



2024/2185

4.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2185

of 3 September 2024

concerning the authorisation of a preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 as a feed additive for all poultry species for fattening, all poultry species reared for laying or breeding and ornamental birds (holder of authorisation: Toa Biopharma Co., Ltd.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 as a feed additive to be used in feed and water for drinking for chickens for fattening, chickens reared for laying or breeding, turkeys for fattening, turkeys reared for laying or breeding and all minor avian species, including sporting, exotic and all other ornamental birds, to slaughter or point of lay, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 4 May 2022 ⁽²⁾ and 27 September 2023 ⁽³⁾ that, under the proposed conditions of use, the preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 is safe for the target species, the consumers and the environment. It also concluded that the preparation is not irritant to skin and eyes but is a respiratory sensitiser, while due to the lack of information provided no conclusion could be drawn on its potential to be a skin sensitiser. The Authority further concluded that the preparation is efficacious for the target species under the proposed conditions of use. The Authority concluded that the preparation is compatible with the coccidiostats diclazuril, decoquinate and halofuginone, while no conclusion could be drawn on the compatibility of that preparation with the coccidiostats monensin sodium, salinomycin sodium, narasin, robenidine hydrochloride and maduramicin ammonium. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed and water submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2022;20(6):7342.

⁽³⁾ EFSA Journal 2023;21(11):8343.

- (5) On 21 June 2024, the applicant withdrew the application as regards the recognition of the compatibility of use of the preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 with the following coccidiostats: monensin sodium, salinomycin sodium, narasin, robenidine hydrochloride and maduramicin ammonium.
- (6) In view of the above, the Commission considers that the preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. It is appropriate to indicate that the preparation may be used simultaneously with the coccidiostats diclazuril, decoquinate and halofuginone. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) 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

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Entry into force

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, 3 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			
Category: zootechnical additives. Functional groups: gut flora stabilisers											
4b1895	Toa Bio-pharma Co., Ltd., Japan, represented by Toa Bio-pharma Co., Ltd., Europe Representative Office	Bacillus subtilis FERM BP-07462, Enterococcus lactis FERM BP-10867 and Clostridium butyricum FERM BP-10866	Additive composition	All poultry species for fattening	-	2,4 × 10 ⁸	-	1,2 × 10 ⁸	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: diclazuril, decoquinate and halofuginone.	24 September 2034
			Preparation of Bacillus subtilis FERM BP-07462, Enterococcus lactis FERM BP-10867 and Clostridium butyricum FERM BP-10866 containing a minimum of 12 × 10 ⁸ CFU/g additive (1:10:1 ratio) Solid form	All poultry species reared for laying All poultry species reared for breeding							
			Characterisation of the active substance	Ornamental birds	Point of lay	2,4 × 10 ⁸	-	1,2 × 10 ⁸	-		
			Viable spores of Bacillus subtilis FERM BP-07462, Enterococcus lactis FERM BP-10867 and Clostridium butyricum FERM BP-10866								

			<i>Analytical method</i> ⁽¹⁾ Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697. Enumeration in the feed additive, pre-mixtures, compound feed and water of: <i>Bacillus subtilis</i> FERM BP-07462: Spread plate method on tryptone soya agar (EN 15784) <i>Enterococcus lactis</i> FERM BP-10867: Spread plate method using bile esculin azide agar (EN 15788) <i>Clostridium butyricum</i> FERM BP-10866: Pour plate method using iron sulfite agar (ISO 15213)								4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.