SCOTTISH STATUTORY INSTRUMENTS

2024 No. 330

AGRICULTURE

The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Miscellaneous Amendment) (Scotland) Regulations 2024

Made - - - -	*6th November 2024*
Laid before the Scottish Parliament	*8th November 2024*
Coming into force - -	*20th December 2024*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by Articles 9(1), 10(5) and 18A(3) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition(**a**) and section 74A(1) of the Agriculture Act 1970(**b**), 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(**c**).

PART 1

Introduction

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Miscellaneous Amendment) (Scotland) Regulations 2024 and come into force on 20 December 2024.

(2) These Regulations extend to Scotland only.

(**a**) EUR 2003/1831 ("Regulation 1831/2003"). Article 9(1) was amended by S.I. 2019/654 and S.I. 2022/377. Article 10(5) was substituted by S.I. 2019/654. Article 18A was inserted by S.I. 2019/654. S.I. 2019/654 was amended by S.I. 2020/1504. Article 2 contains definitions of "prescribe" and "appropriate authority" relevant to the exercise of the powers in Regulation 1831/2003 under which these Regulations are made and was amended by S.I. 2019/654. Article 9(1) applies in relation to renewals in accordance with Article 14.

(**b**) 1970 c. 40. Section 66(1) contains definitions of "the Ministers", "prescribed" and "regulations" relevant to the exercise of the power in section 74A(1). Section 74A was inserted by paragraph 6 of schedule 4 of the European Communities Act 1972 (c. 68) and was relevantly amended by S.I. 2011/1043.

(**c**) EUR 2002/178.

Interpretation

2.—(1) In these Regulations—

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

"Regulation 429/2008" means 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**),

"Regulation 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, 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(**b**).

(2) Expressions used in these Regulations and in Regulation 1831/2003 or Regulation 767/2009 have the same meaning as in Regulation 1831/2003 or Regulation 767/2009, respectively.

(3) In schedules 1 to 20—

(a) expressions used to refer to species or categories of animals that are also used in Annex 4 (categories and definitions of target animals and indication of the minimum duration of efficacy studies) of Regulation 429/2008 have the same meaning as in that Annex,

(b) any reference to a minor species is to be read in accordance with the definition of "minor species" in Article 1 (definitions) of Regulation 429/2008.

PART 2

Feed Additive Authorisations

3.—(1) Schedules 1 to 20 have effect.

(2) Subject to Article 14(4) (renewal of authorisation) of Regulation 1831/2003, the authorisations set out in schedules 1 to 20 cease to have effect at the end of 19 December 2034.

Modification of authorisations for a preparation of *Bacillus velezensis* (DSM 15544) (identification number 4b1820)

4.—(1) Commission Implementing Regulation (EU) 2016/897 concerning the authorisation of a preparation of *Bacillus subtilis* (C-3102) (DSM 15544) as a feed additive for laying hens and ornamental fish (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) and amending Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011(**c**) is amended as follows.

(2) Omit Articles 2 to 4.

(3) In the Annex, in the table—

(a) in the second column (name of the holder of authorisation), for "Asahi Calpis Wellness Co. Ltd, represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office" substitute "Asahi Biocycle Co., Ltd, (represented by Pen & Tec Consulting S.L.U., now trading as Argenta)",

(b) in the third column (additive) and the fourth column (composition, chemical formula, description, analytical method), for "*Bacillus subtilis* C-3102", in each place it occurs, substitute "*Bacillus velezensis*",

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(**a**) EUR 2008/429, to which there are amendments not relevant to these Regulations.
(**b**) EUR 2009/767, amended by S.I. 2019/654 and S.I. 2022/1351.
(**c**) EUR 2016/897, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 22 and schedule 21 of these Regulations.

(c) in the fifth column (species or category of animal), omit "Laying hens",

(d) in the sixth column (minimum content), omit "3×10^8".

5.—(1) In Commission Implementing Regulation (EU) 2017/2312 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for sows, suckling piglets and dogs (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**a**), in the Annex, the table is amended as follows.

(2) In the second column (name of the holder of authorisation), for "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." substitute "Asahi Biocycle Co., Ltd (represented by Pen & Tec Consulting S.L.U., now trading as Argenta)".

(3) In the third column (additive), for "*Bacillus subtilis*" substitute "*Bacillus velezensis*".

(4) In the fourth column (composition, chemical formula, description, analytical method)—

(a) in the section headed "*Additive composition*", for "*Bacillus subtilis* C-3102" substitute "*Bacillus velezensis*",

(b) in the section headed "*Characterisation of the active substance*", for "*Bacillus subtilis*" substitute "*Bacillus velezensis*".

6.—(1) In Commission Implementing Regulation (EU) 2018/1081 concerning the authorisation of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for pigs for fattening (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**b**), in the Annex, the table is amended as follows.

(2) In the second column (name of the holder of authorisation), for "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." substitute "Asahi Biocycle Co., Ltd (represented by Pen & Tec Consulting S.L.U., now trading as Argenta)".

(3) In the third column (additive) and the fourth column (composition, chemical formula, description, analytical method), for "*Bacillus subtilis* C-3102", in each place it occurs, substitute "*Bacillus velezensis*".

Modification of authorisation for selenised yeast produced from *Saccharomyces cerevisiae* CNCM I-3060 (identification number 3b810)

7.—(1) In Commission Implementing Regulation (EU) 2019/804 concerning the renewal of the authorisation of organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives for all animal species(**c**), in the Annex, the entry for "3b810" is amended as follows.

(2) In the third column (composition, chemical formula, description, analytical method), for the section headed "*Additive composition*", substitute—

"*Additive composition* Preparation of organic selenium (Se) produced by Saccharomyces cerevisiae (CNCM I-3060) containing 2000 to 3500 mg Se/kg with the below components: • Organic selenium: 97% minimum of total selenium • Selenomethionine: 63% minimum of total selenium".

(**a**) EUR 2017/2312, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 22 and schedule 21 of these Regulations.

(**b**) EUR 2018/1081, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 22 and schedule 21 of these Regulations.

(**c**) EUR 2019/804.

(3) In the ninth column (other provisions), after point 4, insert—

"5. The dusting potential of the additive must ensure a maximum selenium exposure of 0.2 mg Se/m^3."

Removal of authorisation of Butylated hydroxyanisole as an existing product for the purposes of Article 10 of Regulation 1831/2003 (identification number 1b320)

8. Butylated hydroxyanisole (E 320) is authorised to be placed on the market, processed or used as a feed additive for cats only to the extent that it is covered by and meets the conditions of the authorisation contained in schedule 11 of these Regulations.

Changes of authorisation holder: amendment of Commission Implementing Regulations (EU) 887/2011, 2017/961 and 2020/1395

9.—(1) Commission Implementing Regulation (EU) No 887/2011 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as feed additive for chickens for fattening (holder of the authorisation Evonik Nutrition & Care GmbH)(**a**) is amended as follows.

(2) In the Annex, in the second column of both tables (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH)", in each place it occurs, substitute "Evonik Operations GmbH".

10.—(1) Commission Implementing Regulation (EU) 2017/961 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as a feed additive for weaned piglets, and a new use in water for drinking for weaned piglets and chickens for fattening, and amending Regulation (EC) No 2036/2005 and Regulation (EU) No 887/2011 (holder of authorisation Evonik Nutrition & Care GmbH)(**b**) is amended as follows.

(2) In Annex 1, in the table, in the second column (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH)" substitute "Evonik Operations GmbH".

11.—(1) Commission Implementing Regulation (EU) 2020/1395 concerning the renewal of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive for chickens for fattening, its authorisation for chickens reared for laying, and repealing Regulation (EC) No 1292/2008 (holder of authorisation Evonik Nutrition & Care GmbH)(**c**) is amended as follows.

(2) In the Annex, in the table, in the second column (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH" substitute "Evonik Operations GmbH".

PART 3

Uses of feed intended for particular nutritional purposes

Modification of an essential nutritional characteristic for feed intended to reduce the risk of milk fever and subclinical hypocalcaemia

12.—(1) In Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes(**d**), in the Annex, in Part B (list of intended uses), the table is amended as follows.

(**a**) EUR 2011/887, amended prior to implementation period completion day by Commission Implementing Regulations (EU) 2017/173 and 961.
(**b**) EUR 2017/961.
(**c**) EUR 2020/1395.
(**d**) EUR 2020/354.

(2) In entry 60 (reduction of the risk of milk fever and subclinical hypocalcaemia), in column number 2 (essential nutritional characteristics), in the section of the entry starting "Low cations/anions ratio", for "Objective: 0 < DCADs (mEq/kg dry matter) < 100" substitute "Objective: Range from -200 mEq/kg dry matter DCADs to <100 mEq/kg dry matter DCAD".

PART 4

Transitional provisions

Transitional provision: *Bacillus velezensis* (DSM 15544) (formerly *Bacillus subtilis* C-3102) (identification number 4b1820)

13.—(1) Any substance or product labelled "*Bacillus subtilis* (C-3102)", or as containing "*Bacillus subtilis* (C-3102)", but otherwise produced and labelled in accordance with an authorisation contained in assimilated direct legislation mentioned in regulations 4 to 6, 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 19 June 2025 in accordance with the conditions of the prior authorisations and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(3) Compound feed and feed materials containing the relevant feed additive, and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in accordance with the conditions of the prior authorisations and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) Compound feed and feed materials containing the relevant feed additive, and intended for non-food-producing animals, which are produced and labelled before the end of 19 December 2026 in accordance with the conditions of the prior authorisations and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(5) In this regulation—

"relevant feed additive" means the feed additive of a preparation of *Bacillus velezensis* (DSM 15544) (formerly *Bacillus subtilis* C-3102), with the identification number 4b1820, authorised under the prior authorisations;

"prior authorisations" means the authorisations contained in—

(i) Commission Regulation (EU) No 333/2010 concerning the authorisation of a new use of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets(**a**),

(ii) Commission Regulation (EU) No 184/2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds(**b**),

(iii) Commission Implementing Regulation (EU) 2016/897 concerning the authorisation of a preparation of *Bacillis subtilis* C-3102 (DSM 15544) as a feed additive for laying hens and ornamental fish(**c**),

(iv) Commission Implementing Regulation (EU) 2019/893 concerning the renewal of the authorisation of *Bacillus subtilis* DSM 15544 as a feed additive for chickens for fattening(**d**).

(**a**) EUR 2010/333. This Regulation is revoked by regulation 22 and schedule 21 of these Regulations.
(**b**) EUR 2011/184. This Regulation is revoked by regulation 22 and schedule 21 of these Regulations.
(**c**) EUR 2016/897. This Regulations is revoked by regulation 22 and schedule 21 of these Regulations.
(**d**) EUR 2019/893. This Regulation is revoked by regulation 22 and schedule 21 of these Regulations.

Transitional provision: Selenised yeast produced from *Saccharomyces cerevisiae* (CNCM I-3060), inactivated (identification number 3b810)

14.—(1) The relevant feed additive, and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing the relevant feed additive, and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(3) Compound feed and feed materials containing the relevant feed additive, and intended for non-food-producing animals, which are produced and labelled before the end of 19 December 2026 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation—

"relevant feed additive" means the feed additive selenised yeast Saccharomyces cerevisiae (CNCM 1-3060), inactivated, with the identification number 3b810 authorised under the prior authorisation,

"prior authorisation" means the authorisation contained in Commission Implementing Regulation (EU) 2019/804 concerning the renewal of the authorisation of organic form selenium produced by Saccharomyces cerevisiae CNCM I-3060 and of selenomethionine produced by Saccharomyces cerevisiae NCYC R397 as feed additives for all animal species(**a**).

Transitional provision: Butylated hydroxyanisole as a feed additive for cats (identification number 1b320)

15.—(1) Butylated hydroxyanisole as a feed additive for cats, and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in accordance with the conditions of authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing butylated hydroxyanisole, intended for cats, which are produced and labelled before the end of 19 December 2026 in accordance with the conditions of authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

Transitional provision: 6-phytase (EC 3.1.3.26) produced from *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) (identification number 4a16)

16.—(1) The relevant feed additive, and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing the relevant feed additive, and intended for food-producing animals, which are produced and labelled before the end of 19 June 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(3) In this regulation—

(**a**) See regulation 7 of these Regulations for amendments to EUR 2019/804.

"relevant feed additive" means the feed additive 6-phytase (EC 3.1.3.26), with the identification number 4a16 authorised under the prior authorisation,

"prior authorisation" means the authorisation contained in Commission Implementing Regulation (EU) No 98/2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Pichia pastoris* (DSM 23036) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows (holder of authorisation Huvepharma AD)(**a**).

Transitional provision: Copper chelate of hydroxy analogue of methionine (identification number 3b410i) (formerly 3b4.10)

17.—(1) The relevant feed additive, and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing the relevant feed additive, and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(3) Compound feed and feed materials containing the relevant feed additive, and intended for non-food-producing animals, which are produced and labelled before the end of 19 December 2026 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation—

"relevant feed additive" means copper chelate of hydroxy analogue of methionine, with the identification number 3b410i authorised under the prior authorisation,

"prior authorisation" means the authorisation contained in Commission Regulation (EU) No 349/2010 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species(**b**).

Transitional provision: Manganese chelate of hydroxy analogue of methionine (identification number 3b510)

18.—(1) The relevant feed additive, and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing the relevant feed additive, and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(3) Compound feed and feed materials containing the relevant feed additive, and intended for non-food-producing animals, which are produced and labelled before the end of 19 December 2026 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation—

(**a**) EUR 2012/98. This Regulation is revoked by regulation 22 and schedule 21 of these Regulations.
(**b**) EUR 2010/349. This Regulation is revoked by regulation 22 and schedule 21 of these Regulations.

"relevant feed additive" means manganese chelate of hydroxy analogue of methionine, with the identification number 3b510 authorised under the prior authorisation,

"prior authorisation" means the authorisation contained in Commission Regulation (EU) No 350/2010 concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species(**a**).

Transitional provision: Zinc chelate of hydroxy analogue of methionine (identification number 3b610) (formerly 3b6.10)

19.—(1) The relevant feed additive, and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing the relevant feed additive, and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(3) Compound feed and feed materials containing the relevant feed additive, and intended for non-food-producing animals, which are produced and labelled before the end of 19 December 2026 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation—

"relevant feed additive" means zinc chelate of hydroxy analogue of methionine, with the identification number 3b610 authorised under the prior authorisation,

"prior authorisation" means the authorisation contained in Commission Regulation (EU) No 335/2010 concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species(**b**).

PART 5

Revocations

Amendment of Commission Implementing Regulation (EU) 2016/1095

20. In Commission Implementing Regulation (EU) 2016/1095 concerning the authorisation of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species(**c**), omit Article 4 (Amendment to Regulation (EU) No 335/2010).

Amendment of Commission Implementing Regulation (EU) 2018/1039

21. In Commission Implementing Regulation (EU) 2018/1039 concerning the authorisation of Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine

(**a**) EUR 2010/350. This Regulation is revoked by regulation 22 and schedule 21 of these Regulations.
(**b**) EUR 2010/335. This Regulation is revoked by regulation 22 and schedule 21 of these Regulations.
(**c**) EUR 2016/1095.

hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) as feed additives for all animal species(**a**), omit Article 5 (Amendment to Regulation (EU) No 349/2010).

Revocations

22.—(1) The instruments listed in paragraphs 2, 3, 4, 5, 7, 8 and 10 of schedule 21 are revoked subject to Part 4.

(2) The instruments listed in paragraphs 1, 6, 9 and 11 of schedule 21 are revoked.

JENNI MINTO
Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
6th November 2024

(**a**) EUR 2018/1039.

SCHEDULES

SCHEDULE 1

Regulation 3(1)

Authorisation of a preparation of chromium chelate of DL-methionine (identification number GB4d0001) as a feed additive for dairy cows

Authorisation

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

Additive	Chromium chelate of DL-methionine
Identification number	GB4d0001
Authorisation holder	Zinpro Animal Nutrition (Europe), Inc
Additive category	Zootechnical additives
Functional group	Other zootechnical
Additive composition	Solid preparation of chelates of chromium (Cr) with DL-methionine with the below components: • Calcium carbonate: 95.6% • Chromium-DL-Methionine: 3.4% • Vegetable oil: 1.0%
Characterisation of the active substance(s)	Chromium chelate of DL-methionine ($[CH_3S(CH_2)_2CH(NH_2)COO]_3$ Cr)
Analytical methods(**a**)	For quantification of chromium in the feed additive: • Inductively coupled plasma-mass spectrometry (ICP-MS) in accordance with BS EN 17053:2018(**b**) For quantification of methionine in the feed additive: • Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) in accordance with BS EN ISO 13903:2005(**c**) For proving the chelated structure of the feed additive: • Mid-infrared (IR) spectrometry together with the determination of the content of chromium and methionine in the feed additive
Species or category of animal	Dairy cows
Maximum age	No maximum

(**a**) Details of the analytical methods are set out in the document referenced "JRC F.5/CvH/ZE/AS/Ares" and last updated on 18 October 2019 are available at: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0021_en.

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

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

Content of chromium in complete feed with a moisture content of 12%	*Minimum content*	0.2 mg/kg
	Maximum content	0.5 mg/kg
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

SCHEDULE 2

Regulation 3(1)

Renewal of authorisation of a preparation of *Saccharomyces cerevisiae* (MUCL 39885) (identification number 4b1710) as a feed additive for weaned piglets, and its authorisation as a feed additive extending existing uses to cover all *Suidae* other than sows and suckling piglets, and cats and dogs

Authorisation

1. The preparation specified in the table, belonging to the additive category "zootechnical additives" and to the functional group "gut flora stabilisers", is authorised as an additive in animal nutrition, subject to the conditions set out in the table(**a**).

Additive		*Saccharomyces cerevisiae* (MUCL 39885)
Identification number		4b1710
Authorisation holder		Prosol S.p.A
Additive category		Zootechnical additives
Functional group		Gut flora stabilisers
Additive composition		Solid preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1×10^9 colony forming units (CFU)/g
Characterisation of the active substance(s)		Viable cells of *Saccharomyces cerevisiae* (MUCL 39885)
Analytical methods(**b**)		For enumeration: • Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021(**c**) For identification of the yeast strain: • Polymerase chain reaction (PCR) method (DD CEN/TS 15790:2008(**d**))
Species or category of animal		All *Suidae* other than sows and suckling piglets Cats Dogs
Maximum age		No maximum
Colony forming units of additive/ kg complete	*Minimum content*	For all *Suidae* other than sows and suckling piglets, and *Suidae* for reproduction purposes: • 3×10^9 CFU/kg For all *Suidae* for reproduction purposes, other than sows: • 6.4×10^9 CFU/kg

(**a**) This authorisation is a renewal (with modifications) of the authorisation granted under Commission Regulation (EU) No 170/2011 (EUR 2011/170). That Regulation is revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications made to that authorisation.

(**b**) Details of the analytical methods are set out in the document referenced "D06/FSQ/CVH/CMP/mdr/ARES (2010)58412", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en.

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

(**d**) DD CEN/TS 15790:2008 "Animal feeding stuffs. PCR typing of probiotic strains of Saccharomyces cerevisiae (yeast)". Published by the British Standards Institution on 31 January 2009 (ISBN 978 0 580 61806 2). Available at: https://knowledge.bsigroup.com.

feed with a moisture content of 12%		For cats and dogs: • 7×10^{10} CFU/kg
	Maximum content	No maximum
Other provisions		The storage conditions must be indicated in the directions for use of the feed additive and premixture

SCHEDULE 3

Regulation 3(1)

Authorisation of a preparation of *Pediococcus acidilactici* (CNCM I-4622) (identification number 4d1712) as a feed additive for all animal species

Authorisation

1. The preparation specified in the table, belonging to the additive category "technological additives" and to the functional groups "acidity regulators" and "hygiene condition enhancers", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive		*Pediococcus acidilactici* (CNCM I-4622)
Identification number		4d1712
Authorisation holder(**a**)		None
Additive category		Technological additives
Functional groups		• Acidity regulators • Hygiene condition enhancers
Additive composition		Solid preparation of *Pediococcus acidilactici* (CNCM I-4622) containing a minimum of 1×10^{10} colony forming units (CFU)/g
Characterisation of the active substance(s)		Viable cells of *Pediococcus acidilactici* (CNCM I-4622)
Analytical methods(**b**)		For enumeration (colony count) of the feed additive: • Spread plate method using MRS agar in accordance with BS EN 15786:2021(**c**) For identification of the bacterial strain: • Pulsed-Field Gel Electrophoresis (PFGE)
Species or category of animal		All animal species
Maximum age		No maximum
Colony forming units of additive/ kg complete feed with a moisture content of 12%	*Minimum content*	1×10^9 CFU/kg
	Maximum content	No maximum

(**a**) 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.

(**b**) Details of the analytical methods are set out in the document referenced "Ares(2014)1202206 - 16/04/2014" and "JRC.D.5/SFB/CvH/JO/mds/Ares", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2013-0031_en.

(**c**) BS EN 15786:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Pediococcus spp. used as feed additive". Published by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99830). Available at: https://knowledge.bsigroup.com.

Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. To be used only in mash compound feed intended for preparation of liquid feed on farm, or solid feed materials intended for preparation of liquid feed on farm 3. If *Pediococcus acidilactici* (CNCM I-4622) is to be used in feed containing coccidiostats, this feed additive is authorised for use with the following coccidiostats only, and in accordance with their individual authorisation criteria: • Decoquinate • Diclazuril • Halofuginone • Nicarbazin • Robenidine hydrocholoride

SCHEDULE 4

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of monensin sodium (produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419)) (carrier: perlite, calcium carbonate) (identification number 51701) as a feed additive for chickens for fattening, chickens reared for laying, and turkeys for fattening, and its authorisation as a feed additive extending existing uses to cover turkeys reared for breeding

Authorisation

1. The preparation specified in the table, belonging to the additive category "coccidiostats and histomonostats", is authorised as an additive in animal nutrition, subject to the conditions set out in the table(**a**).

Additive	Monensin sodium
Identification number	51701
Authorisation holder	Huvepharma NV
Additive category	Coccidiostats and histomonostats
Functional group	None
Additive composition	Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419) in powder form with the below components: • Monensin sodium technical substance: 250 g/kg containing: — Monensin A: 90% minimum — Monensin A + B: 95% minimum — Monensin C: 0.2% – 0.3% • Perlite: 150 – 200 g/kg • Calcium carbonate: 550 – 600 g/kg
Characterisation of the active substance(s)	Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419): • Monensin sodium A ($C_{36}H_{61}NaO_{11}$) • Monensin sodium B ($C_{35}H_{59}NaO_{11}$) • Monensin sodium C ($C_{37}H_{63}NaO_{11}$) • CAS number: 22373-78-0(**b**)

(**a**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EC) No 109/2007 (EUR 2007/109). Those Regulations are revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications and new use made to that authorisation.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

Analytical methods(**a**)		For quantification of monensin in the feed additive, premixtures and compound feed: • Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008(**b**) For quantification of monensin sodium in chicken and turkey tissues: • Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods
Species or category of animal		• Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
Maximum age		For chickens for fattening: • No maximum For chickens reared for laying; turkeys for fattening; turkeys reared for breeding: • 16 weeks
Content of monensin (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	For chickens for fattening; chickens reared for laying: • 100 mg/kg For turkeys for fattening; turkeys reared for breeding: • 60 mg/kg
	Maximum content	For chickens for fattening; chickens reared for laying: • 125 mg/kg For turkeys for fattening; turkeys reared for breeding: • 100 mg/kg
Maximum residue limits (MRLs) of monensin sodium in food of animal origin		For wet skin and fat: • 25 µg/kg For wet liver; wet kidney; wet muscle: • 8 µg/kg
Other provisions		1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. The feed additive must be incorporated into compound feed in the form of a premixture 3. Monensin sodium must not be mixed with other coccidiostats 4. The following must be stated in the directions for use: • "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances."

(**a**) Details of the analytical methods are set out in the document referenced "Ares(2017)1087313 - 01/03/2017" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 27 April 2017. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en.

(**b**) BS EN ISO 14183:2008 "animal feeding stuffs. Determination of monensin, narasin and salinomycin contents. Liquid chromatographic method using post-column derivatization". Published by the British Standards Institution on 24 January 2006 (ISBN 978 0 580 62955 6). Available at: https://knowledge.bsigroup.com.

	5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria* spp. A report containing the outcome of that programme must be submitted to the Scottish Ministers before the end of 19 December 2033

SCHEDULE 5

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of monensin sodium (produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419)) (carrier: perlite, wheat bran) (identification number 51701) as a feed additive for chickens for fattening, and turkeys for fattening, and its authorisation as a feed additive extending existing uses to cover chickens reared for laying, and turkeys reared for breeding

Authorisation

1. The preparation specified in the table, belonging to the additive category "coccidiostats and histomonostats", is authorised as an additive in animal nutrition, subject to the conditions set out in the table(**a**).

Additive	Monensin sodium
Identification number	51701
Authorisation holder	Huvepharma NV
Additive category	Coccidiostats and histomonostats
Functional group	No functional group
Additive composition	Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419) in powder form with the below components: • Monensin sodium technical substance: 250g/kg containing: — Monensin A: 90% minimum — Monensin A + B: 95% minimum — Monensin C: 0.2 – 0.3% • Perlite: 150 – 200 g/kg • Wheat bran: 550 – 600 g/kg
Characterisation of the active substance(s)	Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419): • Monensin sodium A ($C_{36}H_{61}NaO_{11}$) • Monensin sodium B ($C_{35}H_{59}NaO_{11}$) • Monensin sodium C ($C_{37}H_{63}NaO_{11}$) • CAS number: 22373-78-0(**b**)

(**a**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EC) No 109/2007 (EUR 2007/109). That Regulation is revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications and new use made to that authorisation.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

Analytical methods(**a**)		For quantification of monensin in the feed additive, premixtures and compound feed: • Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008(**b**) For quantification of monensin sodium in chicken and turkey tissues: • Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods
Species or category of animal		• Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
Maximum age		For chickens for fattening: • No maximum For chickens reared for laying; turkeys for fattening; turkeys reared for breeding: • 16 weeks
Content of monensin (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	For chickens for fattening; chickens reared for laying: • 100 mg/kg For turkeys for fattening; turkeys reared for breeding: • 60 mg/kg
	Maximum content	For chickens for fattening; chickens reared for laying: • 125 mg/kg For turkeys for fattening; turkeys reared for breeding: • 100 mg/kg
Maximum residue limits (MRLs) of monensin sodium in food of animal origin		For wet skin and fat: • 25 µg/kg For wet liver; wet kidney; wet muscle: • 8 µg/kg
Other provisions		1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. The feed additive must be incorporated into compound feed in the form of a premixture 3. Monensin sodium must not be mixed with other coccidiostats 4. The following must be stated in the directions for use: "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances."

(**a**) Details of the analytical methods are set out in the document referenced "Ares(2017)1087313 - 01/03/2017" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 27 April 2017. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en.

(**b**) BS EN ISO 14183:2008 "Animal feeding stuffs. Determination of monensin, narasin and salinomycin contents. Liquid chromatographic method using post-column derivatization". Published by the British Standards Institution on 24 January 2006 (ISBN 978 0 580 62955 6). Available at: https://knowledge.bsigroup.com.

	5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria* spp. A report containing the outcome of that programme must be submitted to the Scottish Ministers before the end of 19 December 2033

SCHEDULE 6

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of 6-phytase (EC 3.1.3.26) produced from *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) (identification number 4a16) as a feed additive for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, other avian species for fattening and laying, sows, pigs for fattening and weaned piglets, and its authorisation as a feed additive extending existing uses to cover all avian species and all porcine species

Authorisation

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

Additive	6-phytase (EC 3.1.3.26)
Identification number	4a16
Authorisation holder	Huvepharma NV
Additive category	Zootechnical additives
Functional group	Digestibility enhancers
Additive composition	Preparation of 6–phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) having a minimum enzyme activity of: • 4,000 OTU/g(**b**) in solid form • 8,000 OTU/g in liquid form
Characterisation of the active substance(s)	6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036): • CAS number: 9001-89-2(**c**) • EC (IUBMB) number(**d**): 3.1.3.26
Analytical methods(**e**)	For the quantification of phytase activity in the feed additive, premixtures and compound feed: • Colorimetric method based on the quantification of the inorganic phosphate released by the enzyme from the sodium phytate

(**a**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Implementing Regulation (EC) No 98/2012 (EUR 2012/98). That Regulation is revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications and new use made to that authorisation.

(**b**) OptiPhos technical units (phytase activity) : 1 OTU is the amount of enzyme that catalyses the release of 1 µmol of inorganic phosphate per minute from 5.1 mM sodium phytate in pH 5.5 citrate buffer at 37ºC, measured as the blue P-molybdate complex colour at 820 nm.

(**c**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**d**) Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) https://iubmb.org.

(**e**) Details of the analytical methods are set out in the document referenced "Ares(2016)5971303 - 17/10/2016" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 17 November 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0019_en.

Species or category of animal		• All avian species • All *Suidae* species
Maximum age		No maximum
Content of 6-phytase (EC 3.1.3.26) (units of activity (OUT/kg) of complete feed with a moisture content of 12%)	*Minimum content*	For all avian species other than turkeys, and all *Suidae* species other than piglets: • 125 OTU/kg For turkeys and piglets: • 250 OTU/kg
	Maximum content	No maximum
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

SCHEDULE 7

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of *Bacillus velezensis* (formerly *Bacillus subtilis*) (DSM 15544) (identification number 4b1820) as a feed additive for weaned piglets, chickens reared for laying, turkeys, minor avian species, ornamental birds and game birds and its authorisation as a feed additive extending and consolidating existing authorised uses to cover all avian species

Authorisation

1. The preparation specified in the table, belonging to the additive category "zootechnical additives" and to the functional group "gut flora stabilisers", is authorised as an additive in animal nutrition, subject to the conditions set out in the table(**a**).

Additive		*Bacillus velezensis* (DSM 15544)
Identification number		4b1820
Authorisation holder		Asahi Biocycle Co., Ltd
Additive category		Zootechnical additives
Functional group		Gut flora stabilisers
Additive composition		Solid preparation of *Bacillus velezensis* (DSM 15544) containing a minimum of 1×10^{10} colony forming units (CFU)/g
Characterisation of the active substance(s)		Viable spores of *Bacillus velezensis* (DSM 15544)
Analytical methods(**b**)		For enumeration (colony count) of the feed additive: • Spread plate method using tryptone soya agar in all target matrices in accordance with BS EN 15784:2021(**c**) For identification of the feed additive: • Pulsed-field gel electrophoresis (PFGE)
Species or category of animal		• Weaned piglets • All avian species
Maximum age		No maximum
Colony forming	*Minimum content*	3×10^{8} CFU/kg

(**a**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EU) No 333/2010 (EUR 2010/333). That Regulation is revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications and new use made to that authorisation.

(**b**) Details of the analytical methods are set out in the document referenced "D08/FSQ/CVH/CMP/mds/ARES (2009)347415" and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2009-0013_en.

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

units of additive/ kg complete feed with a moisture content of 12%	*Maximum content*	No maximum
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

SCHEDULE 8

Regulation 3(1)

Authorisation of a preparation of L-histidine monohydrochloride monohydrate (produced from *Escherichia coli* K-12 (KCCM 80212)) (identification number 3c352i) as a feed additive for all animal species

Authorisation

1. The preparation specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	L-histidine monohydrochloride monohydrate
Identification number	3c352i
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	L-histidine monohydrochloride monohydrate with a purity criteria not less than 98% as a powder with the following components: • Moisture: 1% maximum • Histidine: 72% minimum • Histamine: 100ppm maximum
Characterisation of the active substance(s)	L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) ($C_6H_{12}ClN_3O_3$): • CAS number: 5934-29-2(**b**) • EINECS number: 611-821-4(**c**)
Analytical methods(d)	For quantification of histidine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) in accordance with BS EN ISO 13903:2005(**e**), or • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(**d**) Details of the analytical methods are set out in the document referenced "Ares(2020)3718494 – 14/07/2020" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0016_en.

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

		For quantification of histidine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3-F)(**a**) For quantification of histamine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) in accordance with BS EN ISO 13903:2005
Species or category of animal		All animal species
Maximum age		No maximum
Content of L-histidine monohydrochloride monohydrate (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation 3. The histidine content must be indicated on the label of the additive and must contain the following declaration on the label of the additive and premixture: "The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depends on the environmental conditions, the species, physiological state, performance level of the animal and level of other amino acids and essential trace elements such as copper and zinc." 4. The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3air(**b**)

(**a**) EUR 2009/152, to which there amendments not relevant to these Regulations.
(**b**) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

SCHEDULE 9

Regulation 3(1)

Authorisation of a preparation of L-tryptophan (produced from *Escherichia coli* (KCCM 80210)) (identification number 3c440i) as a feed additive for all animal species

Authorisation

1. The preparation specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	L-tryptophan
Identification number	3c440i
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	L-tryptophan with a purity criteria on a dry matter basis not less than 98% as a powder with the following components: • Moisture content: 1% maximum • 1,1'-ethylidene-bis-L-tryptophan: 10 mg/kg maximum
Characterisation of the active substance(s)	L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) ($C_{11}H_{12}N_2O_2$): • CAS number: 73-22-3(**b**) • EINECS number: 200-795-6(**c**)
Analytical methods(**d**)	For identification of L-tryptophan in the feed additive: • Food Chemical Codex "L-tryptophan monograph"(**e**) For determination of tryptophan in the feed additive and premixtures: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with BS EN ISO 13904:2016(**f**) For determination of tryptophan in feed materials and compound feed: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3-G)

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(**d**) Details of the analytical methods are set out in the document referenced "Ares(2020)7146784 – 27/11/2020" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 19 December 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0038_en.

(**e**) Food Chemicals Codex (FCC), 13th edition (Method: FCC L-tryptophan monograph published). Published by the United States Pharmacopeial Convention on 1 March 2022 (ISSN 2153-1455). Available at: https://www.foodchemicalscodex.org.

(**f**) BS EN ISO 13904:2016 "Animal feeding stuffs. Determination of tryptophan content". Published by the British Standards Institution on 31 March 2016 (ISBN 978 0 580 84452 2). Available at: https://knowledge.bsigroup.com.

Species or category of animal		All animal species
Maximum age		No maximum
Content of L-tryptophan (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		1. L-tryptophan must be rumen protected when administered to ruminants 2. Declaration to be made on the label of the additive and premixture: "The supplementation with L-tryptophan must take into account all essential and conditionally essential amino acids in order to avoid imbalances." 3. The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3air(**a**)

(**a**) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

SCHEDULE 10

Regulation 3(1)

Authorisation of a preparation of L-lysine sulphate (produced from *Corynebacterium glutamicum* (KCCM 80227)) (identification number 3c324i) as a feed additive for all animal species

Authorisation

1. The preparation specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	L-lysine sulphate
Identification number	3c324i
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	Granulated preparation of L-lysine sulphate with a minimum of 52% L-lysine, a maximum of 24% sulphate and a maximum moisture content of 4%
Characterisation of the active substance(s)	L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) ($C_{12}H_{28}N_4O_4 \cdot H_2SO_4$): • CAS Number: 60343-69-3(**b**)
Analytical methods(**c**)	For quantification of lysine in the feed additive and premixtures containing more than 10% lysine: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013(**d**) For identification of sulphate in the feed additive: • European Pharmacopoeia Monograph 20301(**e**) For quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3-F)

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) Details of the analytical methods are set out in the document referenced "Ares(2021)2533252 – 14/04/2021" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 2 July 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00820085_en.

(**d**) BS EN ISO 17180:2013 "Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures". Published by the British Standards Institution on 30 April 2013 (ISBN 978 0 580 76077 8). Available at: https://knowledge.bsigroup.com.

(**e**) European Pharmacopoeia Monograph – Ph. Eur. 6.0, 01/2008: 20301: "Identification reactions of ions and functional groups – sulphates". Published online by the European Directorate for the Quality of Medicines and Healthcare. Available at https://pheur.edqm.eu/home.

		For quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013
Species or category of animal		All animal species
Maximum age		No maximum
Content of L-lysine sulphate (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	10,000 mg/kg
Other provisions		1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. The L-lysine content must be stated on the labelling of the additive 3. The following must be stated on the labelling of the additive and premixture: "The supplementation with L-lysine should take into account all essential and conditionally essential amino acids in order to avoid imbalances."

SCHEDULE 11

Regulation 3(1)

Authorisation of the substance butylated hydroxyanisole (identification number 1b320) as a feed additive for cats

Authorisation

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

Additive		Butylated hydroxyanisole (BHA)
Identification number		1b320
Authorisation holder(**a**)		None
Additive category		Technological additives
Functional group		Antioxidants
Additive composition		Butylated hydroxyanisole (BHA) with a minimum content of 98.5% in a waxy solid form
Characterisation of the active substance(s)		Butylated hydroxyanisole containing a mixture of 2-tert-butyl-4-hydroxyanisole and a minimum of 85% 3-tert-butyl-4-hydroxyanisole ($C_{11}H_{16}O_2$): • CAS number: 25013-16-5(**b**)
Analytical methods(**c**)		For quantification of butylated hydroxyanisole (BHA) in feed additives: • Gas chromatography coupled to flame ionization detection (GC-FID) Food Chemical Codex 7th edition method(**d**) For quantification of butylated hydroxyanisole (BHA) in premixtures and compound feed: • Reversed phase high performance liquid chromatography coupled to ultraviolet-diode-array detection (RP-HPLC-UV-DAD, 285 nm)
Species or category of animal		Cats
Maximum age		No maximum
Content of butylated hydroxyanisole	*Minimum content*	No minimum
	Maximum content	150 mg/kg

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) Details of the analytical methods are set out in the document referenced "JRC.D.5/CvH/SB/ag/ARES(2012)40826", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0132_en.

(**d**) Food Chemicals Codex (FCC), 7th edition (Method: BHA-FCC V1 monograph _ published). Published by the United States Pharmacopeial Convention on 1st March 2010. Available at: https://www.foodchemicalscodex.org

(mg/kg of complete feed with a moisture content of 12%)		
Other provisions		1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. Butylated hydroxyanisole (BHA) is authorised to be used in combination with butylated hydroxytoluene (BHT) only up to a maximum combined content of 150 mg/kg of complete feed

SCHEDULE 12

Regulation 3(1)

Authorisation of a preparation of L-lysine base (liquid) (produced from *Corynebacterium glutamicum* (KCCM 80183)) (identification number 3c320) as a feed additive for all animal species

Authorisation

1. The preparation specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	L-lysine base (liquid)
Identification number	3c320
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	Aqueous solution with a minimum of 50% L-lysine
Characterisation of the active substance(s)	L-lysine base (liquid) ($NH_2(CH_2)CH(NH_2)COOH$) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183): • CAS no: 56-87-1(**b**)
Analytical methods(**c**)	For quantification of lysine in the feed additive and premixtures containing more than 10% lysine: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013(**d**) For quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3, F)

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) Details of the analytical methods are set out in the document referenced "Ares(2019)7003671 - 12/11/2019" and "JRC F.5/CvH/SB/AS/Ares", and last updated on 27 January 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en.

(**d**) BS EN ISO 17180:2013 "Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures". Published by the British Standards Institution on 30 April 2013 (ISBN 978 0 580 76077 8). Available at: https://knowledge.bsigroup.com.

		For quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013, or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3-F)
Species or category of animal		All animal species
Maximum age		No maximum
Content of L-lysine (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		1. The L-lysine content must be stated on the labelling of the additive
		2. The additive may be used via water for drinking
		3. The following must be stated on the labelling of the additive and premixture: "The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances."

SCHEDULE 13

Regulation 3(1)

Authorisation of the substance L-lysine monohydrochloride (technically pure) (produced from *Corynebacterium glutamicum* (KCCM 80183)) (identification number 3c322ii) as a feed additive for all animal species

Authorisation

1. The substance specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	L-lysine monohydrochloride (technically pure)
Identification number	3c322ii
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	Powder of L-lysine monohydrochloride with a minimum of 78% L-lysine and a maximum moisture content of 1.5%
Characterisation of the active substance(s)	L-lysine monohydrochloride (technically pure) ($NH_2(CH_2)_4CH(NH_2)COOH$) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183): • CAS number: 657-27-2(**b**)
Analytical methods(**c**)	For identification of L-lysine monohydrochloride in the feed additive: • Food Chemicals Codex "L-lysine monohydrochloride monograph"(**d**) For quantification of lysine in the feed additive and premixtures containing more than 10% lysine: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013(**e**) For quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3, F)

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) Details of the analytical methods are set out in the document referenced "Ares(2019)7003671 - 12/11/2019" and "JRC F.5/CvH/SB/AS/Ares", and last updated on 27 January 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en.

(**d**) Food Chemicals Codex (FCC), 13th edition (Method: FCC L-lysine monohydrochloride monograph published). Published by the United States Pharmacopeial Convention on 1 March 2022 (ISSN 2153-1455). Available at: https://www.foodchemicalscodex.org/.

