
SCOTTISH STATUTORY INSTRUMENTS

2022 No. 288

AGRICULTURE

**The Feed Additives (Authorisations)
(Scotland) Regulations 2022**

Made - - - - 27th September 2022
*Laid before the Scottish
Parliament* - - - - 29th September 2022
Coming into force - - 24th November 2022

The Scottish Ministers make the following Regulations in exercise of the powers conferred by Articles 9(1), 13(6) 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⁾, and all other powers enabling them to do so.

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⁾.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Feed Additives (Authorisations) (Scotland) Regulations 2022 and come into force on 24 November 2022.

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations—

“Regulation (EC) 1831/2003” means Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, and

“Regulation (EC) 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, amending European Parliament and Council Regulation (EC) No. 1831/2003 and repealing Council Directive 79/373/EEC,

(1) EUR 1831/2003 as amended by S.I. 2019/654 and 2022/377. Article 9 was substituted by S.I. 2019/654 and amended by S.I. 2022/377. Article 13 was substituted and article 18A was added by S.I. 2019/654. The terms “prescribe” and “appropriate authority” are defined in Article 2 of EUR 1831/2003.

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

Commission Directive [80/511/EEC](#), Council Directives [82/471/EEC](#), [83/228/EEC](#), [93/74/EEC](#), [93/113/EC](#) and [96/25/EC](#) and Commission Decision [2004/217/EC](#)(3).

(2) Unless the contrary intention appears, any expression used both in these Regulations and in Regulation (EC) [1831/2003](#) or Regulation (EC) [767/2009](#) has the same meaning as it has in those Regulations.

Authorisations

3.—(1) The terms of modifications of authorisations in these Regulations are to be in the same form as authorisations under Article 9 of Regulation (EC) [1831/2003](#).

(2) Schedules 1 to 11 have effect.

(3) Subject to Article 14(4) (renewal of authorisation) of Regulation (EC) [1831/2003](#), the authorisations set out in schedules 1 to 11 cease to have effect at the end of 23 November 2032.

Amendment of Commission Implementing Regulation (EU) No. 306/2013

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* (holder of authorisation Kemin Europa N.V.)(4) is amended as follows.

(2) In the Annex, in the table, in the column headed—

- (a) “Additive”, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”, and
- (b) “Composition, chemical formula, description, analytical method”, for “*Bacillus subtilis*”, in each place it occurs, substitute “*Bacillus velezensis*”.

Amendment of Commission Implementing Regulation (EU) No. 787/2013

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 (holder of authorisation Kemin Europa N.V.)(5) is amended as follows.

(2) In the Annex, in the table, in the column headed—

- (a) “Additive”, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”, and
- (b) “Composition, chemical formula, description, analytical method”, for “*Bacillus subtilis*”, in each place it occurs, substitute “*Bacillus velezensis*”.

Amendment of Commission Implementing Regulation (EU) 2015/1020

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 (holder of the authorisation Kemin Europa NV)(6) is amended as follows.

(2) In the Annex, in the table, in the column headed—

- (a) “Additive”, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”, and
- (b) “Composition, chemical formula, description, analytical method”, for “*Bacillus subtilis*”, in each place it occurs, substitute “*Bacillus velezensis*”.

(3) EUR 767/2009 as amended by S.I. 2019/654. S.I. 2019/641 was amended by S.I. 2020/1504.

(4) EUR 306/2013.

(5) EUR 787/2013.

(6) EUR 2015/1020.

Amendment of Commission Implementing Regulation (EU) 2017/2276

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 (holder of the authorisation Kemin Europa N.V.)(7) is amended as follows.

(2) In the Annex, in the table, in the column headed—

- (a) “Additive”, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”, and
- (b) “Composition, chemical formula, description, analytical method”, for “*Bacillus subtilis*”, in each place it occurs, substitute “*Bacillus velezensis*”.

Transitional provision: *Saccharomyces cerevisiae* (identification number 4b1702)

8.—(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, 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” means the feed additive *Saccharomyces cerevisiae* CNCM I-4407, with the identification number 4b1702, which was previously authorised under the prior authorisation, and

“the prior authorisation” means [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)(8).

Transitional: *Bacillus velezensis* (identification number 4b1823)

9.—(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 retained direct EU legislation 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, 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, 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—

(7) EUR 2017/2276.

(8) EUR 883/2010. This Regulation is revoked by regulation 11 of these Regulations.

“relevant feed additive” means 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, and

“the prior authorisation” means—

[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)(**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 (holder of the authorisation Kemin Europa N.V.)(**10**).

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

10.—(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” means the feed additive decoquate (Deccox®), which was previously authorised under the prior authorisation with the identification number E756, and

“the prior authorisation” means [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**).

Revocations

11. The retained direct EU legislation listed in schedule 12 is revoked subject to regulations 8, 9(2) to (5) and 10.

St Andrew’s House,
Edinburgh
27th September 2022

MAREE TODD
Authorised to sign by the Scottish Ministers

(9) EUR 107/2010 as amended by EUR 168/2011. EUR 107/2010 is revoked by regulation 11 of these Regulations.

(10) EUR 885/2011. This Regulation is revoked by regulation 11 of these Regulations.

(11) EUR 1289/2004 as amended by EUR 552/2008, EUR 118/2012, EUR 1014/2013 and EUR 291/2014. EUR 1289/2004 is revoked by regulation 11 of these Regulations.

SCHEDULE 1

Regulation 3(2)

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

Authorisation

1. The preparation specified in the table in this schedule, 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 in this schedule.

Table

| <i>Column 1</i> | <i>Column 2</i> |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Additive</i> | <i>Manganese chelate of lysine and glutamic acid</i> |
| <i>Identification number of the additive</i> | 3b509 |
| <i>Authorisation holder(12)</i> | |
| <i>Additive category</i> | Nutritional additives |
| <i>Functional group</i> | Compounds of trace elements |
| <i>Additive composition</i> | 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: <ul style="list-style-type: none"> • Manganese 15-17% • Lysine 20-21.5% • Glutamic acid 22-24% • Moisture 3.5% maximum • Nickel 4 ppm maximum |
| <i>Characterisation of the active substance(s)</i> | Manganese-2,6-diaminohexanoic acid, chloride and hydrogen sulphate salt (C ₆ H ₁₉ ClN ₂ O ₈ SMn). Manganese-2-aminopentanedioic acid, sodium and hydrogen sulphate salt (C ₅ H ₁₀ NN _a O ₉ SMn). |
| <i>Analytical method(13)</i> | 1. For quantification of total manganese in the feed additive and premixtures: <ul style="list-style-type: none"> • Atomic Absorption Spectrometry (AAS) in accordance with international standard BS EN ISO 6869:2000 entitled "Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry"(14); |

(12) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.

(13) 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>.

(14) 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

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| Column 1 | Column 2 |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <ul style="list-style-type: none"> • Inductively Coupled Plasma-Atomic Emission Spectrometry, (ICP-AES) in accordance with European standard EN 15510:2017 entitled “<i>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</i>”(15) (for premixtures and feed only); or • Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) in accordance with European standard EN 15621:2017 entitled “<i>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</i>”(16). <p>2. For quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> • 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)(17); • Atomic Absorption Spectrometry, AAS in accordance with international standard BS EN ISO 6869:2001; • Inductively Coupled Plasma-Atomic Emission Spectrometry, (ICP-AES) in accordance with European standard EN 15510:2017 entitled “<i>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</i>” (for premixtures and feed only); or • Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621). <p>3. For quantification of lysine and glutamic acid in the feed additive:</p> <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS). <p>4. For proving the chelated structure of the feed additive:</p> <ul style="list-style-type: none"> • Mid-infrared (IR) spectrometry together with the determination of the content of trace element and lysine and glutamic acid in the feed additive. |
| <i>Species or category of animal</i> | All animal species |

Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. Under reference BS EN ISO 6869:2001, it was published as a UK standard by the British Standards Institution on 15 March 2001 (ISBN 0 580 36933 1).

(15) This standard was approved by the European Committee for Standardization (CEN) on 6 February 2017. Under reference BS EN 15510:2017, it was published as a UK standard by the British Standards Institution on 30 August 2017 (ISBN 978 0 580 94541 0).

(16) This standard was approved by the European Committee for Standardization (CEN) on 6 February 2017. Under reference BS EN 15621:2017, it was published as a UK standard by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4).

(17) EUR 152/2009. There are amendments to EUR 152/2009 not relevant to these Regulations.

| Column 1 | Column 2 | |
|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------|
| Maximum age | Not applicable | |
| Content of Manganese chelate of lysine and glutamic acid in mg/kg of complete feed with a moisture content of 12% | Minimum content | No minimum |
| | Maximum content | Fish 100 (total) All other animal species 150 (total) |
| Other provisions | The additive must be incorporated into the feed in the form of a premixture. | |

SCHEDULE 2

Regulation 3(2)

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

Authorisation

1. The preparation specified in the table in this schedule, 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 in this schedule.

Table

| Column 1 | Column 2 |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Additive | <i>Lactobacillus buchneri</i> DSM 29026 |
| Identification number of the additive | 1k20759 |
| Authorisation holder(18) | |
| Additive category | Technological additives |
| Functional group | Silage additives |
| Additive composition | A preparation of <i>Lactobacillus buchneri</i> DSM 29026 containing a minimum of 2×10^{10} CFU/g additive |
| Characterisation of the active substance(s) | Viable cells of <i>Lactobacillus buchneri</i> DSM 29026 |
| Analytical methods(19) | 1. For enumeration (colony count) of the feed additive: |

(18) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.

(19) Details of the analytical methods are set out in the document referenced "Ares(2019)4747322 – 22/07/2019" and last updated on 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>.

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| Column 1 | Column 2 | |
|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with European standard EN 15787:2021 entitled “<i>Animal feeding stuffs: Methods of sampling and analysis – Detection and enumeration of Lactobacillus spp. used as feed additive</i>”(20) <p>2. For identification of bacterial strain:</p> <ul style="list-style-type: none"> • Pulsed Field Gel Electrophoresis (PFGE) | |
| Species or category of animal | All animal species | |
| Maximum age | Not applicable | |
| Content of <i>Lactobacillus buchneri</i> DSM 29026 in CFU of additive/kg of fresh material | Minimum content | Minimum content of the 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(21). |
| | Maximum content | No maximum |
| Other provisions | In the directions for use of the additive and premixtures, the storage conditions must be indicated. | |

SCHEDULE 3

Regulation 3(2)

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

Authorisation

1. The preparation specified in the table in this schedule, 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 in this schedule.

Table

| Column 1 | Column 2 |
|---------------------------------------|---------------------------------------------|
| Additive | Serine protease |
| Identification number of the additive | 4a13 |
| Authorisation holder | DSM Nutritional Products Ltd in Switzerland |

(20) This standard was approved by the European Committee for Standardization (CEN) on 2 August 2021. Under reference BS EN 15787:2021, it was published as a UK standard by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7).

(21) 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 of 25 April 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 additives (EUR 2008/429, amended by S.I. 2019/654. S.I. 2019/654 was amended by 2020/1504).

| Column 1 | Column 2 |
|---------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Additive category | Zootechnical additives |
| Functional group | Digestibility enhancers |
| Additive composition | Solid and liquid preparation of serine protease (EC 3.4.21. ⁻¹) <ul style="list-style-type: none"> Produced by <i>Bacillus licheniformis</i> DSM 19670 Having a minimum activity of 75,000 PROT/g(22) |
| Characterisation of the active substance(s) | Serine protease (EC 3.4.21. ⁻¹) produced by <i>Bacillus licheniformis</i> DSM 19670 CAS number: 37259-58-8 (serine protease)(23) EINECS number: 253-431-3(24) IUB number: 3.4.21. ⁻¹ (25) |
| Analytical methods(26) | For quantification of serine protease activity in the feed additive, premixtures, compound feed and feed materials: <ul style="list-style-type: none"> 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 | Not applicable |
| Content of Serine protease (units of activity/kg of complete feed with a moisture content of 12%) | Minimum content 15,000 PROT/kg Maximum content No maximum |
| Other provisions | In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated. |

(22) 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.

(23) This is a reference to the CAS Registry Number assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.

(24) The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1.

(25) This is the identification number allotted by the International Union of Biochemistry (IUB), which is now the International Union of Biochemistry and Molecular Biology (IUBMB) iubmb.org.

(26) Details of the analytical methods are set out in the document referenced "Ares(2019)6802986 – 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>.

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SCHEDULE 4

Regulation 3(2)

Renewal of authorisation of pyridoxine hydrochloride (vitamin B₆)
(identification number 3a831) as a feed additive for all animal species

Authorisation

1. The additive specified in the table in this schedule, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, is authorised as an additive in animal nutrition, subject to the conditions set out in the table in this schedule(27).

Table

| <i>Column 1</i> | <i>Column 2</i> |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Additive</i> | Pyridoxine hydrochloride (vitamin B ₆) |
| <i>Identification number of the additive</i> | 3a831 |
| <i>Authorisation holder(28)</i> | |
| <i>Additive category</i> | Nutritional additives |
| <i>Functional group</i> | Vitamins, pro-vitamins and chemically well-defined substances having similar effect |
| <i>Additive composition</i> | Pyridoxine hydrochloride: C ₈ H ₁₁ NO ₃ HCl Purity criteria not less than 98.5% |
| <i>Characterisation of the active substance(s)</i> | Pyridoxine hydrochloride CAS no:58-56-0(29) EINECS no:200-386-2(30) |
| <i>Analytical methods(31)</i> | 1. For the determination of pyridoxine hydrochloride (Vitamin B ₆) in the feed additive: <ul style="list-style-type: none"> • Titration with perchloric acid (Ph.Eur. 10th edition, monograph 0245) 2. For the determination of pyridoxine hydrochloride (Vitamin B ₆) in premixtures: |

(27) This authorisation is a renewal of the authorisation granted under Commission Implementing Regulation (EU) No. 515/2011. That Regulation is revoked by regulation 11 of these Regulations.

(28) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.

(29) This is a reference to the CAS Registry Number assigned to this additive by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.

(30) The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1.

(31) Details of the analytical methods are set out in the document referenced “JRC.DG.D.6/CvH/GB/ag/ARES(2011)356822” 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-2010-0139>.

| Column 1 | Column 2 | |
|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| | <ul style="list-style-type: none"> Reversed phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) in accordance with the VDLUFA Method Book, Volume III, 13.9.1(32) <p>3. For the determination of pyridoxine hydrochloride (Vitamin B₆) in feed and water:</p> <ul style="list-style-type: none"> Reversed phase High Performance Liquid Chromatography coupled to fluorescence detector (RP-HPLC-FLD) – method based in accordance with European standard EN 14164:2014 entitled “<i>Foodstuffs – Determination of vitamin B6 by high performance chromatography</i>”(33) | |
| Species or category of animal | All animal species | |
| Maximum age | Not applicable | |
| Content of Pyridoxine hydrochloride (Vitamin B ₆) in mg/kg of complete feed with a moisture content of 12% | Minimum content | No minimum |
| | Maximum content | No maximum |
| Other provisions | <ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated. Pyridoxine hydrochloride (Vitamin B₆) may be used via water for drinking. | |

SCHEDULE 5

Regulation 3(2)

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

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(34).

(32) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method book, Volume III, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6) is available at the following address: [Method book Volume III Feedingstuffs \(vdlufa.de\)](#). Copies of a translated version of Part 13.9.1 may be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL.

(33) This standard was approved by the European Committee for Standardization (CEN) on 17 April 2014.

(34) This authorisation is a renewal of the authorisation granted under [Commission Regulation \(EU\) No. 883/2010](#). That Regulation is revoked by regulation 11 of these Regulations, subject to the transitional provision in regulation 8.

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Table

| Column 1 | Column 2 | |
|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Additive | <i>Saccharomyces cerevisiae</i> CNCM I-4407 (ACTISAF® Sc 47) | |
| 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 <i>Saccharomyces cerevisiae</i> CNCM I-4407 containing a minimum of 5×10^9 CFU/g | |
| Characterisation of the active substance(s) | Viable dried cells <i>Saccharomyces cerevisiae</i> CNCM I-4407 | |
| Analytical methods(35) | <p>1. For enumeration (colony count):</p> <ul style="list-style-type: none"> Pour plate method using CGYE (yeast extract glucose chloramphenicol) agar in accordance with European standard EN 15789:2021 entitled “<i>Animal feeding stuffs: Methods of sampling and analysis – Detection and enumeration of Saccharomyces cerevisiae used as feed additive</i>”(36) <p>2. For identification of yeast strain:</p> <ul style="list-style-type: none"> Polymerase chain reaction (PCR) method in accordance with DD CEN/TS 15790:2008 entitled “<i>Animal Feeding Stuffs – PCR typing of probiotic strains of Saccharomyces cerevisiae (yeast)</i>”(37) | |
| Species or category of animal | Calves for rearing | |
| Maximum age | Not applicable | |
| Content of <i>Saccharomyces cerevisiae</i> CNCM I-4407 in CFU/kg of complete feed with a moisture content of 12% | Minimum content | 1.5×10^9 CFU/kg |
| | Maximum content | No maximum |

(35) Details of the analytical methods are set out in the document referenced “JRC.DG.D.6/CvH/DM/mds/ARES(2010)967257” 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-2010-0038>.

(36) This standard was approved by the European Committee for Standardization (CEN) on 2 August 2021.

(37) DD CEN/TS 15790:2008, published by the British Standards Institution on 31 January 2009 (ISBN 978 0 580 61806 2).

| <i>Column 1</i> | <i>Column 2</i> |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Other provisions | In the directions of use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated. |

SCHEDULE 6

Regulation 3(2)

Renewal of authorisation (with modification) of a preparation of *Bacillus velezensis* (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

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(38).

