Novel food: 3′-Sialyllactose sodium salt from derivative strains of E. coli

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European Commission authorises 3′-Sialyllactose sodium salt obtained using genetically modified strain BL21(DE3) of E. coli as a novel food

Commission Implementing Regulation (EU) 2023/113 of 16 January 2023 authorising the placing on the market of 3′-Sialyllactose sodium salt produced by derivative strains of Escherichia coli BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470

Update

The European Commission has authorised 3′-Sialyllactose sodium salt, obtained by microbial fermentation using the genetically modified strain BL21(DE3) of *Escherichia coli*, as a novel food.

Impacted products

infant formula, follow-on formula, baby foods, baby foods for special medical purposes, milk-based drinks, food supplements

What is changing?

3′-Sialyllactose sodium salt from derivative strains of *E. coli* BL21(DE3), now authorised as a novel food, can be used in the following products (regulated under Regulation (EU) No 609/2013):

- infant formula and follow-on formula
- processed cereal-based food for infants and young children
- baby food for infants and young children
- foods for special medical purposes (including for infants and young children)
- milk-based drinks and similar products intended for young children.

It can also be used in food supplements as defined in Directive 2002/46/EC. Details on the permitted use are set out in the Annex to the Regulation.

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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 this sodium salt (without reference to scientific data protected by Chr. Hansen) or with the agreement of Chr. Hansen.

Timeline

The 5-year period of exclusive rights of Chr. Hansen A/S to put this novel food on the market ends 6 February 2028.

Background

This Regulation updates the Annex to Implementing Regulation (EU) 2017/2470 which lists authorised novel foods.

Sources

Commission Implementing Regulation (EU) 2023/113

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

Regulation (EU) 2015/2283

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