(**e**) BS EN ISO 17180:2013 "Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures". Published by the British Standards Institution on 30 April 2013 (ISBN 978 0 580 76077 8). Available at: https://knowledge.bsigroup.com.

		For quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013, or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3, F)
Species or category of animal		All animal species
Maximum age		No maximum
Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		1. The L-lysine content must be stated on the labelling of the additive 2. The additive may be used via water for drinking 3. The following must be stated on the labelling of the additive and premixture: "The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances."

SCHEDULE 14

Regulation 3(1)

Authorisation of the substance disodium 5'-guanylate (GMP) (produced from *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067)) (identification number 2b627i) as a feed additive for all animal species

Authorisation

1. The substance specified in the table, belonging to the additive category "sensory additives" and to the functional group "flavouring compounds", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive		Disodium 5'-guanylate
Identification number		2b627i
Authorisation holder(**a**)		None
Additive category		Sensory additives
Functional group		Flavouring compounds
Additive composition		Powder of disodium 5'-guanylate with a minimum purity criteria of 97%
Characterisation of the active substance(s)		Hydrated form of disodium 5'-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia c*oli K-12 (KFCC 11067) ($C_{10}H_{12}N_5Na_2O_8P$): • CAS number: 5550-12-9(**b**) • EINECS number: 226-914-1(**c**)
Analytical methods(**d**)		For identification of disodium 5'-guanylate (GMP) in the feed additive: • FAO JECFA monograph "disodium 5'-guanylate"(**e**) For determination of disodium 5'-guanylate (GMP) in the feed additive, flavouring premixtures and water: • High performance liquid chromatography coupled to UV detection (HPLC-UV)
Species or category of animal		All animal species
Maximum age		No maximum
Content of	*Minimum content*	No minimum

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(**d**) Details of the analytical methods are set out in the document referenced "Ares(2020)4619276 – 04/09/2020" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0085_en.

(**e**) Food and Agriculture Organisation of the United Nations (FAO) Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Combined Compendium of Food Additive Specifications, "Disodium 5'-guanylate". Published by the FAO and last updated (Web version) August 2011 (ISBN 92-5-105569-6). Available at: http://www.fao.org.

disodium 5'-guanylate (mg/kg of complete feed with a moisture content of 12%)	*Maximum content*	No maximum
Other provisions		1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. The additive must be incorporated into the feed in the form of a premixture 3. The following must be stated on the labelling of the additive: "Recommended maximum content of the active substance when used alone or in combination with other ribonucleotides up to the same level per kg (mg/kg of complete feed with a moisture content of 12%): 50 mg." 4. The functional group, identification number, name and added amount of the active substance must be indicated on the label of the premixture where the use level on the label of the premixture would result in the level of active substance (alone or in combination with other ribonucleotides) in complete feed exceeding 50 mg/kg

SCHEDULE 15

Regulation 3(1)

Authorisation of a preparation of muramidase (produced by fermentation with *Trichoderma reesei* (DSM 32338)) (identification number 4d16) as a feed additive for weaned piglets

Authorisation

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

Additive		Muramidase (EC 3.2.1.17)
Identification number		4d16
Authorisation holder		DSM Nutritional Products Ltd
Additive category		Zootechnical additives
Functional group		Other zootechnical additives
Additive composition		Solid and liquid preparations of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) having a minimum enzyme activity of 60,000 LSU(F)/g(**a**)
Characterisation of the active substance(s)		Muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338): • CAS number: 9001-63-2(**b**) • EINECS number: 232-620-4(**c**) • EC (IUBMB) number: 3.2.1.17(**d**)
Analytical methods(**e**)		For quantification of muramidase in the feed additive, premixtures and compound feed: • Fluorescence-based enzyme assay method that determines the enzyme-catalysed depolymerisation of a fluorescein-labelled peptidoglycan preparation at pH 6.0 and 30 °C.
Species or category of animal		Weaned piglets
Maximum age		No maximum
Content of muramidase (LSU(F)/kg of complete feed with	*Minimum content*	50,000 LSU(F)/kg
	Maximum content	65,000 LSU(F)/kg

(**a**) 1 LSU(F) is defined as the amount of enzyme that increases the fluorescence of 12.5 µg/ml fluorescein-labelled peptidoglycan per minute at pH 6.0 and 30 ºC by a value that corresponds to the fluorescence of approximately 0.06 nmol fluorescein isothiocyanate isomer.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(**d**) Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) https://iubmb.org.

(**e**) Details of the analytical methods are set out in the document referenced "Ares(2018)811287 - 12/02/2018" and "JRC F.5/CvH/SB/AS/Ares", and last updated on 2 March 2018. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2017-0046_en.

a moisture content of 12%)		
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

SCHEDULE 16

Regulation 3(1)

Authorisation of the substance vitamin K_1 or Phytomenadione (identification number 3a712) as a feed additive for horses

Authorisation

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

Additive	Vitamin K_1 or Phytomenadione
Identification number	3a712
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Vitamins, pro-vitamins and chemically well-defined substances having similar effect
Additive composition	Produced by chemical synthesis: • Solid preparation containing a minimum of 4.2% of phytomenadione (vitamin K_1)
Characterisation of the active substance(s)	2-methyl-3-[(E-7R,11R)-3,7,11,15-tetramethylhexadec-2- enyl] naphthalene-1,4-dione (phytomenadione) ($C_{31}H_{46}O_2$): • CAS number: 84-80-0(**b**) • EINECS number: 201-564-2(**c**) with the following components: • E-phytomenadione: 75% minimum • E-epoxyphytomenadione: 4% maximum • Total purity of E-phytomenadione, E-epoxyphytomenadione and Z-phytomenadione isomers: 97% minimum
Analytical methods(**d**)	For determination of phytomenadione (vitamin K_1) in the feed additive: • High performance liquid chromatography (HPLC) in accordance with the European Pharmacopoeia monograph(**e**)

(**a**) 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.

(**b**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**c**) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(**d**) Details of the analytical methods are set out in the document referenced "Ares(2021)145311 – 07/01/2021" and "JRC F.5/CvH/SB/AS/Ares", and last updated on 17 February 2021. Available at https://joint-research-centre.ec.europa.eu/publications/fad-2020-0006_en.

(**e**) European Pharmacopoeia monograph – Ph. Eur. 8.0, 01/2014:1036. Published online by the European Directorate for the Quality of Medicines and Healthcare on 1st January 2024. Available at: https://pheur.edqm.eu/home.

		For determination of phytomenadione in the additive preparation and in complimentary feed: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with BS EN 14148:2003(**a**)
Species or category of animal		Horses
Maximum age		No maximum
Content of phytomenadione (vitamin K1) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

(**a**) BS EN 14148:2003 "Foodstuffs. Determination of vitamin K1 by HPLC". Published by the British Standards Institution on 25 July 2003 (ISBN 0 580 42317 4). Available at: https://knowledge.bsigroup.com.

SCHEDULE 17

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of copper chelate of hydroxy analogue of methionine (identification number 3b410i (formerly 3b4.10)) as a feed additive for all animal species

Authorisation

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

Additive	Copper chelate of hydroxy analogue of methionine
Identification number	3b410i
Authorisation holder(**b**)	None
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Copper chelate of hydroxy analogue of methionine in solid form containing a minimum of 16% copper and the following components: • (2-hydroxy-4-methylthio) butanoic acid: 78% minimum • Nickel: 20 ppm maximum
Characterisation of the active substance(s)	Copper chelate of hydroxy analogue of methionine ($Cu(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$): • CAS number: 292140-30-8(**c**)
Analytical methods(**d**)	For quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For quantification of total copper in the feed additive: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017(**e**) or BS EN 15621:2017(**f**)); or

(**a**) This authorisation contains a renewal (with modifications) of the authorisation granted under Commission Regulation (EU) No 349/2010 (EUR 2010/349). That Regulation is revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications made to that authorisation.

(**b**) 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.

(**c**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**d**) Details of the analytical methods are set out in the document referenced "D08-FSQ(2007)D/29104", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0012_en.

(**e**) BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94541 0). Available at: https://knowledge.bsigroup.com.

