STATUTORY INSTRUMENTS

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AGRICULTURE, ENGLAND

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

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Schedule 21 — Revocation of assimilated direct legislation
Part 1 — Revocation of assimilated direct legislation in accordance with regulation 17(1)
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The Secretary of State makes 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(**a**) and sections 74A(1)(a) and (b) of the Agriculture Act 1970(**b**).

(**a**) EUR 2003/1831, amended by S.I. 2019/654, 2022/377 and 1351. See Article 2 for the definitions of "appropriate authority" and "prescribe".

(**b**) 1970 c. 40. Section 74A was inserted by paragraph 6 of Schedule 4 to the European Communities Act 1972 (c. 68) and amended by section 33(3) of the Agriculture Act 2020 (c. 21). There are other amendments, but these are not relevant

There has been open and transparent public consultation during the preparation and evaluation of Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**a**).

PART 1

Introductory

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (England) Regulations 2024 and come into force on 20th December 2024.

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

Interpretation

2.—(1) In these Regulations —

"Regulation (EC) 152/2009" means Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed(**b**).

(2) Any expression used both 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 (EC) No 767/2009(**c**) of the European Parliament and of the Council on the placing on the market and use of feed, etc. has the same meaning as it has in those Regulations.

(3) In Schedules 1 to 20, in the tables, in the row relating to "*Species or category of animal*", expressions used that are also used in Annex 4 of Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) 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 (categories and definitions of target animals etc.) have the same meaning as in that Annex.

PART 2

Feed additive authorisations

Authorisation of various feed additives

3.—(1) Schedules 1 to 20 (which contain authorisations for feed additives) have effect.

(2) Subject to Article 14 (renewal of authorisation) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, the authorisations set out in Schedules 1 to 20 cease to have effect at the end of 19th December 2034.

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for this instrument. The Feeding Stuffs (Safety Requirements for Feed for Food-Producing Animals) Regulations 2004. The terms "the Minister", "prescribed" and "regulations" are defined in section 66(1) of the Agriculture Act 1970.

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

(**b**) EUR 152/2009, amended by S.I. 2019/654 and 2022/1351.

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

PART 3

Uses of feed intended for particular nutritional purposes

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

4. In Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes, etc.(**a**), in the Annex, in Part B (list of intended uses), 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 4

Amendment of assimilated direct legislation

Modification of authorisation: a preparation of *Bacillus velezensis* (DSM 15544), (identification number 4b1820)

5.—(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, etc.(**b**), is amended as follows—

(a) omit Articles 2 to 4;

(b) in the Annex, in the table:

(i) in the second column (name of the holder of authorisation), for "Asahi Calpis Wellness" to the end substitute "Asahi Biocycle Co., Ltd";

(ii) in the third column (additive) and the fourth column (composition, etc.), for "*Bacillus subtilis* C-3102", in each place, substitute "*Bacillus velezensis*";

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

(iv) in the seventh column (minimum content), omit "3 x 10^{8}".

(2) 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, etc.(**c**), in the Annex, the table is amended as follows—

(a) in the second column (name of the holder of authorisation), for "Asahi Calpis Wellness" to the end substitute "Asahi Biocycle Co., Ltd";

(b) in the third column (additive) for "*Bacillus subtilis*" substitute "*Bacillus velezensis*";

(c) in the fourth column (composition, etc.)—

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

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

(**a**) EUR 2020/354.
(**b**) EUR 2016/897.
(**c**) EUR 2017/2312.

(3) 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, etc.(**a**), in the Annex, the table is amended as follows—

(a) in the second column (name of the holder of authorisation), for "Asahi Calpis Wellness" to the end substitute "Asahi Biocycle Co., Ltd";

(b) in the third column (additive) and the fourth column (composition, etc.), for "*Bacillus subtilis* C-1302", in each place, substitute "*Bacillus velezensis*".

Modification of authorisation: selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated (identification number 3b810)

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

(a) in the fourth column (composition, etc.), for the section headed "Additive composition" substitute—

"Preparation of organic selenium (Se) produced by *Saccharomyces cerevisiae* (CNCM I-3060) containing 2,000 to 3,500 mg Se/kg with the below components:

• Organic selenium: 97% minimum of total selenium

• Selenomethionine: 63% minimum of total selenium";

(b) 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".

Changes of authorisation holder: amendment of Commission Implementing Regulation (EU) No 887/2011 and Commission Implementing Regulations (EU) 2017/961 and 2020/1395

7.—(1) In 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, etc.(**c**), in the Annex, in the second column of both tables (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH)", substitute "Evonik Operations GmbH".

(2) In Commission Implementing Regulation (EU) 2017/961 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as a feed additive for weaned piglets, and a new use in water for drinking for weaned piglets and chickens for fattening, etc.(**d**), in Annex I, in the table, in the second column (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH" substitute "Evonik Operations GmbH".

(3) In 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, etc.(**e**), 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".

(**a**) EUR 2018/1081.
(**b**) EUR 2019/804.
(**c**) EUR 2011/887.
(**d**) EUR 2017/961.
(**e**) EUR 2020/1395.

Amendment of Commission Implementing Regulation (EU) 2016/1095

8. In Commission Implementing Regulation (EU) 2016/1095 concerning the authorisation of zinc acetate dihydrate, zinc chloride anhydrous, zinc oxide, zinc sulphate heptahydrate, zinc sulphate monohydrate, zinc chelate of amino acids hydrate, zinc chelate of protein hydrolysates, zinc chelate of glycine hydrate (solid) and zinc chelate of glycine hydrate (liquid) as feed additives for all animal species, etc.(**a**), omit Article 4.

Amendment of Commission Implementing Regulation (EU) 2018/1039

9. 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, etc.(**b**), omit Article 5.

PART 5

Transitional Provisions

Transitional provision: a preparation of *Bacillus velezensis* (DSM 15544) (identification number 4b1820)

10.—(1) Any substance or product labelled "*Bacillus subtilis* C-3102 (DSM 15544)" or as containing "*Bacillus subtilis* C-3102 (DSM 15544)", but otherwise produced and labelled in accordance with an authorisation contained in an instrument mentioned in regulation 6, may continue to be placed on the market and used under that authorisation.

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

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

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

(5) In this regulation—

> "relevant feed additive" means the feed additive of a preparation of *Bacillus velezensis* (DSM 15544), with the identification number 4b1820 authorised under the prior authorisation;
>
> "prior authorisation" means the authorisations contained in Commission Implementing Regulation (EU) 2016/897 concerning the authorisation of a preparation of *Bacillus subtilis*

(**a**) EUR 2016/1095.
(**b**) EUR 2018/1039.

(C-3102) (DSM 1544) as a feed additive for laying hens and ornamental fish, etc., 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, etc., and 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, etc.(**a**), as the Regulations had effect immediately before 20th December 2024.

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

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

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

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

(4) In this regulation—

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

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

Transitional provision: butylated hydroxyanisole (identification number 1b320)

12.—(1) Butylated hydroxyanisole (E 320) is authorised to be placed on the market, processed or used as a feed additive for cats only to the extent that it is covered by and meets the conditions of the authorisation contained in Schedule 11 to these Regulations(**c**), and in consequence of that authorisation butylated hydroxyanisole (E 320) shall no longer be treated as an existing product under, and for the purposes of, Article 10 of Regulation (EC) No 1831/2003.

(2) Stocks of butylated hydroxyanisole as a feed additive for cats, and premixtures containing it, which are produced and labelled before the end of 19th June 2025 in compliance with the conditions of the authorisation and the labelling requirements applicable before 20th December 2024, may continue to be placed on the market and used until they are exhausted.

(**a**) EUR 2016/897, EUR 2017/2312, EUR 2018/1081.
(**b**) EUR 2019/804.
(**c**) Prior to the coming into force of these Regulations, butylated hydroxyanisole has been treated as an 'existing product' for the purposes of Article 10 of Regulation (EC) 1831/2003.

(3) Stocks of feed materials and compound feed containing butylated hydroxyanisole, intended for cats, which are produced and labelled before the end of 19th December 2026 in compliance with the conditions of the authorisation and the labelling requirements applicable immediately before 20th December 2024, may continue to be placed on the market and used until they are exhausted.

Transitional provision: 6-phytase (EC 3.1.3.26) (identification number 4a16)

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

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

(3) In this regulation—

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

"prior authorisation" means the authorisation contained in Commission Implementing Regulation (EU) No 98/2012(**a**), as it had effect immediately before 20th December 2024, 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)(**b**).

Transitional provision: copper chelate of hydroxy analogue of methionine (identification number 3b410i)

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

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

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

(4) In this regulation—

(**a**) EUR 2012/98.
(**b**) Save to the extent that its continued operation is needed for the operation of this transitional provision, this Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

"prior authorisation" means the authorisation contained in Commission Regulation (EU) No 349/2010(**a**), as it had effect immediately before 20th December 2024, concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species(**b**).

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

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

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

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

(4) In this regulation—

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

"prior authorisation" means the authorisation contained in Commission Regulation (EU) No 350/2010(**c**), as it had effect immediately before 20th December 2024, concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species(**d**).

Transitional provision: zinc chelate of hydroxy analogue of methionine (identification number 3b610)

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

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

(**a**) EUR 2010/349.
(**b**) Save to the extent that its continued operation is needed for the operation of this transitional provision, this Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.
(**c**) EUR 2010/350.
(**d**) Save to the extent that its continued operation is needed for the operation of this transitional provision, this Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

(4) In this regulation—

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

"prior authorisation" means the authorisation contained in Commission Regulation (EU) No 335/2010(**a**), as it had effect immediately before 20th December 2024, concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species(**b**).

PART 6

Revocation of assimilated direct legislation

Revocation of assimilated direct legislation

17.—(1) The instruments in Part 1 of Schedule 21 are revoked subject to Part 5 of these Regulations.

(2) The instruments in Part 2 of Schedule 21 are revoked.

Andrew Gwynne
Parliamentary Under-Secretary of State,
Department of Health and Social Care

4th November 2024

(**a**) EUR 2010/335.
(**b**) Save to the extent that its continued operation is needed for the operation of this transitional provision, this Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

SCHEDULE 1

Regulation 3

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, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical', is authorised as an additive in animal nutrition, in accordance with the specifications in the following 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	Chromium chelate of DL-methionine ($[CH_3S(CH_2)_2CH(NH_2)COO]_3$ Cr)
Analytical method(**a**)	For the quantification of chromium in the feed additive: • inductively coupled plasma mass spectrometry (ICP-MS) in accordance with European standard BS EN 17053:2018(**b**) For the quantification of methionine in the feed additive: • ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) in accordance with BS EN ISO 13903:2005(**c**) For proving the chelated structure of the feed additive: • mid-infrared (IR) spectrometry together with the determination of the content of chromium and methionine in the feed additive

(**a**) Details of the analytical methods set out in the document referenced "Ares(2019) 611519 - 03/10/2019" and "JRC F.5/CvH/ZE/AS/Ares" last updated on 18th October 2019 are available at: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0021_en.

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

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

Species or category of animal		Dairy cows
Maximum age		Not applicable
Content of chromium in complete feed with a moisture content of 12%	*Minimum content*	0.2 mg/kg
	Maximum content	0.5 mg/kg
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

SCHEDULE 2

Regulation 3

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

The preparation of *Saccharomyces cerevisiae* (MUCL 39885), belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

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 x 10^9 Colony Forming Units (CFU)/g
Characterisation of the active substance		Viable cells of *Saccharomyces cerevisiae* (MUCL 39885)
Analytical method(**b**)		For enumeration: • Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021(**c**) For identification of the yeast strain: • Polymerase chain reaction (PCR) method in accordance with DD CEN/TS15790:2008(**d**)
Species or category of animal		• All *Suidae* other than suckling piglets or sows • Cats • Dogs
Maximum age		Not applicable
Colony Forming Units (CFU) of additive/kg complete	*Minimum content*	• For all *Suidae* (other than suckling piglets, sows and *Suidae* for reproduction) 3 x 10^9 CFU/kg • For all *Suidae* for reproduction purposes other than sows: 6.4 x 10^9 CFU/kg

(**a**) This authorisation is a renewal and a replacement of the authorisation granted under Commission Regulation (EU) No 170/2011. That Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

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

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

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

SCHEDULE 3

Regulation 3

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), belonging to the additive category 'technological' and to the functional groups of 'acidity regulator' and 'hygiene condition enhancer', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table.

Additive		*Pediococcus acidilactici* (CNCM I-4622)
Identification number		4d1712
Authorisation holder(**a**)		None
Additive category		Technological
Functional groups		Acidity regulator and hygiene condition enhancer
Additive composition		Solid preparation of *Pediococcus acidilactici* (CNCM I-4622) containing a minimum of $1x10^{10}$ Colony Forming Units (CFU)/g
Characterisation of the active substance(s)		Viable cells of *Pediococcus acidilactici* (CNCM I-4622)
Analytical method (**b**)		For enumeration (colony count) of the feed additive: • Spread plate method using MRS agar in accordance with BS EN 15786:2021(**c**) For identification of the bacterial strain: • Pulsed-Field Gel Electrophoresis (PFGE)
Species or category of animal		All animal species
Maximum age		Not applicable
Colony Forming Units (CFU) of additive/kg of complete feed with a moisture content of 12%	*Minimum content*	$1x10^9$ CFU/kg
	Maximum content	No maximum
Other provisions		**1.** The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

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

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

(**c**) BS EN 15876:2021 "*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 30th November 2021 (ISBN 978 0 580 99830 0) and available at: https://knowledge.bsigroup.com

	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 hydrochloride

SCHEDULE 4

Regulation 3

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 extending to the use for turkeys reared for breeding

The preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (carrier: perlite, calcium carbonate), belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

Additive	Monensin sodium
Identification number	51701
Authorisation holder	Huvepharma NV
Additive category	Coccidiostats and histomonostats
Functional group	No separate functional groups
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 no: 22373-78-0(**b**)
Analytical method(**c**)	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

(**a**) This authorisation is a renewal (with modification) and a replacement of the authorisation granted under Commission Regulation (EC) No 109/2007 and Commission Implementing Regulation (EU) No 140/2012. Those Regulations are revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

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

		detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008(**a**) 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
Species or category of animal		• Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
Maximum age		• Chickens for fattening: none • Chickens reared for laying, turkeys for fattening and turkeys reared for breeding: 16 weeks
Content of monensin (mg/kg of complete feed with a moisture content of 12%)	Minimum content	• Chickens for fattening and chickens reared for laying: 100 mg/kg • Turkeys for fattening and turkeys reared for breeding: 60 mg/kg
	Maximum content	• Chickens for fattening and chickens reared for laying: 125 mg/kg • Turkeys for fattening and turkeys reared for breeding: 100 mg/kg
Maximum residue limits (MRLs) of monensin sodium in food of animal origin		• Wet skin and fat: 25 µg/kg • Wet liver, wet kidney, and 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 additive must be incorporated in compound feed in the form of a premixture. **3.** Monensin sodium must not be mixed with other coccidiostats. **4.** Declaration to be made in the directions for use: "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances". **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 the

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

	post-market monitoring programme must be submitted to the appropriate authority(**a**) by 19th December 2033.

