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COMMISSION REGULATION (EC) No 903/2009

of 28 September 2009

concerning the authorisation of the preparation of ► M1 *Clostridium butyricum* FERM-BP 2789 ◀ as a feed additive for chickens for fattening (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by ► M1 Miyarisan Pharmaceutical Europe S.L.U ◀)

(Text with EEA relevance)

(OJ L 256, 29.9.2009, p. 26)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011	L 102	10	16.4.2011
► <u>M2</u>	Commission Implementing Regulation (EU) No 357/2013 of 18 April 2013	L 109	22	19.4.2013

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 ►**M1** *Clostridium butyricum* FERM-BP 2789 ◀ as a feed
 additive for chickens for fattening (holder of authorisation
 Miyarisan Pharmaceutical Co. Ltd, represented by
 ►**M1** Miyarisan Pharmaceutical Europe S.L.U ◀)

(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 ►**M1** *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 ►**M1** *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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ *The EFSA Journal* (2009) 1039, p. 1.

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- (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:

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.

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	Miyarisan Pharmaceutical Co. Ltd represented by ► M1 Miyarisan Pharmaceutical Europe S.L.U ◀	► M1 <i>Clostridium butyricum</i> FERM-BP 2789 ◀	<p>Additive composition:</p> <p>Preparation of ► M1 <i>Clostridium butyricum</i> FERM-BP 2789 ◀ containing a minimum of solid form 5×10^8 CFU/g additive</p> <p>Characterisation of the active substance:</p> <p>► M1 <i>Clostridium butyricum</i> FERM-BP 2789 ◀</p> <p>Analytical method ⁽¹⁾:</p> <p>Quantification: iron sulphite agar for the additive and premixtures and selective ► M1 <i>Clostridium butyricum</i> FERM-BP 2789 ◀ agar for feedingstuffs</p> <p>Identification: pulsed-field gel electrophoresis (PFGE) method</p>	Chickens for fattening	—	► M2 $2,5 \times 10^8$ ◀	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. The use is allowed in feed containing the permitted coccidiostats: monensin sodium, diclazuril, maduramicin ammonium, robenidine, narasin, narasin/nicarbazin, semduramycin, decoquinatate , ► M1 monensin sodium or lasalocid ◀. For safety reasons: breathing protection shall be used during handling. 	19 October 2019
⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives									