WELSH STATUTORY INSTRUMENTS

2024 No. 1251 (W. 209)

AGRICULTURE, WALES

The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision, in relation to Wales, in relation to animal feed additive authorisations, and in relation to a use of feed for a particular nutritional purpose.

Part 2 of these Regulations (regulations 3 to 11, and Schedules 1 to 20) is made in exercise of powers in Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (EUR 2003/1831). Part 2 makes provision in relation to the authorisation for the placing on the market, processing and use of certain feed additives.

Regulation 3, and Schedules 1 to 20, provide for the authorisation of feed additives.

- Schedule 1 contains a new authorisation for a preparation of chromium chelate of DL-methionine (identification number GB4d0001).
- Schedule 2 contains a renewal of an authorisation of a preparation of *Saccharomyces cerevisiae* (MUCL 39885) (identification number 4b1710), and new authorisation extending 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 renewals of authorisations (with modification) 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 of an authorisation (with modification) 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 12 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 authorisations (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 5×10^8 to 3×10^8 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 *Corynebacterium glutamicum* (KCCM 80227) (identification number 3c324i).
- Schedule 11 contains a new authorisation of the substance butylated hydroxyanisole (BHA) (identification number 1b320) as a feed additive for cats. BHA as a feed additive for cats is separately an 'existing product' for the purpose of Article 10 of EUR 2003/1831 – see regulation 8 for removal of the 'existing product' status.
- Schedule 12 contains a new authorisation of a preparation of L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c320).
- Schedule 13 contains a new authorisation of the substance L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c322ii).
- Schedule 14 contains a new authorisation of the substance disodium 5'-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) (identification number 2b627i).
- Schedule 15 contains a new authorisation of a preparation of muramidase produced by fermentation with *Trichoderma reesei* (DSM 32338) (identification number 4d16).
- Schedule 16 contains a new authorisation of a preparation of phytomenadione (vitamin K_1) (identification number 3a712).
- Schedule 17 contains a renewal of authorisation (with modification) of a preparation of copper chelate of hydroxy analogue of methionine (identification number 3b410i). See regulation 16 for transitional provision. The modifications on renewal are:

— The identification number is changed from 3b4.10 to 3b410i.

— There are changes to the composition of the authorised preparation.

— A maximum level for nickel (20 ppm) is added.

— The analytical methods are updated.

- Schedule 18 contains a renewal of authorisation (with modification) of a preparation of manganese chelate of hydroxy analogue of methionine (identification number 3b510). See regulation 16 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 are updated.

- Schedule 19 contains a renewal of authorisation (with modification) of a preparation of zinc chelate of hydroxy analogue of methionine (identification number 3b610). See regulation 16 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 of a preparation of fumonisin esterase (EC 3.1.1.87) (identification number 1m03i).

Regulation 3(2) provides that authorisations granted by these Regulations are valid for a period of ten years in accordance with Article 9(7) of 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 where an application for renewal has been submitted.

Regulations 4 to 6 amend certain instruments containing authorisations for the feed additive *Bacillus velezensis* (DSM 15544). The authorisations are modified to update the name of the authorisation

holder, and to update the name of the bacterial strain *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102).

Regulation 4 also amends Commission Implementing Regulation (EU) 2016/897 (EUR 2016/897) to remove the authorisation for *Bacillus velezensis* (DSM 15544) in relation to laying hens. That authorisation is superseded by, and consolidated within, the authorisation contained in Schedule 7.

Regulation 7 amends Commission Implementing Regulation (EU) 2019/804 (EUR 2019/804), which contains an authorisation for the feed additive selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060, inactivated, with the identification number 3b810. The authorisation is modified in relation to the permitted selenium content of the additive, and to introduce a requirement in relation to the dusting potential of the additive. See regulation 14 for transitional provision.

Regulation 8 makes provision to remove the authorisation in relation to butylated hydroxyanisole (BHA) as a feed additive for cats as an 'existing product' under Article 10 of EUR 2003/1831. To remain on the market as feed additive for cats, the additive must comply with the conditions of the new authorisation contained in Schedule 11 to these Regulations. But regulation 15 makes transitional provision to allow existing products (that cannot comply with the new authorisation) produced and labelled within specified periods to continue be marketed and used until stocks are exhausted.

Regulations 9 to 11 amend a number of instruments to update the name of the authorisation holder.

Part 3 (regulations 12 to 16) contain transitional provisions in relation to feed additive authorisations that are modified or renewed by these Regulations. The transitional provisions allow the continued production and labelling of specified feed additives and products containing them, for limited time periods, under the conditions of authorisation applicable immediately before these Regulations come into force. Products produced and labelled within the transitional periods may be marketed and used until stocks are exhausted.

Part 4 (regulation 17) is made in exercise of powers in the Agriculture Act 1970 (1970 c.40). Regulation 17 amends Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes (EUR 2020/354). An amendment is made to an essential nutritional characteristic for the lawful marketing of feed intended for use for the reduction of the risk of milk fever and subclinical hypocalcaemia.

Part 5 (regulations 18 to 20, and Schedule 21) is made in exercise of powers in EUR 2003/1831 and contains revocations in consequence of provision made by Part 2.

Regulations 18 and 19 make minor consequential amendments.

Regulation 20 and Schedule 21 revoke, in relation to Wales, spent instruments including those containing prior authorisations for the feed additives now renewed by these Regulations (contained in Schedules 2, 4 to 7, and 17 to 19).

Further information, including in relation to any documentation referenced in the Schedules, can be obtained from the Food Standards Agency in Wales, 4th Floor, Welsh Government Building, Cathays Park, Cardiff, CF10 3NQ or by writing to regulated.products.wales@food.gov.uk.

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

WELSH STATUTORY INSTRUMENTS

2024 No. 1251 (W. 209)

AGRICULTURE, WALES

The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024

Made	*27 November 2024*
Laid before Senedd Cymru	*29 November 2024*
Coming into force	*20 December 2024*

The Welsh Ministers make these 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(**1**), and section 74A(1)(a) and (b) of the Agriculture Act 1970(**2**).

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

(**1**) EUR 2003/1831, amended by S.I. 2019/654, 2022/377 and 1351. S.I. 2019/654 was amended by S.I. 2020/1504. The terms "prescribe" and "appropriate authority" are defined in Article 2 of EUR 2003/1831. Article 9(1) applies in relation to modifications or renewals in accordance with Articles 13 or 14 respectively.

(**2**) 1970 c. 40. Section 74A was inserted by paragraph 6 of Schedule 4 to the European Communities Act 1972 (c. 68); that section was subsequently amended by section 33(3) of the Agriculture Act 2020 (c. 21); there are other amending instruments but none is relevant. The terms "the Ministers", "prescribed" and "regulations" are defined in section 66(1) of the Agriculture Act 1970. Functions formerly exercisable by "the Ministers", so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672. Those functions are now exercisable by the Welsh Ministers by virtue of section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006.

principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**1**).

PART 1

Introduction

Title, extent, application and coming into force

1.—(1) The title of these Regulations is the Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024.

(2) These Regulations—

(a) extend to England and Wales;

(b) apply in relation to Wales;

(c) come into force on 20 December 2024.

Interpretation

2.—(1) Expressions used in these Regulations and in Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition or Regulation 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed(**2**) have the same meaning as in Regulation (EC) No 1831/2003 or Regulation (EC) No 767/2009, respectively.

(2) In Schedules 1 to 20, expressions used to refer to species or categories of animals that are also used in Annex 4 (categories and definitions of target animals etc.) to 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(**3**) have the same meaning as in that Annex.

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

(**2**) EUR 2009/767, amended by S.I. 2019/654, 2022/1351. S.I. 2019/654 was amended by S.I. 2020/1504.

(**3**) EUR 2008/429, to which there are amendments not relevant to these Regulations.

PART 2

Feed additive authorisations

Authorisations

3.—(1) Schedules 1 to 20 contain authorisations of feed additives.

(2) Subject to Article 14(4) (renewal of authorisation) of Regulation (EC) No 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: 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(**1**) 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 in the European Union by Pen & Tec Consulting S.L.U." substitute "Asahi Biocycle Co., Ltd";

(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"*;

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

(d) in the seventh 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

(**1**) EUR 2016/897. See regulation 13 of these Regulations for transitional provision. EUR 2016/897 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 and Schedule 21 to these Regulations.

Union by Pen & Tec Consulting S.L.U.)(**1**), 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".

(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.)(**2**), 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".

(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: selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060, inactivated (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

(**1**) EUR 2017/2312. See regulation 13 of these Regulations for transitional provision. EUR 2017/2312 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 and Schedule 21 to these Regulations.

(**2**) EUR 2018/1081. See regulation 13 of these Regulations for transitional provision. EUR 2018/1081 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 and Schedule 21 to these Regulations.

Saccharomyces cerevisiae CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives for all animal species(**1**), in the Annex, the entry for "3b810" is amended as follows.

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

> "*Additive composition*
>
> Preparation of organic selenium (Se) produced by fermentation with *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".

(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 (EC) No 1831/2003

8. Butylated hydroxyanisole (E 320) may no longer be placed on the market or used as a feed additive for cats under Article 10 of Regulation (EC) No 1831/2003(**2**).

Changes of authorisation holder: amendment of Commission Implementing Regulation (EU) No 887/2011 and Commission Implementing Regulations (EU) 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

(**1**) EUR 2019/804. See regulation 14 of these Regulations for transitional provision.

