

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.

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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