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

		• Atomic absorption spectrometry (AAS) in accordance with BS EN ISO 6869:2001(**a**) For quantification of total copper in premixtures: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017 or BS EN 15621:2017; • Atomic absorption spectrometry (AAS) in accordance with BS EN ISO 6869:2001; or • Inductively coupled plasma mass spectrometry (ICP-MS) in accordance with BS EN 17053:2018(**b**) For quantification of total copper in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017 or BS EN 15621:2017; • Atomic absorption spectrometry (AAS) in accordance with Commission Regulation (EC) No 152/2009 (Annex 4-C) or BS EN ISO 6869:2001; or • Inductively coupled plasma mass spectrometry (ICP-MS) in accordance with BS EN 17053:2018
Species or category of animal		All animal species
Maximum age		No maximum
Content of copper (Cu) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	For bovines: • before the start of rumination - 15 mg/kg (total) • other - 30 mg/kg (total) For ovines: • 15 mg/kg (total) For caprines: • 35 mg /kg For piglets: • suckling and weaned up 4 weeks after weaning – 150 mg/kg (total) • from 5th week up to 8 weeks after weaning – 100 mg/kg (total) For crustaceans: • 50 mg/kg (total) For all other animal species: • 25 mg/kg (total)
Other provisions		1. The additive must be incorporated into feed in the form of a premixture

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

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

	2. For feed for sheep, where the level of copper in the feed exceeds 10 mg/kg, the following must be stated on the labelling of the feed: “The level of copper in this feed may cause poisoning in certain breeds of sheep.” 3. For feed for bovines after the start of rumination, where the level of copper in the feed is less than 20 mg/kg, the following must be stated on the labelling of the feed: “The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.”

SCHEDULE 18

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of manganese chelate of hydroxy analogue of methionine (identification number 3b510 (formerly 3b5.10)) as a feed additive for all animal species

Authorisation

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

Additive	Manganese chelate of hydroxy analogue of methionine
Identification number	3b510
Authorisation holder(**b**)	None
Additive category	Nutritional
Functional group	Compounds of trace elements
Additive composition	Manganese chelate of hydroxy analogue of methionine in solid form containing a minimum of 14% manganese and the following components: • (2-hydroxy-4-methylthio) butanoic acid: 76% minimum • Nickel: 170 ppm maximum
Characterisation of the active substance(s)	Manganese chelate of hydroxy analogue of methionine ($Mn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$): • CAS number: 292140-29-5(**c**)
Analytical methods(**d**)	For quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction

(**a**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EU) No 350/2010 (EUR 2010/350). That Regulation is revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications made to that authorisation.

(**b**) 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.

(**c**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**d**) Details of the analytical methods are set out in the document referenced "D08-FSQ(2007)D/29224", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0011_en.

		For quantification of total manganese in the feed additive and premixtures: • Atomic absorption spectrometry, (AAS) in accordance with BS EN ISO 6869:2001, • Inductively coupled plasma atomic emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017(**a**), or • Inductively coupled plasma atomic absorption spectrometry (AAS) after pressure digestion, (ICP-AES) in accordance with BS EN 15621:2017 For quantification of total manganese in feed materials and compound feed: • Atomic absorption spectrometry (AAS) in accordance with Commission Regulation (EC) No 152/2009 (Annex 4-C), • Atomic absorption spectrometry (ASS) in accordance with BS EN ISO 6869:2001, • Inductively coupled plasma – atomic emission spectrometry, (ICP-AES) in accordance with BS EN 15510:2017, or • Inductively coupled plasma – atomic emission spectrometry after pressure digestion, (ICP-AES) in accordance with BS EN 15621:2017
Species or category of animal		All animal species
Maximum age		No maximum
Content of manganese (Mn) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	For fish: • 100 mg/kg (total)
		For all other animal species: • 150 mg/kg (total)
Other provisions		1. The additive must be incorporated into feed in the form of a premixture 2. Manganese chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation

(**a**) BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94541 0). Available at: https://knowledge.bsigroup.com.

SCHEDULE 19

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of zinc chelate of hydroxy analogue of methionine (identification number 3b610 (formerly 3b6.10)) as a feed additive for all animal species

Authorisation

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

Additive	Zinc chelate of hydroxy analogue of methionine
Identification number	3b610
Authorisation holder(**b**)	None
Additive category	Nutritional
Functional group	Compounds of trace elements
Additive composition	Zinc chelate of hydroxy analogue of methionine in solid form containing a minimum of 17% zinc and the following components: • (2-hydroxy-4-methylthio) butanoic acid: 79% minimum • Nickel: 1.7 ppm maximum
Characterisation of the active substance(s)	Zinc chelate of hydroxy analogue of methionine ($Zn(CH_3S(CH_2)_2$-$CH(OH)$-$COO)_2$): • CAS number: 292140-29-5(**c**)
Analytical methods(**d**)	For quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For quantification of total zinc in the feed additive: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017(**e**) or BS EN 15621:2017(**f**), or

(**a**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EU) No 350/2010 (EUR 2010/350). That Regulation is revoked by regulation 22 and schedule 21 of these Regulations. The explanatory note to these Regulations sets out the modifications made to that authorisation.

(**b**) 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.

(**c**) This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(**d**) Details of the analytical methods are set out in the document referenced "D08-FSQ(2007)D/29110", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0010_en.

(**e**) BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94541 0). Available at: https://knowledge.bsigroup.com.

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

		• Atomic absorption spectrometry (AAS) in accordance with BS EN ISO 6869:2001(**a**) For quantification of total zinc in premixtures: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017 or BS EN 15621:2017, • Atomic absorption spectrometry (AAS) in accordance with BS EN ISO 6869:2001, or • Inductively coupled plasma mass spectrometry (ICP-MS) in accordance with BS EN 17053:2018(**b**) For quantification of total zinc in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017 or BS EN 15621:2017, • Atomic absorption spectrometry (AAS) in accordance with Commission Regulation (EC) No 152/2009 (Annex 4-C) or BS EN ISO 6869:2001, or • Inductively coupled plasma mass spectrometry (ICP-MS) in accordance with BS EN 17053:2018
Species or category of animal		All animal species
Maximum age		No maximum
Content of zinc (Zn) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	For cats: • 200 mg/kg (total) For dogs: • 200mg/kg (total) For fish: • Salmonids – 180 mg/kg (total) • Other – 150 mg/kg (total) For milk replacers for calves: • 180 mg/kg (total) For rabbits: • 150 mg/kg (total) For Suidae: • Piglets, sows – 150 mg/kg (total) • Other – 120 mg/kg (total) For all other animal species: • 120 mg/kg (total)

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

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

Other provisions	1. The additive must be incorporated into feed in the form of a premixture 2. Zinc chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation

SCHEDULE 20

Regulation 3(1)

Authorisation of a preparation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffi* (DSM 32159) (identification number 1m03i) as a feed additive for all animal species, for use only in maize-based silages

Authorisation

1. The preparation specified in the table, belonging to the additive category "technological additives" and to the functional group "substances for reduction of the contamination of feed by mycotoxins", is authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive		Fumonisin esterase (EC 3.1.1.87)
Identification number		1m03i
Authorisation holder(**a**)		None
Additive category		Technological additives
Functional group		Substances for reduction of the contamination of feed by mycotoxins
Additive composition		Preparation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) having a minimum enzyme activity of 3000 U/g(**b**)
Characterisation of the active substance(s)		Fumonisin esterase (EC 3.1.1.87) produced by *Komagataella phaffii* (DSM 32159): • EC (IUBMB) Number: 3.1.1.87(**c**)
Analytical methods(**d**)		For determination of fumonisin esterase activity: • High performance liquid chromatography coupled with a tandem mass spectrometry (HPLC-MS/MS) method based on the quantification of the tricarballylic acid released from the action of the enzyme on fumonisin B1 at pH 8.0 and 30 ºC
Species or category of animal		All animal species
Maximum age		No maximum
Units of activity/kg of fresh material	*Minimum content*	40 U/kg
	Maximum content	No maximum
Other provisions		1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in maize-based silages

(**a**) 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.

(**b**) 1 U is the enzymatic activity that releases 1 µmol tricarballylic acid per minute from 100 µM fumonisin B1 in 20 mM Tris-Cl buffer pH 8.0 with 0.1 mg/ml bovine serum albumin at 30 ºC.

(**c**) Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) https://iubmb.org.

(**d**) Details of the analytical methods are set out in the document referenced "Ares(2017)2516958 - 17/05/2017" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 18 May 2017. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2017-0005_en.