(**2**) But see regulation 15 of these Regulations for transitional provision. See Schedule 11 to these Regulations for the new authorisation of butylated hydroxyanisole as a feed additive for cats.

authorisation Evonik Nutrition & Care GmbH)(**1**) is amended as follows.

(2) In the Annex, in the second table (authorisation expiring 28 June 2027), in the second column (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH)" substitute "Evonik Operations GmbH".

10.—(1) Commission Implementing Regulation (EU) 2017/961 of 7 June 2017 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)(**2**) 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)(**3**) 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

Transitional provisions

Transitional provision: 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella p*haffii (formerly *Komagataella pastoris*) (DSM 23036) (identification number 4a16)

12.—(1) The relevant feed additive and premixtures, compound feed or feed materials containing it, which are produced and labelled before the end of 19 June 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue

(**1**) EUR 2011/887, amended prior to implementation period completion day by Commission Implementing Regulations (EU) 2017/173 and 961.
(**2**) EUR 2017/961.
(**3**) EUR 2020/1395.

to be placed on the market and used until stocks are exhausted.

(2) In paragraph (1), the reference to the "relevant feed additive" is a reference to the feed additive 6-phytase (EC 3.1.3.26) (identification number 4a16)(**1**) as authorised immediately before 20 December 2024 under 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(**2**).

Transitional provision: *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544) (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 an instrument mentioned in regulations 4 to 6 of these Regulations, 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 compliance with the conditions of authorisation and the labelling requirements applicable immediately 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 compliance with the conditions of authorisation and the labelling requirements applicable immediately 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 compliance with the conditions of the authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(**1**) See Schedule 6 to these Regulations for relevant renewed authorisation of this feed additive.

(**2**) EUR 2012/98, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2016/348 (EUR 2016/348). EUR 2012/98 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

(5) In this regulation, references to the "relevant feed additive" are references to the feed additive *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544), with the identification number 4b1820(**1**), as authorised immediately before 20 December 2024 under—

(a) 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(**2**);

(b) 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(**3**);

(c) 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(**4**);

(d) 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(**5**).

Transitional provision: Selenised yeast produced by fermentation with *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 compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(**1**) See Schedule 7 to these Regulations for relevant renewed and consolidated authorisation of this feed additive.

(**2**) EUR 2010/333, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2010/333 and 2020/146 are revoked by regulation 20 of, and Schedule 21 to, these Regulations

(**3**) EUR 2011/184, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2011/184 and 2020/146 are revoked by regulation 20 of, and Schedule 21 to, these Regulations

(**4**) See regulation 4 of these Regulations for amendments to EUR 2016/897.

(**5**) EUR 2019/893, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2019/893 and 2020/146 are revoked by regulation 20 of, and Schedule 21 to, these Regulations.

(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 compliance with the conditions of authorisation and the labelling requirements applicable immediately 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 compliance with the conditions of the authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation, references to the "relevant feed additive" are references to the feed additive selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060, inactivated, with the identification number 3b810, as authorised immediately before 20 December 2024 under Commission Implementing Regulation (EU) 2019/804(**1**).

Transitional provision: Butylated hydroxyanisole as a feed additive for cats

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 compliance with the conditions of authorisation and the labelling requirements applicable immediately 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 compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

Transitional provisions: Copper, manganese and zinc chelates of hydroxy analogue of methionine (identification numbers 3b410i, 3b510 and 3b610 respectively)

16.—(1) A relevant feed additive and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in compliance with the conditions of authorisation and the labelling

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

requirements applicable immediately 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 a relevant feed additive and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately 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 a relevant feed additive and intended for non-food-producing animals, which are produced and labelled before the end of 19 December 2026 in compliance with the conditions of the authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation, references to a "relevant feed additive" are references to each of the following feed additives.

Copper chelate of hydroxy analogue of methionine

(a) The feed additive copper chelate of hydroxy analogue of methionine, with the identification number 3b410i (formerly 3b4.10)(**1**) as authorised immediately before 20 December 2024 under 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(**2**).

Manganese chelate of hydroxy analogue of methionine

(b) The feed additive manganese chelate of hydroxy analogue of methionine, with the identification number 3b510 (formerly 3b5.10)(**3**) as authorised immediately before 20 December 2024 under 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(**4**).

(**1**) See Schedule 17 to these Regulations for the renewed authorisation of this feed additive.

(**2**) EUR 2010/349, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2018/1039 (EUR 2018/1039). EUR 2010/349 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

(**3**) See Schedule 18 to these Regulations for the renewed authorisation of this feed additive.

(**4**) EUR 2010/350. EUR 2010/350 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Zinc chelate of hydroxy analogue of methionine

(c) The feed additive zinc chelate of hydroxy analogue of methionine, with the identification number 3b610 (formerly 3b6.10)(**1**) as authorised immediately before 20 December 2024 under 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(**2**).