Table

| <i>Column 1</i> | <i>Column 2</i> |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Additive</i> | <i>Bacillus velezensis</i> (ATCC PTA-6737) |
| <i>Identification number of the additive</i> | 4b1823 |
| <i>Authorisation holder</i> | Kemin Europa N.V. |
| <i>Additive category</i> | Zootechnical additives |
| <i>Functional group</i> | Gut flora stabilisers |
| <i>Additive composition</i> | Preparation of <i>Bacillus velezensis</i> ATCC PTA-6737 containing a minimum of 8×10^{10} CFU/g additive |
| <i>Characterisation of the active substance(s)</i> | Viable spores of <i>Bacillus velezensis</i> (ATCC PTA-6737) |
| <i>Analytical methods(39)</i> | <p>1. For enumeration (colony count):</p> <ul style="list-style-type: none"> • Spread plate method using tryptone soya agar with pre-heat treatment of feed samples <p>2. For identification of bacterial strain</p> <ul style="list-style-type: none"> • Pulsed-field gel electrophoresis (PFGE) |

(38) 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 11 of these Regulations, subject to the transitional provision in regulation 9(2) to (5). This feed additive is separately authorised for use in feed for specified other species or categories of animals by [Commission Implementing Regulations \(EU\) No. 306/2013](#), [787/2013](#), [2015/1020](#) and [2017/2276](#).

(39) Details of the analytical methods are set out in the document referenced “D08/FSQ/CVH/SY/Ares(2009)61627” 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-2008-0039>.

Status: This is the original version (as it was originally made).

| Column 1 | Column 2 | |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Species or category of animal | Chickens for fattening, chickens reared for laying, minor poultry species (except for laying), ornamental, sporting and game birds | |
| Maximum age | Not applicable | |
| Content of <i>Bacillus velezensis</i> (ATCC PTA-6737) in CFU/kg of complete feed with a moisture content of 12% | Minimum content | 1 x 10 ⁷ CFU/kg |
| | Maximum content | No maximum |
| 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>Bacillus velezensis</i> (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:</p> <ul style="list-style-type: none"> • Decoquinate, • Diclazuril, • Lasalocid, • Maduramycin, • Monensin, • Narasin, • Narasine/Nicarbazin (as combined use only), • Robenidine, • Salinomycin. | |

SCHEDULE 7

Regulation 3(2)

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

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.

Table

| <i>Column 1</i> | <i>Column 2</i> | |
|--------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| <i>Additive</i> | <i>Bacillus licheniformis</i> DSM 28710 | |
| <i>Identification number of the additive</i> | 4b1828 | |
| <i>Authorisation holder</i> | HuvePharma NV | |
| <i>Additive category</i> | Zootechnical additives | |
| <i>Functional group</i> | Gut flora stabilisers | |
| <i>Additive composition</i> | Solid form preparation of <i>Bacillus licheniformis</i> DSM 28710 containing a minimum of 3.2×10^9 CFU/g of additive | |
| <i>Characterisation of the active substance(s)</i> | Viable spores of <i>Bacillus licheniformis</i> DSM 28710 | |
| <i>Analytical methods(40)</i> | <p>1. For enumeration (colony count) in the additive, premixture and feed:</p> <ul style="list-style-type: none"> • Spread plate method in accordance with European standard EN 15784:2021 entitled “<i>Animal feeding stuffs: Methods of sampling and analysis – Detection and enumeration of Bacillus spp. used as feed additive</i>”(41) <p>2. For identification of bacterial strain:</p> <ul style="list-style-type: none"> • Pulsed field gel electrophoresis (PFGE) | |
| <i>Species or category of animal</i> | Laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds | |
| <i>Maximum age</i> | Not applicable | |
| <i>Content of Bacillus licheniformis DSM 28710 in CFU/kg of complete feed with a moisture content of 12%</i> | <i>Minimum content</i> | 1.6×10^9 CFU/kg |
| | <i>Maximum content</i> | No maximum |
| <i>Other provisions</i> | 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated. | |

(40) Details of the analytical methods are set out in the document referenced “Ares(2015)4524025 – 23/10/2015” 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-2015-0016>.

(41) This standard was approved by the European Committee for Standardization (CEN) on 2 August 2021. Under reference BS EN 15784:2021, it was published as a UK standard by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99829 4).