(**a**) Article 2 of Regulation (EC) No. 1831/2003.

SCHEDULE 5

Regulation 3

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, turkeys for fattening and its authorisation extending to the use for chickens reared for laying and turkeys reared for breeding

The preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (carrier: perlite, wheat bran), belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

Additive	Monensin sodium
Identification number	51701
Authorisation holder	Huvepharma NV
Additive category	Coccidiostats and histomonostats
Functional group	No separate functional groups
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 • 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 no: 22373-78-0(**b**)
Analytical method(**c**)	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

(**a**) This authorisation is a renewal (with modification) and a replacement of the authorisation granted under Commission Regulation (EC) No 109/2007. That Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

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

		spectrophotometric detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008(**a**) 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
Species or category of animal		• Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
Maximum age		• Chickens for fattening: None • Chickens reared for laying, turkeys for fattening and turkeys reared for breeding: 16 weeks
Content of monensin (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	• Chickens for fattening and chickens reared for laying: 100 mg/kg • Turkeys for fattening and turkeys reared for breeding: 60 mg/kg
	Maximum content	• Chickens for fattening and chickens reared for laying: 125 mg/kg • Turkeys for fattening and turkeys reared for breeding: 100 mg/kg
Maximum residue limits (MRLs) of monensin sodium in food of animal origin		• Wet skin and fat: 25 µg/kg • Wet liver, wet kidney, and 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 additive must be incorporated in compound feed in the form of a premixture. **3.** Monensin sodium must not be mixed with other coccidiostats. **4.** Declaration to be made in the directions for use: "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when use concurrently with other medicinal substances". **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 the post-market monitoring programme must be submitted to the appropriate authority by 19th December 2033.

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

SCHEDULE 6

Regulation 3

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 extending to the use for all avian species and all *Suidae*

The preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036), belonging to the additive category 'zootechnical' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

Additive	6-phytase (EC 3.1.3.26)
Identification number	4a16
Authorisation holder	Huvepharma NV
Additive category	Zootechnical additives
Functional group	Digestibility enhancers
Additive composition	Preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) having a minimum enzyme activity of 4,000 OTU/g in solid form and 8,000 OTU/g in liquid form(**b**)
Characterisation of the active substance(s)	6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) • CAS no: 9001-89-2(**c**) • EC (IUBMB) no: 3.1.3.26(**d**)
Analytical method(**e**)	For the quantification of phytase activity in the feed additive, premixtures and compound feed: • Colorimetric method based on the quantification of the inorganic phosphate released by the enzyme from the sodium phytate
Species or category of animal	• All avian species

(**a**) This authorisation is a renewal (with modification) and a replacement of the authorisation granted under Commission Implementing Regulation (EC) No 98/2012. That Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

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

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

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

		• All *Suidae*
Maximum age		Not applicable
Content of 6-phytase (EC 3.1.3.26) (units of activity (OTU)/kg of complete feed with a moisture content of 12%)	*Minimum content*	• All avian species other than turkeys and all *Suidae* other than piglets: 125 OTU/kg • Turkeys and piglets: 250 OTU/kg
	Maximum content	No maximum level
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

SCHEDULE 7

Regulation 3

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 authorised uses to cover all other avian species

The preparation of *Bacillus velezensis* (formerly *Bacillus subtilis*) (DSM 15544), belonging to the additive category 'zootechnical' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

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 $1x10^{10}$ Colony Forming Units (CFU)/g
Characterisation of the active substance(s)	Viable spores of *Bacillus velezensis* (DSM 15544)
Analytical method(**b**)	For enumeration (colony count) of the feed additive: • Spread plate method using tryptone soya agar in all target matrices in accordance with BS EN 15784:2021(**c**) For identification of the feed additive: • Pulsed-field gel electrophoresis (PFGE)
Species or category of animal	• Weaned piglets • All avian species
Maximum age	Not applicable

(**a**) This authorisation is a renewal and a replacement of the authorisation granted under Commission Regulation (EU) No 333/2010 (EUR 333/2010), a renewal (with modification) and a replacement of the authorisation granted under Commission Regulation (EU) No 184/2011 (EUR 184/2011) and a consolidation of authorisations granted under Commission Implementing Regulations (EU) 2016/897 (EUR 2016/897) and 2019/893 (EUR 2019/893). EUR 2016/897 is amended by regulation 5 of these Regulations. EUR 333/2010, EUR 184/2011 and EUR 2019/893 are revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

(**c**) 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 30th November 2021 (ISBN 978 0 580 99829 4) and available at: https://knowledge.bsigroup.com

Colony Forming Units (CFU)/kg of complete feed with a moisture content of 12%	*Minimum content*	$3x10^8$ CFU/kg
	Maximum content	No maximum level
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

SCHEDULE 8

Regulation 3

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 80210), 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, in accordance with the specifications in the following table.

