

**2022 No. 1129**

**AGRICULTURE, ENGLAND**

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

<i>Made</i>	- - - -	<i>3rd November 2022</i>
<i>Laid before Parliament</i>		<i>4th November 2022</i>
<i>Coming into force</i>		<i>25th November 2022</i>

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The Secretary of State makes 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<sup>(a)</sup>.

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<sup>(b)</sup> there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

### **Citation, commencement, extent and application**

**1.**—(1) These Regulations may be cited as the Feed Additives (Authorisations) (England) Regulations 2022 and come into force on 25th November 2022.

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(a) EUR 2003/1831, amended by S.I. 2019/654 and S.I. 2022/377. See Article 2 for the definitions of “appropriate authority” and “prescribe”.

(b) EUR 2002/178, amended by S.I. 2019/641.

(2) These Regulations extend to England and Wales but apply in relation to England 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.

(2) Any expression used both in these Regulations and in Regulation (EC) 1831/2003 or Regulation (EC) 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, etc(a) has the same meaning as it has in those Regulations.

### **Authorisation of various feed additives**

**3.** Schedules 1 to 11 have effect.

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

**4.** In the Annex to 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.)(b), in the table, in each place it occurs, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”.

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

**5.** In the Annex to 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.)(c), in the table, in each place it occurs, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”.

### **Amendment of Commission Implementing Regulation (EU) 2015/1020**

**6.** In the Annex to 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)(d), in the table, in each place it occurs, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”.

### **Amendment of Commission Implementing Regulation (EU) 2017/2276**

**7.** In the Annex to 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.)(e), in the table, in each place it occurs, for “*Bacillus subtilis*” substitute “*Bacillus velezensis*”.

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

**8.**—(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.

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(a) EUR 2009/767, amended by S.I. 2019/654.

(b) EUR 2013/306.

(c) EUR 2013/787.

(d) EUR 2015/1020.

(e) EUR 2017/2276.

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

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

(4) Stocks of 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 23rd November 2024 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until they are exhausted.

(5) In this regulation—

“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;

“prior authorisation” means 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 (holder of authorisation Kemin Europa NV)(a),

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.)(b).

**Transitional provision: *Saccharomyces cerevisiae* (formerly *Saccharomyces cerevisiae* NCYC Sc.47) (identification number 4b1702)**

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

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

“prior authorisation” means an authorisation contained in 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)(c).

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

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

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(a) EUR 2010/107. This Regulation is revoked by regulation 11.

(b) EUR 2011/885. This Regulation is revoked by regulation 11.

(c) EUR 2010/883. This Regulation is revoked by regulation 11.

(2) In this regulation–

“relevant feed additive” means the feed additive decoquinate (Deccox<sup>®</sup>), which was previously authorised under the prior authorisation with the identification number E756;

“prior authorisation” means an authorisation contained in Regulation (EC) No 1289/2004 concerning the authorisation for 10 years of the additive Deccox<sup>®</sup> in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances(a).

### Revocation of retained direct EU legislation

11. The instruments in Schedule 12 are revoked subject to regulations 8(2) to (5), 9 and 10.

3rd November 2022

*Neil O'Brien*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

## SCHEDULE 1

Regulation 3

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

The preparation of Manganese chelate of lysine and glutamic acid, belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	Manganese chelate of lysine and glutamic acid
<i>Identification number of the additive</i>	3b509
<i>Authorisation holder<sup>(1)</sup></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"><li>— Manganese 15-17%</li><li>— Lysine 20-21.5%</li><li>— Glutamic acid 22-24%</li><li>— Moisture 3.5% maximum</li><li>— Nickel 4 ppm maximum</li></ul>
<i>Characterisation of the active substance(s)</i>	Manganese-2,6-diaminohexanoic acid, chloride and hydrogen sulphate salt (C <sub>6</sub> H <sub>19</sub> ClN <sub>2</sub> O <sub>8</sub> SMn). Manganese-2-aminopentanedioic acid, sodium and hydrogen sulphate salt (C <sub>5</sub> H <sub>10</sub> NNaO <sub>9</sub> SMn).
<i>Analytical methods<sup>(2)</sup></i>	For quantification of total manganese in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"><li>— Atomic Absorption Spectrometry (AAS) in accordance</li></ul>

(a) EUR 2004/1289. This Regulation is revoked by regulation 11.