Status: This is the original version (as it was originally made).

| Column 1 | Column 2 |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>2. Where <i>Bacillus licheniformis</i> 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:</p> <ul style="list-style-type: none"> • Diclazuril • Lasalocid A sodium |

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 pigs and suckling minor porcine species

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(42).

Table

| Column 1 | Column 2 |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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</i> (43) | <p>1. For enumeration (colony count):</p> <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</i> |

(42) 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.

(43) 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>.

| Column 1 | Column 2 |
|------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>of sulphite-reducing bacteria growing under anaerobic conditions”(44)</p> <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); piglets and piglets of minor porcine species |
| 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>Turkeys: 1.25×10^8 CFU/kg</p> <p>Chickens, minor avian species, piglets and minor porcine species: 2.5×10^8 CFU/kg</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, • Maduramicin ammonium, • Monensin sodium, • Narasin, • Narasin/Nicarbazin (as combined use only), • Robenidine, • Salinomycin sodium, • Semduramicin sodium. |

(44) 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).

Status: This is the original version (as it was originally made).

SCHEDULE 9

Regulation 3(2)

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 and minor porcine species for fattening or reproduction

Authorisation

1. The preparation specified in the table in this schedule, 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 in this schedule.

Table

| <i>Column 1</i> | <i>Column 2</i> |
|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Additive</i> | 6-phytase (EC 3.1.3.26) |
| <i>Identification number of the additive</i> | 4a32 |
| <i>Authorisation holder</i> | Huvepharma EOOD |
| <i>Additive category</i> | Zootechnical additives |
| <i>Functional group</i> | Digestibility enhancers |
| <i>Additive composition</i> | Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Komagataella phaffii</i> (DSM 32854) In granular, coated and liquid forms, minimum activity 5000 FTU/g(45) |
| <i>Characterisation of the active substance(s)</i> | 6-phytase (EC 3.1.3.26) produced by <i>Komagataella phaffii</i> (DSM 32854) |
| <i>Analytical methods(46)</i> | 1. For quantification of phytase activity in the feed additive: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with the VDLUFA Method Book, Volume III, Part 27.1.4(47) 2. For quantification of phytase activity in feed materials and compound feed: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with international standard BS EN ISO 30024:2009 entitled “<i>Animal feeding stuffs. Determination of phytase activity</i>”(48) |

(45) FTU means 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.

(46) Details of the analytical methods are set out in the document referenced “Ares(2020)762221 – 06/02/2020” and last updated on 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>.

(47) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method book, Volume III, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6) is available at the following address: [Method book Volume III Feedingstuffs \(vdlufa.de\)](https://www.vdlufa.de). Copies of a translated version of Part 27.1.4 may be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL.

(48) 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

| <i>Column 1</i> | <i>Column 2</i> | |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| | 3. For quantification of phytase activity in premixtures: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with the VDLUFA Method Book, Volume III, Part 27.1.3(49) | |
| <i>Species or category of animal</i> | All poultry species; ornamental birds; piglets; pigs for fattening; sows; minor porcine species for fattening or reproduction | |
| <i>Maximum age</i> | Not applicable | |
| <i>Content of 6-phytase (units of activity/kg of complete feed with a moisture content of 12%)</i> | <i>Minimum content</i> | 250 FTU |
| | <i>Maximum content</i> | No maximum |
| <i>Other provisions</i> | In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated. | |

SCHEDULE 10

Regulation 3(2)

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

Authorisation

1. The substance Decoquinat specified in the table in this schedule, 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 in this schedule(50).

Table

| <i>Column 1</i> | <i>Column 2</i> |
|----------------------------------------------|----------------------|
| <i>Additive</i> | Decoquinat (Deccox®) |
| <i>Identification number of the additive</i> | 51756i |
| <i>Authorisation holder</i> | Zoetis Belgium SA |

Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. Under reference BS EN ISO 30024:2009, it was published as a UK standard by the British Standards Institution on 30 September 2009 (ISBN 0 580 62651 7).

(49) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method book, Volume III, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6) is available at the following address: [Method book Volume III Feedingstuffs \(vdlufa.de\)](http://www.vdlufa.de). Copies of a translated version of Part 27.1.3 may be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL.