Additive	L-histidine monohydrochloride monohydrate
Identification number	3c352i
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	L-histidine monohydrochloride monohydrate with a purity criteria not less than 98% as a powder with the following components: • Moisture: 1% maximum • Histidine: 72% minimum • Histamine: 100ppm maximum
Characterisation of the active substance(s)	L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) ($C_6H_{12}ClN_3O_3$) • CAS no: 5934-29-2(**b**) • EINECS no: 611-821-4(**c**)
Analytical method(**d**)	For the quantification of histidine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) in accordance with BS EN ISO 13903:2005(**e**); or • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) For the quantification of histidine in premixtures, feed materials and compound feed:

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

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

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

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

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

		• Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) 152/2009 (Annex III, F) For the quantification of histamine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) in accordance with BS EN ISO 13903:2005
Species or category of animal		All animal species
Maximum age		Not applicable
Content of L-histidine monohydrochloride monohydrate (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		**1.** The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. **2.** L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. **3.** The histidine content must be indicated on the label of the additive and premixture and must contain the following declaration on the label of the additive and the premixture: "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". **4.** The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air(**a**).

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

SCHEDULE 9

Regulation 3

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), 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, in accordance with the specifications in the following table.

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

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

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

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

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

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

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

		• High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with Commission Regulation (EC) 152/2009 (Annex III, G)
Species or category of animal		All animal species
Maximum age		Not applicable
Content of L-tryptophan (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		**1.** L-tryptophan must be rumen protected when administered to ruminants. **2.** Declaration to be made on the label of the additive and premixture: "The supplementation with L-tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances". **3.** The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air(**a**).

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

SCHEDULE 10

Regulation 3

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), 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, in accordance with the specifications in the following table.

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

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

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

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

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

(**e**) European Pharmacopoeia, monograph - Ph. Eur. 6.0, 01/2008:20301. Published online by the European Directorate for the Quality of Medicines and Healthcare on 1st January 2024 and available at: https://pher.edqm.eu/home

		For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013
Species or category of animal		All animal species
Maximum age		Not applicable
Content of L-lysine sulphate (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	10,000 mg/kg
Other provisions		**1.** The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. **2.** The L-lysine content must be stated on the labelling of the additive. **3.** Declaration to be made on the label of the additive and premixture: "The supplementation with L-lysine should take into account all essential and conditionally essential amino acids in order to avoid imbalances".

SCHEDULE 11

Regulation 3

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

The substance butylated hydroxyanisole, belonging to the additive category 'technological feed additive' and to the functional group 'antioxidants', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

Additive	Butylated hydroxyanisole
Identification number	1b320
Authorisation holder(**b**)	None
Additive category	Technological
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 no: 25013-16-5(**c**)
Analytical method(**d**)	For the quantification of butylated hydroxyanisole in feed additives: • Gas chromatography coupled to flame ionization detection (GC-FID) (Food Chemical Codex 7th edition method)(**e**) 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	Not applicable

(**a**) This Schedule is a new authorisation of a substance that has, prior to these Regulations, been on the market as an existing product for the purposes of Article 10 of Regulation (EC) 1831/2003. Prior to IP completion day, an application was submitted to the European Commission, pursuant to Article 10(2) of Regulation (EC) 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. Subject to regulation 12 of these Regulations, BHA as a feed additive for cats as an existing product must (unless it complies with the conditions of new authorisation in this Schedule) be withdrawn from the market.

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

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

(**d**) 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 6th June 2016 and available at: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0132_en

(**e**) Food Chemicals Codex (FCC), 7th edition (Method: BHA-FCC V1 monograph_published). Published by the United States Pharmacopeial Convention on 1st March 2022 and available at: https://www.foodchemicalscodex.org

Content of butylated hydroxyanisole (mg/kg of complete feed with a moisture content of 12%)	Minimum content	No minimum
	Maximum content	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.

SCHEDULE 12

Regulation 3

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), 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, in accordance with the specifications in the following table.

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

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

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

(**c**) Details of the analytical methods are set out in the document referenced "Ares (2019) 7003671 - 12/11/2019" and "JRC F.5/CvH/SB/AS/Ares" last updated on 27th January 2020 and available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019000160028_en

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

		accordance with Commission Regulation (EC) 152/2009 (Annex III, F)
Species or category of animal		All animal species
Maximum age		Not applicable
Content of L-lysine (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		**1.** The L-lysine content must be stated on the labelling of the additive. **2.** The additive may be used via water for drinking. **3.** Declaration to be made on the label of the additive and premixture: "The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances".

SCHEDULE 13

Regulation 3

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), 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, in accordance with the specifications in the following table.

