

THE LATEST ON EU AGRI-FOOD POLICIES IMPACTING LOW-INCOME & MIDDLE-INCOME COUNTRIES

Novel food: 2'-Fucosyllactose from Corynebacterium glutamicum ATCC 13032

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European Commission amends Regulation on 2'-Fucosyllactose produced from Corynebacterium glutamicum ATCC 13032 as a novel food

Commission Implementing Regulation (EU) <u>2023/859</u> of 25 April 2023 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food 2'-Fucosyllactose (microbial source) to authorise its production by a derivative strain of *Corynebacterium glutamicum* ATCC 13032

Update

The European Commission has authorised a new source of 2'-Fucosyllactose produced by a derivative strain of *Corynebacterium glutamicum* ATCC 13032 as a novel food.

What is changing?

The EU has authorised 2'-Fucosyllactose produced by a derivative strain of *Corynebacterium glutamicum* ATCC 13032 as a novel food that may be placed on the EU market. Details on the permitted use are set out in the Annex to Regulation (EU) <u>2017/2470</u>.

Only the company that applied for the authorisation, Advanced Protein Technologies Corporation, is authorised to place the novel food on the EU market for a period of 5 years, unless another company obtains an authorisation, or has the agreement of Advanced Protein Technologies Corporation.

Why?

EFSA has established that 2'-Fucosyllactose, produced by microbial fermentation using a genetically modified derivative strain of *Corynebacterium glutamicum* ATCC 13032, is safe to be placed on the market.





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Timeline

The 5-year period of exclusive rights of Advanced Protein Technologies Corporation to put this novel food on the EU market ends on 16 May 2028.

Background

This Regulation updates the Annex to Implementing Regulation (EU) <u>2017/2470</u> which <u>lists</u> <u>authorised novel foods</u>. For further information on the authorisation procedure, see <u>Novel foods</u> <u>explained</u>.

Resources

EFSA (2022) <u>Safety of 2'-fucosyllactose (2'-FL) produced by a derivative strain (APC199) of</u> <u>Corynebacterium glutamicum ATCC 13032 as a novel food pursuant to Regulation (EU)</u> <u>2015/2283</u>. EFSA Journal, 20(12): 7647.

Sources

Commission Implementing Regulation (EU) 2023/859

Commission Implementing Regulation (EU) <u>2017/2470</u> establishing the Union list of novel foods

Regulation (EU) 2015/2283 on novel foods

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