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

Status: This is the original version (as it was originally made).

| Column 1 | Column 2 | | | | |
|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------|-----------------|----------|
| Additive category | Coccidiostats and Histomonostats | | | | |
| Functional group | None | | | | |
| Additive composition | <ul style="list-style-type: none"> Decoquinatate: 60.0g/kg Refined deodorised soya oil: 28.5g/kg Colloidal silica: 0.6g/kg Wheat middlings: q.s. 1kg | | | | |
| Characterisation of the active substance(s) | <ul style="list-style-type: none"> Decoquinatate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate) Chemical formula: C₂₄H₃₅NO₅ CAS No: 18507-89-6(51) 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(52) | <p>1. For quantification of Decoquinatate in the feed additive, premixtures and feed:</p> <ul style="list-style-type: none"> Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) in accordance with European standard EN 16162:2012 entitled “<i>Animal feeding stuffs – Determination of decoquinatate by HPLC with fluorescence detection</i>”(53) <p>2. For quantification of Decoquinatate in tissues:</p> <ul style="list-style-type: none"> Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) | | | | |
| Species or category of animal | Chickens for fattening | | | | |
| Maximum age | Not applicable | | | | |
| Content of Decoquinatate (Deccox®) in mg/kg of complete feed with a moisture content of 12% | <table border="1"> <tr> <td>Minimum content</td> <td>30 mg/kg</td> </tr> <tr> <td>Maximum content</td> <td>40 mg/kg</td> </tr> </table> | Minimum content | 30 mg/kg | Maximum content | 40 mg/kg |
| Minimum content | 30 mg/kg | | | | |
| Maximum content | 40 mg/kg | | | | |

(51) This is a reference to the CAS Registry Number assigned to this substance by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.

(52) Details of the analytical methods are set out in the document referenced “Ares(2013)3639174 – 04/12/2013” 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-2013-0034>.

(53) This standard was approved by the European Committee for Standardization (CEN) on 4 February 2012. Under reference BS EN 16162:2012, it was published as a UK standard by the British Standards Institution on 31 March 2012 (ISBN 978 0 580 67002 2).

| <i>Column 1</i> | <i>Column 2</i> |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Other provisions | <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. The 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. Post-market monitoring programmes must be carried out by the holder of authorisation for resistance to bacteria and <i>Eimeria spp</i> and submitted to the Scottish Ministers by the end of 23 November 2031. |

SCHEDULE 11

Regulation 3(2)

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

Authorisation

1. The substance Decoquinate specified in the table in this schedule, 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 in this schedule(54).

Table

| <i>Column 1</i> | <i>Column 2</i> |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Additive</i> | Decoquinate (Avi-Deccox® 60G) |
| <i>Identification number of the additive</i> | 51756ii |
| <i>Authorisation holder</i> | Zoetis Belgium SA |
| <i>Additive category</i> | Coccidiostats and Histomonostats |
| <i>Functional group</i> | None |
| <i>Additive composition</i> | <ul style="list-style-type: none"> • 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 1,000 g |
| <i>Characterisation of the active substance(s)</i> | Decoquinate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate) |

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

Status: This is the original version (as it was originally made).

| Column 1 | Column 2 | |
|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| | <ul style="list-style-type: none"> • Chemical Formula: C₂₄H₃₅NO₅ • CAS No: 185-7-89-6(55) <p>Related impurities:</p> <ul style="list-style-type: none"> • 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(56) | <p>1. For the quantification of Decoquinatate in the feed additive, premixtures and feed:</p> <ul style="list-style-type: none"> • Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) in accordance with European standard EN 16162:2012 entitled “<i>Animal feeding stuffs – Determination of decoquinatate by HPLC with fluorescence detection</i>” <p>2. For quantification of Decoquinatate in tissues:</p> <ul style="list-style-type: none"> • Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any other analytical method complying with the requirements set by Retained EU Decision 2002/657/EC(57) | |
| Species or category of animal | Chickens for fattening | |
| Maximum age | Not applicable | |
| Content of Decoquinatate (Avi-Deccox®) in mg/kg of complete feed with a moisture content of 12% | Minimum content | 30 mg/kg |
| | Maximum content | 40 mg/kg |
| 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. The additive must be incorporated in compound feed in the form of a premixture.</p> <p>3. Decoquinatate must not be mixed with other coccidiostats.</p> | |

(55) This is a reference to the CAS Registry Number assigned to this substance by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.

(56) Details of the analytical methods are set out in the document referenced “Ares(2014)2704635 – 18/08/2014” and “JRC.D.5/SFB/CvH/MGH/mds/Ares” 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-2014-0014>.

