

Product: *Clostridium butyricum* TO-A  
Novel food category: Foods consisting of, isolated from or  
produced from microorganisms, fungi or algae

Applicant: TOA BIOPHARMA Co., Ltd.  
EFSA-ID-2021-000216  
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(a) *the name and address of the applicant*

Applicant: TOA Biopharma Co. Ltd.  
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(b) *the name and description of the novel food*

*C. butyricum* TO-A is a white-grey powder that containing *C. butyricum* TO-A at  $1 \times 10^9$  cfu/g. It is manufactured by fermentation. *C. butyricum* TO-A is a spore-former, strictly anaerobic, and belongs to the Gram-positive *Clostridium* genus.

*C. butyricum* TO-A is intended to be used as an ingredient in food supplements, it is not intended to replace another food and the maximum intended doses are:

- Infants (3- <12 months) and toddlers:  $1 \times 10^8$  cfu/day
- Other children:  $3 \times 10^8$  cfu/day
- Adolescents:  $6 \times 10^8$  cfu/day
- Adults:  $1 \times 10^9$  cfu/day

(c) *scientific evidence demonstrating that the novel food does not pose a safety risk to human health*

The analysis of the whole genome sequence of *C. butyricum* TO-A showed that *C. butyricum* TO-A does not harbour any acquired antimicrobial resistance genes. Furthermore, no potential virulence factor genes were identified and no botulinum neurotoxin genes were found in *C. butyricum* TO-A.

Additionally, *C. butyricum* TO-A was shown to be safe in a subacute and a subchronic oral toxicity study in which a NOEL of 3,000 mg/kg bw/day ( $3 \times 10^{10}$  cfu/kg bw/day) and a NOAEL of 3,000 mg/kg bw/day ( $9 \times 10^8$  cfu/kg bw/day) were derived, respectively. Considering the maximum exposure to *Clostridium butyricum* TO-A of 14.93 mg/kg/day for infants of 3- <6 months, the lowest margins of exposure are 2,010 (derived from subacute toxicity study) and 60.3 (derived from subchronic toxicity study), respectively.

A literature search to investigate the safety of *C. butyricum* TO-A and other non-pathogenic strains of *C. butyricum* was performed. No adverse effects or allergenic reactions were identified in the literature.