PART 4

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

17.—(1) In Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes(**3**), in the Annex, in Part B (list of intended uses), the table is amended as follows.

(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 < $DCAD^s$ (mEq/kg dry matter) < 100" substitute "Objective: Range from -200 mEq/kg dry matter $DCAD^s$ to <100 mEq/kg dry matter DCAD".

PART 5

Revocations

Amendment of Commission Implementing Regulation (EU) 2016/1095

18. 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

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(**1**) See Schedule 19 to these Regulations for the renewed authorisation of this feed additive.

(**2**) EUR 2010/335, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2016/1095 (EUR 2016/1095). EUR 2010/335 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

(**3**) EUR 2020/354, to which there are amendments not relevant to these Regulations.

(solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species(**1**), omit Article 4 (amendment to Regulation (EU) No 335/2010).

Amendment of Commission Implementing Regulation (EU) 2018/1039

19. 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 hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) as feed additives for all animal species(**2**), omit Article 5 (amendment to Regulation (EU) No 349/2010).

Revocations

20. The instruments listed in Schedule 21 are revoked.

Sarah Murphy
Minister for Mental Health and Wellbeing, under the authority of the Cabinet Secretary for Health and Social Care, one of the Welsh Ministers
27 November 2024

(**1**) EUR 2016/1095.
(**2**) 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

The preparation of chromium chelate of DL-methionine 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[(1)]	For the quantification of chromium in the feed additive: • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[(2)]) For the quantification of methionine in the feed additive: • Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) (BS EN ISO 13903:2005[(3)]) 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	None
Minimum content[(4)]	0.2 mg/kg
Maximum content[(4)]	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

[(1)] Details of the analytical methods are set out in the document referenced "Ares(2019)6115119 - 03/10/2019" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 18 October 2019. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0021_en.

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

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

[4] Content of chromium (mg/kg of complete feed with a moisture content of 12%).

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, cats, and dogs

The preparation of *Saccharomyces cerevisiae* (MUCL 39885) 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(**1**).

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[(1)]	For enumeration: • Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar (BS EN 15789:2021[(2)]) For identification of the yeast strain: • Polymerase chain reaction (PCR) method (DD CEN/TS 15790:2008[(3)])
Species or category of animal	• All *Suidae* other than suckling piglets or sows • Cats • Dogs
Maximum age	None
Minimum content[(4)]	For *Suidae*: • *Suidae* other than suckling piglets, sows and *Suidae* for reproduction purposes: 3×10^9 CFU/kg • *Suidae* for reproduction purposes other than sows: 6.4×10^9 CFU/kg For cats • 7×10^{10} CFU/kg For dogs: • 7×10^{10} CFU/kg
Maximum content[(4)]	None
Other provisions	The storage conditions must be indicated in the directions for use of the feed additive and premixtures

[(1)] 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.

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 170/2011 (EUR 2011/170). EUR 2011/170 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

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

(3) Under reference 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.

(4) Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%.

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

The preparation of *Pediococcus acidilactici* (CNCM I-4622) specified in the table, belonging to the additive category "technological additives" and to the functional groups "acidity regulator" and "hygiene condition enhancer", 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	None
Additive category	Technological additives
Functional group	• 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(1)	For enumeration (colony count) of the feed additive: • Spread plate method using MRS agar (BS EN 15786:2021(2)) For identification of the bacterial strain: • Pulsed-field gel electrophoresis (PFGE)
Species or category of animal	All animal species
Maximum age	None
Minimum content(3)	1×10^9 CFU/kg
Maximum content(3)	None
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

(1) 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.

(2) Under reference 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 0). Available at: https://knowledge.bsigroup.com.

[3] Colony forming units (CFU) of additive/kg of complete feed with a moisture content of 12%.

SCHEDULE 4

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of monensin sodium produced by fermentation with *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

The preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) 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(**1**).

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* 28682 (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* 28682 (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(1): 22373-78-0
Analytical methods(2)	For the 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) (BS EN ISO 14183:2008(3)) For the 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.

(**1**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EC) No 109/2007 (EUR 2007/109) and Commission Implementing Regulation (EU) No 140/2012 (EUR 2012/140). EUR 2007/109 and 2012/140 are revoked by regulation 20 of, and Schedule 21 to, these Regulations.

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: • None For chickens reared for laying: • 16 weeks For turkeys for fattening, turkeys reared for breeding: • 16 weeks
Minimum content(4)	For chickens for fattening; chickens reared for laying: • 100 mg/kg For turkeys for fattening; turkeys reared for breeding: • 60 mg/kg
Maximum content(4)	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 in combination with wet 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 English or in English and Welsh, in the directions for use: • In English: "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". • In Welsh: "Yn beryglus i geffylau. Mae'r bwyd anifeiliaid hwn yn cynnwys ionoffor. Dylid osgoi ei roi ar yr un pryd â tiamwlin, a dylid monitro ar gyfer adweithiau andwyol posibl wrth ei ddefnyddio gyda sylweddau meddygol eraill". 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 Welsh Ministers before the end of 19 December 2033.