Additive	L-lysine monohydrochloride (technically pure)
Identification number	3c322ii
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Amino acids, theirs 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 no: 657-27-2(**b**)
Analytical method(**c**)	For the identification of L-lysine monohydrochloride in the feed additive: • Food Chemicals Codex "L-lysine monohydrochloride monograph"(**d**) 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) in accordance with BS EN ISO 17180:2013(**e**) For the quantification of lysine in premixtures, feed materials and compound feed:

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

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

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

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

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

		• Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 (Annex III, F) For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013; or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 (Annex III, F)
Species or category of animal		All animal species
Maximum age		Not applicable
Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		**1.** The L-lysine content must be stated on the labelling of the additive. **2.** The additive may be used via water for drinking. **3.** Declaration to be made on the label of the additive and the premixture: "The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances."

SCHEDULE 14

Regulation 3

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), belonging to the additive category 'sensory' and to the functional group 'flavouring compounds', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table.

Additive	Disodium 5' -guanylate
Identification number	2b627i
Authorisation holder(**a**)	None
Additive category	Sensory
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 no: 5550-12-9(**b**) • EINECS no: 226-914-1(**c**)
Analytical method(**d**)	For the identification of disodium 5' -guanylate (GMP) in the feed additive: • FAO JECFA monograph "disodium 5'-guanylate"(**e**) 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	Not applicable

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

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

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

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

(**e**) Food and Agriculture Organisation of the United Nations (FAO) Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Combined Compendium of Food Additive Specifications, "Disodium 5'-guanylate" 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

Content of disodium 5' -guanylate (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		**1.** The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. **2.** The additive must be incorporated into the feed in the form of a premixture. **3.** On the label of the additive the following must be indicated: '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%: 50mg'. **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 the active substance (alone or in combination with other ribonucleotides) in complete feed exceeding 50mg/kg.

SCHEDULE 15

Regulation 3

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), belonging to the additive category 'zootechnical' and to the functional group 'other zootechnical', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table.

Additive		Muramidase (EC 3.2.1.17)
Identification number		4d16
Authorisation holder		DSM Nutritional Products Ltd
Additive category		Zootechnical
Functional group		Other zootechnical
Additive composition		Solid and liquid preparations of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) having a minimum enzyme activity of 60,000 LSU(F)/g(**a**)
Characterisation of the active substance(s)		Muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338): • CAS no: 9001-63-2(**b**) • EINECS no: 232-620-4(**c**) • EC (IUBMB) no: 3.2.1.17
Analytical method(**d**)		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		Not applicable
Content of muramidase (units of	*Minimum content*	50,000 LSU(F)/kg

(**a**) 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 °C by a value that corresponds to the fluorescence of approximately 0.06 nmol fluorescein isothiocyanate isomer.

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

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

(**d**) 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" last updated on 2nd March 2018 and available at: https://joint-research-centre.ec.europa.eu/publications/fad-2017-0046_en.

activity/kg of complete feed with a moisture content of 12%)	*Maximum content*	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.

SCHEDULE 16

Regulation 3

Authorisation of the substance of phytomenadione (Vitamin K_1) (identification number 3a712) as a feed additive for horses

The substance phytomenadione (Vitamin K_1), belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table.

Additive	Vitamin K_1 or phytomenadione
Identification number	3a712
Authorisation holder(**a**)	None
Additive category	Nutritional additives
Functional group	Vitamins, pro-vitamins and chemically well-defined substances having similar effect
Additive composition	Produced by chemical synthesis • Solid preparation containing a minimum of 4.2% of phytomenadione (Vitamin K_1)
Characterisation of the active substance(s)	2-methyl-3-[(E-7R,11R)-3,7,11,15-tetramethylhexadec-2-enyl] naphthalene-1, 4-dione (phytomenadione) ($C_{31}H_{46}O_2$) • CAS no: 84-80-0(**b**) • EINECS no: 201-564-2(**c**) with the following components: • E-phytomenadione: 75% minimum • E-epoxyphytomenadione: 4% maximum • Total purity of E-phytomenadione, E-epoxyphytomenadione and Z-phytomenadione isomers: 97% minimum
Analytical method(**d**)	For the determination of phytomenadione (Vitamin K_1) in the feed additive: • High performance liquid chromatography (HPLC) in accordance with the European Pharmacopoeia(**e**) For the determination of phytomenadione in the additive preparation and in complimentary feed:

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

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

(**c**) The EINECS (European Inventory of Existing Commercial Chemical Substances) number as published in O.J. No. C146A, 15.6.90, p.1.

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

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

		• High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with BS EN 14148:2003(**a**)
Species or category of animal		Horses
Maximum age		Not applicable
Content of phytomenadione (Vitamin K_1) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	No maximum
Other provisions		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

(**a**) BS EN 14148:2003 "*Foodstuffs. Determination of Vitamin K_1 by HPLC*". Published by the British Standards Institution on 25th July 2003 (ISBN 0 580 42317 4) and available at: https://knowledge.bsigroup.com

SCHEDULE 17

Regulation 3

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, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

Additive	Copper chelate of hydroxy analogue of methionine
Identification number	3b410i
Authorisation holder(**b**)	None
Additive category	Nutritional additives
Function 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 no: 292140-30-8(**c**)
Analytical method(**d**)	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(**e**) or BS EN 15621:2017(**f**)); or

(**a**) This authorisation is a renewal and a replacement of the authorisation granted under Commission Regulation (EU) No 349/2010. That Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

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

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

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

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

		• Atomic absorption spectrometry, AAS (BS EN ISO 6869:2001(**a**)) For the quantification of total copper in premixtures: • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017 or BS EN 15621:2017); or • Atomic absorption spectrometry, AAS (BS EN ISO 6869:2001); or • Inductively coupled plasma mass spectrometry, ICP-MS (BS EN 17053:2018(**b**)) For the quantification of total copper in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017 or BS EN 15621:2017); or • Atomic absorption spectrometry, AAS (in accordance with Commission Regulation (EC) 152/2009 (Annex IV, C) or BS EN ISO 6869:2001); or • Inductively coupled plasma mass spectrometry, ICP-MS (BS EN 17053:2018)
Species or category of animal		All animal species
Maximum age		Not applicable
Content of copper (Cu) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	• Bovines before the start of rumination and ovines: 15 mg/kg (total) • Other bovines: 30 mg/kg (total) • Caprines: 35 mg/kg (total) • Piglets —Suckling and weaned up to 4 weeks after weaning: 150 mg/kg (total) —From 5th week up to 8 weeks after weaning: 100 mg/kg (total) • Crustaceans: 50 mg/kg (total) • Other animal species: 25 mg/kg (total)
Other provisions		**1.** The additive must be incorporated into feed in the form of a premixture. **2.** The following words must be included in the labelling:—for feed for sheep if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.'—for feed in bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper

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

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

	deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'

SCHEDULE 18

Regulation 3

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, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

Additive	Manganese chelate of hydroxy analogue of methionine
Identification number	3b510
Authorisation holder(**b**)	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 no: 292140-29-5(**c**)
Analytical method(**d**)	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(**e**)); or • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017(**f**)); or

(**a**) This authorisation is a renewal and a replacement of the authorisation granted under Commission Regulation (EU) No 350/2010. That Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

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

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

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

(**f**) 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 31st August 2017 (ISBN 978 0 580 94541 0) and available at: https://knowledge.bsigroup.com

		• Inductively coupled plasma atomic emission spectrometry after pressure digestion, ICO-AES (BS EN 15621:2017(**a**)) For the quantification of total manganese in feed materials and compound feed: • Atomic absorption spectrometry, AAS (in accordance with Commission Regulation (EC) 152/2009 (Annex IV, C) or BS EN ISO 6869:2001); or • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017); or • Inductively coupled plasma atomic emission spectrometry after pressure digestion, ICP-AES (BS EN 15621:2017)
Species or category of animal		All animal species
Maximum age		Not applicable
Content of manganese (Mn) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	• Fish: 100 mg/kg (total) • Other animal species: 150 mg/kg (total)
Other provisions		**1.** The additive must be incorporated into feed in the form of a premixture. **2.** Manganese chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation.

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

SCHEDULE 19

Regulation 3

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, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(**a**).

Additive	Zinc chelate of hydroxy analogue of methionine
Identification number	3b610
Authorisation holder(**b**)	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 no: 292140-29-5(**c**)
Analytical method(**d**)	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(**e**) or BS EN 15621:2017(**f**)); or

(**a**) This authorisation is a renewal and a replacement of the authorisation granted under Commission Regulation (EU) No 355/2010. That Regulation is revoked by regulation 17(1) of, and Part 1 of Schedule 21 to, these Regulations.

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

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

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

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

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

		• Atomic absorption spectrometry, AAS (BS EN ISO 6869:2001(**a**)) For the quantification of total zinc in premixtures: • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017 or BS EN 15621:2017); or • Atomic absorption spectrometry, AAS (BS EN ISO 6869:2001); or • Inductively coupled plasma mass spectrometry, ICP-MS (BS EN 17053:2018(**b**)) For the quantification of total zinc in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017 or BS EN 15621:2017); or • Atomic absorption spectrometry, AAS (in accordance with Commission Regulation (EC) 152/2009 (Annex IV, C) or BS EN ISO 6869:2001); or • Inductively coupled plasma mass spectrometry, ICP-MS (BS EN 17053:2018)
Species or category of animal		All animal species
Maximum age		Not applicable
Content of zinc (Zn) (mg/kg of complete feed with a moisture content of 12%)	*Minimum content*	No minimum
	Maximum content	• Dogs and cats: 200 mg/kg (total) • Salmonids and milk replacers for calves: 180 mg/kg (total) • Piglets, sows, rabbits and all fish other than salmonids: 150 mg/kg (total) • 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.

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

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

SCHEDULE 20

Regulation 3

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), belonging to the additive category 'technological' and to the functional group 'substances for reduction of the contamination of food by mycotoxins: fumonisins', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table.

Additive		Fumonisin esterase (EC 3.1.1.87)
Identification number		1m03i
Authorisation holder(**a**)		None
Additive category		Technological
Functional group		Substances for reduction of the contamination of feed by mycotoxins: fumonisins
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 3,000 U/g(**b**)
Characterisation of the active substance(s)		Fumonisin esterase (EC 3.1.1.87) produced by *Komagataella phaffii* (DSM 32159) • EC (IUBMB) no: 3.1.1.87
Analytical method(**c**)		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°C
Species or category of animal		All animal species
Maximum age		Not applicable
Units of activity/kg of fresh material	*Minimum content*	40 U/kg
	Maximum content	No maximum

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

(**b**) 1 U is the enzymatic activity that releases 1 µmol tricarballylic acid per minute from 100 µM fumonisin B_1 in 20 mM Tris-Cl buffer pH 8.0 with 0.1mg/ml bovine serum albumin at 30°C.

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

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 use of the additive is only authorised in maize-based silages.

SCHEDULE 21

Regulation 17

Revocation of assimilated direct legislation

PART 1

Revocation of assimilated direct legislation in accordance with regulation 17(1)

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.)(**a**).

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(**b**).

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(**c**).

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(**d**).

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)(**e**).

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.)(**f**).

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)(**g**).

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

(**a**) EUR 2010/333, amended by S.I. 2020/146. S.I. 2020/146 is revoked by regulation 17(1) of, and Schedule 21 to, these Regulations. See regulation 10 of these Regulations for transitional provision.
(**b**) EUR 2010/335, amended by S.I. 2016/1095. S.I. 2016/1095 is amended by regulation 8 of these Regulations. See regulation 16 of these Regulations for transitional provision.
(**c**) EUR 2010/349, amended by S.I. 2018/1039. S.I. 2018/1039 is amended by regulation 9 of these Regulations. See regulation 14 of these Regulations for transitional provision.
(**d**) EUR 2010/350. See regulation 15 of these Regulations for transitional provision.
(**e**) EUR 2011/170. See regulation 11 of these Regulations for transitional provision.
(**f**) EUR 2011/184, amended by S.I. 2020/146. S.I. 2020/146 is revoked by regulation 17(1) of, and Schedule 21 to, these Regulations. See regulation 10 of these Regulations for transitional provision.
(**g**) EUR 2012/98. See regulation 13 of these Regulations for transitional provision.
(**h**) EUR 2019/893, amended by S.I. 2020/146. S.I. 2020/146 is revoked by regulation 17(1) of, and Schedule 21 to, these Regulations. See regulation 10 of these Regulations for transitional provision.

9. 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 authorisation of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive(**a**).

PART 2

Revocation of assimilated direct legislation in accordance with regulation 17(2)

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

11. 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)(**c**).

(**a**) EUR 2020/146. See regulation 10 of these Regulations for transitional provision.
(**b**) EUR 2007/109.
(**c**) EUR 2012/140.

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

Regulation 3 and Schedules 1 - 20 contain the following authorisations—

- 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).
- Schedule 4 and 5 contain a renewal (with modification) of an authorisation of preparations of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (carriers: perlite and (respectively) calcium carbonate or wheat bran) (identification number 51701), and new authorisation extending authorised uses to cover an additional category of animal. The modifications on renewal are:

  —a correction to the description of an animals species/category (turkey) covered;

  —the removal of the requirement for a 1-day (before slaughter) withdrawal period.
- Schedule 6 contains a renewal (with modification) of an authorisation of a preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) (identification number 4a16), and new authorisation extending authorised uses to cover additional species/categories of animals. See regulation 13 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 14 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 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 13 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 the substance phytomenadione (vitamin K1) (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 15 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 of 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 17 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) as a feed additive for all animal species, for use only in maize-based silages.

Authorisations granted by these Regulations are valid for a period of ten years in accordance with Article 9(7) of Regulation (EC) No 1831/2003 (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.

Part 3 (regulation 5) is made in exercise of powers in the Agriculture Act 1970 (1970 c. 40). Regulation 5 amends Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes, etc. 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 hypocalcemia.

Regulation 6 amends 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 6(1) amends Commission Implementing Regulation (EU) 2016/897 concerning the authorisation of a preparation of *Bacillus subtilis* (C-3102) (DSM 1544) as a feed additive for laying hens and ornamental fish, etc., 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 concerning the renewal of the authorisation of organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives for all animal species, etc., 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 12 for transitional provision.

Regulation 8 amends a number a instruments to update the name of the authorisation holder.

Regulations 9 and 10 make minor consequential amendments.

Regulation 11 makes provision to remove the authorisation in relation to butylated hydroxyanisole as a feed additive for cats as an existing product under Article 10 of EUR 2003/1831. 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. Regulation 13 makes transitional provision to allow existing products (that cannot comply with the new authorisation) produced and labelled within specified periods to continue to be markets and used until stocks are exhausted.

Part 5 (regulations 11 to 17) of these Regulations contains transitional provisions in relation to feed additive authorisations that are modified or renewed by the 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.

Regulation 18 and Schedule 21 revoke, in relation to England, assimilated direct legislation that contain previous authorisations for feed additives now authorised by Schedules 2 to 7, 11, 18 and 19.

Hard copies of the documents in the Schedules are available for inspection at the Food Standards Agency, Food House, Kings Pool, 1-2 Peasholme Green, York YO1 7PR following a written request to that address or to FeedAdditives@food.gov.uk.

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

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