(57) EUD 2002/657 as amended by [S.I. 2020/1461](#).

| Column 1 | Column 2 |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>4. Decoquate must not be used in feed containing bentonite.</p> <p>5. Post-market monitoring programmes must be carried out by the holder of the authorisation for resistance to bacteria and <i>Eimeria spp</i> and submitted to the Scottish Ministers by the end of 23 November 2031.</p> |

SCHEDULE 12

Regulation 11

Revocation of retained direct EU legislation

1. [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**(58)**.
2. [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)**(59)**.
3. [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)**(60)**.
4. [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)**(61)**.
5. [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)**(62)**.
6. [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**(63)**.
7. [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)**(64)**.
8. [Commission Implementing Regulation \(EU\) No. 515/2011](#) concerning the authorisation of vitamin B₆ as a feed additive for all animal species**(65)**.
9. [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

(58) EUR 1289/2004 as amended by EUR 291/2014.**(59)** EUR 903/2009 as amended by EUR 373/2011 and EUR 1126/2017.**(60)** EUR 8/2010.**(61)** EUR 2010/107.**(62)** EUR 883/2010.**(63)** EUR 168/2011.**(64)** EUR 2011/373 as amended by EUR 1126/2017.**(65)** EUR 2011/515.

Status: This is the original version (as it was originally made).

fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches (holder of the authorisation Kemin Europa N.V.)(66).

10. 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.)(67).

11. 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)(68).

12. 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(69).

13. 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 for fattening and turkeys reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)(70).

14. Commission Implementing Regulation (EU) No. 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)(71).

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision as regards the authorisation of feed additives under Regulation (EC) 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (“Regulation (EC) 1831/2003”).

Regulation 3 and schedules 1 to 11 prescribe the authorisation of 11 feed additives, in accordance with article 9(1) of Regulation (EC) 1831/2003.

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).

(66) EUR 885/2011.

(67) EUR 2013/357.

(68) EUR 2013/374 as amended by EUR 1126/2017.

(69) EUR 291/2014.

(70) EUR 2014/1108 as amended by EUR 1126/2017.

(71) EUR 2017/1126.

Schedule 3 is a new authorisation, for a preparation of Serine protease (EC 3.4.21.⁻¹) produced by *Bacillus licheniformis* (DSM 19670) (identification number 4a13).

Schedule 4 is a renewal of the authorisation of Pyridoxine hydrochloride (vitamin B₆) (identification number 3a831).

Schedule 5 is a renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 (ACTISAF® Sc47) (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). The authorisation has been modified as follows:-

- the bacterial strain name from “*Bacillus subtilis*” to “*Bacillus velezensis*”,
- the minimum content of the feed additive in the preparation is increased from 1×10^{10} to 8×10^{10} colony forming units per gram (CFU/g).

Schedule 7 is a new authorisation, for a preparation of *Bacillus licheniformis* DSM 28710 (identification number 4b1828).

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 to be used in feed for chickens for fattening, suckling piglets and minor porcine species (suckling).

Schedule 9 is a new authorisation, for a preparation of 6-phytase produced by *Komagataella phaffii* DSM 32854 (identification number 4a32).

Schedule 10 authorises a new formulation of Decoquinat (Deccox®) (identification number E756) as Decoquinat (Deccox®) (identification number 51756i) following a re-evaluation requested by the holder.

Schedule 11 authorises a modified form of Decoquinat (Deccox®) (identification number E756) as Decoquinat (Avi-Deccox® 60G) (identification number 51756ii). This feed additive differs from Decoquinat (Deccox®) in physical form and in the dilutant used being calcium sulphate dehydrate.

The authorisations are valid for a period of 10 years, in accordance with Article 9(7) of Regulation (EC) 1831/2003. This is subject to Article 14(4) of that Regulation, which provides for an extension of the authorisation period in certain circumstances following the submission of an application for renewal. Relevant provision is made by regulation 3(3) of these Regulations.

Regulations 4 to 7 modify 4 retained EU Regulations that authorise the feed additive *Bacillus subtilis* ATCC PTA-6737 for differing poultry and pig sub-groups. The name of the feed additive is updated from “*Bacillus subtilis*” to “*Bacillus velezensis*”. Regulation 9(1) is a transitional provision which allows products labelled using the name “*Bacillus subtilis*” to continue to be marketed and used under the relevant authorisations despite the name change.

Regulations 8, 9(2) to (5) and 10 make transitional provision to enable the continued production and labelling of products, for limited time periods, under the conditions of previous authorisations where authorisations are renewed under schedules 5, 6 and 10 respectively.

Regulation 11 and schedule 12 revoke retained direct EU legislation that contains previous authorisations for the feed additives now authorised by schedules 3, 4, 5, 6, 8 and 10.

A business and regulatory impact assessment has not been produced for this instrument as no significant impact on the private or voluntary sector is foreseen.