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

(2) Details of the analytical methods 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.

(3) Under reference 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.

(4) Content of monensin (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 5

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of monensin sodium produced by fermentation with *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

The preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) 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(**1**).

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* 28682 (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* 28682 (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[(2)]: 22373-78-0
Analytical methods[(2)]	For the 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) (BS EN ISO 14183:2008[(3)]) For the 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.

(**1**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EC) No 109/2007 (EUR 2007/109). EUR 2007/109 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

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: • None For chickens reared for laying: • 16 weeks For turkeys for fattening; turkeys reared for breeding: • 16 weeks
Minimum content(4)	For chickens for fattening; chickens reared for laying: • 100 mg/kg For turkeys for fattening; turkeys reared for breeding: • 60 mg/kg
Maximum content(4)	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 in combination with wet 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 English or in English and Welsh, in the directions for use: • In English: "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". • In Welsh: "Yn beryglus i geffylau. Mae'r bwyd anifeiliaid hwn yn cynnwys ionoffor. Dylid osgoi ei roi ar yr un pryd â thiamwlin, a dylid monitro ar gyfer adweithiau andwyol posibl wrth ei ddefnyddio gyda sylweddau meddygol eraill". 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 Welsh Ministers before the end of 19 December 2033.

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

(2) Details of the analytical methods 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.

(3) Under reference 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.

(4) Content of monensin (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 6

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *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 *Suidae*

The preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) 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(**1**).

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(1) 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(2): 9001-89-2 • EC (IUBMB) number(3): 3.1.3.26
Analytical methods(4)	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
Species or category of animal	• All avian species • All *Suidae*
Maximum age	None
Minimum content(5)	For avian species: • All avian species other than turkeys: 125 OTU/kg • Turkeys: 250 OTU/kg For *Suidae*: • All *Suidae* other than piglets: 125 OTU/kg • Piglets: 250 OTU/kg
Maximum content(5)	None

(**1**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Implementing Regulation (EC) No 98/2012 (EUR 2012/98). EUR 2012/98 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

(1) 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

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

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

(4) 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.

(5) Content of 6-phytase (EC 3.1.3.26) (units of activity (OTU)/kg of complete feed with a moisture content of 12%).

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; consolidation of existing authorised uses for laying hens and chickens for fattening; and its authorisation as a feed additive extending existing uses to cover all avian species

The preparation of *Bacillus velezensis* (DSM 15544) 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(**1**).

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[(1)]	For enumeration (colony count) of the feed additive: • Spread plate method using tryptone soya agar in all target matrices (BS EN 15784:2021[(2)]) For identification of the feed additive • Pulsed-field gel electrophoresis (PFGE)
Species or category of animal	• Weaned piglets • All avian species
Maximum age	None
Minimum content[(3)]	3×10^8 CFU/kg
Maximum content[(3)]	None
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

[(1)] 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.

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

[(3)] Colony forming units (CFU)/kg of complete feed with a moisture content of 12%.

(**1**) This authorisation contains a renewal of the authorisations granted under Commission Regulation (EU) No 333/2010 (EUR 2010/333) and Commission Regulation (EU) No 184/2011 (EUR 2011/184) and consolidates authorisations for categories of avian species granted under Commission Implementing Regulations (EU) 2016/897 (EUR 2016/897) and 2019/893 (EUR 2019/893). EUR 2016/897 is amended by regulation 4 of these Regulations. EUR 2010/333, 2011/184 and 2019/893 are revoked by regulation 20 of, and Schedule 21 to, these Regulations.

SCHEDULE 8

Regulation 3(1)

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

The preparation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) 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	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(1) • EINECS number: 611-821-4(2)
Analytical methods(3)	For the quantification of histidine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) (BS EN ISO 13903:2005(4)), or • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) For the quantification of histidine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed(**1**) - Annex 3, F) For the quantification of histamine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) (BS EN ISO 13903:2005(4))
Species or category of animal	All animal species
Maximum age	None
Minimum content(5)	None
Maximum content(5)	None

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

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 stated on the labelling of the additive and premixture. 4. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depend on the species, the physiological state of the animal, the performance level, the environmental conditions, the level of other amino acids in the diet and the level of essential trace elements such as copper and zinc". • In Welsh: "Rhaid i'r ychwanegiad â L-histidin monohydroclorid monohydrad fod yn gyfyngedig i ofynion maethol yr anifail targed, sy'n dibynnu ar y rhywogaeth, cyflwr ffisiolegol yr anifail, lefel perfformiad, yr amodau amgylcheddol, lefel asidau amino eraill yn y diet a lefel elfennau hybrin hanfodol fel copor a zinc". 5.The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air[(6)].