	<p>with BS EN ISO 6869:2001<sup>(3)</sup>;</p> <ul style="list-style-type: none"> <li>— Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) in accordance with European standard in accordance with BS EN 15621:2017<sup>(4)</sup>.</li> </ul>
	<p>For the quantification of total manganese in premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Inductively Coupled Plasma-Atomic Emission Spectrometry, (ICP-AES) in accordance with BS EN 15510<sup>(5)</sup>;</li> <li>— Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) in accordance with European standard BS EN 17053:2018.</li> </ul>
	<p>For quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry (AAS) –Commission Regulation (EC) 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 4-C)(a).</li> </ul>
	<p>For quantification of lysine and glutamic acid in the feed additive:</p> <ul style="list-style-type: none"> <li>— Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) in accordance with BS EN ISO 13903:2005<sup>(6)</sup>.</li> </ul>
	<p>For determination of the chelated form of the feed additive:</p> <ul style="list-style-type: none"> <li>— Mid-infrared (IR) spectrometry together with the determination of the content of trace element and lysine and glutamic acid in the feed additive.</li> </ul>
<i>Species or category of animal</i>	All animal species.
<i>Maximum age</i>	Not applicable.
<i>Minimum content</i> <sup>(7)</sup>	No minimum.
<i>Maximum content</i> <sup>(7)</sup>	Fish 100 (total). All other animal species 150 (total).
<i>Other provisions</i>	The additive must be incorporated into the feed in form of a premixture.

<sup>(1)</sup> 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.

<sup>(2)</sup> 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 28th January 2020. These documents are available at the following address:

[https://joint-research-centre.ec.europa.eu/publications/fad-2018-0009\\_en](https://joint-research-centre.ec.europa.eu/publications/fad-2018-0009_en)

<sup>(3)</sup> 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 15th March 2001 (ISBN 0 580 36933 1). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

<sup>(4)</sup> 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 31st August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

(a) EUR 2009/152, as amended by S.I. 2019/654. S.I. 2019/654 was itself amended by S.I. 2020/1504.

<sup>(5)</sup> BS EN 15510:2017 “*Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES*”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 539 09335 3). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

<sup>(6)</sup> BS EN ISO 13903:2005 “*Animal feeding stuffs – Determination of amino acids content*”. Published by the British Standards Institution on 24th October 2005 (ISBN 0 580 46218 8). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

## SCHEDULE 2

Regulation 3

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

The preparation of *Lactobacillus buchneri* (DSM 29026), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	<i>Lactobacillus buchneri</i> (DSM 29026)
<i>Identification number of the additive</i>	1k20759
<i>Authorisation holder</i> <sup>(1)</sup>	
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Preparation of <i>Lactobacillus buchneri</i> (DSM 29026) containing a minimum of: $2 \times 10^{10}$ CFU/g additive.
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lactobacillus buchneri</i> (DSM 29026).
<i>Analytical methods</i> <sup>(2)</sup>	For enumeration (colony count) of the feed additive: — Spread plate method on MRS agar in accordance with BS EN 15787:2021 <sup>(3)</sup> .
	For identification of bacterial strain: — Pulsed Field Gel Electrophoresis (PFGE).
<i>Species or category of animal</i>	All animal species.
<i>Maximum age</i>	Not applicable.
<i>Minimum content</i> <sup>(4)</sup>	Minimum content of the additive when not combined with other micro-organisms as silage additives: $5 \times 10^7$ CFU/kg of easy and moderately difficult to ensile fresh material <sup>(5)</sup> .
<i>Maximum content</i> <sup>(4)</sup>	No maximum.
<i>Other provisions</i>	In the directions for use of the additive and premixtures, the storage conditions must be indicated.

<sup>(1)</sup> 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.

<sup>(2)</sup> Details of the analytical methods set out in the document referenced “Ares(2019)4747322 – 22/07/2019” and last updated 18th October 2019. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2018-0093>.

<sup>(3)</sup> 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 31st December 2021 (ISBN 978 0 580 99831 7). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

<sup>(4)</sup> Content of *Lactobacillus buchneri* (DSM 29026) : CFU of additive/kg of fresh material.

<sup>(5)</sup> 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 additives(a).

## SCHEDULE 3

Regulation 3

### 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

The preparation of Serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* (DSM 19670), belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	Serine protease (EC 3.4.21.-)
<i>Identification number of the additive</i>	4a13
<i>Authorisation holder</i>	DSM Nutritional Products Ltd (Switzerland)
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Digestibility enhancers
<i>Additive composition</i>	Solid and liquid preparation of serine protease (EC 3.4.21.-): — Produced by <i>Bacillus licheniformis</i> (DSM 19670) — Having a minimum activity of 75,000 PROT <sup>(1)</sup> /g
<i>Characterisation of the active substance(s)</i>	Serine protease (EC 3.4.21.-) produced by <i>Bacillus licheniformis</i> (DSM 19670). — CAS number: 37259-58-8 (serine protease) <sup>(2)</sup> . — EINECS number: 253-431-3 <sup>(3)</sup> . — IUB number: 3.4.21.- <sup>(4)</sup> .
<i>Analytical methods<sup>(5)</sup></i>	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.
<i>Species or category of animal</i>	Chickens for fattening
<i>Maximum age</i>	Not applicable
<i>Minimum content<sup>(6)</sup></i>	Minimum level: 15,000 PROT/kg
<i>Maximum content<sup>(6)</sup></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.

<sup>(1)</sup> 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.

<sup>(2)</sup> This is a reference to the CAS Registry Number assigned to this preparation by the Chemical Abstracts Service <http://cas.org.uk/cas-data/cas-registry>.

(a) EUR 2008/429, amended by S.I. 2019/654. S.I. 2019/654 was itself amended by S.I.2020/1504.



<sup>(3)</sup> The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J No. C146A, 16.6.90, p.1.

<sup>(4)</sup> 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) <https://iubmb.org>.

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

<sup>(6)</sup> Content of Serine protease: units of activity/kg of complete feed with a moisture content of 12%.

## SCHEDULE 4

Regulation 3

### Renewal of authorisation of Pyridoxine hydrochloride (vitamin B<sub>6</sub>) (identification number 3a831) as a feed additive for all animal species

The substance Pyridoxine hydrochloride (vitamin B<sub>6</sub>), 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 in accordance with the specifications in the following table(a).

<i>Additive</i>	Pyridoxine hydrochloride (Vitamin B <sub>6</sub> )
<i>Identification number of the additive</i>	3a831
<i>Authorisation holder</i> <sup>(1)</sup>	
<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 with a purity criteria not less than 98.5%.
<i>Characterisation of the active substance(s)</i>	<ul style="list-style-type: none"> <li>— Pyridoxine hydrochloride: C<sub>8</sub>H<sub>11</sub>NO<sub>3</sub>·HCl</li> <li>— CAS no:58-56-0<sup>(2)</sup>.</li> <li>— EINECS no:200-386-2<sup>(3)</sup>.</li> </ul>
<i>Analytical methods</i> <sup>(4)</sup>	For determination of pyridoxine hydrochloride (vitamin B <sub>6</sub> ) in the feed additive: <ul style="list-style-type: none"> <li>— Titration with perchloric acid (Ph. Eur. 10th edition, monograph 0245<sup>(5)</sup>).</li> </ul>
	For determination of pyridoxine hydrochloride (Vitamin B <sub>6</sub> ) in premixtures: <ul style="list-style-type: none"> <li>— Reversed phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) in accordance with VDLUFA Method Book, Volume III, (3rd edition 1976, revised), Method No.13.9.1<sup>(6)</sup>.</li> </ul>
	For determination of pyridoxine hydrochloride (Vitamin B <sub>6</sub> ) in feed and water: <ul style="list-style-type: none"> <li>— Reversed phase High Performance Liquid Chromatography coupled to fluorescence detector (RP-HPLC-FLD) in accordance with BS EN 14164:2014<sup>(7)</sup>.</li> </ul>
<i>Species or category of animal</i>	All animal species.
<i>Maximum age</i>	Not applicable

(a) This authorisation is a renewal of the authorisation granted under Commission Implementing Regulation (EU) 515/2011. That Regulation is revoked by regulation 11 of these Regulations.

<i>Minimum content</i> <sup>(8)</sup>	No minimum
<i>Maximum content</i> <sup>(8)</sup>	No maximum
<i>Other provisions</i>	<ol style="list-style-type: none"> <li>1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and in water must be indicated.</li> <li>2) Pyridoxine hydrochloride (Vitamin B<sub>6</sub>) may be used via water for drinking.</li> </ol>

<sup>(1)</sup> 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.

<sup>(2)</sup> 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>.

<sup>(3)</sup> 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.

<sup>(4)</sup> Details of the analytical methods set out in the document referenced “JRC.DG.D.6/CvH/GB/ag/ARES(2011)356822” and last updated 6th June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0139>.

<sup>(5)</sup> European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare 10<sup>th</sup> edition. Published 1st July 2019 (ISBN 9789999146111).

<sup>(6)</sup> The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method book, Volume III, 6<sup>th</sup> Supplement, 2006, 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://vdlufa.de)). For access to a translated version of Part 13.9.1 may be obtained from the Food Standards Agency, Foss House, Kings Pool, 1-2 Peasholm Green, York, YO1, 7PR.

<sup>(7)</sup> BS EN 14164:2014 “Foodstuffs. Determination of vitamin B<sub>6</sub> by high performance chromatography”. Published by the British Standards Institution on 30th June 2014 (ISBN 978 0 580 77941 1). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

<sup>(8)</sup> Content of Pyridoxine HCl (Vitamin B<sub>6</sub>): mg of additive/kg of complete feed with a moisture content of 12%.

## SCHEDULE 5

Regulation 3

### 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

The preparation of *Saccharomyces cerevisiae* CNCM I-4407, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table(a).

<i>Additive</i>	<i>Saccharomyces cerevisiae</i> (CNCM I-4407)
<i>Identification number of the additive</i>	4b1702
<i>Authorisation holder</i>	S.I. Lesaffre
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Gut flora stabilisers
<i>Additive composition</i>	Solid form preparation of <i>Saccharomyces cerevisiae</i> (CNCM I-4407) containing a minimum of $5 \times 10^9$ CFU/g additive.
<i>Characterisation of the active substance(s)</i>	Viable dried cells of <i>Saccharomyces cerevisiae</i> (CNCM I-4407).

(a) 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 but see the transitional provision in regulation 9.

<i>Analytical methods</i> <sup>(1)</sup>	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: — Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021 <sup>(2)</sup> .
	For identification of yeast strain: — Polymerase chain reaction (PCR) method in accordance with DD CEN/TS 15790:2008 <sup>(3)</sup> .
<i>Species or category of animal</i>	Calves for rearing
<i>Maximum age</i>	Not applicable
<i>Minimum content</i> <sup>(4)</sup>	1.5 x 10 <sup>9</sup> CFU/kg
<i>Maximum content</i> <sup>(4)</sup>	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.

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

<sup>(2)</sup> 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 30th November 2021 (ISBN 978 0 580 99832 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

<sup>(3)</sup> DD CEN/TS:15790:2008 “*Animal Feeding Stuffs – PCR typing of probiotic strains of Saccharomyces cerevisiae (yeast)*”. Published by the British Standards Institution on 31st January 2009 (ISBN 978 0 580 61806 2). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

## SCHEDULE 6

Regulation 3

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

The preparation of *Bacillus velezensis* (ATCC PTA-6737), belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table(a).

(a) 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 but see the transitional provision in regulation 8. 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.

<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 $8 \times 10^{10}$ CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable spores of <i>Bacillus velezensis</i> (ATCC PTA-6737).
<i>Analytical methods</i> <sup>(1)</sup>	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed <sup>(2)</sup> : — Spread plate method using tryptone soya agar with pre-heat treatment of feed samples.
	For identification of bacterial strain: — Pulsed-field gel electrophoresis (PFGE).
<i>Species or category of animal</i>	— Chickens for fattening — Chickens reared for laying — Minor poultry species (except for laying) — Ornamental, sporting and game birds
<i>Maximum age</i>	Not applicable
<i>Minimum content</i> <sup>(3)</sup>	$1 \times 10^7$ CFU/kg
<i>Maximum content</i> <sup>(3)</sup>	No maximum
<i>Other provisions</i>	<ol style="list-style-type: none"> <li>1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated.</li> <li>2) If <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, and in accordance with their individual authorisation criteria for: lasalocid A sodium, maduramicin ammonium, monensin sodium, narasin, narasin/nicarbazin (as combined use only) salinomycin sodium, decoquinate, robenidine hydrochloride or diclazuril.</li> </ol>

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

<sup>(2)</sup> This method is not suitable for the detection of *Bacillus velezensis* at concentrations below the minimum content level in feed materials and compound feed.

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

## SCHEDULE 7

Regulation 3

### 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

The preparation of *Bacillus licheniformis* (DSM 28710), belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, in accordance with the specifications in the following table.

<i>Additive</i>	<i>Bacillus licheniformis</i> (DSM 28710)
<i>Identification number of the additive</i>	4b1828
<i>Authorisation holder</i>	HuvePharma N.V.
<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 $3.2 \times 10^9$ CFU/g additive.
<i>Characterisation of the active substance(s)</i>	Viable spores of <i>Bacillus licheniformis</i> DSM 28710.
<i>Analytical methods</i> <sup>(1)</sup>	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: — Spread plate method in accordance with BS EN 15784:2021 <sup>(2)</sup> .
	For identification of bacterial strain: — Pulsed Field Gel Electrophoresis (PFGE).
<i>Species or category of animal</i>	— Laying hens — Minor poultry species for laying — Poultry species for breeding — Ornamental birds
<i>Maximum age</i>	Not applicable
<i>Minimum content</i> <sup>(3)</sup>	$1.6 \times 10^9$ CFU/kg
<i>Maximum content</i> <sup>(3)</sup>	No maximum
<i>Other provisions</i>	<ol style="list-style-type: none"> <li>1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated.</li> <li>2) If <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 for: diclazuril or lasalocid A sodium.</li> </ol>

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

<sup>(2)</sup> BS EN 15784:2021. “*Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Bacillus spp. used as feed additive*”. Published by British Standards Institution on 30th November 2021 (ISBN 978 0 580 99829 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

## SCHEDULE 8

Regulation 3

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

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

<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 $5 \times 10^8$ 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> <sup>(1)</sup>	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: — Pour plate method in accordance with BS ISO 15213:2003 <sup>(2)</sup> .
	For identification of bacterial strain: — Pulsed-field gel electrophoresis (PFGE).
<i>Species or category of animal</i>	<ul style="list-style-type: none"> <li>— Chickens for fattening</li> <li>— Chickens reared for laying</li> <li>— Turkeys for fattening</li> <li>— Turkeys reared for breeding</li> <li>— Minor avian species (excluding laying birds)</li> <li>— Piglets (suckling and weaned)</li> <li>— Minor porcine species (suckling and weaned)</li> </ul>
<i>Maximum age</i>	Not applicable.
<i>Minimum content</i> <sup>(3)</sup>	For all species set out above other than turkeys for fattening and turkeys for reared for breeding: — $2.5 \times 10^8$ CFU/kg.
	For turkeys for fattening and turkeys reared for breeding: — $1.25 \times 10^8$ CFU/kg.
<i>Maximum content</i> <sup>(3)</sup>	No maximum
<i>Other provisions</i>	1) In the directions for use of the additive and premixtures,

(a) 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.

	<p>the storage conditions and stability to heat treatment must be indicated.</p> <p>2) If <i>Clostridium butyricum</i> (FERM BP-2789) is to be used in feed containing coccidiostats, this feed additive is authorised for use with the following coccidiostats only, and in accordance with their individual authorisation criteria for: decoquinat, diclazuril, lasalocid A sodium, maduramicin ammonium, monensin sodium, narasin, narasin/nicarbazin (as combined use), robenidine hydrochloride, salinomycin sodium or semduramicin sodium.</p>
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<sup>(1)</sup> Details of the analytical methods set out in the document referenced “JRC.DG.D.6.CvH/DM/hn/ARES (2010)-355411” and last updated 6th June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0005>.

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

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

## SCHEDULE 9

Regulation 3

### 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

The preparation of 6-phytase (EC 3.1.3.26), belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive nutrition in accordance with the specifications in the following table.

<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) with a minimum activity of: <ul style="list-style-type: none"> <li>— 5 000 FTU/g<sup>(1)</sup> in granular form</li> <li>— 5 000 FTU/g in coated form</li> <li>— 5 000 FTU/g in liquid form.</li> </ul>
<i>Characterisation of the active substance(s)</i>	6-phytase (EC 3.1.3.26) produced by fermentation with <i>Komagataella phaffii</i> (DSM 32854).
<i>Analytical methods</i> <sup>(2)</sup>	For quantification of phytase activity in the feed additive: <ul style="list-style-type: none"> <li>— Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with the VDLUFA Method Book, Volume III (3rd edition 1976, revised), Method No. 27.1.4<sup>(3)</sup>.</li> </ul>

	<p>For quantification of phytase activity in premixtures:</p> <ul style="list-style-type: none"> <li>— Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with VDLUFA, Method Book, Volume III, (3rd edition 1976, revised), Method No. 27.1.3<sup>(4)</sup>.</li> </ul>
	<p>For quantification of phytase activity in feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with BS EN ISO 30024:2009<sup>(5)</sup>.</li> </ul>
<i>Species or category of animal</i>	<ul style="list-style-type: none"> <li>— All poultry species</li> <li>— Ornamental birds</li> <li>— Piglets</li> <li>— Pigs for fattening</li> <li>— Sows</li> <li>— Minor porcine species for fattening or reproduction.</li> </ul>
<i>Maximum age</i>	Not applicable
<i>Minimum content</i> <sup>(6)</sup>	250 FTU
<i>Maximum content</i> <sup>(6)</sup>	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.

<sup>(1)</sup> FTU means phytase enzyme units. One FTU is the amount of enzyme that releases 1 micromole ( $\mu\text{m}$ ) of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5.5 and 37°C.

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

<sup>(3)</sup> The Association of German Agriculture Analytical and Research Institutes (VDLUFA) Method Book, Volume III, New Single Methods 2016, the Chemical Analysis of Feedingstuff (ISBN 978 3 941273 14 6) is available at the following address: Method book Volume III Feedingstuffs (vdlufa.de). For access to a translated version of Part 27.1.4 contact the Food Standards Agency, Foss House, Kings Pool, 1-2 Peasholm Green, York, YO1, 7PR.

<sup>(4)</sup> The Association of German Agriculture Analytical and Research Institutes (VDLUFA) Method Book, Volume III, 8th supplement 2012, the Chemical Analysis of Feedingstuff (ISBN 978 3 941273 14 6) is available at the following address: Method book Volume III Feedingstuffs (vdlufa.de). For access to a translated version of Part 27.1.3 contact the Food Standards Agency, Foss House, Kings Pool, 1-2 Peasholm Green, York, YO1, 7PR.

<sup>(5)</sup> BS EN ISO 30024:2009. “*Animal feeding stuffs – Determination of phytase activity*”. Published by the International Organization for Standardization on 30th September 2009 (ISBN 978 0 580 62651 7). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

<sup>(6)</sup> Content of 6-phytase: units of activity/kg of complete feed with a moisture content of 12 %.



## SCHEDULE 10

Regulation 3

### Authorisation of Decoquinat (Deccox<sup>®</sup>) (identification number 51756i, formerly E756) as a feed additive for chickens for fattening

The substance of Decoquinat (Deccox<sup>®</sup>), belonging to the additive category ‘coccidiostats and histomonostats’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table(a).

<i>Additive</i>	Decoquinat (Deccox <sup>®</sup> )
<i>Identification number of the additive</i>	51756i
<i>Authorisation holder</i>	Zoetis Belgium SA
<i>Additive category</i>	Coccidiostats and Histomonostats
<i>Functional group</i>	Not applicable
<i>Additive composition</i>	<ul style="list-style-type: none"> <li>— Decoquinat, 60.0 g/kg</li> <li>— Refined deodorised soya oil, 28.5 g/kg</li> <li>— Colloidal silica, 0.6 g/kg</li> <li>— Wheat middlings, q.s. 1,000 g</li> </ul>
<i>Characterisation of the active substance(s)</i>	<p>Decoquinat: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate)</p> <ul style="list-style-type: none"> <li>— Chemical Formula: C<sub>24</sub>H<sub>35</sub>NO<sub>5</sub></li> <li>— CAS No: 18507-89-6<sup>(1)</sup></li> </ul> <p>Related impurities:</p> <ul style="list-style-type: none"> <li>— Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: &lt; 1.0%</li> <li>— 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: &lt; 0.5%</li> <li>— Diethyl-4-decycloxy-3-ethoxyanilinomethylene-malonate: &lt; 0.5%</li> </ul>
<i>Analytical methods<sup>(2)</sup></i>	<p>For quantification of decoquinat in the feed additive, premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none"> <li>— Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) in accordance with BS EN 16162:2012<sup>(3)</sup>.</li> </ul> <p>For quantification of decoquinat in tissues:</p> <ul style="list-style-type: none"> <li>— Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS<sup>(4)</sup>).</li> </ul>
<i>Species or category of animal</i>	Chickens for fattening
<i>Maximum age</i>	None
<i>Minimum content<sup>(5)</sup></i>	30 mg/kg
<i>Maximum content<sup>(5)</sup></i>	40 mg/kg
<i>Other provisions</i>	1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must

(a) This authorisation replaces the authorisation Decoquinat (Deccox<sup>®</sup>) under Regulation (EC) No 1289/2004. That Regulation is revoked by regulation 11 of these Regulations but see the transitional provision in regulation 10. See also Schedule 11 to these Regulations, which contains a separate authorisation of Decoquinat (Deccox<sup>®</sup>), but in a modified formulation as Decoquinat (Avi-Deccox<sup>®</sup> 60G).

	<p>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> <p>4) Decoquinatate must not be used in feed containing bentonite.</p> <p>5) A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and <i>Eimeria</i> spp. A report containing the outcome of the post market monitoring programme must be submitted to the Secretary of State before 25th November 2031.</p>
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<sup>(1)</sup> 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>.

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

<sup>(3)</sup> BS EN 16162:2012. “*Animal feeding stuffs. Determination of decoquinatate by HPLC with fluorescence detection*”. Published by the British Standards Institution on 31st March 2012 (ISBN 978 0 580 67002 2). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

<sup>(5)</sup> Content of Decoquinatate (Deccox<sup>®</sup>): mg/kg of complete feed with a moisture content of 12%.

## SCHEDULE 11

Regulation 3

### Authorisation of Decoquinatate (Avi-Deccox<sup>®</sup> 60G) (identification number 51756ii) as a feed additive for chickens for fattening

The substance of Decoquinatate (Avi-Deccox<sup>®</sup> 60G), belonging to the additive ‘coccidiostats and histomonostats’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table(a).

<i>Additive</i>	Decoquinatate (Avi-Deccox <sup>®</sup> 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>	Not applicable
<i>Additive composition</i>	<ul style="list-style-type: none"> <li>— Decoquinatate, 60.0 g/kg</li> <li>— Colloidal silica, 0.6 g/kg</li> <li>— Silicon dioxide, 4.0 g/kg</li> <li>— Carboxymethylcellulose sodium, 30.0 g/kg</li> <li>— Calcium sulphate dihydrate, q.s. ad 1,000 g</li> </ul>
<i>Characterisation of the active substance(s)</i>	<p>Decoquinatate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate)</p> <ul style="list-style-type: none"> <li>— Chemical Formula: C<sub>24</sub>H<sub>35</sub>NO<sub>5</sub></li> </ul>

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

	<p>— CAS No: 18507-89-6<sup>(1)</sup></p> <p>Related impurities:</p> <p>— Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: &lt; 1.0%</p> <p>— 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: &lt; 0.5%</p> <p>— Diethyl-4-decycloxy-3-ethoxyanilinomethylene-malonate: &lt; 0.5%</p>
<i>Analytical methods</i> <sup>(2)</sup>	<p>For quantification of decoquinatate in the feed additive, premixtures feed materials and compound feed:</p> <p>— Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) in accordance with BS EN 16162:2012<sup>(3)</sup>.</p>
	<p>For quantification of decoquinatate in tissues:</p> <p>— Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS<sup>(4)</sup>) or any other analytical method complying with the requirements set by Commission Decision 2002/657/EC(a).</p>
<i>Species or category of animal</i>	Chickens for fattening
<i>Maximum age</i>	Not applicable
<i>Minimum content</i> <sup>(5)</sup>	30 mg/kg
<i>Maximum content</i> <sup>(5)</sup>	40 mg/kg
<i>Other provisions</i>	<ol style="list-style-type: none"> <li>1) In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated.</li> <li>2) The additive must be incorporated in compound feed in the form of a premixture.</li> <li>3) Decoquinatate must not be mixed with other coccidiostats.</li> <li>4) Decoquinatate must not be used in feed containing bentonite.</li> <li>5) A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and <i>Eimeria</i> spp. A report containing the outcome of the post market monitoring programme must be submitted to the Secretary of State before 25th November 2031.</li> </ol>

<sup>(1)</sup> 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>.

