Commission Regulation (EC) No 903/2009 of 28 September 2009 concerning the authorisation of the preparation of Clostridium butyricum FERM-BP 2789 as a feed additive for chickens for fattening (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium) (Text with EEA relevance)

COMMISSION REGULATION (EC) No 903/2009

of 28 September 2009

concerning the authorisation of the preparation of **[**F1*Clostridium butyricum* FERM-BP 2789**]** as a feed additive for chickens for fattening (**[**F2holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium**]**)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 the preparation set out in the Annex to this Regulation. 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 the preparation of **[**F1*Clostridium butyricum* FERM-BP 2789**]** as a feed additive for chickens for fattening, to be classified in the additive category ‘zootechnical additives’.

(4) From the opinion of the European Food Safety Authority (the Authority) of 2 April 2009(2) it results that the preparation of **[**F1*Clostridium butyricum* FERM-BP 2789**]** does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can have a significant benefit on feed to gain ratio. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, 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.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Textual Amendments

F1 Substituted by 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 Miyarisan Pharmaceutical Europe S.L.U.) (Text with EEA relevance).

F2 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 20th day following 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 Regulation (EC) No 903/2009. (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	[F2Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium]	[F1*Clostridium butyricum* FERM-BP 2789]	Additive composition: Preparation of [F1*Clostridium butyricum* FERM-BP 2789] containing a minimum of solid form 5×10^8 CFU/g additive Characterisation of the active substance: [F1*Clostridium butyricum* FERM-BP 2789] Analytical method[a]:	Chickens for fattening	—	[F3$2,5 \times 10^8$]	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. The use is allowed in feed containing the permitted coccidiostats: monensin sodium, diclazuril, maduramicin ammonium, robenidine, narasin, narasin/nicarbazin, semduramycin, decoquinate[F4,][F4 monensin	19 October 2019

a Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives