WELSH STATUTORY INSTRUMENTS

2022 No. 1118 (W. 233)

AGRICULTURE, WALES

The Feed Additives (Authorisations) (Wales) Regulations 2022

Made - - - -	*31 October 2022*
Laid before Senedd Cymru	*2 November 2022*
Coming into force - -	*24 November 2022*

The Welsh Ministers make these Regulations in exercise of the powers conferred by Articles 9(1) and 18A(3) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition(**1**).

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**2**).

Title, extent, application and commencement

1.—(1) The title of these Regulations is the Feed Additives (Authorisations) (Wales) Regulations 2022.

(2) These Regulations—

(a) extend to England and Wales;

(b) apply in relation to Wales;

(c) come into force on 24 November 2022.

Commencement Information

I1 Reg. 1 in force at 24.11.2022, see **reg. 1(2)(c)**

Interpretation

2.—(1) In these Regulations—

(**1**) EUR 2003/1831, amended by S.I. 2019/654 and 2022/377. S.I. 2019/654 was amended by S.I. 2020/1504. The terms "prescribe" and "appropriate authority" are defined in Article 2 of EUR 2003/1831.

(**2**) EUR 2002/178, amended by S.I. 2019/641. S.I. 2019/641 was amended by S.I 2020/1504.

"Regulation 1831/2003" ("*Rheoliad 1831/*2003") means Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;

"Regulation 767/2009" ("*Rheoliad 767/*2009") means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed(**3**).

(2) Any expression used both in these Regulations and in Regulation 1831/2003 or Regulation 767/2009 has the same meaning as it has in **[**[F1]Regulation 1831/2003 or Regulation 767/2009, respectively**]**.

Textual Amendments

F1 Words in reg. 2(2) substituted (1.1.2024) by The Retained EU Law (Revocation and Reform) Act 2023 (Consequential Amendments) (Wales) Regulations 2023 (S.I. 2023/1332), regs. 1(2), **25**

Commencement Information

I2 Reg. 2 in force at 24.11.2022, see **reg. 1(2)(c)**

Authorisations

3.—(1) Schedules 1 to 11 contain authorisations of feed additives.

(2) Subject to Article 14(4) (renewal of authorisation) of Regulation 1831/2003, the authorisations set out in Schedules 1 to 11 cease to have effect at the end of 23 November 2032.

Commencement Information

I3 Reg. 3 in force at 24.11.2022, see **reg. 1(2)(c)**

Amendment of existing *Bacillus velezensis* ATCC PTA-6737 authorisations

4.—(1) Commission Implementing Regulation (EU) No 306/2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) for weaned piglets and weaned Suidae other than *Sus scrofa domesticus*(**4**) is amended as follows.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for "*Bacillus subtilis",* in each place it occurs, substitute "*Bacillus velezensis"*.

5.—(1) Commission Implementing Regulation (EU) No 787/2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding(**5**) is amended as follows.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for "*Bacillus subtilis*", in each place it occurs, substitute "*Bacillus velezensis*".

6.—(1) Commission Implementing Regulation (EU) 2015/1020 concerning the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying(**6**) is amended as follows.

(**3**) EUR 2009/767, amended by S.I. 2019/654. S.I 2019/654 was amended by S.I. 2020/1504.
(**4**) EUR 2013/306.
(**5**) EUR 2013/787.
(**6**) EUR 2015/1020.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for "*Bacillus subtilis*" in each place it occurs substitute "*Bacillus velezensis*".

7.—(1) Commission Implementing Regulation (EU) 2017/2276 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for sows(**7**) is amended as follows.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for "*Bacillus subtilis*", in each place it occurs, substitute "*Bacillus velezensis*".

Commencement Information

I4 Reg. 4 in force at 24.11.2022, see **reg. 1(2)(c)**
I5 Reg. 5 in force at 24.11.2022, see **reg. 1(2)(c)**
I6 Reg. 6 in force at 24.11.2022, see **reg. 1(2)(c)**
I7 Reg. 7 in force at 24.11.2022, see **reg. 1(2)(c)**

Revocations

8. The instruments listed in Schedule 12 are revoked.

Commencement Information

I8 Reg. 8 in force at 24.11.2022, see **reg. 1(2)(c)**

Transitional provisions: *Saccharomyces cerevisiae* CNCM I-4407 (formerly *Saccharomyces cerevisiae* NCYC Sc 47) (identification number 4b1702)

9.—(1) The relevant feed additive and premixtures containing it, which are produced and labelled before the end of 23 May 2023 in accordance with the conditions of the prior authorisation may continue to be placed on the market and used until the existing stocks are exhausted.

(2) Compound feed and feed materials containing the relevant feed additive and intended for food-producing animals, which are produced and labelled before the end of 23 November 2023 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(3) In this regulation—

"relevant feed additive" ("*chwanegyn bwyd anifeiliaid perthnasol*") refers to the feed additive *Saccharomyces cerevisiae* CNCM I-4407, or as formerly designated, *Saccharomyces cerevisiae* NCYC Sc 47, with the identification number 4b1702, which was previously authorised under the prior authorisation;

"the prior authorisation" ("*yr awdurdodiad ymlaen llaw*") refers to the authorisation contained in Commission Regulation (EU) Regulation No 883/2010 concerning the authorisation of a new use of *Saccharomyces cerevisiae* NCYC Sc 47 as a feed additive for calves for rearing(**8**).

(**7**) EUR 2017/2276.
(**8**) EUR 2010/883. This Regulation is revoked by regulation 8 of these Regulations.

Commencement Information

I9 Reg. 9 in force at 24.11.2022, see **reg. 1(2)(c)**

Transitional provisions: *Bacillus velezensis* ATCC PTA-6737 (formerly *Bacillus subtilis* ATCC PTA-6737) (identification number 4b1823)

10.—(1) Any substance or product labelled "*Bacillus subtilis* ATCC PTA-6737" or as containing "*Bacillus subtilis* ATCC PTA-6737", but otherwise produced and labelled in accordance with an authorisation contained in an instrument mentioned in regulations 4 to 7, may continue to be placed on the market and used under that authorisation.

(2) The relevant feed additive and premixtures containing it, which are produced and labelled before the end of 23 May 2023 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(3) Compound feed and feed materials containing the relevant feed additive and intended for food-producing animals, which are produced and labelled before the end of 23 November 2023 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(4) Compound feed and feed materials containing the relevant feed additive and intended for non-food-producing animals, which are produced and labelled before the end of 23 November 2024 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(5) In this regulation—

"relevant feed additive" ("*ychwanegyn bwyd anifeiliaid* perthnasol") refers to the feed additive *Bacillus velezensis* ATCC PTA-6737 or, as formerly designated, *Bacillus subtilis* ATCC PTA-6737, with the identification number 4b1823, which was previously authorised under the prior authorisation;

"the prior authorisation" ("*yr awdurdodiad ymlaen llaw*") refers to an authorisation contained in—

Commission Regulation (EU) No 107/2010 concerning the authorisation of *Bacillus subtilis* ATCC PTA-6737 as a feed additive for chickens for fattening (**9**), or

Commission Implementing Regulation (EU) No 885/2011 concerning the authorisation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches(**10**).

Commencement Information

I10 Reg. 10 in force at 24.11.2022, see **reg. 1(2)(c)**

(**9**) EUR 2010/107. This Regulation is revoked by regulation 8 of these Regulations.
(**10**) EUR 2011/885. This Regulation is revoked by regulation 8 of these Regulations.

Transitional provision: Decoquinate (Deccox®) (identification number 51756i (formerly E756))

11.—(1) The relevant feed additive and feed containing it, which are produced and labelled before the end of 23 May 2023 in accordance with the conditions of the prior authorisation may, continue to be placed on the market and used until the existing stocks are exhausted.

(2) In this regulation—

"relevant feed additive" ("*ychwanegyn bwyd anifeiliaid perthnasol*") refers to the feed additive Decoquinate (Deccox®)which was previously authorised under the prior authorisation with the identification number E756;

"the prior authorisation" ("*yr awdurdodiad ymlaen* llaw") refers to the authorisation contained in Commission Regulation (EC) No 1289/2004 concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances(**11**).

Commencement Information

I11 Reg. 11 in force at 24.11.2022, see **reg. 1(2)(c)**

Lynne Neagle
Deputy Minister for Mental Health and Wellbeing, under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

31 October 2022

(**11**) EUR 2004/1289. This Regulation is revoked by regulation 8 of these Regulations.

SCHEDULE 1

Regulation 3(1)

Authorisation of a preparation of manganese chelate of lysine and glutamic acid (identification number 3b509) as a feed additive for all animal species

Commencement Information

I12 Sch. 1 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, belonging to the additive category "nutritional additives" and to the functional group "compounds of trace elements", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	Manganese chelate of lysine and glutamic acid
Identification number of the additive	3b509
Authorisation holder	None specified
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	A preparation of chelates of manganese with lysine and chelates of manganese with glutamic acid in a ratio of 1:1 as a powder with the following components: • Manganese 15-17% • Lysine 20-21.5% • Glutamic acid 22-24% • Moisture 3.5% maximum • Nickel 4 ppm maximum
Characterisation of the active substance(s)	Manganese-2,6-diaminohexanoic acid, chloride and hydrogen sulphate salt ($C_6H_{19}ClN_2O_8SMn$)Manganese-2-aminopentanedioic acid, sodium and hydrogen sulphate salt ($C_5H_{10}NN_aO_9SMn$)
Analytical methods[1]	For quantification of total manganese in the feed additive: Atomic Absorption Spectrometry (AAS) (BS EN ISO 6869:2001[2]), or Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017[4]).
	For quantification of total manganese in premixtures: • Atomic Absorption Spectrometry (AAS) (BS EN ISO 6869:2001[2]), • Inductively Coupled Plasma-Atomic Emission Spectrometry (ICP-AES) (BS EN 15510:2017[3]), • Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017[4]), or • Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) (BS EN 17053:2018[5]).

	For quantification of total manganese in feed materials and compound feed: • Atomic Absorption Spectrometry (AAS) – Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 4-C)(**12**), • Atomic Absorption Spectrometry (AAS) (BS EN ISO 6869:2001[(2)]), • Inductively Coupled Plasma-Atomic Emission Spectrometry (ICP-AES) (BS EN 15510:2017[(3)]), • Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017[(4)]), or • Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) (BS EN 17053:2018[(5)]).
	For quantification of lysine and glutamic acid content in the feed additive: • Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) (BS EN ISO 13903:2005[(6)]).
	For determination of the chelated form of the feed additive: • Mid-infrared (IR) spectrometry together with the determination of the content of trace element and lysine and glutamic acid in the feed additive.
Species or category of animal	All animal species
Maximum age	None
Minimum content[(7)]	None
Maximum content[(7)]	Fish: 100mg/kg (total)
	All other animal species: 150mg/kg (total)
Other provisions	The feed additive must be incorporated into the feed in the form of a premixture.

(1) Details of the analytical methods are set out in the document referenced "Ares(2018)3918699 - 24/07/2018" and the document referenced "Ares(2019)7167892 - 20/11/2019" and last updated 28 January 2020. These documents are available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2018-0009?search&form-return

(2) Under reference BS EN ISO 6869:2001 "Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry". Published by the British Standards Institution on 15 March 2001 (ISBN 0 580 36933 1). Available from the British Standards Institution https://knowledge.bsigroup.com.

(3) Under reference BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES". Published by the British Standards Institution on 30 August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution https://knowledge.bsigroup.com.

(4) Under reference BS EN 15621:2017 "Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution https://knowledge.bsigroup.com.

(**12**) EUR 2009/152, to which there amendments not relevant to these Regulations.

(5) Under reference BS EN 17053:2018 "Animal feeding stuffs: Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)". Published by the British Standards Institution on 28 February 2018 (978 0 580 94471 0). Available from the British Standards Institution https://knowledge.bsigroup.com.

(6) Under reference BS EN ISO 13903:2005 "Animal feeding stuffs. Determination of amino acids content". Published by the British Standards Institution on 24 October 2005 (ISBN 0 580 46218 8). Available from the British Standards Institution https://knowledge.bsigroup.com.

(7) Content of element (Mn) in mg/kg of complete feed with a moisture content of 12%.

SCHEDULE 2

Regulation 3(1)

Authorisation of a preparation of *Lactobacillus buchneri*DSM 29026 (identification number 1k20759) as a feed additive for all animal species

Commencement Information

I13 Sch. 2 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, belonging to the additive category "technological additives" and to the functional group "silage additives", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	*Lactobacillus buchneri* DSM 29026
Identification number of the additive	1k20759
Authorisation holder	None specified
Additive category	Technological additives
Functional group	Silage additives
Additive composition	Preparation of *Lactobacillus buchneri* DSM 29026 containing a minimum of 2×10^{10} CFU/g additive
Characterisation of the active substance(s)	Viable cells of *Lactobacillus buchneri* DSM 29026
Analytical methods[(1)]	For enumeration (colony count) of the feed additive: • Spread plate method on MRS agar (BS EN 15787:2021[(2)]).
	For identification of bacterial strain: • Pulsed Field Gel Electrophoresis (PFGE).
Species or category of animal	All animal species
Maximum age	None
Minimum content[(3)]	Minimum content of the feed additive when not combined with other micro-organisms as silage additives: 5×10^7 CFU/kg of easy and moderately difficult to ensile fresh material[(4)]
Maximum content[(3)]	None

Other provisions	In the directions for use of the feed additive and premixtures, the storage conditions must be indicated.

(1) Details of the analytical methods set out in the document referenced "Ares(2019)4747322 - 22/07/2019" and last updated 18 October 2019. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2018-0093.

(2) Under reference BS EN 15787:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Lactobacillus spp. used as feed additive". Published by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7). Available from the British Standards Institution https://knowledge.bsigroup.com.

(3) Content of element *Lactobacillus buchneri* DSM 29026 in CFU of additive/kg of fresh material.

(4) Easy to ensile forage: > 3% soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in the fresh material in accordance with Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives13.

SCHEDULE 3

Regulation 3(1)

Authorisation of a preparation of serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* DSM 19670 (identification number 4a13) as a feed additive for chickens for fattening

Commencement Information

I14 Sch. 3 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, belonging to the additive category "zootechnical additives" and to the functional group "digestibility enhancers", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	Serine protease (EC 3.4.21.-)
Identification number of the additive	4a13
Authorisation holder	DSM Nutritional Products Ltd (Switzerland)
Additive category	Zootechnical additives
Functional group	Digestibility enhancers
Additive composition	Solid and liquid preparation of serine protease (EC 3.4.21.-): • produced by *Bacillus licheniformis* DSM 19670 • having a minimum activity of 75,000 PROT[(1)]/g

(1) One PROT is the amount of serine protease that liberates one micromole/minute of para-nitroaniline (pNA) from 1 millimolar (mM) Suc-Ala-Ala-Pro-Phe-pNA substrate at pH 9 & 37°C.

(2) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(3) European Inventory of Existing Commercial Substances, number as published in OJ No C 146 A, 15.6.90, p.1.

(4) Identification number assigned by the International Union of Biochemistry (IUB), now the International Union of Biochemistry and Molecular Biology (IUBMB) iubmb.org.

(5) Details of the analytical methods set out in the document referenced "Ares(2019)6802984 - 04/11/2019" and last updated 27 January 2020. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0010.

(6) Content of Serine protease in PROT/kg of complete feed with a moisture content of 12%.

Characterisation of the active substance(s)	• Serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* DSM 19670 • CAS number[(2)]: 37259-58-8 (serine protease) • EINECS number[(3)]: 253-431-3 • IUB number[(4)]: 3.4.21.-
Analytical methods[(5)]	For quantification of serine protease activity in the feed additive, premixtures, compound feed and feed materials: • Colourimetric method based on the enzymatic reaction of serine protease on the Suc-Ala-Ala-Pro-Phe-pNA substrate.
Species or category of animal	Chickens for fattening
Maximum age	None
Minimum content[(6)]	15,000 PROT[(1)]/kg
Maximum content[(6)]	None
Other provisions	In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

(1) One PROT is the amount of serine protease that liberates one micromole/minute of para-nitroaniline (pNA) from 1 millimolar (mM) Suc-Ala-Ala-Pro-Phe-pNA substrate at pH 9 & 37°C.

(2) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(3) European Inventory of Existing Commercial Substances, number as published in OJ No C 146 A, 15.6.90, p.1.

(4) Identification number assigned by the International Union of Biochemistry (IUB), now the International Union of Biochemistry and Molecular Biology (IUBMB) iubmb.org.

(5) Details of the analytical methods set out in the document referenced "Ares(2019)6802984 - 04/11/2019" and last updated 27 January 2020. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0010.

(6) Content of Serine protease in PROT/kg of complete feed with a moisture content of 12%.

SCHEDULE 4

Regulation 3(1)

Renewal of authorisation of pyridoxine hydrochloride (vitamin B_6) (identification number 3a831) as a feed additive for all animal species

Commencement Information

I15 Sch. 4 in force at 24.11.2022, see **reg. 1(2)(c)**

The substance specified in the table, belonging to the additive category "nutritional additives" and to the functional group "vitamins, pro-vitamins and chemical well-defined substances having a similar effect", is authorised as an additive in animal nutrition subject to the conditions set out in the table(**14**).

Additive	Pyridoxine hydrochloride (vitamin B_6)

(**14**) This authorisation is a renewal of the authorisation granted under Commission Implementing Regulation (EU) No 515/2011. That Regulation is revoked by regulation 8 of these Regulations.

Identification number of the additive	3a831
Authorisation holder	None specified
Additive category	Nutritional additives
Functional group	Vitamins, pro-vitamins and chemically well-defined substances having similar effect
Additive composition	Pyridoxine hydrochloride, with a purity criteria not less than 98.5%
Characterisation of the active substance(s)	• Pyridoxine hydrochloride: $C_8H_{11}NO_3 \cdot HCl$ • CAS number[(1)]: 58-56-0 • EINECS number[(2)]: 200-386-2
Analytical methods[(3)]	For determination of pyridoxine hydrochloride (vitamin B_6) in the feed additive: • Titration with perchloric acid (Ph. Eur. 10th edition, monograph 0245[(4)]).
	For determination of pyridoxine hydrochloride (vitamin B_6) in premixtures: • Reversed phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) (VDLUFA 13.9.1[(5)]).
	For determination of pyridoxine hydrochloride (vitamin B_6) in feed and water: • Reversed phase High Performance Liquid Chromatography coupled to fluorescence detector (RP-HPLC-FLD) – method based on BS EN 14164:2014[(6)].
Species or category of animal	All animal species
Maximum age	None
Minimum content[(7)]	None
Maximum content[(7)]	None
Other provisions	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment and in water must be indicated.
	2. Pyridoxine hydrochloride (vitamin B_6) may be used via water for drinking.

(1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(2) European Inventory of Existing Commercial Substances, number as published in OJ No C 146 A, 15.6.90, p.1.

(3) Details of the analytical methods set out in the document referenced "JRC.DG.D.6/CvH/GB/ag/ARES(2011)356822" and last updated 6 June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0139.

(4) European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 10th edition. Published 1 July 2019 (ISBN 9789999146111).

(5) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method Book, Volume III, 6th supplement 2006, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6), https://vdlufa.de.

(6) Under reference BS EN 14164:2014 "Foodstuffs. Determination of vitamin B_6 by high performance chromatography". Published by the British Standards Institution on 30 June 2014 (ISBN 978 0 580 77941 1). Available from the British Standards Institution https://knowledge.bsigroup.com.

(7) Content of pyridoxine hydrochloride(vitamin B_6) in mg of additive/kg of complete feed with a moisture content of 12%.

SCHEDULE 5

Regulation 3(1)

Renewal of authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 (formerly *Saccharomyces cerevisiae* NCYC Sc 47) (identification number 4b1702) as a feed additive for calves for rearing

Commencement Information

I16 Sch. 5 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, 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(**15**).

Additive	*Saccharomyces cerevisiae* CNCM I-4407
Identification number of the additive	4b1702
Authorisation holder	S.I. Lesaffre
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Solid form preparation of *Saccharomyces cerevisiae* CNCM I-4407 containing a minimum of $5x10^9$ CFU/g
Characterisation of the active substance(s)	Viable dried cells *Saccharomyces cerevisiae* CNCM I-4407
Analytical methods[(1)]	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: • Pour plate method using CGYE (chloramphenicol, glucose, yeast extract) agar (BS EN 15789:2021[(2)]).
	For identification of yeast strain: • Polymerase chain reaction (PCR) method (DD CEN/TS 15790:2008[(3)]).
Species or category of animal	Calves for rearing
Maximum age	None
Minimum content[(4)]	1.5×10^9 CFU/kg

(15) This authorisation is a renewal of the authorisation granted under Commission Regulation (EU) No 883/2010. That Regulation is revoked by regulation 8 of these Regulations but see the transitional provision in regulation 9.

Maximum content[4]	None
Other provisions	In the directions of use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

(1) Details of the analytical methods set out in the document referenced "JRC.DG.D.6/CvH/DM/mds/ARES(2010)967257" and last updated 6 June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0038.

(2) Under reference BS EN 15789:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Saccharomyces cerevisiae used as feed additive". Published by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99832 4). Available from the British Standards Institution https://knowledge.bsigroup.com.

(3) Under reference DD CEN/TS 15790:2008 "Animal Feeding Stuffs – PCR typing of probiotic strains of Sacccharomyces cerevisiae (yeast)". Published by British Standards Institution on 31 January 2009 (ISBN 978 0 580 61806 2). Available from the British Standards Institution https://knowledge.bsigroup.com.

(4) Content of *Saccharomyces cerevisiae* CNCM I-4407 in CFU/kg of complete feed with a moisture content of 12%.

SCHEDULE 6

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of *Bacillus velezensis* ATCC PTA-6737 (formerly *Bacillus Subtilis* ATCC PTA-6737) (identification number 4b1823) as a feed additive for chickens for fattening, chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches, and its authorisation as a feed additive extending existing uses to cover all minor poultry species (except for laying), ornamental birds, sporting birds and game birds

Commencement Information

I17 Sch. 6 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, 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(**16**).

Additive	*Bacillus velezensis* ATCC PTA-6737
Identification number of the additive	4b1823
Authorisation holder	Kemin Europa N.V.
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers

(1) Details of the analytical methods set out in the document referenced "D08/FSQ/CVH/SY/Ares(2009)61627" and last updated 6 June 2016. This document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0039.

(2) This method is not suitable for the detection of *Bacillus velezensis* ATCC PTA-6737 in feed materials and compound feed at concentrations below the minimum content level.

(3) Content of *Bacillus velezensis* ATCC PTA-6737 in CFU/kg of complete feed with a moisture content of 12%.

(**16**) This authorisation is a renewal of the authorisations granted under Commission Regulation (EU) No 107/2010 and Commission Implementing Regulation (EU) No 885/2011. Those Regulations are revoked by regulation 8 of these Regulations but see the transitional provision in regulation 10.

Additive composition	Preparation of *Bacillus v*elezensis ATCC PTA-6737 containing a minimum of 8 x 10^{10} CFU/g additive
Characterisation of the active substance(s)	Viable spores of *Bacillus velezensis* ATCC PTA-6737
Analytical methods[(1)]	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: • Spread plate method using tryptone soya agar with pre-heat treatment of feed samples[(2)].
	For identification of bacterial strain: Pulsed-field gel electrophoresis (PFGE).
Species or category of animal	• Chickens for fattening • Chickens reared for laying • Minor poultry species (except for laying) • Ornamental birds • Sporting birds • Game birds
Maximum age	None
Minimum content[(3)]	1 x 10^7 CFU/kg
Maximum content[(3)]	None
Other provisions	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. If *Bacillus velezensis* ATCC PTA-6737 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: • Decoquinate • Diclazuril • Lasalocid A sodium • Maduramicin ammonium • Monensin sodium • Narasin • Narasin/Nicarbazin (as combined use only) • Robenidine hydrochloride • Salinomycin sodium

(1) Details of the analytical methods set out in the document referenced "D08/FSQ/CVH/SY/Ares(2009)61627" and last updated 6 June 2016. This document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0039.

(2) This method is not suitable for the detection of *Bacillus velezensis* ATCC PTA-6737 in feed materials and compound feed at concentrations below the minimum content level.

(3) Content of *Bacillus velezensis* ATCC PTA-6737 in CFU/kg of complete feed with a moisture content of 12%.

SCHEDULE 7

Regulation 3(1)

Authorisation of a preparation of *Bacillus licheniformis* DSM 28710 (identification number 4b1828) as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds

Commencement Information

I18 Sch. 7 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, 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.

Additive	*Bacillus licheniformis* DSM 28710
Identification number of the additive	4b1828
Authorisation holder	HuvePharma NV
Additive category	Zootechnical feed additive
Functional group	Gut flora stabilisers
Additive composition	Solid form preparation of *Bacillus licheniformis* DSM 28710 containing a minimum of 3.2×10^9 CFU/g of additive
Characterisation of the active substance(s)	Viable spores of *Bacillus licheniformis* DSM 28710
Analytical methods[(1)]	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: • Spread plate method (BS EN 15784:2021[(2)]).
	For identification of bacterial strain: • Pulsed Field Gel Electrophoresis (PFGE).
Species or category of animal	• Laying hens • Minor poultry species for laying • Poultry species for breeding • Ornamental birds
Maximum age	None
Minimum content[(3)]	1.6×10^9 CFU/kg
Maximum content[(3)]	None
Other provisions	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

(1) Details of the analytical methods set out in the document referenced "Ares(2015)4524025 – 23/10/2015" and last updated 6 June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2015-0016.

(2) Under reference BS EN 15784:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Bacillus spp. Used as feed additive". Published by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99829 4). Available from the British Standards Institution https://knowledge.bsigroup.com.

(3) Content of *Bacillus licheniformis* DSM 28710 in CFU/kg of complete feed with a moisture content of 12%.

	2. If *Bacillus licheniformis* DSM 28710 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: • Diclazuril • Lasalocid A sodium

(1) Details of the analytical methods set out in the document referenced "Ares(2015)4524025 – 23/10/2015" and last updated 6 June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2015-0016.

(2) Under reference BS EN 15784:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Bacillus spp. Used as feed additive". Published by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99829 4). Available from the British Standards Institution https://knowledge.bsigroup.com.

(3) Content of *Bacillus licheniformis* DSM 28710 in CFU/kg of complete feed with a moisture content of 12%.

SCHEDULE 8

Regulation 3(1)

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

Commencement Information

I19 Sch. 8 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, 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(**17**).

Additive	*Clostridium butyricum* FERM BP-2789
Identification number of the additive	4b1830
Authorisation holder	Miyarisan Pharmaceutical Co Ltd
Additive category	Zootechnical additive
Functional group	Gut flora stabilisers

(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 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.

(2) Under reference 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 16 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 in CFU/kg of complete feed with a moisture content of 12%.

(**17**) This authorisation is a renewal of the authorisations granted under Commission Implementing Regulations (EU) No 373/2011, No 374/2013 and No 1108/2014. Those Regulations are revoked by regulation 8 of these Regulations.

Additive composition	Solid form preparation of *Clostridium butyricum* FERM BP-2789 containing a minimum of 5×10^8 CFU/g of additive
Characterisation of the active substance(s)	Viable spores of *Clostridium butyricum* FERM BP-2789
Analytical methods[(1)]	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: • Pour plate method based on BS ISO 15213:2003[(2)].
	For identification of bacterial strain: • Pulsed-field gel electrophoresis (PFGE).
Species or category of animal	• 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)
Maximum age	None
Minimum content[(3)]	For turkeys for fattening and turkeys reared for breeding: 1.25×10^8 CFU/kg
	For the other species/categories: 2.5×10^8 CFU/kg
Maximum content[(3)]	None
Other provisions	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. If *Clostridium butyricum* 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: • Decoquinate • Diclazuril • Lasalocid A sodium • Maduramicin ammonium • Monensin sodium • Narasin • Narasin/Nicarbazin (as combined use) • Robenidine hydrochloride • Salinomycin sodium • 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 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.

(2) Under reference 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 16 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 in CFU/kg of complete feed with a moisture content of 12%.

SCHEDULE 9

Regulation 3(1)

Authorisation of a preparation of 6-phytase (EC 3.1.3.26) (identification number 4a32) as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows, minor porcine species for fattening or reproduction

Commencement Information

I20 Sch. 9 in force at 24.11.2022, see **reg. 1(2)(c)**

The preparation specified in the table, belonging to the additive category "zootechnical additives" and to the functional group "digestibility enhancers", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	6-phytase (EC 3.1.3.26)
Identification number of the additive	4a32
Authorisation holder	Huvepharma EOOD
Additive category	Zootechnical additives
Functional group	Digestibility enhancers
Additive composition	Preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella phaffii* DSM 32854 with a minimum activity of 5000 FTU [(1)]/g in granular, coated or liquid forms
Characterisation of the active substance(s)	6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* DSM 32854
Analytical methods[(2)]	For quantification of phytase activity in the feed additive: • Colorimetric method based on the enzymatic reaction of phytase on the phytate (VDLUFA 27.1.4[(3)]).
	For quantification of phytase activity in premixtures: • Colorimetric method based on the enzymatic reaction of phytase on the phytate (VDLUFA 27.1.3[(4)]).
	For quantification of phytase activity in feed materials and compound feed: • Colorimetric method based on the enzymatic reaction of phytase on the phytate (BS EN ISO 30024:2009[(5)]).
Species or category of animal	• All poultry species • Ornamental birds • Piglets • Pigs for fattening • Sows • Minor porcine species for fattening or reproduction
Maximum age	None
Minimum content[(6)]	250 FTU/kg
Maximum content[(6)]	None

Other provisions	In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

(1) FTU = phytase enzyme units. One FTU is the amount of enzyme that releases 1 micromole (µm) of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5.5 and 37°C.

(2) Details of the analytical methods set out in the document referenced "Ares(2020)762221 – 06/02/2020" and last updated 4 May 2020. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0052.

(3) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method Book, Volume III, New single methods 2016, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6), https://vdlufa.de.

(4) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method Book, Volume III, 8th supplement 2012, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6), https://vdlufa.de.

(5) Under reference BS EN ISO 30024:2009 "Animal feeding stuffs. Determination of phytase activity". Published by the British Standards Institution on 30 September 2009 (ISBN 978 0 580 62651 7). Available from the British Standards Institution https://knowledge.bsigroup.com.

(6) Content of 6-phytase in FTU/kg of complete feed with a moisture content of 12%.

SCHEDULE 10

Regulation 3(1)

Authorisation of decoquinate (Deccox®) (identification number 51756i) as a feed additive for chickens for fattening

Commencement Information

I21 Sch. 10 in force at 24.11.2022, see **reg. 1(2)(c)**

The substance decoquinate specified in the table, belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition subject to the conditions set out in the table(**18**).

Additive	Decoquinate (Deccox®)
Identification number of the additive	51756i
Authorisation holder	Zoetis Belgium SA
Additive category	Coccidiostats and Histomonostats
Functional group	None
Additive composition	• Decoquinate, 60.0 g/kg • Refined deodorised soya oil, 28.5 g/kg • Colloidal silica, 0.6 g/kg • Wheat middlings, q.s. 1kg
Characterisation of the active substance(s)	Decoquinate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate)

(18) This authorisation replaces the authorisation of decoquinate (Deccox®) under Commision Regulation (EC) No 1289/2004. That Regulation is revoked by regulation 8 of these Regulations but see the transitional provision in regulation 11. See also Schedule 11 to these Regulations, which contains a separate re-authorisation of decoquinate (Deccox®), but in a modified form - decoquinate (Avi-Deccox® 60G).

	• Chemical formula: $C_{24}H_{35}NO_5$ • CAS number[(1)]: 18507-89-6
	Related impurities: • Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1.0% • 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0.5% • Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate: < 0.5%
Analytical methods[(2)]	For quantification of decoquinate in the feed additive, premixtures, feed materials and compound feed: • Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) (BS EN 16162:2012[(3)]).
	For quantification of decoquinate in tissues: • Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS[(4)]).
Species or category of animal	Chickens for fattening
Maximum age	None
Minimum content[(5)]	30 mg/kg
Maximum content[(5)]	40 mg/kg
Other provisions	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. The feed additive must be incorporated in compound feed in the form of a premixture.
	3. Decoquinate must not be mixed with other coccidiostats.
	4. Decoquinate must not be used in feed containing bentonite.
	5. A post-market monitoring programme must be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp. A report containing the outcome of that programme must be submitted to the Welsh Ministers by the end of 23 November 2031.