SCHEDULE 21

Regulation 22

Revocations

1. Commission Regulation (EC) No 109/2007 concerning the authorisation of monensin sodium (Coxidin) as a feed additive(**a**).

2. Commission Regulation (EU) No 333/2010 concerning the authorisation of a new use of Bacillus subtilis C-3102 (DSM 15544) as a feed additive for weaned piglets (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**b**).

3. Commission Regulation (EU) No 335/2010 concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species(**c**).

4. Commission Regulation (EU) No 349/2010 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species(**d**).

5. Commission Regulation (EU) No 350/2010 concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species(**e**).

6. Commission Regulation (EU) No 170/2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA)(**f**).

7. Commission Regulation (EU) No 184/2011 concerning the authorisation of Bacillus subtilis C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**g**).

8. Commission Implementing Regulation (EU) No 98/2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Pichia pastoris* (DSM 23036) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows (holder of authorisation Huvepharma AD)(**h**).

9. Commission Implementing Regulation (EU) No 140/2012 concerning the authorisation of monensin sodium as a feed additive for chickens reared for laying (holder of authorisation Huvepharma NV Belgium)(**i**).

10. Commission Implementing Regulation (EU) 2019/893 concerning the renewal of the authorisation of Bacillus subtilis DSM 15544 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1444/2006 (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**j**).

11. Commission Implementing Regulation (EU) 2020/146 amending Regulation (EU) No 333/2010, Implementing Regulation (EU) 2017/2312, Implementing Regulation (EU) 2018/1081, Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2019/893 and

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(**a**) EUR 2007/109.
(**b**) EUR 2010/333.
(**c**) EUR 2010/335.
(**d**) EUR 2010/349.
(**e**) EUR 2010/350.
(**f**) EUR 2011/170.
(**g**) EUR 2011/184.
(**h**) EUR 2012/98.
(**i**) EUR 2012/140.
(**j**) EUR 2019/893.

Regulation (EU) No 184/2011 concerning the authorisations of the preparation of Bacillus subtilis C-3102 (DSM 15544) as a feed additive(**a**).

(**a**) EUR 2020/146.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision regarding the authorisation of feed additives under Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition ("EUR 2003/1831") and regarding use of feed for a particular nutritional purpose, in Scotland.

Regulation 3(1) and schedules 1 to 20 provide for the authorisation of 20 feed additives.

Regulation 3(2) provides that the authorisations are valid for a period of 10 years, in accordance with Article 9(7) of EUR 2003/1831. 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.

Regulations 4 to 6 amend certain specified Commission Implementing Regulations which make provision concerning the feed additive *Bacillus velezensis* (DSM 15544).

Regulation 7 amends Commission Implementing Regulation (EU) 2019/804 which makes provision concerning the authorisation of the feed additive selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060.

Regulation 8 makes provision to remove the authorisation in relation to Butylated hydroxyanisole as a feed additive for cats as an 'existing product' under Article 10 of EUR 2003/1831. In order to remain on the market the feed additive for cats must meet the conditions of the authorisation contained in schedule 11 of these Regulations. Regulation 15 makes transitional provision whereby in certain specified circumstances existing products can be placed on the market and used until stocks are exhausted.

Regulations 9 to 11 amend certain specified Commission Implementing Regulations which make provision concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 and the authorisation of *Bacillus amyloliquefaciens* CECT 5940.

Part 3 (regulation 12) amends Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes. The amendment relates to an essential nutritional characteristic regarding feed intended for use to reduce the risk of milk fever and subclinical hypocalcaemia.

Part 4 (regulations 13 to 19) contains transitional provisions made in relation to authorisations of feed additives which are modified or renewed by these Regulations. The provisions allow the continued production and labelling of products, for specified limited time periods, under the conditions of the prior authorisation and the labelling requirements applicable immediately before the coming into force of these Regulations. Products produced within the transitional periods may be marketed and sold until stocks are exhausted.

Part 5 (regulations 20 to 22) makes revocation provision. Regulations 20 and 21 make minor consequential amendments. Regulation 22 and schedule 21 revoke spent assimilated direct legislation, including those which contain authorisations which are now renewed by these Regulations.

Schedule 1 contains a new authorisation, for a preparation of chromium chelate of DL-methionine (identification number GB4d0001).

Schedule 2 contains a renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* (MUCL 39885) (identification number 4b1710). The authorisation extends authorised uses to cover additional species/categories of animal.

Schedule 3 contains a new authorisation, for a preparation of *Pediococcus acidilactici* (CNCM I-4622) (identification number 4d1712).

Schedules 4 and 5 contain a renewal (with modification) of an authorisation of preparations of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC

3419) (carriers: perlite and (respectively) calcium carbonate or wheat bran) (identification number 51701), and new authorisation extending authorised uses to cover an additional category of animal. The modifications on renewal are—

- a correction to the description of an animal species/category (turkey) covered,
- the removal of the requirement for a 1-day (before slaughter) withdrawal period.

Schedule 6 contains a renewal (with modification) of an authorisation of a preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) (identification number 4a16), and new authorisation extending authorised uses to cover additional species/categories of animals. See regulation 16 for transitional provision. The modifications on renewal are—

- the name of the bacterial strain is updated to *Komagataella phaffii* (formerly *Komagataella pastoris*),
- a requirement as to use listed under "other provisions" (relating to phosphorus content in feed) is removed.

Schedule 7 contains a renewal of the authorisation (with modification) of a preparation of *Bacillus velezensis* (DSM 15544) (identification number 4b1820), and new authorisation extending and consolidating authorised uses to cover additional species of animal. See regulation 13 for transitional provision. The modifications on renewal are—

- the name of the authorisation holder is updated,
- the name of the bacterial strain is updated to *Bacillus velezensis* (formerly *Bacillus subtilis*),
- the minimum content requirement for chickens reared for laying is reduced (from 5 × 108 to 3 × 108 CFU/kg) to align with the minimum content requirement for other avian species/categories.

Schedule 8 contains a new authorisation, for a preparation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) (identification number 3c352i).

Schedule 9 contains a new authorisation, for a preparation of L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) (identification number 3c440i).

Schedule 10 contains a new authorisation, for a preparation of L-lysine sulphate produced by fermentation with by fermentation with *Corynebacterium glutamicum* (KCCM 80227) (identification number 3c324i).

Schedule 11 contains a new authorisation, of the substance butylated hydroxyanisole (identification number 1b320).

Schedule 12 contains a new authorisation, for a preparation of L-lysine base (liquid) produced from *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c320).

Schedule 13 contains a new authorisation, of the substance L-lysine monohydrochloride (technically pure) (produced from *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c322ii).

Schedule 14 contains a new authorisation, of the substance disodium 5'-guanylate (GMP) produced from *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) (identification number 2b627i).

Schedule 15 contains a new authorisation, for a preparation of muramidase produced by fermentation with *Trichoderma reesei* (DSM 32338) (identification number 4d16).

Schedule 16 contains a new authorisation, of the substance vitamin K_1 or Phytomenadione (identification number 3a712).

Schedule 17 contains a renewal of the authorisation (with modification) of a preparation of copper chelate of hydroxy analogue of methionine (identification number 3b410i). See regulation 17 for transitional provision. The modifications on renewal are—

- the identification number is changed from 3b4.10 to 3b410i,
- there are changes to the specification of the authorised preparation,
- a maximum level for nickel (20 ppm) is added,
- the analytical methods have been updated.

Schedule 18 contains a renewal of the authorisation (with modification) of a preparation of manganese chelate of hydroxy analogue of methionine (identification number 3b510). See regulation 18 for transitional provision. The modifications on renewal are—

- the identification number is changed from 3b5.10 to 3b510,
- there are changes to the specification of the authorised preparation,
- a maximum level for nickel (170 ppm) is added,
- the analytical methods have been updated.

Schedule 19 contains a renewal of the authorisation (with modification) of a preparation of zinc chelate of hydroxy analogue of methionine (identification number 3b610). See regulation 19 for transitional provision. The modifications on renewal are—

- the identification number is changed from 3b6.10 to 3b610,
- there are changes to the specification of the authorised preparation,
- a maximum level for nickel (1.7 ppm) is added,
- the analytical methods have been updated.

Schedule 20 contains a new authorisation, for a preparation of fumonisin esterase produced by fermentation with *Komagataella phaffi* (DSM 32159) (EC 3.1.1.87) (identification number 1m03i).

A Policy Note has been published alongside this instrument at www.legislation.gov.uk.

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