

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

Published by AGRINFO on 20 Aug 2023

## 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.

## 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](#)

**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.*