(1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(2) Details of the analytical methods set out in the document referenced "Ares(2013)3639174 - 04/12/2013 " and last updated 6 June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2013-0034.

(3) Under reference BS EN 16162:2012 "Animal feeding stuffs. Determination of decoquinate by HPLC with fluorescence detection". Published by the British Standards Institution on 31 March 2012 (ISBN 978 0 580 67002 2). Available from the British Standards Institution https://knowledge.bsigroup.com.

(4) "Safety and efficacy of Deccox® (decoquinate) for chickens for fattening". Published by the European Food Safety Authority (EFSA) in the EFSA Journal, Volume 17, Issue 1 on 14 January 2019. This document is available at the following address: https://www.efsa.europa.eu/en/efsajournal/pub/5541.

(5) Content of decoquinate (Deccox®) in mg/kg of complete feed with a moisture content of 12%.

SCHEDULE 11

Regulation 3(1)

Authorisation of decoquinate (Avi-Deccox® 60G) (identification number 51756ii) as a feed additive for chickens for fattening

Commencement Information

I22 Sch. 11 in force at 24.11.2022, see **reg. 1(2)(c)**

The substance decoquinate specified in the table, belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition subject to the conditions set out in the table(**19**).

Additive	Decoquinate (Avi-Deccox® 60G)
Identification number of the additive	51756ii
Authorisation holder	Zoetis Belgium SA
Additive category	Coccidiostats and histomonostats
Functional group	None
Additive composition	• Decoquinate, 60.0 g/kg • Colloidal silica, 0.6 g/kg • Silicon dioxide, 4.0 g/kg • Carboxymethylcellulose sodium, 30.0 g/kg • Calcium sulphate dihydrate, q.s. ad 1kg
Characterisation of the active substance(s)	Decoquinate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate) • Chemical formula: $C_{24}H_{35}NO_5$ • CAS number[(1)]: 18507-89-6
	Related impurities: • Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1.0% • 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0.5% • Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate: < 0.5%
Analytical methods[(2)]	For quantification of decoquinate in the feed additive, premixtures, feed materials and compound feed: • Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) (BS EN 16162:2012[(3)]).
	For quantification of decoquinate in tissues: • Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS[(4)]) or any other analytical method complying with the requirements set by Commission Decision 2002/657/EC

(19) This authorisation is for a modified form of decoquinate (Deccox®), which was previously authorised under Commission Regulation (EC) No 1289/2004, and now authorised under Schedule 10 to these Regulations.

	concerning the performance of analytical methods and the interpretation of results(**20**).
Species or category of animal	Chickens for fattening
Maximum age	None
Minimum content[5]	30 mg/kg
Maximum content[5]	40 mg/kg
Other provisions	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. The feed additive must be incorporated in compound feed in the form of a premixture.
	3. Decoquinate must not be mixed with other coccidiostats.
	4. Decoquinate must not be used in feed containing bentonite.
	5. A post-market monitoring programme must be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp. A report containing the outcome of that programme must be submitted to the Welsh Ministers by the end of 23 November 2031.

(1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(2) Details of the analytical methods set out in the document referenced "Ares(2014)2704635 - 18/08/2014" and "JRC.D.5/SFB/CvH/MGH /mds/Ares" and last updated 6 June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2014-0014.

(3) Under reference BS EN 16162:2012 "Animal feeding stuffs. Determination of decoquinate by HPLC with fluorescence detection". Published by the British Standards Institution on 31 March 2012 (ISBN 978 0 580 67002 2). Available from the British Standards Institution https://knowledge.bsigroup.com.

(4) "Safety and efficacy of Deccox® (decoquinate) for chickens for fattening". Published by the European Food Safety Authority (EFSA) in the EFSA Journal, Volume 17, Issue 1 on 14 January 2019. This document is available at the following address: https://www.efsa.europa.eu/en/efsajournal/pub/5541.

(5) Content of decoquinate (Avi-Deccox®) in mg/kg of complete feed with a moisture content of 12%.

SCHEDULE 12

Regulation 8

Revocation of retained direct EU legislation

Commencement Information

I23 Sch. 12 in force at 24.11.2022, see **reg. 1(2)(c)**

Commission Regulation (EC) No 1289/2004 concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances(**21**).

(**20**) EUD 2002/657, amended by S.I. 2020/1461.
(**21**) EUR 2004/1289.

Commission Regulation (EC) No 903/2009 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)(**22**).

Commission Regulation (EU) No 8/2010 concerning the authorisation of the serine protease produced by *Bacillus licheniformis* (DSM 19670) as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp.Z.o.o)(**23**).

Commission Regulation (EU) No 107/2010 concerning the authorisation of *Bacillus subtilis* ATCC PTA-6737 as a feed additive for chickens for fattening (holder of authorisation Kemin Europa NV)(**24**).

Commission Regulation (EU) No 883/2010 concerning the authorisation of a new use of *Saccharomyces cerevisiae* NCYC Sc 47 as a feed additive for calves for rearing (holder of the authorisation Société industrielle Lesaffre)(**25**).

Commission Regulation (EU) No 168/2011 amending Regulation (EU) No 107/2010 as regards the use of the feed additive *Bacillus subtilis* ATCC PTA-6737 in feed containing maduramycin ammonium, monensin sodium, narasin, or robenidine hydrochloride(**26**).

Commission Implementing Regulation (EU) No 373/2011 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 Huvepharma NV Belgium)(**27**).

Commission Implementing Regulation (EU) No 515/2011 concerning the authorisation of vitamin B_6 as a feed additive for all animal species(**28**).

Commission Implementing Regulation (EU) No 885/2011 concerning the authorisation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches (holder of authorisation Kemin Europa NV)(**29**).

Commission Implementing Regulation (EU) No 357/2013 amending Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 as regards the minimum content of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for chickens for fattening and minor avian species (excluding laying birds) (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.)(**30**).

Commission Implementing Regulation (EU) No 374/2013 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for chickens reared for laying (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)(**31**).

Commission Implementing Regulation (EU) No 291/2014 amending Regulation (EC) No 1289/2004 as regards the withdrawal time and maximum residues limits of the feed additive decoquinate(**32**).

(**22**) EUR 2009/903.
(**23**) EUR 2010/8.
(**24**) EUR 2010/107
(**25**) EUR 2010/883.
(**26**) EUR2011/168.
(**27**) EUR 2011/373.
(**28**) EUR 2011/515.
(**29**) EUR 2011/885.
(**30**) EUR 2013/357.
(**31**) EUR 2013/374.
(**32**) EUR 2014/291.

Commission Implementing Regulation (EU) No 1108/2014 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for turkeys reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)(**33**).

Commission Implementing Regulation (EU) 2017/1126 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)(**34**).

EXPLANATORY NOTE

(This note is not part of the Regulations)

The Welsh Ministers make these Regulations pursuant to Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition ("Regulation 1831/2003"). These Regulations make provision for the authorisation of eleven feed additives.

Regulation 3 and Schedules 1 to 11 provide for the authorisation of the following feed additives—

- Schedule 1 is a new authorisation, for a preparation of Manganese chelate of lysine and glutamic acid (identification number 3b509);
- Schedule 2 is a new authorisation, for a preparation of *Lactobacillus buchneri*DSM 29026 (identification number 1k20759);
- Schedule 3 is a new authorisation, for a preparation of Serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* (DSM 19670) (identification number 4a13);
- Schedule 4 is a renewal of the authorisation of Pyridoxine hydrochloride (vitamin B_6) (identification number 3a831);
- Schedule 5 is a renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 (identification number 4b1702). The name of the bacterial strain is changed from " *Saccharomyces cerevisiae* NCYC Sc 47" to "*Saccharomyces cerevisiae* CNCM I-4407";
- Schedule 6 is a renewal of the authorisation of a preparation of *Bacillus velezensis* (ATCC PTA-6737) (identification number 4b1823), and an extension of existing authorised uses to cover all minor poultry species (except for laying), ornamental birds, sporting birds and game birds. The authorisation has been modified as follows:
  - the bacterial strain name is changed from *"Bacillus subtilis"* to *"Bacillus velezensis"*;
  - the minimum content of the feed additive in the preparation is increased from $1x10^{10}$ to $8x10^{10}$ colony forming units per gram (CFU/g);
- Schedule 7 is a new authorisation of a preparation of *Bacillus licheniformis* DSM 28710 (identification number 4b1828);

(**33**) EUR 2014/1108.
(**34**) EUR 2017/1126.

- Schedule 8 is a renewal of the authorisations of a preparation of *Clostridium butyricum* (FERM BP-2789) (identification number 4b1830) and authorises it for a new use in feed for chickens for fattening, suckling piglets and minor porcine species (suckling);
- Schedule 9 is a new authoristion, for a preparation of 6-phytase produced by *Komagataella phaffii* DSM 32854 (identification number 4a32);
- Schedule 10 authorises a new formulation of decoquinate (Deccox®) (identification number E756) as decoquinate (Deccox®) (identification number 51756i);
- Schedule 11 authorises a modifed form of decoquinate (Deccox®) (identification number E756) as decoquinate (Avi-Deccox® 60G) (identification number 51756ii). This feed additive differs from decoquinate (Deccox®) in physical form and in the dilutant used being calcium sulphate dihydrate.

Regulation 3(2) provides that authorisations granted by these Regulations are valid for a period of ten years in accordance with Article 9(7) of Regulation 1831/2003. This is subject to Article 14(4) of that Regulation, which provides for an extension of the authorisation period in certain circumstances where an application for renewal has been submitted.

Regulations 4 to 7 amend four retained EU Regulations that authorise the feed additive *Bacillus subtilis* ATCC PTA-6737 for differing poultry and pig sub-groups. The name of the bacterial strain is updated from "*Bacillus subtilis"* to "*Bacillus velezensis"*. Regulation 10(1) contains a transitional provision that allows products labelled using the name "*Bacillus subtilis"* to continue to be marketed and used under the relevant authorisations despite the change to the name.

Regulation 8 and Schedule 12 revoke, in relation to Wales, retained EU Regulations that contain prior authorisations for the feed additives now authorised by Schedules 3, 4, 5, 6, 8 and 10.

Regulations 9, 10(2) to (5) and 11 contain transitional provisions that allow the continued production and labelling of products, for limited time periods, under the conditions of prior authorisations of the relevant feed additives. Those feed additives are now authorised by Schedules 5, 6 and 10 respectively.

Further information, including in relation to any documentation referenced in the Schedules, can be obtained from the Food Standards Agency, 11th Floor, Southgate House, Cardiff, CF10 1EW or by writing to regulated.products.wales@food.gov.uk.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

Changes to legislation:
There are currently no known outstanding effects for the The Feed Additives (Authorisations) (Wales) Regulations 2022.