

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1411

of 27 August 2021

concerning the renewal of the authorisation of *Clostridium butyricum* FERM BP-2789 as a feed additive for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, its authorisation for chickens for fattening, suckling piglets and suckling minor porcine species, and repealing Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)

(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 and renewing such authorisation.
- (2) The preparation of *Clostridium butyricum* FERM BP-2789 was authorised for 10 years as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) by Commission Implementing Regulation (EU) No 373/2011 ⁽²⁾, for chickens reared for laying by Commission Implementing Regulation (EU) No 374/2013 ⁽³⁾ and for turkeys for fattening and turkeys reared for breeding by Commission Implementing Regulation (EU) No 1108/2014 ⁽⁴⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of the authorisation of the preparation of *Clostridium butyricum* FERM BP-2789 as a feed additive for the renewal of the authorisation for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, and for a new authorisation for chickens for fattening, suckling piglets and suckling minor porcine species, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Articles 7(3) and 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2021 ⁽⁵⁾ that the applicant had provided evidence that the additive complies with the conditions of authorisation. The Authority further concluded that the preparation of *Clostridium butyricum* FERM BP-2789 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the preparation is not an irritant to skin

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011 concerning the authorisation of the preparation of *Clostridium butyricum* FERM-BP 2789 as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 903/2009 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium (OJ L 102, 16.4.2011, p. 10).

⁽³⁾ Commission Implementing Regulation (EU) No 374/2013 of 23 April 2013 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for chickens reared for laying (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium (OJ L 112, 24.4.2013, p. 13).

⁽⁴⁾ Commission Implementing Regulation (EU) No 1108/2014 of 20 October 2014 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium (OJ L 301, 21.10.2014, p. 16).

⁽⁵⁾ EFSA Journal 2021;19(3):6450.

and eyes and that sensitisation via respiratory route could not be excluded. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to users of the additive. The Authority also concluded that the additive has the potential to be efficacious in chickens for fattening, suckling piglets and suckling minor porcine species.

- (5) The assessment of the preparation of *Clostridium butyricum* FERM BP-2789 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of the preparation of *Clostridium butyricum* FERM BP-2789 as a feed additive under the conditions laid down in the Annex to this Regulation, Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 should be repealed.
- (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

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species is renewed, and for the same category and functional group for chickens for fattening, suckling piglets and suckling minor porcine species is authorised subject to the conditions laid down in that Annex.

Article 2

Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 are repealed.

Article 3

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the 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	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1830	Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium	<i>Clostridium butyricum</i> FERM BP-2789	Additive composition Preparation of <i>Clostridium butyricum</i> FERM BP-2789 containing a minimum of 5×10^8 CFU/g additive. Solid form	Chickens for fattening Chickens reared for laying Minor avian species (excluding laying birds)	-	$2,5 \times 10^8$	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the permitted coccidiostats: decoquinat, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramycin sodium. 3. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	19.9.2031
			Characterisation of active substance Viable spores of <i>Clostridium butyricum</i> FERM BP-2789.	Piglets and piglets of minor porcine species	-	$1,25 \times 10^8$	-		
			Analytical method ⁽¹⁾ Enumeration: pour plate method based on ISO 15213 standard. Identification: pulsed-field gel electrophoresis (PFGE) method	Turkeys for fattening Turkeys reared for breeding					

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>