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

[(2)] European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

[(3)] 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.

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

[(5)] Content of L-histidine monohydrochloride monohydrate (mg/kg of complete feed with a moisture content of 12%).

[(6)] Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by the European Food Safety Authority (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia (Ph. Eur.): Supplement 6.6 (official January 1, 2010), Bacterial Endotoxins (reference 01/2010:20614).

SCHEDULE 9

Regulation 3(1)

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

The preparation of L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) 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	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(1) • EINECS number: 200-795-6(2)
Analytical methods(3)	For the identification of L-tryptophan in the feed additive: • Food Chemical Codex "L-tryptophan monograph"(4) For the determination of tryptophan in the feed additive and premixtures: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) (BS EN ISO 13904:2016(5)) For the determination of tryptophan in feed materials and compound feed: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, G)
Species or category of animal	All animal species
Maximum age	None
Minimum content(6)	None
Maximum content(6)	None
Other provisions	1. L-tryptophan must be rumen protected when administered to ruminants. 2. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "The supplementation with L-tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances". • In Welsh: "Rhaid i'r atchwanegiad ag L-tryptophan ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd". 3. The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air(7).

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

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

(3) 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.

(4) 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.

(5) Under reference 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.

(6) Content of L-tryptophan (mg/kg of complete feed with a moisture content of 12%).

(7) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by the European Food Safety Agency (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia (Ph. Eur.): Supplement 6.6 (official January 1, 2010), Bacterial Endotoxins (reference 01/2010:20614).

SCHEDULE 10

Regulation 3(1)

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

The preparation of L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) 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	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[(1)]
Analytical methods[(2)]	For the 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) (BS EN ISO 17180:2013[(3)]) For the identification of sulphate in the feed additive: • European Pharmacopoeia Monograph 20301[(4)] For quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS - Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, F) For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013[(3)])
Species or category of animal	All animal species
Maximum age	None
Minimum content[(5)]	None
Maximum content[(5)]	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, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "The supplementation with L-lysine should take into

	account all essential and conditionally essential amino acids in order to avoid imbalances". • In Welsh: "Dylai'r atchwanegiad ag L-lysin ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd".

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

(2) Details of the analytical methods 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

(3) Under reference 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.

(4) 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.

(5) Content of L-lysine sulphate (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 11

Regulation 3(1)

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

The substance butylated hydroxyanisole (identification number 1b320) 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(**1**).

Additive	Butylated hydroxyanisole
Identification number	1b320
Authorisation holder	None
Additive category	Technological additives
Functional group	Antioxidants
Additive composition	Butylated hydroxyanisole 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[(1)]
Analytical methods[(2)]	For the quantification of butylated hydroxyanisole in feed additives: • Gas chromatography coupled to flame ionization detection (GC-FID) (Food Chemicals Codex 7th edition method[(3)]) For the quantification of butylated hydroxyanisole 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	None
Minimum content[(4)]	None
Maximum content[(4)]	150 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. Butylated hydroxyanisole is authorised to be used in combination with butylated hydroxytoluene up to a maximum combined content of 150 mg/kg of complete feed.

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

[(2)] Details of the analytical methods 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.

(**1**) This Schedule contains a new authorisation of a substance that is currently on the market as an 'existing product' under Article 10 of EUR 2003/1831. Prior to implementation period completion day, an application was submitted to the European Commission, pursuant to Article 10(2) of Regulation (EC) No 1831/2003, for the re-evaluation of butylated hydroxyanisole (BHA) as a feed additive for all animal species. The applicant later withdrew the application with regard to cats. BHA was re-evaluated and was subsequently authorised as a feed additive for all species except cats under Commission Implementing Regulation (EU) 2020/1399 (EUR 2020/1399). As a feed additive for cats, the authorisation of BHA as an 'existing product' under Article 10 of EUR 2003/1831 is withdrawn by regulation 8 of these Regulations, but see regulation 15 for transitional provision.

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

[4] Content of butylated hydroxyanisole (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 12

Regulation 3(1)

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

The preparation of L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) 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	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 number: 56-87-1[(1)]
Analytical methods[(2)]	For the 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) (BS EN ISO 17180:2013[(3)]) For quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, F) For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013[(3)]), or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 - Annex 3, F)
Species or category of animal	All animal species
Maximum age	None
Minimum content[(4)]	None
Maximum content[(4)]	None
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, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "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". • In Welsh: "Dylai'r atchwanegiad ag L-lysin, yn arbennig drwy ddŵr i'w yfed, ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd".

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

(2) Details of the analytical methods 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.

(3) Under reference 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.

(4) Content of L-lysine (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 13

Regulation 3(1)

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

The substance L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) 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	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[(1)]
Analytical methods[(2)]	For the identification of L-lysine monohydrochloride in the feed additive: • Food Chemicals Codex "L-lysine monohydrochloride monograph"[(3)] For the 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) (BS EN ISO 17180:2013[(4)]) For the quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, F) For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013[(4)]), or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 - Annex 3, F)
Species or category of animal	All animal species
Maximum age	None
Minimum content	None
Maximum content	None
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, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "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". • In Welsh: "Dylai'r atchwanegiad ag L-lysin, yn arbennig drwy ddŵr i'w yfed, ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd".

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

(2) Details of the analytical methods 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.

(3) 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/.

(4) Under reference 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.

(5) Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 14

Regulation 3(1)

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

The substance disodium 5'-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) 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	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 coli* K-12 (KFCC 11067) ($C_{10}H_{12}N_5Na_2O_8P$) • CAS number: 5550-12-9(1) • EINECS number: 226-914-1(2)
Analytical methods(3)	For the identification of disodium 5'-guanylate (GMP) in the feed additive: • FAO JECFA monograph "disodium 5'-guanylate"(4) For the 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	None
Minimum content(5)	None
Maximum content(5)	None
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, in English or in English and Welsh, on the labelling of the additive: • In English: "Recommended maximum content of the active substance when used alone or in combination with other ribonucleotides up to the same level per kg of complete feedingstuff with a moisture content of 12%: 50 mg". • In Welsh: "Yr uchafswm cynnwys a argymhellir o'r sylwedd actif pan y'i defnyddir ar ei ben ei hun neu mewn cyfuniad â riboniwcleotidau eraill hyd at yr un lefel fesul kg o fwyd anifeiliaid â chynnwys lleithder o 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.

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

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

(3) 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.

(4) 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" Monograph 1 (2006). Published by the FAO and last updated (Web version) August 2011 (ISBN 92-5-105569-6). Available at: https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/detail/en/c/255

(5) Content of disodium 5'-guanylate (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 15

Regulation 3(1)

Authorisation of a preparation of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) (identification number 4d16) as a feed additive for weaned piglets

The preparation of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) 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[(1)]
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[(2)] • EINECS number: 232-620-4[(3)] • EC (IUBMB) number: 3.2.1.17[(4)]
Analytical methods[(5)]	For the 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	None
Minimum content[(6)]	50,000 LSU(F)/kg
Maximum content[(6)]	65,000 LSU(F)/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.

(1) 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.

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

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

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

(5) 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.

(6) Content of muramidase (LSU(F)/kg of complete feed with a moisture content of 12%)

SCHEDULE 16

Regulation 3(1)

Authorisation of a preparation of phytomenadione (vitamin K_1) (identification number 3a712) as a feed additive for horses

The preparation of phytomenadione (vitamin K_1) 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	Phytomenadione or vitamin K_1
Identification number	3a712
Authorisation holder	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(1) • EINECS number: 201-564-2(2) 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(3)	For the determination of phytomenadione (vitamin K_1) in the feed additive: • High performance liquid chromatography (HPLC) (European Pharmacopoeia monograph 1036(4)) For the determination of phytomenadione in the additive preparation and in complimentary feed: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) (BS EN 14148:2003(5))
Species or category of animal	Horses
Maximum age	None
Minimum content(6)	None
Maximum content(6)	None
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

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

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

(3) 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.

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

(5) Under reference 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.

(6) Content of phytomenadione (vitamin K_1) (mg/kg of complete feed with a moisture content of 12%).

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

The preparation of copper chelate of hydroxy analogue of methionine 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(**1**).

Additive	Copper chelate of hydroxy analogue of methionine
Identification number	3b410i
Authorisation holder	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[1]
Analytical methods[2]	For the quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For the quantification of total copper in the feed additive: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[3] or BS EN 15621:2017[4]); or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001)[5] For the quantification of total copper in premixtures: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[3] or BS EN 15621:2017[4]); or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[5]); or • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[6])

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 349/2010 (EUR 2010/349). EUR 2010/349 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

	For the quantification of total copper in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[3] or BS EN 15621:2017[4]); or • Atomic absorption spectrometry (AAS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for official control of feed - Annex 4, C or BS EN ISO 6869:2001[5]); or • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[6])
Species or category of animal	All animal species
Maximum age	None
Minimum content[7]	None
Maximum content[7]	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 (total) 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. 2. For feed for sheep, where the level of copper in the feed exceeds 10 mg/kg, the following must be stated, in English or in English and Welsh, on the labelling of the feed: • In English: "The level of copper in this feed may cause poisoning in certain breeds of sheep". • In Welsh: "Gall lefel y copr yn y bwyd anifeiliaid hwn achosi gwenwyno mewn rhai bridiau o ddefaid". 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, in English or in English and Welsh, on the labelling of the feed: • In English: "The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur". • In Welsh: "Gall lefel y copr yn y bwyd anifeiliaid hwn achosi diffygion copr mewn gwartheg syn pori tir sydd â chynnwys uchel o folybdenwm neu sylffwr".

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

[2] Details of the analytical methods 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.

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

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

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

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

[7] Content of copper (Cu) (mg/kg of complete feed with a moisture content of 12%).

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

The preparation of manganese chelate of hydroxy analogue of methionine 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(**1**).

Additive	Manganese chelate of hydroxy analogue of methionine
Identification number	3b510
Authorisation holder	None
Additive category	Nutritional additives
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[(1)]
Analytical methods[(2)]	For the quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For the quantification of total manganese in the feed additive and premixtures • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[(3)]), or • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(4)]), or • Inductively coupled plasma atomic emission spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017[(5)]) For the quantification of total manganese in feed materials and compound feed: • Atomic absorption spectrometry (AAS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 4, C or BS EN ISO 6869:2001[(3)]), or • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017[(4)]), or • Inductively coupled plasma atomic emission spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017[(5)])

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 350/2010 (EUR 2010/350). EUR 2010/350 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Species or category of animal	All animal species
Maximum age	None
Minimum content(6)	None
Maximum content(6)	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.

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

(2) Details of the analytical methods 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.

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

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

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

(6) Content of manganese (Mn) (mg/kg of complete feed with a moisture content of 12%).

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

The preparation of zinc chelate of hydroxy analogue of methionine 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(**1**).

Additive	Zinc chelate of hydroxy analogue of methionine
Identification number	3b610
Authorisation holder	None
Additive category	Nutritional additives
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 ($Zn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) • CAS number: 292140-29-5[(1)]
Analytical methods[(2)]	For the quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For the quantification of total zinc in the feed additive: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(3)] or BS EN 15621:2017[(4)]), or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[(5)]) For the quantification of total zinc in premixtures: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(3)] or BS EN 15621:2017[(4)]), or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[(5)]), or • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[(6)])

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 335/2010 (EUR 2010/335). EUR 2010/335 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

	For the quantification of total zinc in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[3] or BS EN 15621:2017[4]), or • Atomic absorption spectrometry (AAS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 4, C or BS EN ISO 6869:2001[5]), or • Inductively coupled plasma mass spectrometry ICP-MS (BS EN 17053:2018[6])
Species or category of animal	All animal species
Maximum age	None
Minimum content[7]	None
Maximum content[7]	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)
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.

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

[2] Details of the analytical methods 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.

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

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

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

[6] Under reference BS EN 17053:2018 "Animal feeding stuffs: Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)".

Published by the British Standards Institution on 28 February 2018 (ISBN 978 0 580 94471 0). Available at: https://knowledge.bsigroup.com.

(7) Content of zinc (Zn) (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 20

Regulation 3(1)

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

The preparation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) 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	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(1)
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(2)
Analytical methods(3)	For the 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 B_1 at pH 8.0 and 30 ºC.
Species or category of animal	All animal species
Maximum age	None
Minimum content(4)	40 U/kg
Maximum content(4)	None
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.

(1) 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.

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

(3) 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.

(4) Units of activity/kg of fresh material.

SCHEDULE 21

Regulation 20

Revocations

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

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.)(**2**)

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(**3**)

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(**4**)

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(**5**)

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)(**6**)

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.)(**7**)

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)(**8**)

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)(**9**)

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)

(**1**) EUR 2007/109.

(**2**) EUR 2010/333. See regulation 13 of these Regulations for transitional provision. EUR 2010/333 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

(**3**) EUR 2010/335. See regulation 16 of these Regulations for transitional provision. EUR 2010/335 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2016/1095 (EUR 2016/1095). EUR 2016/1095 is amended by regulation 18 of these Regulations.

(**4**) EUR 2010/349. See regulation 16 of these Regulations for transitional provision. EUR 2010/349 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2018/1039 (EUR 2018/1039). EUR 2018/1039 is amended by regulation 19 of these Regulations.

(**5**) EUR 2010/350. See regulation 16 of these Regulations for transitional provision.

(**6**) EUR 2011/170.

(**7**) EUR 2011/184. See regulation 13 of these Regulations for transitional provision. EUR 2011/184 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

(**8**) EUR 2012/98. See regulation 12 of these Regulations for transitional provision.

(**9**) EUR 2012/140.

No 1444/2006 (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**1**)

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 Regulation (EU) No 184/2011 concerning the authorisations of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive(**2**)

(**1**) EUR 2019/893, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

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