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► **B** **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 (► M2 holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium ◀)

(Text with EEA relevance)

(OJ L 102, 16.4.2011, p. 10)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Regulation (EU) No 357/2013 of 18 April 2013	L 109	22	19.4.2013
► <u>M2</u>	Commission Implementing Regulation (EU) 2017/1126 of 23 June 2017	L 163	13	24.6.2017



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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

In Regulation (EC) No 903/2009 the words ‘*Clostridium butyricum* MIYAIRI 588 (FERM-P 1467)’ and the words ‘Mitsui & Co. Deutschland GmbH’ are replaced respectively by the words ‘*Clostridium butyricum* FERM-BP 2789’ and by the words ‘Miyarisan Pharmaceutical Europe S.L.U.’.

In point 2 of the ‘Other provisions’ column of the Annex to Regulation (EC) No 903/2009 the words ‘monensin sodium or lasalocid’ are added.

Article 3

Feed containing *Clostridium butyricum* MIYAIRI 588 (FERM-P 1467) labelled in accordance with Regulation (EC) No 903/2009 may continue to be placed on the market and used until stocks are exhausted.

Article 4

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	► M2 Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium ◀	<i>Clostridium butyricum</i> FERM BP-2789	<p><i>Additive composition</i></p> <p>Preparation of <i>Clostridium butyricum</i> FERM BP-2789 containing a minimum of solid form 5×10^8 CFU/g additive.</p> <p><i>Characterisation of the active substance</i></p> <p><i>Clostridium butyricum</i> FERM BP-2789.</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Quantification: pour plate method based on ISO 15213 standard.</p> <p>Identification: pulsed-field gel electrophoresis (PFGE) method.</p>	Minor avian species (excluding laying birds).	—	► M1 $2,5 \times 10^8$ ◀	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>2. The use is allowed in feed containing the authorised coccidiostats: monensin sodium, diclazuril, maduramycin ammonium, robenidine, narasin, narasin/nicarbazin, semduramicin, decoquinate, salinomycin sodium or lasalocid sodium.</p> <p>3. For safety: breathing protection shall be used during the handling.</p>	6 May 2021
				Piglets (weaned) and minor porcine species (weaned).	► M1 $2,5 \times 10^8$ ◀				

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/crl-feed-additives