Novel food: Clostridium butyricum TO-A

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Commission Implementing Regulation (EU) 2025/2233 authorising the placing on the market of *Clostridium butyricum* TO-A as a novel food and amending Implementing Regulation (EU) 2017/2470.

What is changing and why?

The European Union (EU) has authorised the novel food *Clostridium butyricum* TO-A for use in food supplements intended for the general population above 3 years of age, excluding pregnant and lactating women, when it does not exceed specific maximum levels (see Table 1). Specific labelling requirements apply.

Only the company that applied for authorisation, TOA Biopharma Co. Ltd, is authorised to sell this novel food on the EU market over the next 5 years, unless they permit marketing by other companies, or if another company obtains a novel food authorisation without making reference to scientific data protected by TOA Biopharma Co. Ltd.

Timeline

This novel food may be placed on the EU market from **27 November 2025**.

For more information see the full record on the AGRINFO website – where you can also view the latest AGRINFO Update newsletters and search the database.

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Tables & Figures

Table 1
Maximum levels of *Clostridium butyricum* TO-A in food supplements

Product target age group	Maximum level ($\times 10^8$ CFU/day)
Children from 3 to <10 years	1.0
Adolescents from 10 to <14 years	2.0
Adolescents from 14 to <18 years	2.8
Adults, excluding pregnant and lactating women	3.2

CFU, colony-forming units.

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Source: based on Regulation 2025/2233

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