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

<sup>(3)</sup> BS EN 16162:2012. “*Animal feeding stuffs. Determination of decoquinatate by HPLC with fluorescence detection*”. Published by the British Standards Institution on 31st March 2012 (ISBN 978 0 580 67002 2). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

<sup>(5)</sup> Content of Decoquinatate (Avi-Deccox<sup>®</sup>): mg/kg of complete feed with a moisture content of 12%.

(a) EUDN 2002/657, as amended by S.I 2020/1461.

## Revocation of retained direct EU legislation

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(a).

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)(b).

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)(c).

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)(d).

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)(e).

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(f).

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)(g).

Commission Implementing Regulation (EU) No. 515/2011 concerning the authorisation of vitamin B6 as a feed additive for all animal species(h).

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(i).

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.)(j).

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

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- (a) EUR 2004/1289.
  - (b) EUR 2009/903.
  - (c) EUR 2010/8.
  - (d) EUR 2010/107.
  - (e) EUR 2010/883.
  - (f) EUR 2011/168.
  - (g) EUR 2011/373.
  - (h) EUR 2011/515.
  - (i) EUR 2011/885.
  - (j) EUR 2013/357.

laying (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)(a).

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 decoquinat(e)(b).

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)(c).

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)(d).

### EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations authorise the placing on the market of eleven feed additives in England.

Regulation 3 and Schedules 1 to 11 contain the following authorisations: —

- Schedule 1 authorises a new feed additive Manganese chelate of lysine and glutamic acid (identification number 3b509);
- Schedule 2 authorises a new feed additive *Lactobacillus buchneri* (DSM 29026) (identification number 1k20759);
- Schedule 3 authorises a new feed additive Serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* (DSM 19670) (identification number 4a13);
- Schedule 4 renews the authorisation of Pyridoxine hydrochloride (vitamin B<sub>6</sub>) (identification number 3a831);
- Schedule 5 renews the authorisation of *Saccharomyces cerevisiae* (CNCM I-4407) (identification number 4b1702);
- Schedule 6 renews the authorisation (with modification) of *Bacillus velezensis* (ATCC PTA-6737) (identification number 4b1823) and authorises it for a new use to be used in feed for all minor poultry (except for laying) and ornamental, sporting and game birds;
- Schedule 7 authorises a new feed additive *Bacillus licheniformis* (DSM 28710) (identification number 4b1828);
- Schedule 8 renews the authorisation of *Clostridium butyricum* (FERM BP-2789) (identification number 4b1830), authorises it for a new use to be used in feed, suckling piglets and minor porcine species (suckling) and as a new feed additive for chickens for fattening;
- Schedule 9; authorises a new feed additive 6-phytase (EC 3.1.3.26) produced by *Komagataella phaffii* DSM 32854 (identification number 4a32);
- Schedule 10 authorises a new formulation of Deccox<sup>®</sup> (identification number E756) as Decoquinat(e) (Deccox<sup>®</sup>) (identification number 51756i) following a re-evaluation requested by the holder;
- Schedule 11 authorises a modification of Deccox<sup>®</sup> (identification number E756) as Decoquinat(e) (Avi-Deccox<sup>®</sup> 60G) (identification number 51756ii) This feed additive

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(a) EUR 2013/374.

(b) EUR 2014/291.

(c) EUR 2014/1108.

(d) EUR 2017/1126.

differs from Decoquate (Deccox®) in its physical form and in the carrier used being calcium sulphate dihydrate.

Authorisations granted by these Regulations are valid for a period of ten 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 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 bacterial strain name is amended from “*Bacillus subtilis*” to “*Bacillus velezensis*”.

Regulation 8 is a transitional provision which allows products labelled using the name “*Bacillus subtilis*” in Regulations 4 to 7 to continue to be marketed and used under the relevant authorisations despite the name change. It also enables the continued production and labelling of products, for limited periods under the previous authorisation that is now authorised by Schedule 6.

Regulations 9 and 10 contain transitional provisions that enable the continued production and labelling of products, for limited periods, under the conditions of previous authorisations where authorisations are renewed under Schedules 5 and 10 respectively.

Regulation 11 and Schedule 12 revoke, in relation to England, retained EU Regulations that contain previous authorisations for the feed additives now authorised by Schedules 3, 4, 5, 6, 8, 10 and 11.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.

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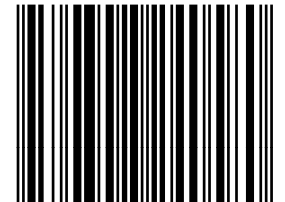
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