

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

Published by AGRINFO on 22 Jan 2023

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](#)

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.*