Changes to specifications of parent strains for Lacto-N-neotetraose

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EU changes specifications of the novel food Lacto-N-neotetraose

Commission Implementing Regulation (EU) 2023/1583 of 1 August 2023 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food Lacto-N-neotetraose (microbial source)

Update

The European Commission has approved changes in the specifications of Lacto-*N*-neotetraose (microbial source), allowing food business operators more flexibility to use authorised derivatives of *Escherichia coli.*

What is changing?

The EU list of novel foods (Implementing Regulation 2017/2470, Annex, Table 2) refers to specific genetically modified derivative strains of *E. coli* for the production of Lacto-*N*-neotetraose. This new Regulation removes references to these specific strains. *E. coli* K-12 and *E. coli* BL21(DE3) are both authorised as parent strains for the production of Lacto-*N*-neotetraose.

Why?

The change allows for more flexibility to use relevant authorised derivatives of *E. coli* strains. It aligns with the specifications of other novel foods of microbial origin, which do not mention specific derivative strains.

Timeline

The changes to the specifications of microbial sources for Lacto-*N*-neotetraose take effect on 22 August 2023.

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What are the major implications for exporting countries?

Producers can now use both *E. coli* K-12 and *E. coli* BL21(DE3) as parent strains for the production of Lacto-*N*-neotetraose, without reference to specific genetically modified derivative strains.

Background

In 2016 the EU approved chemically synthesised Lacto-*N*-neotetraose as a novel food ingredient. The specifications of this novel food were later amended to include its production with genetically modified *E. coli* strain K-12 (in 2019) and strain BL21(DE3) (in 2021). EFSA (2020) concluded that the parent *E. coli* strains BL21(DE3) and K-12, and their genetically modified derivative strains, can be safely used in the production of Lacto-*N*-neotetraose.

Resources

EFSA (2020) Safety of lacto■N■neotetraose (LNnT) produced by derivative strains of E. coli BL21 as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 18(11): 6305.

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

Sources

Implementing Regulation (EU) 2023/1583

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