

SCHEDULE 8

Regulation 3

Renewal of authorisation of a preparation of *Clostridium butyricum* (FERM BP-2789) (identification number 4b1830) 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, and its authorisation as a feed additive for chickens for fattening, suckling piglets and suckling minor porcine species

The preparation of *Clostridium butyricum* (FERM BP-2789), belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition in accordance with the specifications in the following table(1).

<i>Additive</i>	<i>Clostridium butyricum</i> (FERM BP-2789)
<i>Identification number of the additive</i>	4b1830
<i>Authorisation holder</i>	Miyarisan Pharmaceutical Co Ltd
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Gut flora stabilisers
<i>Additive composition</i>	Solid form preparation of <i>Clostridium butyricum</i> (FERM BP-2789) containing a minimum of 5×10^8 CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable spores of <i>Clostridium butyricum</i> (FERM BP-2789).
<i>Analytical methods⁽¹⁾</i>	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: — Pour plate method in accordance with BS ISO 15213:2003 ⁽²⁾ . For identification of bacterial strain: — Pulsed-field gel electrophoresis (PFGE).
<i>Species or category of animal</i>	— Chickens for fattening — Chickens reared for laying — Turkeys for fattening — Turkeys reared for breeding — Minor avian species (excluding laying birds) — Piglets (suckling and weaned) — Minor porcine species (suckling and weaned)
<i>Maximum age</i>	Not applicable.

(1) Details of the analytical methods set out in the document referenced "JRC.DG.D.CvH/DM/hn/ARES (2010)-355411" and last updated 6th June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0005>.

(2) BS ISO 15213:2003 "Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions". Published by the British Standards Institution on 16th May 2003 (ISBN 0 580 41892 8) Available from the British Standards Institution <https://knowledge.bsigroup.com>.

(3) Content of *Clostridium butyricum* (FERM BP-2789): CFU/kg of complete feed with a moisture content of 12%.

(1) This authorisation is a renewal of the authorisations granted under Commission Implementing Regulations (EU) No. 373/2011, 374/2013 and 1108/2014. Those Regulations are revoked by regulation 11 of these Regulations.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Minimum content</i> ⁽³⁾	For all species set out above other than turkeys for fattening and turkeys for reared for breeding: — 2.5 x 10 ⁸ CFU/kg.
	For turkeys for fattening and turkeys reared for breeding: — 1.25 x 10 ⁸ CFU/kg.
<i>Maximum content</i> ⁽³⁾	No maximum
<i>Other provisions</i>	<ol style="list-style-type: none"> 1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated. 2) If <i>Clostridium butyricum</i> (FERM BP-2789) is to be used in feed containing coccidiostats, this feed additive is authorised for use with the following coccidiostats only, and in accordance with their individual authorisation criteria for: decoquinate, diclazuril, lasalocid A sodium, maduramicin ammonium, monensin sodium, narasin, narasin/nicarbazin (as combined use), robenidine hydrochloride, salinomycin sodium or semduramicin sodium.

- (1) Details of the analytical methods set out in the document referenced “JRC.DG.D.6.CvH/DM/hn/ARES (2010)-355411” and last updated 6th June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0005>.
- (2) BS ISO 15213:2003 “Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions”. Published by the British Standards Institution on 16th May 2003 (ISBN 0 580 41892 8) Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (3) Content of *Clostridium butyricum* (FERM BP-2789): CFU/kg of complete feed with a moisture content of 12%.