

SCHEDULE 8

Regulation 3(2)

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 [^{F1} piglets] and suckling minor porcine species

Textual Amendments

- F1** Word in sch. 8 heading substituted (9.2.2023) by The Food and Feed (Miscellaneous Amendments) (Scotland) Regulations 2022 (S.S.I. 2022/373), regs. 1(1), 5(11)(a)

Authorisation

1. The preparation specified in the table in this schedule, 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 set out in the table in this schedule(1).

Table

<i>Column 1</i>	<i>Column 2</i>
<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 x 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(2)</i>	1. For enumeration (colony count) [^{F2} in the feed additive, premixtures, feed materials and compound feed]: <ul style="list-style-type: none"> • Pour plate method in accordance with international standard BS ISO 15213:2003 entitled "<i>Microbiology of food and animal feeding stuffs. Horizontal method for the enumeration of sulphite-reducing bacteria growing under anaerobic conditions</i>"(3)

- (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.
- (2) Details of the analytical methods are set out in the document referenced "JRC.DG.D.6.CvH/DM/hn/ARES (2010)-355411" and last updated on 6 June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0005>.
- (3) ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. Under reference BS ISO 15213:2003, it was published as a UK standard by the British Standards Institution on 16 May 2003 (ISBN 0 580 41892 8).

Changes to legislation: There are currently no known outstanding effects for the The Feed Additives (Authorisations) (Scotland) Regulations 2022, SCHEDULE 8. (See end of Document for details)

Column 1	Column 2
	<p>2. For identification of bacterial strain:</p> <ul style="list-style-type: none"> • Pulsed-field gel electrophoresis (PFGE)
Species or category of animal	Turkeys for fattening; turkeys reared for breeding; chickens for fattening; chickens reared for laying; minor avian species (excluding laying birds); [^{F3} piglets (suckling and weaned) and minor porcine species (suckling and weaned)]
Maximum age	Not applicable
Content of <i>Clostridium butyricum</i> (FERM BP-2789) in CFU/kg of complete feed with a moisture content of 12%	<p>Minimum content</p> <p>Turkeys: 1.25 x 10⁸ CFU/kg</p> <p>Chickens, minor avian species, piglets and minor porcine species: 2.5 x 10⁸ CFU/kg</p> <p>Maximum content</p> <p>All species and categories of animal as provided for above: no maximum</p>
Other provisions	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated.</p> <p>2. Where <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:</p> <ul style="list-style-type: none"> • Decoquinate, • Diclazuril, • Lasalocid [^{F4}A sodium], • Maduramicin ammonium, • Monensin sodium, • Narasin, • Narasin/Nicarbazin (as combined use only), • Robenidine [^{F5}hydrochloride,] • Salinomycin sodium, • Semduramicin sodium.

Textual Amendments

- F2** Words in sch. 8 table inserted (9.2.2023) by The Food and Feed (Miscellaneous Amendments) (Scotland) Regulations 2022 (S.S.I. 2022/373), regs. 1(1), **5(11)(b)(i)**
- F3** Words in sch. 8 table substituted (9.2.2023) by The Food and Feed (Miscellaneous Amendments) (Scotland) Regulations 2022 (S.S.I. 2022/373), regs. 1(1), **5(11)(b)(ii)**
- F4** Words in sch. 8 table inserted (9.2.2023) by The Food and Feed (Miscellaneous Amendments) (Scotland) Regulations 2022 (S.S.I. 2022/373), regs. 1(1), **5(11)(b)(iii)(aa)**
- F5** Word in sch. 8 table inserted (9.2.2023) by The Food and Feed (Miscellaneous Amendments) (Scotland) Regulations 2022 (S.S.I. 2022/373), regs. 1(1), **5(11)(b)(iii)(bb)**

Changes to legislation: *There are currently no known outstanding effects for the The Feed Additives (Authorisations) (Scotland) Regulations 2022, SCHEDULE 8. (See end of Document for details)*

Commencement Information

11 Sch. 8 para. 1 in force at 24.11.2022, see **reg. 1(1)**

Changes to legislation:

There are currently no known outstanding effects for the The Feed Additives (Authorisations) (Scotland) Regulations 2022, SCHEDULE 8.