COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001[1], and in particular Article 12(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470[2] has established a Union list of novel foods.

(3) On 10 November 2021, the company TOA Biopharma Co. Ltd. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place *Clostridium butyricum* TO-A on the Union market as a novel food. The applicant requested for the novel food to be used in food supplements as defined in Directive 2002/46/EC[3] for the general population above 3 months of age.

---

1 OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.

2 Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

3 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

(4) On 10 November 2021, the applicant also made a request to the Commission for the protection of the following proprietary data: manufacturing process[4], nutritional analysis (part 1–5)[5], C. butyricum analysis (part 1–5)[6], purity analysis (part 1–5)[7], AMES study[8], micronucleus study[9], AMES supernatant study[10], micronucleus supernatant study[11], *in vivo* micronucleus comet supernatant study[12], Lysis efficiency French Press study[13], Appendix1 SEM images[14], AMES Lysate study[15], micronucleus Lysate study[16] and subchronic toxicity study[17].

(5) On 8 June 2022, the Commission requested the European Food Safety Authority ('the Authority') to provide a scientific opinion on *Clostridium butyricum* TO-A as a novel food.

(6) On 25 March 2025, the Authority adopted its scientific opinion on the 'Safety of *Clostridium butyricum* TO-A as a novel food pursuant to Regulation (EU) 2015/2283'[18] in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that *Clostridium butyricum* TO-A is safe at 1.0×10^8 CFU/day for other children (3 to < 10 years), 2.0×10^8 CFU/day for adolescents from 10 to < 14years, 2.8×10^8 CFU/day for adolescents from 14 to < 18 years, and 3.2×10^8 CFU/day for adults, excluding pregnant and lactating women.

(8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the proprietary data on the manufacturing process, nutritional analysis (part 1–5), C. butyricum analysis (part 1–5), purity analysis (part 1–5), AMES study, micronucleus study, AMES supernatant study, micronucleus supernatant study, in vivo micronucleus comet supernatant study, Lysis efficiency French Press study, Appendix1 SEM images, AMES Lysate study, micronucleus Lysate study and subchronic toxicity study, without which it could not have assessed the novel food and reached its conclusion.

(9) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2), point (b), of Regulation (EU) 2015/2283.

(10) The applicant declared that they held proprietary and exclusive rights of reference to the data on the identity, the production process and compositional data, at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.

---

4 Annex_I_2_1_1
5 Annex_I_3_1_1
6 Annex_I_3_1_2
7 Annex_I_3_1_3
8 Annex_I_9_2_1
9 Annex_I_9_2_2
10 Annex_I_9_2_3
11 Annex_I_9_2_4
12 Annex_I_9_2_5
13 Annex_I_9_2_6
14 Annex_I_9_2_6
15 Annex_I_9_2_7
16 Annex_I_9 _2_8
17 Annex_I_9_3
18 EFSA Journal. 2025;23:e9371.

(11) The Commission assessed all the information provided by the applicant and considers that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data on the manufacturing process, nutritional analysis (part 1–5), C. butyricum analysis (part 1–5), purity analysis (part 1–5), AMES study, micronucleus study, AMES supernatant study, micronucleus supernatant study, in vivo micronucleus comet supernatant study, Lysis efficiency French Press study, Appendix1 SEM images, AMES Lysate study, micronucleus Lysate study and subchronic toxicity study, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place *Clostridium butyricum* TO-A on the market within the Union during a period of five years from the entry into force of this Regulation.

(12) However, such restriction of the authorisation and the reference to the data contained in the applicant's file for their sole use does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(13) It is appropriate that the inclusion of *Clostridium butyricum* TO-A as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In line with the conditions of use of food supplements containing *Clostridium butyricum* TO-A as proposed by the applicant, it is necessary to inform the consumers in that regard by appropriate labelling about the uses of food supplements containing *Clostridium butyricum* TO-A.

(14) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

(1) *Clostridium butyricum* TO-A is authorised to be placed on the market within the Union.

Clostridium butyricum TO-A shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

(2) The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company TOA Biopharma Co. Ltd. [19] is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from [*the date of entry into force of this Regulation*] [*OP please insert the date*], unless a subsequent applicant obtains an authorisation for the novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of the company TOA Biopharma Co. Ltd..

Article 3

[19] Address: 2-1-11, Sasazuka, Shibuya, Tokyo, Japan

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of the company TOA Biopharma Co. Ltd.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN