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) (Text with EEA relevance)

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 (**[**F1holder 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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of a preparation of *Clostridium butyricum* (FERM BP-2789). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003, and by the relevant data to support its requests.

(3) The application concerns the authorisation of the preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for turkeys for fattening and turkeys reared for breeding, to be classified in the additive category ‘zootechnical additives’.

(4) The use of the preparation of *Clostridium butyricum* (FERM BP-2789), belonging to the additive category of ‘zootechnical additives’, was authorised for 10 years as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 903/2009[(2)] and for minor avian species (excluding laying birds) and for weaned piglets and minor porcine species (weaned) by Commission Implementing Regulation (EU) No 373/2011[(3)].

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 4 March 2014[(4)] that, under the proposed conditions of use, the preparation of *Clostridium butyricum* (FERM BP-2789) does not have an adverse effect on animal health, human

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1108/2014. (See end of Document for details)*

health and the environment. It also concluded that the additive has the potential to improve performance in turkeys for fattening and that this conclusion can be extended to turkeys reared for breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) 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 use of that preparation should be authorised as specified in the Annex to this Regulation.

(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:

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2017/1126 of 23 June 2017 amending Regulation (EC) No 903/2009 and Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 as regards the name of the EU representative of the holder of the authorisation of a preparation of Clostridium butyricum (FERM-BP 2789) (Text with EEA relevance).

Article 1

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

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1108/2014. (See end of Document for details)*

ANNEX

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 of zootechnical additives. Functional group: gut flora stabilisers									
4b1830	[F1Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium]	*Clostridium butyricum* FERM BP-2789	*Additive composition* Preparation of *Clostridium butyricum* FERM BP-2789 containing in solid form a minimum of 5×10^8 CFU/g of additive. *Characterisation of the active substance* Viable spores of *Clostridium butyricum* FERM BP-2789. *Analytical method*[a] Enumeration: pour plate method based on ISO	Turkeys for fattening Turkeys reared for breeding	—	$1{,}25 \times 10^8$	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. Use is allowed in feed containing (for the animal category) the authorised coccidiostats: monensin sodium, robenidine, maduramicin ammonium, lasalocid sodium or diclazuril.	10 November 2024

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx