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

Novel food: 3-Fucosyllactose

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European Commission authorises 3-Fucosyllactose produced by a derivative strain of E. coli as a novel food

Commission Implementing Regulation (EU) <u>2023/52</u> of 4 January 2023 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of Escherichia coli BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470

Update

The European Commission has authorised 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21(DE3) as a novel food.

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 EU has authorised that 3-Fucosyllactose produced with a derivative strain of *E. coli* BL21(DE3) may be placed on the EU market as a novel food. The food can be used in infant formula, follow-on formula, processed cereal-based foods, milk-based drinks, foods for special medical purposes for infants and young children, foods for special medical purposes and food supplements.

Only the company that applied for the authorisation, Chr. Hansen A/S, is authorised to place the novel food on the EU market for a period of 5 years, 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.





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Timeline

The 5-year period of exclusive rights of Chr. Hansen to put this novel food on the market begins on 25 January 2023.

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

European Commission: Union list of novel foods

Sources

Commission Implementing Regulation (EU) 2023/52

Commission Implementing Regulation (EU) 2017/2470 (Union list of novel foods)

Regulation (EU) 2015/2283 on novel foods

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