Novel food: Clostridium butyricum TO-A

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EU authorises use of novel food Clostridium butyricum TO-A

Commission Implementing Regulation (EU) 2025/2233 of 6 November 2025 authorising the placing on the market of *Clostridium butyricum* TO-A as a novel food and amending Implementing Regulation (EU) 2017/2470.

Update

The European Union (EU) has authorised the use of the novel food *Clostridium butyricum* TO-A in food supplements intended for the general population above 3 years of age, excluding pregnant and lactating women, when specific maximum levels are not exceeded.

What is changing?

The EU has authorised the use of *Clostridium butyricum* TO-A as a novel food in food supplements intended for the general population above 3 years of age, excluding pregnant and lactating women.

Food supplements containing *C. butyricum* TO-A must not exceed the maximum levels specified for each age group (see Table 1).

Food supplements that contain *C. butyricum* TO-A must include in their labelling:

- “Clostridium butyricum TO-A”
- a statement of the age groups that should not consume these supplements, depending on the consumers targeted:
  - pregnant and lactating women
  - infants and children under 3, 10, or 14 years of age
  - infants, children, and adolescents under 18 years of age.

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.

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Why?

The European Food Safety Authority (EFSA 2025) has concluded that the novel food *Clostridium butyricum* TO-A is safe when used in food supplements intended for the general population above 3 years of age, excluding pregnant and lactating women, when not exceeding specific maximum levels.

Timeline

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

Background

Clostridium butyricum TO-A is a bacterium with the TO-A strain, deposited under number FERM BP-10866.

This Regulation updates the Annex to Regulation 2017/2470 which lists authorised novel foods (see the Union list of novel foods). For further information on the EU novel foods authorisation process, see Novel foods explained.

Resources

EFSA (2025) Safety of *Clostridium butyricum* TO-A as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 23: e9371.

Regulation 2017/2470 establishing the Union list of novel foods.

Regulation 2015/2283 on novel foods.

Sources

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.

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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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